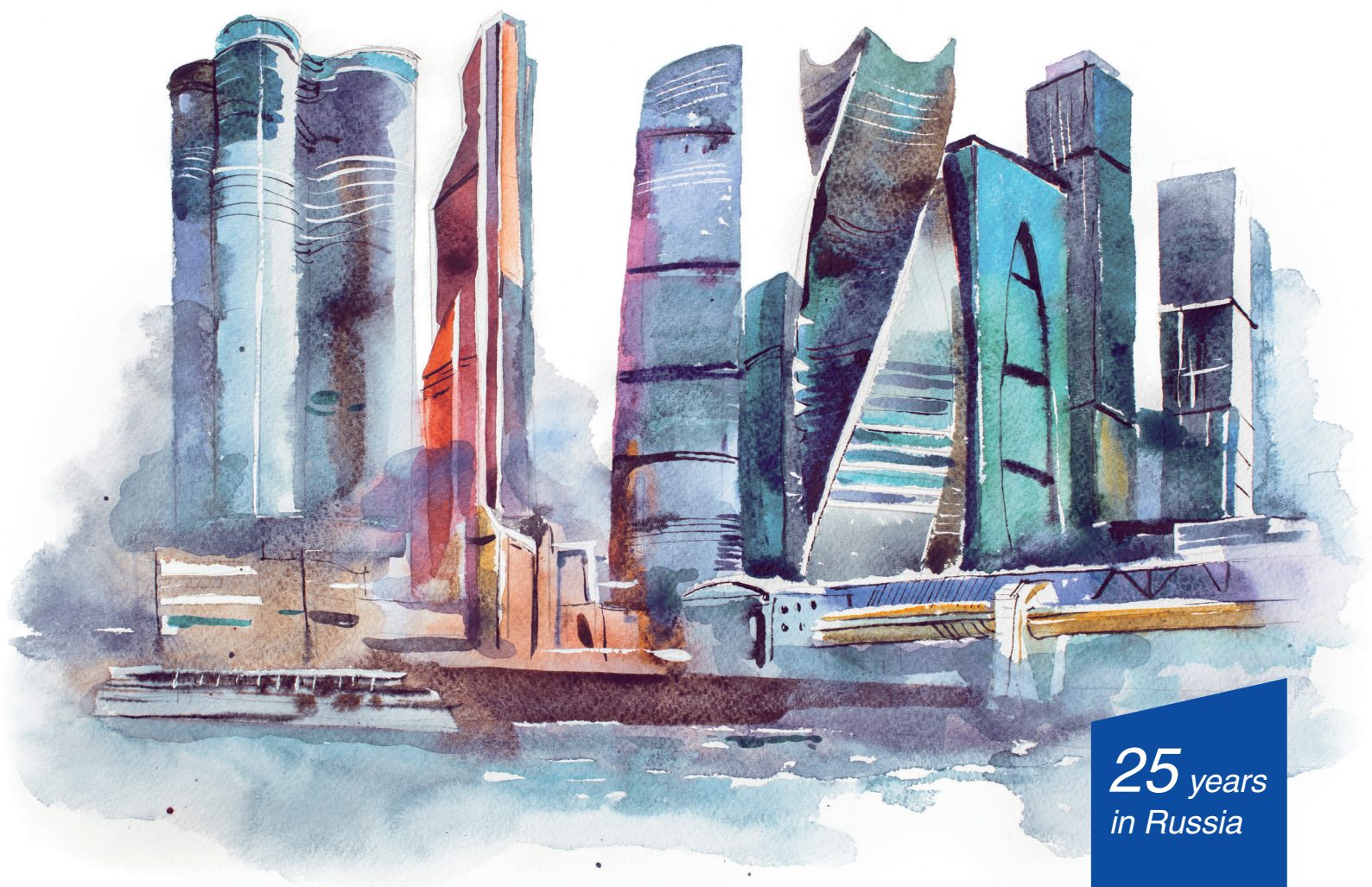




**FOREIGN INVESTMENT
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1. ISSUES AND RECOMMENDATIONS OF FIAC WORKING GROUPS

Foreign Investment Advisory Council

1. Digital Economy and Innovative Technologies

TOPIC 1. Implementation or support of cutting-edge solutions (primarily government information monitoring systems) including Big Data marking, collection, processing and deployment systems.

Issue 1.1. 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.

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.

Order No.2963-r of the Russian Government of 28 December 2018 approved of the Concept of Creating and Operating the Product Identification Marking and Tracking System in the Russian Federation (hereinafter, the "Concept"). The Concept lays down the marking system development principles that are conceptually different from those in the previously negotiated project, expose business operating activities to risks and substantial administrative, logistical and other costs.

The Concept, for example, fails to outline the procedure for deciding whether a group of products should be included in the list. A decision like this should be based solely on an adequate analysis of the rationale for including a particular product group in the tracking system (guided by a set of known transparent criteria), of the costs to be incurred by all the parties (including small businesses), and the results of the pilot project proving that the system will help achieve the Concept objectives. Another principle advocated by market participants was the principle of a unique and only one tracking system for all product groups, which would mitigate costs of market participants and prevent duplicating several systems for one product group. In contrast, the Concept enables end customers (Ministries) to design their own information systems/industry components of state information systems and establish their own requirements, which may expose market participants to substantial administrative costs. Trading enterprises may be hit particularly hard, as, being at the very end of the product chain, they have to meet all those requirements.

Recommendations:

The Russian Ministry of Industry and Trade should set up a dedicated task force involving FIAC, CRPT and other stakeholders for the purpose of outlining the key principles of planning, designing and building a unified national product catalog.

TOPIC 2. 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 2.1. 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.

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

Issue 3.1. 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 agenda 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 3.1:

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

Issue 4.1. 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 4.2. 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. To deliver on this task inevitably implies improving useful lives of road dressings and surfaces of highways, urban streets and roads and cutting down on maintenance costs in the face of larger traffic loads and their effects. According to Government Decree No. 658 of 30 May 2017, mandatory road overhaul periods must nearly double to 24 years for major repairs and 12 years for regular repairs. Useful lives of road dressings abroad are as long as 30 to 50 years.

The task is multifaceted; however, progress has been made in one area only in Russia, which is the improvement of the quality of asphalt concrete surfacing. Measures have been taken to enhance the quality of road bitumen, thicken constructive layers, and improve design and quality control methods. No disruptive technologies are used. International experience has shown that it is impossible to improve useful lives of road dressings and surfaces and, ultimately, reduce operation costs over the useful lives of roads without a

full-scale implementation of modern construction and renovation technologies to build cement concrete surfaces and bases of road dressings.

In the 1980s, the construction of roads with cement concrete surfaces in Russia slowed almost to a standstill, which was caused by a number of factors, including low construction quality, loose technical controls, lack of high-quality concretes, using concrete of low strength and low freeze thaw resistance, lack of effective plastifying and air-entraining concrete agents and sealant materials for expansion joints.

As a result, approximately 99% of roads in Russia have asphalt concrete surfacing, as opposed to Europe and the US where cement concrete highways account for 13%-40% and 60% of total road network, respectively. 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.

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. So far, contractors have bridged the deficit in high-quality cements in Russia 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 by far lower. Taking into account the entire life-cycle costs, cement concrete surfacing is 40-50% cheaper than asphalt concrete pavements. Another way to significantly reduce costs when constructing and renovating roads is to use local road building materials stabilized with inorganic binders. Current prices for cement and bitumen range within RUB 4-5 thousand and RUB 25-30 thousand per ton, respectively.

Given the government 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.

Building cement and concrete roads was a key focus of the Russian Transport Strategy approved in 2008. 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 completely neglected.

A decision has been recently made to build ring roads around large Russian cities and a number of highways, and renovate streets and roads in big cities to make them compliant with the effective standards. Those regions can boast of a developed cement industry, with cement works in close proximity of planned construction locations and contractors ready to start.

We believe a decision at the level of the Russian Government is needed to promote more extensive use of cement and concrete in building and renovating roads relying on leading technologies, which can help to notably cut down on maintenance costs and more than double the useful lives of roads. Decisions concerning the choice of road surfacing should only be based on the economic calculations of costs over the life cycle of the facility.

Recommendations:

1. 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 Russian Government should adopt a decree on extensive construction of cement concrete road surfaces envisaging measures to increase the share of roads with cement concrete surfacing which would gradually amount to 40% of the total number of newly built roads by 2024.

3. Regulation of the Russian Government should be drafted to oblige project entities to submit economic comparisons of rigid and flexible road dressing structures as part of designing roads, urban streets and roads, including the analysis of operating costs over the life cycles of facilities, to the Main State Expert Review Board for the latter to advise on more efficient structures.

4. A set of documents and technical regulations should be designed to ensure high-quality construction of cement and concrete surfaces and road bases on the basis of advanced technologies. Such documents have not been revised or altogether drafted in the last 30 years.

5. Programs should be designed for each federal district to construct and renovate roads using cement and concrete road bases and surfaces so as to ensure significant reductions in subsequent repair and maintenance costs and extend life cycles of roads.

6. A program should be worked out to renovate streets and roads in big cities using cement and concrete surfaces and bases of road dressings, particularly for public transport stops, acceleration and deceleration lanes and belt highways.

7. A program should be designed to promote domestic production of sets of machines to build cement and concrete surfaces.

Monitoring:

Issue: 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 member countries have a lot more to offer in terms of NTI development; as many decisions are currently made without regard to best international practices. 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.

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:

- 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 machine-building industry development. 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.

The new versions of the draft Strategy (2019) do not expressly indicate the need to increase duties. Therefore, the FIAC Working Group expects the document to be finalized to assess the need to continue solving the issue.

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

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

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

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

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

1. List of manufacturing processes.

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

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

2. Accounting for vehicle class specifics.

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

Since versions of the same component for passenger cars and trucks (for example, windscreen, body kit parts) may differ significantly in size and complexity, investments in their production and, respectively, their profitability, may also differ manifold, therefore different score should be assigned to the same processes localized in different segments of automotive industry.

3. Localized production of components.

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

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

Recommendations:

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

Issue 3. Facilitating exports to the CIS and neighboring FSU countries (by monitoring changes in technical regulations in these countries).

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

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

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

Technical regulations adopted in other CIS countries, such as Azerbaijan, Moldova, Mongolia¹, Tajikistan, Turkmenistan² and Uzbekistan, have special provisions that must be taken into account when manufacturing products. Joint efforts have been made to establish interstate standards. These efforts helped partly solve this problem. On the other hand, Moldova, for example, has recently harmonized its technical regulations with European standards that are different from EAEU ones.

¹ Participates in certain CIS structures as an observer.

² Associated member

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

In view of that, it is necessary to monitor changes in technical regulations of countries that are not members of the EAEU. However, language barriers and the lack of special knowledge and competencies constitutes a serious impediment.

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

The situation is still relevant. In 2019, a number of requirements were implemented which Russian goods exporters found confusing.

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

The best option is to add a special service to the Exporter Navigator, which is being developed by the Russian Export Center. The form of implementation (integration with the online service or regular publication of digests on new requirements) may be determined in terms of the REC and FIAC partnership.

Recommendations:

The REC, the key development institution, should ensure development of the specialized service for the Exporter Navigator to support export.

Issue 4. Developing monocities (by drumming up government support for the development of social infrastructure in monocities).

Developing monocities (by drumming up government support for the development of social infrastructure in monocities).

Monocities accommodate production sites of many foreign companies. While operating in these towns and investing in their development, companies face inherent infrastructure constraints which hinder business investment opportunities. The most pressing issue for most companies operating in monocities is the ongoing out-migration and subsequent lack of human resources, which is a serious challenge to the long-term sustainable development of the regions. The analysis carried out by the companies operating in monocities showed that the main reasons for the out-migration are a lack of jobs for high-skilled professionals, limited availability of modern quality dwelling and health care, and the overall poor quality of the urban environment.

Despite existing federal and regional programs aimed to provide significant business incentives, a lack of skilled workforce makes these territories less attractive to investors and obviously influences their investment decisions. These companies have to attract and relocate staff from other Russian regions and incur significant mobility and retention costs, which also increases the payback term and adversely affects regional investment appeal.

A limited access to adequate health care remains an important reason why people leave monocities. Reforms in the health care sector led to a drop in the number of medical facilities, consolidation of service areas and therefore to an increased burden on medical staff, which has reduced dramatically. Given that a significant number of potential employees eager to work in monocities are young families with one or two children, quality health care is the key to attracting and retaining young people and reversing the population decline.

A lack of modern and affordable dwelling for young employees is another serious problem. Companies have to rent old dwelling stock of 1960-70, which deteriorates the attractiveness of jobs in monocities for high-class/ young professionals. That said, building modern dwelling and creating quality urban environment in monocities is fundamental to ensuring their sustainable development and attracting investment. We believe that comprehensive development of comfortable low-rise residential housing will undoubtedly enhance investment appeal of monocities, reduce labor outflow, retain young workforce, attract new talent, including doctors and teachers who will help develop the social sector. To cut costs of the companies investing in production facilities, we propose establishing mechanisms aimed to encourage investment in residential infrastructure.

We believe that the recent persistent trend toward relocating production facilities to monocities, removing infrastructure constraints and creating new business opportunities may give an additional impetus to the Russian economy, as well as boost the socioeconomic development in regions and municipalities.

In July, the Russian Government announced drafting a new state program of monocities development for 2020-24, which is currently under way.

The previous priority program Integrated Development of Monocities drafted by the Ministry of Economic Development covered the period of 2016-25. However, it was early terminated due to inefficiency.

The Russian Government explains the revision of the monocity support program by the need to align it with the national projects. They expect to have the 2020-24 Monocities Development Program approved by the end of 2019.

Recommendations:

Inform the Ministry of Economic Development about the position of international investors concerning the social development of monocities:

- consider the possibility of co-funding budget spending items of the constituent entities and municipalities of the Russian Federation for creating (reconstructing) engineering, transport and utilities infrastructure to remove existing infrastructure constraints and boost residential construction in monocities.

- initiate a program for developing public-private partnerships to build multi-purpose medical centers in monocities;

- draft a federal mortgage program for medical staff working in monocities;

- organize a working meeting with I.V. Egorov, the director of the Regional Development Department of the Russian Ministry of Economic Development.

Once the new program for 2020-24 is approved, the issue will become subject to monitoring.

Issue 5. Need for certification of Russian suppliers of livestock products to develop non-commodity exports from the Russian Federation.

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

Producers are encouraged by the state measures: exports of certain non-commodity products are increasing and the geography is expanding. For example, exports of Russian confectionery products made 421.38 thousand tonnes to total USD 935.33 million in 2018 and 456.22 thousand tonnes to total USD 1,048.59 million in 2017, which is +8.3% y-o-y in physical terms and +12.1% y-o-y in money terms; in 2018 (preliminary data) exports will make 529.45 thousand tonnes to total USD 1,139 million, which is + 16.1% in physical terms and +8.4% in money terms³.

At the same time, Russian manufacturers encountered certain challenges while expanding their export geography to the EU. In accordance with the EU veterinary requirements, if exported goods contain ingredients of animal origin, the suppliers of such ingredients must be certified and registered as exporters in the EU veterinary control systems. In other words, if a Russian chocolate-maker wants to export its produce to the EU, the respective Russian supplier of powdered milk (an ingredient of the exported chocolate) must be registered in the EU veterinary control system. Certain difficulties are caused by absence of a health certificate issuer in the Russian Federation (as required in some countries).

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

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

1. Russian Government - establish an authority responsible for issuance of health certificates.

2. Ministry of Agriculture - accelerate implementation of a register of controlled goods exporters to the countries which are not members of the EAEU.

³According to the Confectionery Industry Association

3. Ministry of Agriculture - raise awareness of Russian agricultural producers; encourage them to register as exporters or get certified for compliance with veterinary requirements of major export destinations in the agroindustrial complex.

4. Ministry of Economic Development - implement educational programs for SMBs (agroindustrial complex) to keep up with the current requirements / certifications in the field of energy efficiency, sustainable development, environmental safety, HACCP.

Issues being monitored:

Issue 1. 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 of Economic Development proposed another scheme for implementing the project: training courses to be made freely available on the Business Environment portal. That has not been done yet.

Given that this issue is relevant for many companies, it will still be monitored.

Issue 2. 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 EAEU 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.

Appendix 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 EAEU 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

	Initiative	Name of document	Value to NCG	Deadline	Service Provider
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 of Economic Development
2.3.	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

3. Improvement of Tax and Customs Law and Administration

Improvement of Tax Law and Administration

In 2018 and 2019, the Working Group for Improvement of Tax Law focused on the following issues.

Issue 1. Verification of intra-group services.

In tax audits in 2018 and 2019, the tax authorities have been scrutinizing service agreements between a Russian legal entity and its foreign parent company or affiliate. The tax authorities claim that such services are not real or justified and reclassify payments for them as passive income (distribution of capital or dividends, for example) and charge income tax at source in Russia.

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

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

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

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

Recommendations:

We believe that the procedure for verifying intra-group services should be regulated to bring it into line with international practice.

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

In 2019, a provision of the Tax Code entered into force requiring foreign companies not registered in Russia to independently pay VAT to the budget and register with the tax authorities when they provide electronic services to Russian purchasers.

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

Consideration was given to applying the previously used tax-agent mechanism to electronic services under intra-group transactions.

As a result of repeated discussions with representatives of the Ministry of Economic Development and the Federal Tax Service, the Federal Tax Service issued a letter of 24 April 2019 which did not formally change the VAT treatment of electronic services, but indicated that a taxpayer is not required to pay VAT a second time if the purchaser of services used the tax-agent mechanism and withheld and paid VAT. This letter improved the situation, but a full solution has yet to be set down in law.

Recommendations:

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

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

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

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

This approach changed dramatically after 2013, and the following trends are of serious concern to business:

- new rules and concepts may be applied to a transaction that was completed before they had been introduced into tax law and doctrine

- numerous transactions are reclassified by the tax authorities, and the criterion of economic substance (justification) is applied to reclassify taxpayers' actions

- the burden of proof in connection with disputed acts adopted by government authorities rests with taxpayers

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

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

Recommendations:

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

Improvement of Customs Law and Administration

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.

Recommendations:

We recommend that the Federal Customs Service consider the possibility of informing low-risk companies, including via their personal accounts, 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. Use of a low risk level when applying for the release of goods prior to submission of a goods declaration.

The EEU Customs Code currently provides for the use of a low risk level when goods belonging to an AEO are declared. However, current law enforcement practice shows that this simplification is not applied when applications are submitted for the release of goods prior to submission of a goods declaration.

We believe that the software and hardware of the Federal Customs Service should be updated to allow the goods of AEOs to be automatically categorized as low-risk.

Issue 2.2. Issues of remote access to 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. Return to the list of issues

Issue 2.3. Requirements for the reporting provided by AEOs.

The order of the Federal Customs Committee approving the AEO report format contains information on all business transactions related to the movement of AEO goods – in particular, acceptance, storage, release into production and sale.

A lot of 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 amend its order by removing information – provided by AEO through remote access – which is contained in the databases of other federal executive authorities, as well as information unrelated to the simplified procedures applied by AEO, from the list of information annually provided by AEO.

Issue 3. Enhancement of state measures to support the processing of goods for domestic consumption and processing in the customs territory.

In addition to the production in Russia of components for the domestic market (or conversion to Russian raw materials), localization may also involve efficient production for the global market (expanded exports from Russia). Incentives for localizing production may include lower administrative barriers for exports of finished goods. The traditionally high share of imported goods in many segments of the Russian market – a result of low domestic supply and growing domestic demand – is a sure indicator of high growth potential for domestic production in terms of both consumer demand and import substitution. Moreover, goods produced in Russia may be viewed as competitive on the 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, as provided in Article 188 of the EEU Customs Code. This would contribute to import substitution (the customs procedure of processing for domestic

consumption). Under these procedures, raw and other materials used in processing are fully exempt from import duties, taxes and non-tariff regulatory measures. Processed products are placed under the customs procedure of release for domestic consumption, subject to import duties at the relevant rates, without the application of non-tariff regulatory measures. Even so, Chapter 26 of the Customs Code of the Customs Union sets clear, unambiguous and exhaustive requirements for foreign trade operators to ensure proper use of the 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 26 of the Customs Code of the Customs Union establishes and allows for the effective use of a customs procedure designed to attract, support and develop high-tech production in the Eurasian Economic Union, regardless of any imbalance in the customs duty rates for raw materials and finished products, while ensuring an appropriate level of control over the correct use of the procedure. Foreign trade operators note two main problems preventing these procedures from being more widely used: 1) The lack of criteria that would allow an authorized body to determine whether a means of identifying foreign goods in processed products is acceptable. 2) The limited number of goods that qualify for the customs procedure of processing for domestic consumption

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

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

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

Under Article 188 of the EEU Customs Code, the customs procedure of processing for domestic consumption may be applied to only a limited number of goods determined by the national laws of Customs Union member countries. In the Russian Federation, this list is established by Article 146 of Federal Law No. 289 and Government Decree No. 565 of 12 July 2011 (hereinafter, the “Decree”). The list is limited to only about 50 goods that are clearly intended for the production of electric trains and aircraft. Consequently, the processing procedure for domestic consumption is actually not used, thereby blocking the real development potential of the local high-tech industry with a high added value and, accordingly, the attraction of new investments into such an industry. An important fact is that the customs regime of processing for domestic consumption is widely used throughout the world and is an effective lever of both the development of the local industry and the attraction of 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 Federal Customs Service and the Russian Export Center, in cooperation with concerned federal executive bodies, should prepare detailed guidelines, based on successful examples, with step-by-step instructions on how to obtain permits to process goods in the customs territory.

Issue 4. 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 EEU 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 EEU 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 50,000. For a repeat offense, the fine is from RUB 50,000 to 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 EEU 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.

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 the aforesaid problems and simplify the export customs procedure, the working group for the 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. 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 must be presented for inspection. This experiment, however, applies only to fish products subject to state veterinary control and cleared by the Northwest Customs Administration and to controlled products cleared in the free port of Vladivostok.

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

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

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

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

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

1. The Federal Customs Service should develop and implement an automated information system to manage risks involved in state phytosanitary control when the products specified by Order No. 1996 of the Federal Customs Service of 30 September 2011 are imported.

2. Until an automated risk management system is introduced, the Federal Customs Service, in cooperation with the Federal Service for Veterinary and Phytosanitary Oversight, should develop a set of

criteria for assessing the phytosanitary risks involved in importing controlled products with a high phytosanitary risk, similar to the criteria currently applied as an experimental part of the risk-oriented approach, to products subject to veterinary control.

3. The Federal Customs Service, in cooperation with the Federal Service for Veterinary and Phytosanitary Oversight, should extend the risk-oriented approach to controlled products entering 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 7. 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.

Issue: 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.

Issue: 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.

Issue: 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 8. Issues of application of transportation cost deductions in customs value estimation.

At present, companies tend to get 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, 3 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;
- the 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 can 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).

MONITORING:

Issue 9. Classification of raw materials used in baby food.

The procedure of processing for domestic 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 needed raw materials are not produced in Russia, and customs duties for those materials are higher than for finished products.

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, recommend that the list of goods that may be processed for domestic 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 10. 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 accredited bodies of Belarus or Kazakhstan?
- If such goods can’t 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 goods are released in view of the time it takes to obtain new authorization documents in Russia?

4. The Development of Consumer Market and Technical Regulation

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

Issue 1.1. Effect of multiple tracking systems.

In recent years, various governmental agencies in Russia have implemented electronic systems that use, inter alia, additional marking to monitor and record movements of goods in the consumer market (tracking systems). This refers to the EGALS, product identification marking (the so-called CIMs and RFID marks), Mercury electronic veterinary certification system, cash register equipment, 'documentary' tracking system, etc. A number of systems are subject to EAEU supranational regulations.

The FIAC working group strongly supports the fight against distribution of counterfeit products, though pointing at a number of factors challenging the proposed measures.

- So far, decisions to introduce marking systems have been based on pilot projects and confidential progress reports for the government prepared by system operators. There is a lack of analytical market data, including on whether the illicit trade of industrial products has gone beyond limits; no discussions are held with dedicated federal executive bodies and industry representatives.

- The implementation of these systems causes significant costs to market participants (equipment purchases, development/customization of IT solutions, training staff and partners). Launching technological solutions is not enough in certain industries where production and logistics processes require redesigning (for example, canceling deliveries to small retail outlets or renting more warehouse spaces). Given the additional expenses, the cost of consumer goods is more than likely to grow substantially (up to 2%), and supply of certain categories of products will certainly reduce as it is technically not feasible to meet system requirements.

- At the end of a pilot project, it takes companies 12 to 18 months on average to eliminate any pilot project errors and align their internal systems with the new legislative requirements. The same applies to the moratorium on fines. For even the slightest changes in marking requirements, the EEC provides a transition period of 12 to 18 months to enable companies to improve their package management and equipment purchases. In the above case, system requirements are enforced as soon as the pilot project is completed.

- Numerous as they are, all those systems cannot address certain industry issues, such as unreported sales within the EAEU.

- Meanwhile, two systems are expected to apply to certain categories simultaneously. For example, dairy enterprises are to run an identification marking pilot project from 15 July 2019 till 29 February 2020 (Ruling No. 836 of the Russian Government of 29 June 2019) and make a transition to the mandatory marking system as early as in mid-2020. At the same time, dairy products are subject to the requirements of the Mercury veterinary tracking system that have applied since 1 July 2019. A current solution designed to integrate the two systems, as required by the Government, is to duplicate operations in both of them. In reality, dairy companies will carry a burden of performing additional functions in the CIM system, be subject to double checking by state bodies, as well as bear twice as great administrative (and criminal) liability. Companies are totally against the situation when one product category is controlled by two or more systems which are integrated through charging market participants with additional duties and costs.

- Even if such systems continue to evolve without overlapping control over certain categories of goods, wholesalers and retailers trading a wide range of consumer goods (including SMEs) will suffer additional pressures having to operate several systems simultaneously. As a result, they will struggle to maintain their financial ratios and consumer service level.

Launch of a tracking system in the EAEU market.

Launching tracking principles in EAEU states is not an even process, with the EEC only starting to build its provisional approach. The key requirements at the EAEU level are general in nature and provide member states with broad powers in terms of the system design and the list of controlled goods, leaving critical issues of business process organization and free movement of goods unaddressed (e.g. the need to develop unified technical marking standards or regulations governing product tracking systems).

The Agreement on Product Identification Marking in the Eurasian Economic Union allows countries to unilaterally introduce marking systems after a notification procedure without input from other EAEU member countries (Article 7 of the Agreement). Thus, the EEC can prescribe EAEU-wide lists of goods to be marked, although each member state may approve its own national lists and related requirements. Storage, transportation and sales requirements may be different or altogether missing in different states, but the exporting state will have to comply with the importer's requirements, which will hit manufacturers with

heavy costs to segment production and manage trade flows based on the 'marking' status of products. This approach is inconsistent with the EAEU's digital agenda for ensuring 'seamlessness' of the EAEU. Despite the intent, voiced in the Agreement's preamble, to ensure the lawful turnover of goods, countries will end up fighting the unlawful circulation of goods in various market segments on their own, undermining any coordination between government policies and failing to resolve the problem at the level of the EAEU as a whole.

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

Companies insist that all EAEU member states must be subject to the unconditional common and unique product tracking system which is based on an exhaustive and transparent set of principles and criteria to follow when making decisions to apply the system to new categories of consumer goods. We regret to say that paragraph 5 of the instructions of Prime Minister Dmitry Medvedev following the 32nd Plenary Session of the FIAC of 15 October 2018 (concerning the need to harmonize the requirements of electronic tracking systems used in Russia and the EAEU) has received little attention so far. The implementation of a number of tracking systems gives rise to significant risks preventing free movement of consumer products around the EAEU.

Appendices

a. Product identification marking in the Russian Federation.

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

In 2018, pilot identification marking projects were launched in Russia for tobacco products, jewelry, pharmaceuticals and footwear. A project was started in 2019 to mark tobacco products starting 1 March; the system is planned to be fully launched for certain categories of pharmaceuticals and footwear. Various proposals are being debated to expand the proposed list to cover other foodstuffs. Up until now, the principle underlying the decision to apply mandatory marking to any new product category remains unknown. Pursuant to the Product Marking Concept, decisions should be based on the proposals of the respective federal executive bodies.

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

b. Mercury electronic veterinary certification system.

Electronic veterinary certification ("EVC") of products of animal origin came into effect on 1 July 2018. As soon as the step-by-step procedure of including products in the EVC system was approved, the burden on the system declined dramatically, preventing significant system failures in processing electronic supporting veterinary documents (eSVDs) in the early stage of the EVC functioning. However, to align market operations with those of the EVC system, a lot of issues have to be resolved manually, which creates various problems for the business community. During the preparation stage and the discussions between the regulator, system designer and business representatives, the system's technical features have been extended, yet, they require further improvement. The legal framework is still weak leaving a number of issues unresolved, including the issues of sanctions and disconnecting users once they violate the SVD preparation procedure. The range of goods in the scope of the Mercury system will be extended again on 1 November 2019 and include all types of processed dairy products (Order No. 193 of the Russian Ministry of Agriculture of 15 April 2019). Given the complexity and amount of products in the category, the smooth transition of all dairy companies to the EVC system should effectively take at least 18 months from the date of the corresponding decision.

c. Documentary tracking system in the EAEU.

The ratification of the Agreement on Tracking Goods Imported into the Customs Territory of the Eurasian Economic Union (hereinafter, the "Agreement") is now underway in EAEU member states. Once ratified, the Agreement will introduce the system of tracking certain categories of imported goods based on supporting documents. On 25 June 2019, the Russian Government adopted Decree No. 807 On the Experiment to Track Goods Released in the Territory of the Russian Federation in Accordance with the Customs

Procedure of Release for Domestic Consumption. The experiment is planned to be completed by late 2019; the mandatory implementation date is as early as 1 July 2020. That is, lots and lots of businesses will have to transfer to the electronic document flow by then. Yet, there is uncertainty in how the mechanism of approving the list of goods to be tracked will work: pursuant to the draft federal law On Amendments to Part One and Part Two of the Russian Tax Code of 27 June 2019 (on establishing a nationwide (documentary) product tracking system — <https://regulation.gov.ru/projects#npa=93083>), it shall be approved by the Government of the Russian Federation (Article 105.32.2), whereas under Article 2 of the Agreement the Eurasian Economic Commission is the approving body. Thus, national regulations are in conflict with supranational regulatory acts, giving rise to more barriers in mutual trade. This method, though advanced and better aligned with the needs of business, when used in combination with the marking system, clearly creates duplicating systems and doubles the burden on businesses. The functions of the system and resulting costs for market participants are still to be determined.

The documentary tracking system should obviously be seen as an alternative to the control identification marking system; the two systems need to be compared to select the best option on the basis of a set of criteria.

Hence, we believe it essential that the Government and business community develop and submit proposals to improve digital data exchange between businesses and the government on statutory accounts, declaration, certification and other statutory compliance matters by creating a uniform information service (a “one stop shop”) guided by the following key principles:

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

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

Recommendations:

1. Legislate the principle of a common and unique product tracking system in the Russian market, harmonize the approaches, ensure integration of all such systems using a single IT platform, and lift any additional burdens for member companies.
2. Determine that one product category must not be in the scope of two or more systems.
3. Harmonize approaches to product tracking throughout the EAEU before they are implemented nationally; transfer to the consensus-based procedure of extending the list of goods to be tracked.
4. In cooperation with the business community, develop criteria for deciding whether to apply tracking systems to particular product categories, including a single fair indicator of the percentage of counterfeit and/or contraband products (based on comprehensive quantitative studies), comparability of the product cost and system implementation costs, and anticipated economic effect.
5. Design a procedure for marking imported goods released into free circulation in the EAEU following customs clearance, and for sales of goods on wholesale and retail markets.
6. Set a mandatory marking transition period of at least 18 months upon approval of a report on completing a pilot project for a particular product category; establish procedures to discuss the report and obtain approval of dedicated federal executive bodies and member companies.
7. Set a moratorium on fines to be applied to system participants for at least 12 months of accepting the information system.
8. Work out the requirements to protect the information uploaded to the system by businesses.

9. Discuss and agree the format and volume of data on the movement of goods generated from the tracking and marking system with the concerned industry associations (including manufacturers, wholesalers and retailers).

10. Remove any legal uncertainties associated with the Mercury system functioning, improve the technical efficiency of certain aspects of the system, including through amending Order No. 589 of the Russian Ministry of Agriculture of 27 December 2016.

11. To mitigate the risks for commodity supply chains, shift the date of including new categories of finished dairy products in the Mercury state information system from 1 November 2019 to 1 February 2020.

II. State policies on healthy lifestyle.

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

Decree No. 204 of the President of the Russian Federation On National Goals and Strategic Development Objectives of the Russian Federation through 2024 of 7 May 2018 determines a strong natural population growth in Russia and an increase in life expectancy to 78 years (80 years by 2030) as priority goals of the national social policy. In this context, health protection and promotion of a healthy lifestyle become issues of primary importance, which, therefore, have been translated into the national Demography and Health Care programs.

Russia has several state projects under way to promote a healthy lifestyle. Yet, they lack coordination, so it is too early to conclude on the systemic government effort in this area.

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 through 2025 (the “Strategy”). The Strategy’s goal is to create an efficient system of public health covering the creation of healthy lifestyles, prevention and control of noncommunicable diseases, which would help improve healthy life expectancy, reduce the number of noncommunicable diseases and mortality rates, as well as increase the proportion of the population leading healthy lifestyles.

Unfortunately, market players affected by the proposed regulation, including importers, producers and retailers, are not involved enough to contribute to the Strategy development. In the absence of a relevant draft of the Strategy, they cannot give any constructive ideas on the issue.

Another problem of the Strategy relates to its inadequate terminology — many terms are not clearly defined and subject to varying interpretations. 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. 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 should be removed.

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 a consistent 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 which was included in the nation-wide Demography project in the form of the Developing Incentives for Citizens to Lead Healthy Lifestyles, Including Healthy Diets and Refusal of Bad Habits section and 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.

A matter of special attention is the approved concept of a healthy lifestyle communication campaign involving manufacturers — a measure to be implemented under the priority project. The campaign is a pilot project for the marking of qualified goods to confirm that they meet the principles of a healthy lifestyle. So far, however, the concept was not supported with any scientific basis for the nutrient profiles underlying the proposed marking pilot project or for its chosen list of products, leaving the justification of these criteria open to debate. FIAC member companies oppose such an approach as discriminatory and incompatible with the principles of a balanced diet.

The proposed criteria conflict with, for example, the criteria of optimal and excessive nutrient content developed by the Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing, jointly with the Nutrition and Biotechnology Federal Research Center, in fulfillment of Paragraph 53 of the

Implementation Plan for the Strategy to Improve the Quality of Food Products in the Russian Federation through 2030. This lack of coordination between various government bodies may result in the parallel development of two conflicting systems of criteria, thus disorienting business and consumers and ultimately discrediting the concept of a healthy lifestyle.

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.

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

Recommendations:

1. Recommend the Ministry of Health of the Russian Federation to enlarge the Interdepartmental Public Health Council, responsible for the coordination of Strategy implementation efforts, by including industry unions, industry associations and researchers in the sphere of food product manufacturing in order to work out systemic solutions that will help to achieve the goals and objectives set in the Strategy.

2. Request that the Government instruct the Ministry of Health to set up a permanent interdepartmental working group on the harmonization of documents concerning the promotion of a healthy lifestyle, prevention of noncommunicable diseases and enhancement of food quality with other program documents (e.g. the Strategy for Increasing the Quality of Food Products in the Russian Federation through 2030) and with EAEU law. The working group should include representatives of concerned executive bodies, including the Ministry of Economic Development, the Ministry of Industry and Trade, the Ministry of Agriculture, the Federal Antimonopoly Service, the Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing, etc., as well as members of business associations and the scientific and expert community.

3. Recommend that the Ministry of Health conduct an obligatory regulatory impact assessment of regulatory and legal acts, which will be drafted to ensure the Strategy is realized.

4. Recommend that the Ministry of Health expand the draft Healthy Lifestyle Strategy so that it covers measures to emphasize a balanced diet, exercise and responsible consumption, and boost the self-regulation potential of market players.

5. Elaborate the terminology and language of the Strategy.

III. State trade policies.

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

The amendments to the Law On Trade effective since 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, which have encountered the greatest difficulties.

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

Players on the food market were seriously inconvenienced by the large-scale inspections that regulatory agencies initiated after 1 January 2017 to ensure that suppliers and retailers complied with the amended law. The inspections, however, revealed no major violations. The process of self-regulation that in 2014-15 partially enabled market participants to find helpful solutions and restrain price growth 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 were 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 was passed in 2018 totally prohibiting returns of food products with a shelf life of under 30 days. Other new legislative initiatives were designed to ban contractual penalties and control prices. Other topics are now being publicly discussed, such as the regulation of markups, direct imports, in-house production and own trademarks, the introduction of shelf quotas for local manufacturers and the limitation of food quality inspections and shopping center hours. All of this raises real risks that state regulation of the economy will continue to intensify and that legislative interference with economic relations between players on the food market will be counterproductive in terms of the development of a modern market economy.

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

Recommendations:

1. Complete 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. In cooperation with suppliers and traders, formulate a federal-wide 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.

IV. Building an integrated regulatory environment of the Eurasian Economic Community and its effect on the consumer market.

Issue 4.1. Creating unreasonable barriers to import and move specialized medical and specialized dietary nutrition products, including clinical and child nutrition products, to and around the EAEU.

Decision of the Board of the Eurasian Economic Commission On Amendments to the Unified List of Goods Subject to Veterinary Control came into force on 22 February 2019 to include new positions (products) under EAEU Classifier codes into the list; a number of the positions have been revised.

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

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

It is noteworthy that most of the above products and ingredients are altogether free from components of animal origin within Group 04 of the EAEU Classifier (dairy products) or any other group from Section 1 of the EAEU Classifier (products of animal origin) and have never been treated as food products exposed to veterinary risk. Moreover, such products have never been subject to veterinary control in EAEU countries.

The logic of the Draft Decision suggests that new descriptions of goods are beyond the scope of the effective exemption from veterinary control for finished food products of less than 50% content of animal origin, where supplies are made to the Russian Federation and the Republic of Kazakhstan. This regulation is in line with the commitments assumed on joining the WTO and fixed in Decision No. 810 of the Customs Union Commission On Exemptions from Veterinary Measures for Goods in the Unified List of Goods Subject to Veterinary Control (Oversight) of 23 September 2011 (“Decision No. 810”) and in Decision No. 317 of the Customs Union Commission On the Application of Veterinary and Sanitary Measures in the Eurasian

Economic Union of 18 June 2010 (Appendix 1 to the Unified Veterinary Requirements for Goods Subject to Veterinary Control (“Decision No. 317,” UVSR).

Such an approach sets a precedent for violating the WTO requirements across the EAEU, with the burden subsequently cascading to manufacturing and logistics operations in member countries that assumed those obligations (to date, Russia and Kazakhstan).

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

To implement the proposed veterinary control measures (for example, requirements for importers of very risky products, such as live stock or non-processed carcasses, to be included in the register of importers and obtain import permits), complex arrangements are required which might take a few years before launching deliveries. This threatens not only the domestic food industry as a whole, but also public health in EAEU member states where such specialized products are a vital means to maintain quality of life.

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

Recommendations:

- Add an exemption to the Draft Decision for products of less than 50% content of animal origin, where supplies are made to the Russian Federation and the Republic of Kazakhstan, and replace the term “milk components’ with the term “Group 04 products.”

- Reduce control measures for products to a simple “veterinary certificate” requirement.

- Provide for an exemption from veterinary control for specialized products, including baby foods, vitamins, minerals and supplements (vitamin and mineral complexes and premixes), flavoring agents, protein concentrates (of animal and vegetable origin) and their mixes, dietary fibers, food supplements (including complex supplements), dietary supplements, food products used as ingredients to make baby foods, stabilizers, flavorants, icings, pastes and fillers.

- Set a transition period for the decision of at least two and a half years from the date of its official publication.

Issue 4.2. Technical regulation of the Eurasian Economic Union On Safety of Chemical Products and its impact on companies in the consumer and chemical sectors.

Summary:

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

This regulation will be a big hurdle for releasing chemical products into the market and, consequently, adversely impact the operating environment in all industrial sectors. Also, national goals and strategic development objectives of the Russian Federation⁴ will be inevitably affected as a result of a reduced production output and slowed product development and localization by foreign entities (frozen domestic production of chemical and other products is a possibility). It will also raise barriers to the release of advanced innovative products in the Russian market, deliveries of raw materials, free movement of goods, services, capital and labor resources in the territory of the Eurasian Economic Union.

⁴ Decree No. 204 of the President of the Russian Federation On National Goals and Strategic Development Objectives of The Russian Federation Through 2024 of 7 May 2017

The above issues result from the following:

- The number of substances subject to registration has grown due to the requirement to register raw materials to produce food products, household chemicals, perfumes, cosmetics, medical devices, pharmaceutical products and products of other industries not currently subject to registration, as well as due to the requirement to register chemical mixtures.
- It takes longer (a year and a half) to market products (and raw materials).
- Substantial funds and resources will have to be spent on product validation.
- There is a risk of loss of confidential information on mixture compositions, which constitutes intellectual property.
- While there is no laboratory infrastructure in Russia to support testing, foreign protocols are not accepted.

Recommendations:

- Advise that the Ministry of Economic Development and Ministry of Industry and Trade initiate amendments to EAEU Technical Regulation 041/2017 that will promote high standards of chemical products safety without complicating the release of those products into the Russian and other EAEU markets.
- Synchronize the amendments to EAEU Technical Regulation 041/2017, the approval of the procedure to create and maintain the EAEU register of chemical substances and mixtures, and the approval of the notification procedure for new chemical substances.
- Revise the effective date of EAEU Technical Regulation 041/2017 to allow a transition period to implement the recommendations above.

Issue 4.3. Issues involved in confirming compliance with Technical Regulation 037/2016 On Restrictions to Use Hazardous Substances in Electrical and Electronic Products of the Eurasian Economic Union.

The Technical Regulation of the Eurasian Economic Union On Restrictions to Use Hazardous Substances in Electrical and Electronic Products adopted by Decision No. 113 of 18 October 2016 (the “Technical Regulation”) became effective on 1 March 2018. The mandatory implementation date is 1 March 2020. From a realistic perspective, at least 10,000 compliance documents have to be designed to govern market activities, with only 64 in effect as per the August data.

More than half (53%) of market participants prepare certificates (34 documents), not declarations (30 documents), though the Technical Regulation focused on European practices so as to motivate market players to undergo the declaration procedure. A greater clarity of the declaration mechanisms and more confidence from market players would reduce the percentage of certificates to 10% maximum.

The use of the certification procedure to confirm compliance makes it clear that market participants are not ready to apply the compliance declaration procedure as intended.

As opposed to the declaration mechanism, the certification procedure is very costly (USD 5,000 to USD 10,000 per document) and lengthy (about two months). With ten accredited laboratories really needed, only five are currently functioning — not enough to issue certificates to even 20% of market participants.

As the case stands, domestic manufacturers will be hit hard, for the laboratories are overloaded with orders for six months ahead, which means they won't manage issuing certificates (and running mandatory tests) to all market participants. A major part of the documents (75% as per statistics) have been issued to foreign producers.

The existing market tension raises the following two major legal and technical issues associated with the varying interpretations of the Technical Regulation and ambiguity of the mechanisms to confirm compliance with Technical Regulation 037/2016.

1. Is it obligatory to conduct tests at EAEU laboratories when declaring compliance under Schemes 1d and 2d?

Pursuant to Paragraph 21 of the Technical Regulation, the declaration of compliance under Schemes 1d and 2d is based on the declarer's own evidence. At the same time, Paragraph 21 refers to the results of sample testing; no other 'own evidence' is specified, such as documented procedures implemented by the manufacturer to comply with the Technical Regulation.

Paragraph 21 of Technical Regulation 037/2016 of the Customs Union

21. The declaration of compliance of electrical and electronic products under Schemes 1d and 2d is based on the declarer's own evidence. At the declarer's discretion, samples of electrical and electronic products shall be tested at the declarer's testing facility, an accredited testing laboratory (center) included in the Customs Union Unified Register of Certification Bodies and Testing Laboratories (Centers) (hereinafter, the "Unified Register") or any other testing laboratory.

According to Paragraph 22 of the Technical Regulation, though, the declarer confirming compliance under Schemes 1d, 2d, 3d, 4d, or 6d may use test reports and (or) other documents, at the declarer's discretion.

Paragraph 22 of Technical Regulation 037/2016 of the Customs Union

22. To declare compliance of electrical and electronic products, the declarer shall:

a) Prepare and analyze documents confirming compliance of the products with the requirements of the Technical Regulation, including:

...

report(s) of testing samples of products and (or) their constituent parts, materials or components for compliance with the requirements of the Technical Regulation and (or) other documents (if any), at the declarer's discretion, that served as grounds to confirm compliance of the products with the requirements of the Technical Regulation (Schemes 1d, 2d, 3d, 4d, and 6d)

Experts are disoriented in this ambiguous situation. Paragraphs 21 and 22 of the Technical Regulation either are in contrast or, conversely, complementary, which, in the latter case, suggests that the declarer may elect to use other documents to confirm compliance under Schemes 1d and 2d. Paragraph 21 specifies how to conduct laboratory tests when using Schemes 1d and 2d to clarify which laboratories to use when the declarer elects to use test reports from the laboratory instead of other documents; therefore, the declarer confirming compliance under Schemes 1d and 2d may elect not to use test reports but use solely other documents as evidential matter.

2. Is it obligatory to upload documents that served as grounds to confirm compliance of products with the Technical Regulation into the Federal State Information System of the Russian Accreditation Service when registering the declaration of compliance under Schemes 1d and 2d?

The problem is that documents evidencing compliance with the Technical Regulation comprise thousands of pages describing, inter alia, all the constituent parts of products, and this information is a trade secret never shared. European regulations do not require sharing the documents with third parties, as third parties cannot review those within a reasonable term, anyway. Technical Regulation 037/2016, in its turn, does not require declarers registering declarations themselves to transfer evidential matter to certification bodies or upload it into information systems (for example, the Federal State Information System of the Russian Accreditation Service); at the same time, it is required in accordance with Paragraph 2 of Order No. 76 of the Russian Ministry of Economic Development of 21 February 2012. It is challenging to meet the contradicting requirements in Order No. 76 and Technical Regulation 037/2016: regulatory bodies are unwilling to use Schemes 1d and 2d under the Technical Regulation without uploading any documents, confidential documents may not be uploaded into the system, and foreign language originals of such documents may not be used unless translated.

To register a declaration of compliance in accordance with Paragraph 4 and Paragraph 5d of the Procedure of Registration, Suspension, Renewal and Termination of Declarations of Compliance of Products with Technical Regulations of the Eurasian Economic Union approved by Decision No. 41 of the EEC Board of 20 March 2018 (hereinafter, the "EAEU Registration Procedure"), the declarer shall provide an authorized (certification) body with a declaration of compliance and the accompanying copies of evidential matter required by the technical regulation(s) to register the declaration of compliance. EAEU Technical Regulation 037/2016 contains no requirement to submit any evidential matter to any authorized (certification) body. Thus, the declarer is not obliged, in registering a declaration of compliance of products with the requirements of EAEU Technical Regulation 037/2016, to submit any evidential matter.

At the same time, Paragraph 2.4 of the Procedure for Registration of Declarations of Compliance approved by Order No. 76 of the Russian Ministry of Economic Development of 21 February 2012 (hereinafter, the "Russian Registration Procedure") requires submitting declarations of compliance together with copies of all evidential matter confirming compliance with the requirements of the technical regulation(s) applicable thereto.

Therefore, the Russian Registration Procedure, compared to the EAEU regulations, contains more extensive requirements to the submission of evidential matter.

Recommendations:

1. Request that the Russian Ministry of Industry and Trade and the Eurasian Economic Commission clarify whether evidential matter has to be uploaded into the Federal State Information System of the Russian Accreditation Service when registering declarations under Schemes 1d and 2d.

2. Request that the Russian Ministry of Industry and Trade and the Eurasian Economic Commission clarify whether tests have to be run at EAEU laboratories when using Schemes 1d and 2d and whether other documents may be provided.

Issue 4.4. Impact of shortcomings of Technical Regulation 017/2011 On Safety of Light Industry Products of the Customs Union on the legalization of light industry turnover in the Eurasian market.

The proposed amendments focus on issues raised by experts of a number of Russian institutions, including the Russian System of Quality autonomous non-commercial institution. The solutions are yet to come, their implementation is very complex and requires a great deal of human resources and financial support from the government before the issues are forwarded to the EEC agenda.

The amendments address the following:

1. Denim or velvet products are illegal as their breathability is measured at 20 dm³/cm²/xs at its best (compared to 50 dm³/cm²/xs as per the Technical Regulation), according to the tests of denim products conducted by Russian System of Quality in 2018.

It is proposed to align the breathability requirements of Technical Regulation 017/2011 of the Customs Union for denim and velvet, the requirements of State Standard 21790-2005 and the actual breathability figures for denim and velvet.

2. Headwear, scarves and gloves are also in the scope of the breathability requirements. It stands to reason, though, that breathability of such products is not exactly a key parameter in the winter, that's why they were exempted from the breathability requirements set for kids' clothing in Technical Regulation 007/2011.

By analogy with the latter, it is proposed to exempt headwear, scarves and gloves from the breathability requirements set for adult apparel in Technical Regulation 017/2011.

Recommendations:

1. Accelerate interdepartmental approvals by responsible federal executive bodies of Russia to move the issue to EEC's activity plan as soon as possible.

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 in the circulation of pharmaceuticals due to production and supply of pharmaceuticals manufactured illegally using registered inventions.

1.1.1. 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.

Such practice results from existing legislative gaps. According to Federal Law No. 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 is 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. Current legislation does not require producers of generic drugs applying for registration with the State Register of Pharmaceuticals to commit to withholding their product from civil circulation until the expiry of effective patents for original drugs. Therefore, contracting authorities and consumers are misled and believe that simultaneous existence of reference and generic pharmaceuticals on the market is appropriate, whereas low prices for generic drugs are misleading for contracting authorities and affect the determination of the initial maximum price of a contract (IMPC).

As a result of actions taken by unscrupulous market participants, patent holders 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. Over the recent years, member companies of FIAC’s Working Group had to initiate tens of court proceedings on this matter.

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).

On 25 October 2018, the Ministry of Health published amendments to Federal Law No. 61-FZ “On the Circulation of Pharmaceuticals” for public discussion. These amendments address the protection of intellectual property rights upon the state registration of a drug. The Working Group supports these amendments; however, the proposed amendments do not solve the problem of registering the prices for drugs that cannot be released for public use due to violation of rights to the results of intellectual activity of other manufacturers.

In collaboration with the Russian Ministry of Economic Development and with the involvement of federal executive bodies, the Working Group initiated an interdepartmental dialogue about the protection of intellectual property rights in the pharmaceutical industry. At the meeting with the Minister for Economic Development of the Russian Federation (Minutes No. 28-MO of 2 October 2018) with the participation of FIAC, the decision was agreed to amend Federal Law No. 61-FZ “On the Circulation of Pharmaceuticals” to ensure the creation of a unified register of pharmacologically active substances whose invention is protected by patents (hereinafter, the “Unified Register”). The contents of the Unified Register should be taken into account by the Russian Ministry of Health when registering a drug. The validity term of the registration certificate for a generic should be set from the date of expiry of patent rights to an invention relating to the relevant reference drug or the date when a right to use the invention is obtained from the rights holder under a license agreement. To implement this provision, the Federal Service for Intellectual Property (Rospatent) set up a working group in July 2019 that comprised representatives of the pharmaceutical industry and federal authorities to develop approaches to establishing and creating this register.

It should be noted that the Russian Ministry of Health has successfully ensured the fulfillment of Article 37 of Federal Law No. 61-FZ “On the Circulation of Pharmaceuticals” of 12 April 2010 by making information about all applications for state registration of pharmaceuticals publicly available on the official website of the Russian Ministry of Health.

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

Recommendations:

1. Pharmaceuticals registered in the period when the respective patent is effective may be introduced into civil circulation only with the consent of the patent holder or upon the patent expiry. Information on existing patents and dates of introducing drugs into civil circulation must be included in the unified state register of pharmaceuticals for medical use.

2. State registration of maximum manufacturer's price for the pharmaceuticals is equivalent to the introduction into civil circulation and is permitted only with the consent of the patent holder or upon the patent expiry.

3. Align Russian legislation with legal acts of the Eurasian Economic Commission in terms of indicating information about the protection of IP rights to the drugs by patents effective in EEU member states upon the registration of drugs, and receiving applicant's confirmation that the rights of third parties protected by the patent or transferred under a license were not breached due to registration of a new drug.

4. Adopt laws regulating the circulation of pharmaceuticals in the Russian Federation and the EEU that would ensure that pharmacologically active substances specified in the respective register are covered by valid patents when setting the term of the registration certificates upon state registration of third parties' drugs.

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

1.2.1. Problem

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).

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.

This provision was met by clause 18 of Federal Law No. 61-FZ prior to its amendments by Federal Law No. 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 No. 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 civil 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 introducing a generic or biosimilar into circulation in respect of the reference pharmaceutical exclusivity period.

Considering that the EEU common pharmaceutical market has operated since 2016 and the state registration of pharmaceuticals during the national procedures will cease to be possible starting 1 January 2021, it seems reasonable to propose to the EEU, in accordance with the established procedure, to consider introducing data exclusivity in the framework of regulation of the state registration of pharmaceuticals.

Recommendations:

1. Amend Part 18 of Article 18 of Federal Law No. 61-FZ "On Circulation of Pharmaceuticals", i.e. to prohibit usage of information about pre-clinical and clinical studies of pharmaceuticals presented by the applicant for the purposes of their state registration without its consent during six years since the date of the state registration of a drug.

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

3. Ensure 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.

5. Add one more line to the state register of pharmaceuticals to present information about the period of introducing a generic or biosimilar into circulation in respect of the reference drug exclusivity period.

6. Amend the regulation of circulation of pharmaceuticals in the EEU to prohibit usage of information about pre-clinical and clinical studies of pharmaceuticals presented by the applicant for the purposes of their state registration without its consent during six years since the date of the state registration of a drug.

1.3. Possible legislative amendments that would introduce compulsory licensing.

1.3.1. Problem

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

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

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

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.

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

Recommendations:

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

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 the end of 2019, 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 two 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 35,000 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.

At the moment, the EEC Working Group on the Formation of Common Approaches to the Regulation of Medical Products Circulation in the Eurasian Economic Union has already developed draft amendments to the Agreement on Common Principles and Rules for Circulation of Medical Products in the EEU countries 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 and after the end of the transition period (after 31 December 2021). At the same time, in order to raise interest of all manufacturers of medical products in accelerating the launch of the common market, it is appropriate to consider introducing a simplified registration/re-registration procedure for medical products locally registered that have successfully circulated in EEU member states and proven their safety and effectiveness.

Special mention goes to current excessive requirements for mandatory confirmation of expert reports by regulators of all EEU member states, where the circulation of manufactured medical products is expected. These requirements contradict the very idea of creating the common market for EEU member states and, in fact, may be deemed as a certain distrust among the regulators of these member states. Therefore, it is

advisable to consider the exclusion of the procedure for confirming expert reports by the regulators of the countries of recognition from the process of registration of medical products in the EEU.

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 after 31 December 2021 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. Decriminalization of the circulation of medical products that cannot endanger life and health (amendments to Article 38 of Federal Law No. 323-FZ “On Principles of Public Health Care in the Russian Federation” of 21 November 2011 and Article 6.33 of the Code of the Russian Federation on Administrative Offenses).

2.2.1. Problem

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

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

In light of the above, we believe it appropriate to legalize the circulation of the medical products that bear no risk of damage to life or health, even if there are inconsistencies in their registration files. This will ensure stable tax proceeds from the circulation of such medical products and alignment of the Russian legislation and international regulations adopted in the 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. The Ministry of Health should accelerate the adoption of the draft law to amend Article 38 of Federal Law No. 323-FZ “On Public Health Care Principles in the Russian Federation,” which has been going through interdepartmental approval process for about two years.

2. Amend the existing term of ‘a poor-quality medical product’ in Article 38.13 of Federal Law No. 323-FZ so that it indicates the potential danger of using the product.

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

2.3 Regulation of prices for implantable medical devices (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).

2.3.1 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 rule out the costliest 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 mechanism envisaged by the current version of Decree No. 1517 of 30 December 2015 cannot be implemented, the Working Group proposes to consider the use of alternative mechanisms for the determination of the initial maximum price of medical products stated in the List, including based on the prices from the Catalog of Goods, Works and Services for State and Municipal Needs (Russian Government Decree No. 145 of 8 February 2017), prices from the register of contracts concluded for previous time periods, as well as prices from suppliers’ proposals.

Issue 3. Access to innovative technologies and localization of production.

3.1. Streamlined drug supply system for Russian citizens.

3.1.1. Problem.

The structure of the pharmaceutical market is now strongly imbalanced, in that the compensation of most of treatment expenses is at the expense of the patient and this situation has not changed for many years. The

state budget provides for a little more than 35% of all expenses for pharmaceuticals (more than RUB 380 billion), while other expenses are covered by patients, and about 50% of that amount are prescription drugs.

An extension to the state drug supply program, particularly in the outpatient segment covering all citizens and not only patients entitled to subsidies, will help to improve treatment and reduce mortality. In order to resolve this problem, one of the instructions of the Russian President of 17 December 2018, issued based on the results of the meeting on the effectiveness of the drug supply system on 16 November 2018 in St. Petersburg, was to ensure submission by the Russian Government of recommendations to modernize the drug supply system for citizens, including concerning the implementation in certain constituent entities of the Russian Federation of relevant pilot projects aimed at analyzing different approaches to the establishment of the universal drug supply system.

In addition, according to Edict No. 254 of the President of the Russian Federation “On the Strategy for the Development of Russian Health Care to 2025” of 6 June 2019, among the priorities for solving the main problems of the development of health care are improvement of drug supply mechanisms, as well as the mechanism of pharmaceutical pricing. Today, it seems necessary to begin training, pilot testing and selecting the best models to be implemented to improve drug supply mechanisms.

At the same time, financing of pilot projects at the regional level, selection of preferred diseases, types of drugs and a regulatory framework governing relations between manufacturers of medicines and regional health authorities and medical organizations involved in the pilot project remain among the most difficult and unresolved tasks aimed to ensure successful implementation of this initiative. In addition, pilot projects and subsequent establishment of the universal drug supply system will ensure that the goals of the Health Care National Project to reduce mortality and increase life expectancy by 2024 are met.

Recommendations:

1. Supplement federal programs under the Health Care National Project with indicators reflecting improved drug supply, particularly in the outpatient segment. Cardiovascular diseases and cancer should be considered as a priority.

2. In order to prepare the pilot projects, in September 2019, set up an interdepartmental working group in cooperation with the Russian Ministry of Health, pharmaceutical industry players (manufacturers, distributors, pharmacies) and regional stakeholders, including those representing pharmaceutical clusters. The working group will help agree on the regions taking part in the pilot projects, diseases and pharmaceuticals most important for pilot projects, and drug supply models evaluated in the course of the pilot projects. For drugs participating in the pilot projects, including those implemented in the Russian Federation, procurement preferences or other benefits may be granted, including tax benefits, which would promote the participation of companies in pilot projects.

3. In order to facilitate the activities of the Healthcare Working Group of the State Council of the Russian Federation, engage FIAC member companies as experts in optimization of drug supply and development of pharmaceutical industry.

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

3.2.1. Problem

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

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

The High-Cost Nosologies State Program (hereinafter, the “HCN Program”) (Decree No. 1416 of the Russian Government of 26 November 2018), which was adopted in 2008 and has made a revolutionary breakthrough in the availability of innovative drugs for treating the most severe diseases with significant medical costs, needs to be further developed today. The criterion of “no negative impact on the existing program budget during the first year and three-year planning period” when considering proposals to include drugs in the list (Decree No. 871 of the Russian Government of 28 August 2014) and a high level of “generification” of the HCN Program create a significant and often impassable barrier to innovation,

especially for unique drugs of the last generation, which are really capable of fundamentally changing the treatment paradigm, and not only save, but also significantly prolong the patient's life and improve its quality.

Another significant barrier to innovation on the Russian market is the existing procurement system. In accordance with the provisions of Federal Law No. 44-FZ of 5 April 2013, the purchase of medicines is carried out mainly through electronic auctions by reducing the initial (maximum) price. The auction method helps to get the lowest offer price only if there are several participants offering a drug with the same international non-proprietary name (INN) and is most suitable for procurement of generic drugs and biosimilars. An innovative drug has a unique INN. Therefore, competitive bidding procedures do not reduce the price, but require temporary and organizational costs for the auction.

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

Furthermore, such long-term approach to planning the procurement of innovative drugs protected by patents should include alternative forms of procurement (other than e-auctions), such as risk-sharing contracts and cost-sharing contracts, which will not only make innovative treatment more affordable for the patients, but also will lead to lower budget costs for the drug supply. A decrease in prices considering supply volume and timing, as well as additional supplier's liabilities related to risk sharing if the treatment does not prove to be positive, seem to be economically feasible for procurement of pharmaceuticals using the federal or regional budget or compulsory health insurance funds, which is important in the context of cost containment and the need to receive reimbursement for costly treatment.

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

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

Recommendations:

1. Introduce a differentiated approach to the assessment of innovative drugs when preparing lists of pharmaceuticals for human use and the minimum assortment of pharmaceuticals needed to provide medical care, taking into account their long-term impact on the quality of life and life expectancy and excluding the criterion of negative impact on the budget for this category of drugs.

2. Develop and implement a mechanism allowing the transfer of pharmaceuticals with registered analogues in the Russian Federation from the HCN Program to other drug supply programs in accordance with their profile (in-patient, outpatient segment), while maintaining their availability in accordance with the actual need.

3. For innovative patent-protected drugs provide for a differentiated mechanism for fixing prices provided by legislation and price regulation.

4. Create a legitimate interdepartmental platform under the patronage of the Russian Ministry of Health to negotiate with manufacturers the conclusion of various purchase agreements for innovative drugs. The government bodies have already worked successfully with manufacturers at joint platforms, for example, within the interdepartmental commission established to negotiate and conclude special investment contracts under the patronage of the Russian Ministry of Industry and Trade.

5. Develop a legal instrument that would enable the formalization of proposals and recording of obligations of the parties when concluding agreements supported at the interdepartmental platform.

6. Amend and improve 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.

7. Introduce a flexible mechanism for planning budgets for government programs based on the assessment of medical technologies, as well as the real needs of patients reflected in the unified register of patients entitled to subsidies and using digital technologies for data procession.

Issue 4. 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 and are actively involved in discussion and development of the basic principles of such a track and trace (T&T) system.

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.

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 2020. And for pharmaceutical drugs used to treat individuals suffering from hemophilia, mucoviscidosis, pituitary dwarfism, Gaucher's disease, malignant tumors of lymphoid, hematopoietic and related tissues, multiple sclerosis, hemolytic uremic syndrome, systemic-onset juvenile arthritis, mucopolysaccharidoses of types I, II and VI, as well as individuals after organ and/or tissue transplantations, and included in the respective list – since 1 October 2019.¹

Due to the reporting requirements, a T&T systems to monitor movements of pharmaceuticals implemented in the Russian Federation is the most ambitious and the most complicated system of this type ever existed. Adding cryptographic protection requirement (electronic signature, verification key) 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 leads to necessity to supplement additional symbols to the means of identification (DataMatrix bar code), which, in its turn, will require larger secondary packages, 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. The Working Group believes it is necessary to change requirements for the crypto code by reducing it to 26 symbols, including the verification key (4 symbols), as well as the electronic signature (19 symbols), including delimiters, by introducing respective amendments to Decree No. 1556 of the Government of the Russian Federation of 14 December 2018.

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 chain.⁵ Namely, ICMRA believes that it is necessary to align

¹ Decree No. 1557 of the Russian Government "On the Implementation of the System for Monitoring the Movements of Pharmaceuticals for Medical Use" of 14 December 2018

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

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.

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).

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

Thus, the drug marking system should be planned and implemented in accordance with the common pharmaceutical market and the possibility of harmonizing the proposed marking model by all member states, as well as be in line with manufacturers of all EEU member states and not lead to isolation of the EEU commodity market in other countries.

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 the 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.

Recommendations:

1. Ensure the use of technical solutions aligned with international standards specifying 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 turnover system and maintain industrial cooperation focused on expanding the pharmaceutical industry's export potential. Also change requirements for the crypto code by reducing it to 26 symbols, including the verification key (4 symbols), as well as the electronic signature (19 symbols), including delimiters, by introducing respective amendments to Decree No. 1556 of the Government of the Russian Federation of 14 December 2018.

2. Together with the Eurasian Economic Commission agree on the consistent mandatory requirements in respect of pharmaceutical marking with means of identification in accordance with Article 30 of Treaty on the Eurasian Economic Union of 29 May 2014, which states that a common market of pharmaceuticals should be based on the following principles: adoption of common rules in the field of circulation of pharmaceuticals and harmonization of member states' legislation with respect to control (supervision) over the circulation of pharmaceuticals.

3. Decide on the date of the implementation of the T&T system to monitor the movement of pharmaceuticals for human use based on the results of testing and new requirements to the security code.

6. Financial Institutions and Capital Markets

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

Issue 1. Taxation.

1.1. Problem of FATCA in Russia and its application models – postponed.

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. 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 2. Problems of amending Currency legislation- issue resolved.

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

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

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

Recommendations:

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

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

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

Status 2015 – 2016:

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

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

On 20 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 3. Standard loan agreement for small and medium-sized enterprises – issue resolved.

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

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

Importance:

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

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

Issue 4. Conversion – issue resolved.

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 organizations in an effort to make them Basel III compliant. Basel III specifies the criteria for debt instruments issued by a bank to qualify as Additional Tier 1 Capital (i.e., additional to the Common Equity Tier 1) which include, inter alia, the requirement for such instruments to contain loss absorption features through

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

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

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

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

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

(a) compliance with certain corporate procedures and regulatory approvals relating to the issuance of additional common stock into which the subordinated loan is 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:

- The conversion of subordinated loans is no longer subject to the requirements of federal laws governing the procedure for obtaining approvals from the Bank of Russia and the FAS of Russia, for the acquisition of thirty or more percent of ordinary shares of a joint-stock company credit institution;

- No involvement of the state financial supervisory body to determine the price for the placement of shares is required;

- The conversion of subordinated loans is no longer subject to requirement to exercise preemptive rights by the persons having preemptive rights to acquire additional shares of the bank;

- In the event of a failure by the borrower bank to fulfil the relevant obligations in relation to the conversion, the CBR could exercise its authority and issue a conversion demand therefore forcing the bank to complete the conversion as potentially, if the trigger events are not remedied, the CBR may need to revoke the banking license.

- There is more transparency envisaged in the conversion process; etc.

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

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

Issue 5. Banking secrecy regulation- issue postponed.

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

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

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

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

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

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

Recommendations:

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

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

Issue 6. Changes in the legislation on Personal Data (Law № 242-FZ dated 21.07.2014) -postponed.

Federal law 242-FZ – challenges for business.

Banking community expresses its concern with the adoption of the Federal Law "On Amendments to Selected Legislative Acts of the Russian Federation with Regard to Clarification of Data Processing of Personal Data across Information and Telecommunications Networks" # 242-FZ dated 21.07.2014 (hereinafter, the "Law"). The Federal Law # 152-FZ dated 27.07.2006 "On personal data" in its current versions covers all operators of personal data without any exceptions which effectively means that all Russian and foreign companies operating in the Russian Federation will have to 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 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 7. 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 8. Unilaterally Accounts Closure – issue resolved 2017-2018.

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

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

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

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

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

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

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

Recommendations:

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

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

On October 27, 2015, the Banks and Financial Markets Group of the Foreign Investments Advisory Council sent to N. N. Gonchar, Chairman, State Duma Committee on Financial Markets, a letter with detailed proposals regarding amendments to be introduced to Article 859 of the Civil Code of the Russian Federation regarding termination of bank account agreements, and to Direction of the Bank of Russia dated July 15, 2013, No. 3026-U. Unfortunately, no response from the State Duma of the Russian Federation has been received to date.

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

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

Current status as of September 2017:

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

Issue 9. Access to state funds and strategic companies for foreign (non-state) financial institutions - issue resolved 2018/2019.

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

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

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

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

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

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

Status 2016:

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

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

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

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

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

Recommendations:

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

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

2017 Status:

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

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

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

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

2. Draft decree of the Government of the Russian Federation On fixing maximum amount of per bank guarantee and the maximum amount for all active guarantees issued by the same bank that can be accepted by tax authorities to ensure payment of taxes”.

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

Recommendations:

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

2018 Status:

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 10. Power of attorney register (changes to 332 FZ) – postponed.

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

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

Questions:

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

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

Proposal:

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

- We also believe that it is necessary to consider the inclusion of other international standards as sufficient for outsourcing the respective functions if there is a relevant international license.

Questions:

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

Issue 13. Calculation basis for fines on credit institutions – changes to §74 of the Federal Law on Central Bank of Russia.

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

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

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

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

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

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

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

Issue 14. Improvement of Regulation in the sphere of Anti-Fraud in Money Transfers in order to introduce effective mechanisms and fraud reduction.

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

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

Here are the three proposals:

1. Making it possible for credit institutions to establish their own list of signs of an unauthorized money transfer. Among other things, they should be allowed to use different models for individuals and legal

entities. This will enable credit institutions to build a more flexible system to counter fraudulent transactions. The current regulation does not give them such rights, therefore, subject to special legislation in the relevant area, the actions of credit institutions might be challenged.

2. As for individuals, the procedure banks should use regarding payment cards has not been clarified.

3. There is no procedure for banks to obtain the client's prior consent to making a payment from a legal entity's account in the case when such consent is received through special secure communication channels, for example, internal authorization systems without using the remote banking (host-to-host) interface.

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

The working group maintains a dialogue with the Bank of Russia and the relevant committee of the State Duma on the aforementioned two issues.

Issue 15. Difference of lists of offshore zones approved for currency control and AML purpose and for tax purposes. – postponed.

There are significant discrepancies in lists of states and territories recognized as offshore areas in the lists of offshore areas approved by the Bank of Russia by its order dated August 7, 2003 (used for currency control and AML/CFT/FWMDP purposes) and by the Ministry of Finance of the Russian Federation in its order dated November 13, 2007 (used for tax purposes).

This issue was raised in the State Duma level in spring 2014, and the Ministry of Finance then supported the proposal; however no amendments were made to the regulatory acts for harmonization purposes.

Offshore areas are specifically monitored by the Bank of Russia and the Federal Tax Service, and, as a result of discrepancies in those lists, the same transaction may be subject to special regulation in terms of currency control, yet not subject to special tax regulation. Such inconsistencies carry major risks for credit institutions.

Task: to standardize the lists of offshore areas used by the Bank of Russia and the Ministry of Finance.

Issue 16. Specifics of performing tax agent functions for a depositary bank / Confirmation of foreign entities' "beneficial ownership of income" (BOI) by Russian organizations transferring income to the benefit of such foreign entities.

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

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

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

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

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

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

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

On August 8, 2019, the working group sent a written petition to the Ministry of Finance together with draft amendments to the Russian Tax Code intended to improve the mechanism used by tax agents to determine whether a foreign organization has beneficial ownership of income.

Issue 17. Foreign payment system being a payment application provider — amendments to the Russian Law “On the National Payment System”.

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

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

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

At the same time, if part 1.1 providing for acceptance of orders with encoded transfer details is added to Article 8 of the Law, amendments will be required to the Regulation on Rules for Transfer of Funds No. 383-P approved by the Bank of Russia on June 19, 2012, as well as to the Rules for Indicating Information in Details of Orders for Transfer of Funds to Effect Payments to the Budget System of the Russian Federation No. 107n approved by order of the Russian Ministry of Finance dated November 12, 2013.

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

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

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

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

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

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

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

7. Natural Resources and the Environment

Subsoil use 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” and No. 57-FZ of 29 April 2008 “On the Procedure of Foreign Investment in Businesses of Strategic Significance for National Defense and State Security”).

1.1. Exploration and mining.

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 the 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.

The ability to terminate the subsoil use right held by legal entities with foreign ownership or foreign investors in the event that they make a discovery of federal significance (Article 2.1 of the Law “On Subsoil Use” is a big disincentive to foreign investment 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 the Procedure of Foreign Investment in Businesses of Strategic Significance for National Defense and State Security” defines the term “Foreign Investor,” the Law “On Subsoil Use” 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 the Procedure of Foreign Investment 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. Classification of fields of federal significance.

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

- Easy-to-find fields are running out
- Replacement of depleting high-grade deposits that are easier to extract gold with lower-grade deposits
- The shift in exploration activity to remote areas with harsh geological and environmental conditions and a lack of 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 the introduction of new, more advanced technology in the industry.

However, Russia’s current legislation contains a number of provisions that restrain growth in investments in exploration activity and exploration enhancement programs. For instance, there are criteria for assigning federal significance status to subsoil areas outlined in the Law “On Subsoil Use,” introduced following the adoption of the Federal Law “On the Procedure of Foreign Investment in Businesses of Strategic Significance for National Defense and State Security.” Currently, subsoil areas of federal significance include subsoil areas containing more than fifty tons of vein gold reserves and 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 trends in Russia’s mineral resource base, including a lower concentration of precious metals in mined ores, subsoil areas of such sizes are too small for their commercially viable exploration and 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 or constituents of the Russian Federation and that contain, based on the state balance sheet of natural resource reserves starting 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.”

1.4. Procedure for subsoil area division.

Currently, there is no procedure for license holders to divide fields and obtain two or more subsoil use licenses (instead of the single one held previously) without the auctioning process.

Once such a procedure is designed, the pipeline projects and associated risks will be diversified, while the field-by-field approach and reliance on innovation technologies required by individual project economics and technical features will boost field exploration and development, which, in turn, will raise the investment appeal of projects for foreign investors.

A license holder needs to design a new field division procedure that would be similar to the existing mechanism of changing (expanding or reducing) site boundaries; the rationale for the division, though, should be different. More specifically, a license holder has to apply to the authorized executive body and provide a feasibility study.

Based on the rationale specified in the application, a license holder should be able to replace the previous license with two or more new ones without the auctioning process.

Recommendations:

Amend the Russian Federal Law “On Subsoil Use,” Ruling No. 429 of the Government of the Russian Federation of 3 May 2012, “On Approval of the Regulation for Delineating and Changing the Boundaries of Subsoil Use Areas” or a new government ruling, and Order No. 315 of the Ministry of Natural Resources and Environment of 29 September 2009.

1.5. Geological study projects to run seismic surveys.

Geological study projects to run seismic surveys are rejected, i.e. obtain adverse determinations of the Russian Geological Expertise Agency, where the works are planned beyond the license site, even if approved by subsoil users of neighboring sites expected to be used to accommodate vessels and run seismic surveys. Yet, seismic surveys should cover adjacent license sites in order to derive full and reliable seismic data for the entire structure and ensure comprehensive and thorough analysis.

Subsoil users need to be able to run seismic surveys and other exploration works that partially cover adjacent subsoil areas. A procedure should be introduced to obtain approvals from neighboring subsoil users and authorized state bodies to run seismic surveys at adjacent license sites. The associated exploration projects of the subsoil user should be accepted for geological expertise purposes; those covering license sites should not be rejected.

Recommendations:

Add Parts 9 and 10 to Article 7 of the Russian Federal Law, “On Subsoil Use” to be read as follows:

“To ensure comprehensive and thorough geological exploration, subsoil exploration works may comprise seismic surveys both at the subsoil area developed by a subsoil user and at adjacent subsoil areas in accordance with the approved project documentation. Where the adjacent subsoil areas have been provided to other subsoil users, seismic surveys are subject to their approval. The approval procedure shall be agreed upon with a respective federal executive body assigned by the Government of the Russian Federation.”

Issue 2. Liberalization of exports of geological information.

We welcome the Administrative Regulations of the Federal Service for Oversight of Natural Resource Use on state services in issuing conclusions (permits) for exports of subsoil information by region and deposit of energy and mineral resources, of mineralogical and paleontological collection materials, and of excavated animal bones and raw minerals. However, even if these regulations are adopted, a foreign

investor that obtains a permit from the Federal Service for Oversight of Natural Resource Use will still have to obtain a license to export any geological information, including information that is not secret. Foreign investors currently have trouble obtaining such licenses, often resulting in project delays and postponed investment decisions.

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

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

Recommendations:

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

If geological information cannot be removed from the List, regulatory acts should be adopted to simplify the procedure/reduce the time involved in obtaining a permit to export geological information, including the Administrative Regulations of the Federal Service for Oversight of Natural Resource Use on the state service of issuing conclusions (permits) for exports of subsoil information, in the light of investors' comments.

Issue 3. Preparation, review and approval of mining plans and schemes.

The preparation and review of mining plans and schemes takes over five months. In practice, however, hydrocarbon fields are developed based on their field development scheme, infrastructure development documentation and well construction program.

At the same time, the fulfillment of industrial safety requirements at hazardous production sites is monitored by the Federal Service for Ecological, Technological and Nuclear Supervision.

The Federal Service for Oversight of Natural Resource Use also conducts geological oversight, including verification of compliance with field development schemes.

In view of the fact that several project documents are required of subsoil users and there is regular state monitoring by the Federal Service for Ecological, Technological and Nuclear Supervision and the Federal Service for Oversight of Natural Resource Use, it is excessive to require yet another, redundant document.

Recommendations:

Eliminate the requirement that mining plans and schemes for raw hydrocarbons be prepared and approved, i.e., add the following wording to Article 24, part 6, of the Law "On Subsoil Use" and Government Decree No. 814 "On the Approval of Rules for the Preparation, Review and Approval of Plans and Schemes for Mining Operations by Type of Mineral."

"Measures to ensure compliance with the principal work safety requirements for subsoil use shall be included in mining plans or schemes subject to approval by the government agency authorized to conduct mining oversight. The procedure for preparing, reviewing and approving mining plans and schemes by type of mineral (excluding hydrocarbons) shall be determined by the Russian Government."

Environmental and other issues.

Issue 1. A new and simplified Federal Waste Classification Catalog (FWCC).

As of today, the FWCC includes over 6,000 waste items, and the list is constantly growing. New waste items must be entered in the FWCC before a waste treatment license and waste disposal limits, etc., can be obtained, but this can take years. Companies have to repeatedly update their permits, and they encounter problems in implementing new technologies, procuring new waste treatment equipment, etc.

Recommendations:

Introduce a simplified waste classification based on hazard rating, similar to the green-amber-red color-coding of waste in European countries. Indicate similar waste classes in waste treatment licenses and permits without excessive detail on current types of waste.

Issue 2. Optimization of the procedure and time required for commissioning new waste treatment facilities.

- a. Entry of new waste treatment facilities in the State Register of Waste Disposal Facilities (SRWDF) to reduce the waiting period before they can go into operation.
- b. Obtaining a license or adding a new waste treatment facility to a current waste treatment license so that it can go into operation sooner.

Under the Law “On Production and Consumption Waste,” a new waste treatment facility may be used only after it is entered in the SRWDF and a license is obtained or updated for the new facility. By law, such registration should take a month, but in practice it takes from two to four, and it may be four to six months before a license can be obtained or updated. During this period, the new facility cannot be used.

Recommendations:

Amend legislation on waste treatment and the Law “On Licensing” to reduce the time it takes to enter new waste facilities in the SRWDF and obtain or update waste treatment licenses.

Issue 3. Disposal of wastewater on land or in a drainage area.

Under the Russian Water Code (Article 1.19), wastewater includes rainwater, snowmelt and infiltration water coming from the entire drainage area of enterprises. After Article 16 of Federal Law No. 7 “On Environmental Protection” (eliminating payment for water disposal in a drainage area) entered into force on 1 January 2016, the disposal of wastewater on land or in a drainage area came to be interpreted as a ban on land disposal, including the drainage of rainwater from uncontaminated areas of industrial sites. Uncontaminated rainwater from enterprises’ non-production areas (where there are no potential sources of pollution such as residences, offices and warehouses) must be collected, purified and discharged into a body of water.

As a result, many enterprises that were built according to approved project documentation incur heavy costs to rebuild their drainage systems and install collectors far from the nearest body of water. This often involves more environmental damage than when uncontaminated wastewater is disposed of in a drainage area and additionally purified by means of ground filtration. Infiltration methods are widely used in the European Union to protect bodies of water against pollution. Many years of monitoring have shown that uncontaminated rainwater has no negative impact on groundwater and bodies of water.

Recommendations:

Allow clean rainwater, snowmelt and infiltration water from non-industrial sites to be disposed of on land or in a drainage area.

Acknowledge that precipitation naturally filtered through the soil into groundwater does not constitute a wastewater discharge.

Amend the Water Code (Article 1, clause 19) to replace the words “runoff from a drainage area” with “runoff from a contaminated area.”

Issue 4. Draft Decree No. 1029 of the Russian Government of 28 September 2015 “On the Approval of Criteria for Assigning Facilities to Categories 1, 2, 3 and 4 Based on Their Negative Environmental Impact”.

The fact that burial sites for production and consumption waste in hazard classes 3 and 5 are placed in Category 1, without considering the method of burial, means that sites where domestic wastewater is pumped into deep isolated strata will be assigned to Category 1, while discharges of the same wastewater into a body of water will be in Category 3.

Production facilities in the agricultural and food sectors are assigned to environmental impact categories 1 and 2 on formal grounds (based on the quantities of processed raw materials) without considering an enterprise's actual impact on the environment.

No consideration is given to the fact that most enterprises in the agricultural and food sectors are not direct users of natural resources, since wastewater is discharged into centralized drainage systems. This process (including permissible discharges and environmental protection measures) is already sufficiently regulated by Federal Law No. 416-FZ and Government Decree No. 644. Air emissions from boilers that provide the utility needs of manufacturing complexes do not have any adverse impact on the environment, since these boilers are support facilities. The waste from such enterprises is in the lowest hazard classes: 4 and 5.

Thus, in most cases, manufacturing processes in the food industry have no direct impact on the environment. The current system of categorization, however, assigns most enterprises in the food industry to categories 1 and 2 instead of 3 and 4.

"Production of carbon oxides" should not be used as a criterion without specifying the substances and production technologies, since various "carbon oxides" and the means of producing them differ widely in terms of environmental impact – something that is not taken into account in the current version of the decree.

Based on this criterion, enterprises in the food industry engaged in the auxiliary production carbon dioxide for their own needs (carbonation of soft drinks) are assigned to Category I.

The production of carbon dioxide, without consideration for the nature and scale of the main process/production, cannot in itself be a criterion for assigning a facility to environmental impact category 1.

It is thus inappropriate for the decree to combine the production of carbon dioxide and other carbon oxides under a single activity, "production of carbon oxides," as far as environmental impact is concerned.

Recommendations:

- The burial of liquid, pulpy and liquefied waste in collector layers, deep isolated strata of licensed fields and/or underground reservoirs should be removed from Category I to stimulate businesses to use the best available technology ITS 17-2016 for waste disposal.
- Clarify subclauses 1-u and 2-j of Government Decree No. 1029 so that agricultural enterprises will be assigned to hazard classes based on their direct environmental impact: direct production processes and the assessment of waste, wastewater and emissions generated as a result.
- Clause 1-e of the draft amendments should be reworded as follows:

"e) in subclause j:

- in the second paragraph, add "(with the exception of carbon dioxide)" after "carbon oxides," and delete "(phosphate)".

- in the fifth paragraph, delete "perborate, silver nitrate";"

Issue 5. Legislation on oil spill prevention in offshore and inland sea waters.

- a. Following the entry into force of Government Decrees Nos. 1188 and 1189 of 14 November 2014, there are different legal requirements for the content and approval of OSR plans for offshore and onshore sites, forcing companies to develop different OSR plans, and yet there are no criteria for classifying sites as offshore or onshore.

Since the requirements for the content of OSR plans for offshore sites have already been established in Government Decree No. 1189, the requirements for onshore sites should be harmonized with them in the same decree, to be revised by the Russian government as part of the "regulatory guillotine."

Recommendations:

The current Government Decree No. 1089 of 14 November 2014 should be revised as regards requirements for the content of onshore OSR plans.

- b. The requirement that a separate state environmental expert review (SEER) be done of OSR plans places additional administrative barriers in the way of their approval, since:

- Under Federal Law No. 174 "On Environmental Expert Reviews," documents examined in a SEER (OSR Plan) must include an environmental impact assessment, but Government Decree No. 1189 does not envisage this requirement for OSR Plans.

- The law provides no clear guidance as to which OSR activities should be given an environmental impact assessment. The time frame for emergency preparedness activities is specified in project documentation. Such uncertainty creates unacceptably high risks for companies using natural resources, which depend on SEER experts' arbitrary interpretation of the requirements.
- The need for a separate environmental impact assessment for OSR plans is an additional administrative barrier and a financial burden for business, making projects less economical. An environmental impact assessment for an OSR plan adds nothing to the emergency assessment in the conclusions of a SEER and the Main State Expert Review Board regarding project documentation for the construction or reconstruction of hazardous production facilities.
- Separate SEERs have already been done of technologies and materials referred to in OSR plans, and there is no other information in such plans that would require an environmental expert review.
- Under Federal Law No. 7-FZ "On Environmental Protection," any contemplated business and other activities must be given an environmental impact assessment. Information provided in OSR plans is intended to mitigate or prevent such impact.
- Damage caused by emergencies cannot be assessed using conventional methods applied to business activities. This makes an environmental impact assessment methodologically cumbersome and allows arbitrary interpretations of the adequacy and level of assessment of such damage.
- The revision of OSR plans is an unresolved issue. As it now stands under Federal Law No. 174, a new SEER must be done when any changes are made in an OSR plan. As a result, most OSR plans could lose their validity and require new reviews (in the event, for example, of a change in membership on the Emergency Prevention and Response Commission, the replacement of an OSR vessel indicated in a SEER report, etc.). Repeat approval of an OSR plan prior to its expiry date was previously required only if changes involved greater efforts and spending.

Recommendations:

Exempt OSR plans from SEER, and amend Federal Laws Nos. 187 and 155 accordingly.

Develop and introduce a unified approach to requirements for the preparation and approval of OSR plans for onshore and offshore facilities.

Issue 6. Maintenance of a predictable investment climate and independent implementation of extended manufacturer responsibility, promotion of waste sorting and elimination of administrative barriers.

1. The risk posed by the initiative of the Ministry of Natural Resources to set 100% recycling quotas, beginning in 2021, for all types of product and packaging waste that are subject to recycling after they lose their consumer properties.

This initiative not only threatens FIAC members' sustainability programs, including the work of nonprofit associations they have collectively established for the independent implementation of extended manufacturer responsibility, it will also drive up consumer prices, causing runaway inflation, and destabilize the investment climate in Russia, but will not have the desired effect of expanded waste recycling because the mechanism for implementing the initiative has not been worked out in detail.

The priority means of implementing extended manufacturer responsibility allows FIAC members to make investment plans based on a gradual, planned increase in recycling quotas, thus giving them time to budget waste-sorting infrastructure, audit recyclers and hold awareness programs to popularize best practices of waste sorting among the younger generation and the public at large. The ministry's initiative to introduce 100% recycling quotas in 2021 essentially cancels the independent implementation of extended manufacturer responsibility due to the technical inability to leap from today's level of municipal solid waste processing (5-7%) to 100%, thus requiring all manufacturers and importers to make payments and turning good intentions to develop recycling into a fiscal levy without any transparent scheme for utilizing the revenues. A related issue is the economic demand for a sudden sharp increase (as envisaged by the Initiator) in the volumes of recyclable materials and products of recycling.

Major manufacturers of consumer goods agree in principle that recycling quotas should be raised, as is clear from the global strategies of FIAC member companies, but they favor a gradual, planned increase to ensure a predictable investment climate and avoid abruptly imposing a heavy financial burden on the population.

Recommendations:

Allow business to continue independently fulfilling its responsibilities as the priority means of promoting best global practice – something that is possible only if recycling quotas are increased gradually in coordination with business and related industry associations.

2. A transparent mechanism for setting environmental fee rates, taking law enforcement practice into account.

Under Article 24.5, clause 5, of Federal Law No. 89-FZ of 24 June 1998 “On Production and Consumption Waste,” environmental fee rates are based on average costs for the collection, transportation, treatment and recycling of a single product or unit weight of a product that has lost its usefulness for consumers. Rates may also include unit costs for the construction of infrastructure for these purposes.

Since some waste processing generates valuable raw materials whose value exceeds the cost of collection, transportation, treatment and recycling (e.g., processed plastic waste may be worth from RUB 35,000 to RUB 80,000 per ton, depending on the fraction and stage of recycling), and the recyclers retain ownership of these products and put them to economic use, waste recycling is doubly financed – by environmental fees and sales of processed products.

FIAC members are currently budgeting expenses for 2020, but the rate of environmental fees for 2020 has not yet been adopted, and this raises the risk of unplanned growth in consumer prices in the event of an unanticipated increase. If at the same time 100% recycling quotas are introduced and environmental fees are raised, the financial burden on the population and the level of inflation will spiral out of control, growing exponentially and bankrupting many small and medium-sized businesses.

Recommendations:

Avoid an unjustified hike in environmental fees, whose rate should be based on:

- a. Independent expert assessments of the market on a national level
- b. Calculation materials, including an assessment of the effectiveness of current and proposed rates
- c. A financial and economic model of environmental fee rates, substantiating the need for an increase in the short and long term
- d. A consideration of the liquidity of products of waste processing

3. Broader administration of extended manufacturer responsibility.

Today, according to the expert opinion of FIAC members, around 0.3% of entities that should recycle packaging waste have come within the purview of regulators. It is impossible, for example, to trace the packaging of imported goods based on customs documents. Customs declarations indicate goods, but not the weight and composition of packaging, so there is still wide latitude for evading responsibility.

In addition, conscientious manufacturers and importers that submit declarations and report on their fulfillment of recycling quotas are exposed to the risk of a double financial burden: they invest in projects for the independent fulfillment of extended manufacturer responsibility, but if recycling documents are rejected by the monitoring agency on formal grounds (because a recycling document has not yet been approved), they will still have to pay environment fees.

Thus, if 100% recycling quotas are introduced, the financial burden will be shouldered by 0.3% of all regulated entities, giving a competitive advantage to those that fail to meet their obligations. At the same time, no measures are being taken to broaden monitoring to include all market players affected by extended manufacturer responsibility.

Recommendations:

Broaden the administration of compliance in order to bring entities that avoid their responsibilities out of the gray area, while not, during this period, toughening conditions for those that already fulfill their responsibility.

4. Sorting, collection and recycling obligations of regional operators that handle solid municipal waste.

Under Article 6 of Federal Law No. 89, the organization of waste sorting and collection comes under the authority of constituent entities of the Russian Federation. If the Russian Federation is legislatively empowered to establish waste sorting and collection obligations under Article 5 of Federal Law No. 89, the government will be able to take the initiative in setting the sorting, collection and recycling obligations of regional operators that handle municipal solid waste.

The introduction of mandatory waste sorting for regional waste operators will help to raise the level of waste processing, develop the system of extended manufacturer responsibility and attract investments for waste processing.

Recommendations:

Amend Federal Law No. 89-FZ “On Production and Consumption Waste.”

5. Eliminate double responsibility for transport packaging and the packaging of raw materials/components.

Double responsibility for transport packaging (such as a pallet’s shrink wrapping, wooden or paper separators between layers of boxes, etc.) should be eliminated, since, for a retail store that receives a pallet with goods from a manufacturer or importer under a sales contract, all packing materials involved in pre-sale preparation (everything remaining after depalletization: corrugated boxes, separators, shrink wrap) are also waste included in waste generation quotas and disposal limits. Thus, responsibility for recycling (or paying environmental fees for) the same type of packaging is assigned to both the producer, under extended manufacturer responsibility, and the consumer goods retailer, which must recycle or otherwise dispose of waste that it generates in accordance with waste generation quotas and disposal limits.

Also eliminate double responsibility for the packaging of raw materials/components purchased by a manufacturer/importer for the manufacture of finished goods at its own production facilities.

Recommendations:

Introduce a mechanism by which extended manufacturer responsibility does not apply to waste regulated by waste generation quotas and disposal limits.

6. An incorrect interpretation by the Ministry of Natural Resources regarding the application of the discount factor to recyclable materials in packaging negates economic incentives for the use of recycled materials.

According to clarifications of 5 March 2019 posted on the official website of the Ministry of Natural Resources, a manufacturer (importer) that has paid the environmental fee for at least one group of goods or packaging cannot carry forward amounts recycled above the quota in the previous period or apply a discount factor. As a result, manufacturers and importers cannot take advantage of the incentives envisaged by Federal Law No. 89-FZ for independent recycling projects and increased use of recycled materials in packaging, since they have to pay environmental fees on some goods that they are unable to recycle.

Recommendations:

Instruct the Ministry of Natural Resources to revise the clarifications or initiate amendments to Federal Law No. 89 “On Production and Consumption Waste” to ensure a transparent interpretation.

7. Eliminate barriers restricting the use of secondary plastic raw materials in food packaging.

The barriers restricting the use of secondary plastic raw materials in packaging for food products should be eliminated. State Standard (GOST) 32686-2014 (<http://docs.cntd.ru/document/1200110949>) prohibits the use of secondary raw materials in the manufacture of packaging (e.g. preforms for plastic bottles) that comes into direct contact with food products, and this constrains projects to expand the processing of plastic waste and its secondary use.

Recommendations:

Revise the state standard/technical regulation to allow recycled materials to be used in the manufacture of food packaging.

8. Introduction of waste recycling reports no earlier than 2020; elimination of the requirement for a state environmental expert review of waste recycling technology from the draft report form.

The recycling report form has not yet been approved by the Federal Service for Supervision of Natural Resources, although projects for independent fulfillment of extended manufacturer responsibility have been under way since the start of 2019. The requirement for a state environmental expert review of waste-processing technology should be eliminated from the draft act on waste recycling, since this is contrary to Federal Law No. 89-FZ, under which a manufacturer and importer provide only a recycling certificate and an agreement on recycling services. The monitoring agency should determine whether a recycler has a state environmental expert review and other permission documents as part of the agency’s monitoring activities.

Recommendations:

Recycling reports should be introduced no early than 2020. The requirement for a state environmental expert review of waste-processing technology should be eliminated from the document under development.

9. The need for clarifications of the term “recycling” in order to avoid litigation in connection with rejection of recycling reports by the Federal Service for Supervision of Natural Resources.

Legal practice concerning the independent fulfillment of extended manufacturer responsibility includes cases in which regional bodies of the Federal Service for Supervision of Natural Resources rejected recycling reports based on State Standard 30772-2001 if the recycling of packaging resulted in an intermediate rather than a finished product (Case No. A44-7947/2018, Arbitration Court of Novgorod Region), e.g., if pellets, rather than a box, are produced from cardboard. Such recycling is interpreted as processing, which is not, in fact, the case.

Recommendations:

The Ministry of Natural Resources and the Federal Service for Supervision of Natural Resources should analyze the materials of court cases provided to the FIAC working group (No. KS-0108-19-vk of 1 August 2019) and clarify the term “recycling” in order to avoid litigation and publish the clarifications on the website.

Issue 7. Amend Order No. 154 of the Ministry of Natural Resources of 18 April 2018 to set criteria and correct factual errors.

The order was prepared and issued behind closed doors and not discussed with concerned executive bodies, the expert community or representatives of business.

As a result, a wide range of stakeholders have no understanding of how or why companies are included in the list, and the selection seems haphazard and unjustified.

The order does not reflect the actual quantity of air pollutants emitted as a result of production and includes a number of enterprises whose emissions constitute only 0.01% of the overall adverse environmental impact in Russia.

Recommendations:

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

Disclose the listing procedure so that the appropriateness of including one or another enterprise can be checked.

Discuss this procedure with the expert community for purposes of optimization.

Issue 8. Amendments to Federal Law No. 195-FZ of 26 July 2019 “On an Experiment to Set Quotas on Pollutant Discharges and on Amendments to Certain Legislative Acts of the Russian Federation to Reduce Air Pollution”.

The law provides for the development and approval of a procedure for making summary calculations of air pollution and applying them to the standardization of pollutant emissions, including the use of a quota system. Constituent entities of the Russian Federation will be authorized to set emission quotas, but there are no criteria in the draft law. The process is not synchronized with the transition to BATs (best available technologies). Setting quotas for a factory or power plant using BATs effectively means closure or a cutback in production.

The law also gives the Federal Service for Supervision of Natural Resources broad powers to conduct unscheduled audits in the event of adverse weather conditions, provided that the general prosecutor’s office is notified. As adverse weather conditions may prevail for over 100 days a year, the Federal Service effectively has the right to conduct unscheduled audits of sites subject to quotas on a weekly basis. This right is excessive, especially since sites in Category I are required to install automatic measuring devices that transmit data on sources of pollutants to supervisory bodies.

Recommendations:

Introduce subordinate acts removing sites with BATs from the list of those subject to quotas. The Federal Service’s right to conduct audits during periods of adverse weather conditions at sites where automatic measuring devices have been installed to monitor sources of pollutants should be eliminated from the law.

Issue 9. Improvement of the regulatory framework and clarification of regulatory acts relating to Federal Law No. 219-FZ “On Environmental Protection” and Certain Legislative Acts of the Russian Federation as regards the adoption of BATs by major industrial enterprises.

Among efforts important for the successful implementation of BATs within the time frame indicated by the Russian Government, the following should be singled out:

- compatibility of sanitary/hygienic and commercial fishing law with technical regulation for purposes of issuing integrated environmental permits;
- continuing efforts and decisions to implement pilot projects for the technical regulation of wastewater based on BATs;
- continuing efforts to equip industrial facilities with automatic measuring instruments and measurement of the weight of pollutant emissions and discharges;
- further development, in partnership with business, of regulatory acts to provide economic incentives for the use of BATs and promote investments in eco-technologies.

Recommendations:

- Amend the Law “On Environmental Protection” to stimulate businesses to use BATs.
- Adopt all technological indicators in all BAT reference documents in the shortest time possible.

Issue 10. Correction of draft amendments to the Rules for Cold Water Supply and Wastewater Disposal, approved by Government Decree No. 644 of 29 July 2013 “On Approval of the Rules for Cold Water Supply and Wastewater Disposal and on Amendments to Certain Acts of the Government of the Russian Federation”.

1. The draft amendments place excessive and hard-to-meet obligations on users in terms of establishing the maximum permitted concentrations of pollutants in wastewater, monitoring wastewater composition and properties and determining the measures of such composition and properties and the regularity of routine inspections, the obligations of users, the use of parallel and reserve samples, the setting of limits and the procedures for calculating surface runoff and fees for discharges of wastewater containing pollutants above the established limits.

The heading of Appendix 4.1 contains the word “recommended” (“List of pollutants that it is recommended to identify ...”), which is imprecise, resulting in a list of prohibited discharges that is not clearly exhaustive.

This wording allows a loose interpretation and is at variance with clause 4 of Appendix 4, which refers to the list in Appendix 4.1. as exhaustive.

Recommendations:

- Delete the word “recommended” and reword the heading as follows:
“List of pollutants to be identified in users’ wastewater for purposes of monitoring prohibited discharges under clause 4 of Appendix 4 to the Rules for Cold Water Supply and Wastewater Disposal.”
- Obtain conclusions from research institutions on the appropriate maximum concentrations of pollutants in wastewater. Use these conclusions to adjust the current limits and establish a reasonable and exhaustive list of controlled substances whose discharge into centralized drainage systems is prohibited.

2. As currently regulated, the mechanism of environmental fees for discharges into centralized drainage systems, does not ensure:

- conditions for improving the ecology of bodies of water and enhancing the capabilities and infrastructure of Vodokanal enterprises
- transparent, predictable and technically feasible conditions for responsible wastewater disposal by Russian industrial enterprises, furthering the development of such enterprises and the improvement of the national economy

Recommendations:

The following should be done to eliminate this deficiency in regulation:

- Introduce mechanisms for controlling expenses for negative impact on centralized drainage systems (“Fee”), ensure proper use by Vodokanal enterprises of such payment to maintain and improve centralized drainage systems and clean up bodies of water, and also introduce monitoring

and liability for improper use of funds collected by Vodokanal enterprises from users for negative impact on centralized drainage systems.

- Establish a procedure entitling users to obtain a refund of the Fee without going to court if a Vodokanal enterprise is found to have used such payment improperly.

3. Collective liability for conscientious users.

A decree has been drafted that would amend the Rules for Cold Water Supply and Wastewater Disposal, approved by Government Decree No. 644 of 29 July 2013 (hereinafter, the "Rules"), effectively eliminating economic incentives for water disposal organizations to provide for the effective treatment of wastewater and so reduce the negative impact on bodies of water.

For example, clause 199.5 of Chapter 15 establishes a procedure: "Compensation by users of a water disposal organization's expenses in connection with damage done to a body of water by wastewater discharges, if it is determined that users did not discharge pollutants in excess of wastewater composition limits and that users and other entities did not damage the body of water by discharging pollutants into the centralized drainage (sewage) system."

- This provision gives all users collective liability to Vodokanal enterprises in the form of an unjustified additional payment charged to all conscientious users to compensate the expenses of Vodokanal enterprises in connection with damage to a body of water without regard to whether a specific user has complied with the established limits on the composition and properties of wastewater
- Since Vodokanal enterprises are natural monopolies, it will be impossible in practice to avoid such collective liability. Vodokanal enterprises will be able to charge high monopolistic fees, inevitably raising the cost of goods manufactured by enterprises that use water in their production cycle and ultimately making Russian goods less competitive with those of other EEU countries.
- This provision violates the principle that there should be no additional liability/payment for negative consequences that a conscientious user had no part in
- This provision also subjects users to an unjustified additional financial burden and is unreasonable in view of the fact that regulatory acts do not require water disposal organizations to identify users whose discharges damage a body of water, there are no transparent and effective mechanisms for identifying such users, and there is no mechanism for ensuring that such organizations conscientiously and fully meet their obligations to treat wastewater. This effectively means that additional liability may be imposed on a user that complies with all established limits.

Recommendations:

- Delete this clause from the proposed version of the decree before related regulatory acts are adopted establishing mechanisms for regulating and controlling the actions of Vodokanal enterprises.

4. The draft decree would introduce provisions making comprehensive measures to ensure the required composition and properties of wastewater and reduce the burden on centralized sewage systems substantially less attractive for users from an economic standpoint.

For example, clause 185 of Chapter 14 (The required content of a discharge reduction plan, the procedure and time limits for its approval and grounds for refusing to approve such a plan) limits the stages of a discharge reduction plan to no more than two years. This limitation is inappropriate, inasmuch as the same clause sets the overall length of such plans at up to seven years.

The need to divide a plan into stages, each of which is limited to two years, could greatly complicate the planning and implementation of these measures as well as raising the risk that users will be unable to deduct costs involved in implementing the plan envisaged by the proposed version of Decree No. 644, clauses 116 (3) and 204.

Moreover, under clauses 116 (3) and 204, costs involved in implementing plans (stages of plans) to ensure the required composition and properties of wastewater and reduce discharges are deductible only for stages that can be shown to result in a reduced concentration of pollutants in wastewater. The inevitable result of dividing such a plan into stages is that a user's costs for essential and integral stages of the technical solution development, design, expert examination, etc., will be nondeductible, since it will not be possible to achieve a reduced concentration of pollutants in wastewater as a result of these individual stages.

Recommendations:

Eliminate provisions requiring that plans to ensure the required composition and properties of wastewater and reduce discharges be divided into stages from the draft Rules, including from clauses 116 (1), 116 (3), 185 and 204.

Issue 11. Elimination of the excessive burden on processing waste from own products (such as defective or expired products).

Such activity currently comes under Federal Law No. 99-FZ “On the Licensing of Certain Types of Activity” (Article 12, clause 30: activities involving the collection, transportation, processing, recycling, decontamination and disposal of waste in hazard classes 1-4) as well as Federal Law No. 174-FZ “On Expert Environmental Examinations” (Article 11, clauses 5 and 7.2.) and is classified as decontamination if the waste-processing technology is regarded by regulatory agencies as “new” or the technical process involves a change in the hazard class or physical state of waste.

Recommendations:

1. Amend Federal Law No. 99-FZ to remove the processing of own products with core equipment from the list of licensed activities.

2). Amend Federal Law No. 174-FZ to clarify the concept of “new technology.”

Issue 12. Adopt the regulatory acts required so that companies can obtain integrated environmental permits and submit environmental impact declarations.

Under Federal Law No. 219-FZ of 21 July 2014 “On Amendments to the Federal Law ‘On Environmental Protection’ and Other Legislative Acts of the Russian Federation,” companies that operate at Category 1 sites must by 2025 obtain an integrated environmental permit, and Category 2 sites must submit environmental impact declarations every seven years.

While the legal framework for issuing and re-issuing integrated environmental permits and limits for Category 1 sites has been created, this is not the case for Category 2 sites and declarations, and there is no procedure in place for the review of declarations by the Federal Service for Supervision of Natural Resources. As a result, Category 2 sites find themselves in a situation where permits and limits have run out and declarations are not accepted by the Federal Service for Supervision of Natural Resources.

Recommendations:

The Ministry of Natural Resources and Ecology should consider promptly developing and adopting the regulatory acts required so that integrated environmental permits can be issued and declarations accepted.

Other issues

Issue 1. State services involving the issuance of permits and licenses, including in electronic form, for foreign investors operating in the Russian Federation via accredited branches.

1.1. State agencies currently decline to provide foreign companies operating in the Russian Federation via accredited branches with services involving the issuance of permits and licenses on grounds that applicants must be individuals, including individual entrepreneurs, and legal entities registered in the unified state register of legal entities under Federal Law No. 129-FZ of 8 August 2001 “On the State Registration of Legal Entities and Individual Entrepreneurs” and possessing the appropriate registration number (OGRN).

Because foreign investors lack an OGRN, they encounter problems or are denied in many instances: for example, when applying to register sites with a negative environmental impact (Federal Service for the Supervision of Natural Resources); when applying for main state expert reviews (Main State Expert Review Board); for licenses to operate production facilities that present explosion, fire and chemical hazards (Federal Service for Ecological, Technological and Nuclear Supervision); for cargo handling licenses (Ministry of Transport, Federal Transportation Inspection Service); for licenses to collect, transport, process, recycle, decontaminate and dispose of waste (Federal Service for the Supervision of Natural Resources), etc.

Recommendations:

Add provisions to Federal Law No. 99-FZ 4 May 2011 “On the Licensing of Certain Types of Activity” and other relevant regulatory documents so that a foreign legal entity applying for a state service (licenses, permits, registration, etc.), in view of its legal status, can provide information from the state register of accredited branches and representative offices of foreign legal entities instead of an OGRN.

1.2. In addition, some permits can be obtained only via the State Services portal – for example, for a state expert examination of project documentation. Under Article 2, clause 3, of Federal Law No. 210-FZ of 27

July 2010 “On the Provision of State and Municipal Services,” applicants for this service, including legal entities, must be registered in the federal Unified Identification and Authentication System (UIAS). However, regulatory acts lack any procedure for registering foreign legal entities and their branches that are entered in the State Register of Accredited Branches and Representative Offices of Foreign Legal Entities under Federal Law No. 160-FZ of 9 July 1999 “On Foreign Investments in the Russian Federation” (Article 21), and such entities and their branches are thus unable to apply for state services involving the issuance of permits.

Recommendations:

Amend the following legislative acts to allow foreign legal entities and their branches to be entered in the UIAS using their accreditation number:

- Government Decree No. 977 of 28 November 2011 “On the Federal Unified Identification and Authentication System in the IT Support Structure for Information Systems Used to Provide Electronic State and Municipal Services.”
- Order No. 107 of the Ministry of Communication of 13 April 2012 “On Approval of the Statute on the Unified State Identification and Authentication System in the IT Support Structure for Information Systems Used to Provide Electronic State and Municipal Services”

Issue 2. The need to adopt legislation regulating the work of employees who are temporarily provided by an employer that is not a private employment agency to other legal entities under staff leasing agreements.

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

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

Major investment projects, both internationally and in Russia, are generally carried out by groups of investors in various forms: joint ventures, consortia, operating agreements, etc. In such arrangements, highly skilled foreign specialists are often provided under staff leasing agreements.

The limitation of staff leasing agreements to only a small group of entities effectively precludes the leasing of highly skilled foreign personnel to and from entities outside the group indicated in Law No. 116-FZ.

This problem could be resolved by draft laws prepared by the Russian Ministry for Economic Development in 2018-19: “On Amendments to the Labor Code of the Russian Federation to Regulate the Labor of Employees Temporarily Provided by an Employer to Other Legal Entities under Staff Leasing Agreements” and “On an Amendment to Article 18.1 of the Law of the Russian Federation ‘On Employment in the Russian Federation’ in Connection with the Adoption of the Federal Law ‘On Amendments to the Labor Code of the Russian Federation to Regulate the Labor of Employees Temporarily Provided by an Employer to Other Legal Entities under Staff Leasing Agreements.’”

The adoption of this legislation is equally important to Russian companies, because it will ensure continued access to unique foreign technology, skills, expertise and experience in a range of areas, including the production and processing of minerals at capital-intensive and remote sites, more effective operation of high-tech equipment purchased from foreign manufacturers and access to new technologies, including their subsequent localization in Russia.

Prompt adoption of the laws drafted by the Ministry of Economic Development will eliminate the existing legal uncertainty and substantially lower the risks of investment projects jointly undertaken by Russian and foreign partners.

Recommendations:

Accelerate the process of adopting legislation regulating the work of employees temporarily provided by an employer that is not a private employment agency to other legal entities under staff leasing agreements.