REFORMS FOR ECONOMIC GROWTH AND BUSINESS RESILIENCE 2022

TRADE FACILITATION COMMITTEE

AMCHAM SERBIA
A LEADER IN CHANGE

TRADE FACILITATION COMMITTEE

OBJECTIVE 1: ENSURE GREATER EFFICIENCY OF EXPORT AND IMPORT PROCEDURES AND ONLINE COMMUNICATION WITH CUSTOMS AUTORITIES

…BY IMPLEMENTING A NATIONAL SINGLE POINT OF CONTACT SYSTEM

CHALLENGE: Electronic communication is not fully available with all government authorities when importing and exporting goods. Existing online systems operated by the authorities vary widely in terms of comprehensiveness and digital accessibility. A number of bodies are unable to receive some documents in an electronic form, whereas others allow no electronic submissions at all. In addition, border authorities do not control shipments based on risk assessment, with some requiring physical inspections of all shipments that contain a specific product regardless of any other considerations (such as producer certification, country of origin, importer performance to date as evidenced by results of previous inspections, and the like).

> **RECOMMENDATION:** Implement a **National Single Point of Contact** system that ought to entail **complete digitalisation of all import and export procedures**, allow **exchange of all import and export documents digitally**, and include development or integration of a **risk assessment module**. The National Single Point of Contact system should serve as an umbrella for all services inspecting imported goods before these are marketed in Serbia and goods intended for export, including the Customs Administration, sanitary, phytosanitary, and veterinary inspection services, and the Serbian Medicines and Medical Devices Agency (ALIMS). The objective here is to provide businesses with a single electronic point of contact with inspections and other relevant authorities and improve the quality of data collected and facilitate their analysis. This system should also allow electronic payment of fees, taxes, and other levies, customs clearance procedures, and any additional information sharing between government services to expedite oversight of foreign trade whilst eliminating undue administrative barriers.

…BY SHORTENING IMPORT PROCEDURES FOR AGRICULTURAL PRODUCE AND FOOD

CHALLENGE: Even though Serbia has made some progress in recent years, import procedures for agricultural produce are still time-consuming. Lengthy procedures incur unnecessary costs, and long delays prevent efficient importation and marketing of products with short shelf lives and lead to major losses for importers.

The current system is characterised by a multitude of problems: time-consuming procedures are required once goods are sampled; laboratory findings become available only after prolonged delays (with these findings often taking a long time to reach the relevant authorities); and local bodies fail to recognise findings of accredited laboratories in EU member states and/or third countries with which Serbia has agreements governing recognition of laboratory results. Progress has been made recently in a number of areas, from the introduction of a new information technology management, communications and control system (ITCM) for the Phytosanitary Inspection, which has shortened the time needed to input data into the variety of previous systems, to reduced costs in terms of time and money for importers of goods from Open Balkans countries.

RECOMMENDATIONS: Until the National Single Point of Contact is established, several measures can be taken to shorten import procedures for agricultural produce and food:

- Allow **shipments to be announced in advance to permit pre-arrival processing**.
- In cases where goods are sampled, permit **random selection of authorised laboratories** able to perform all required analyses that are geographically closer to the customs post so as to reduce time needed for sample analysis.
- Ensure laboratories are able to efficiently **exchange samples and analysis reports** with relevant inspections bodies **electronically**.
- Publish **up-to-date lists of authorised laboratories** and types of accredited analyses they are able to perform on the web sites of the Ministry of Agriculture and Ministry of Health.
- Establish an **effective oversight and control mechanism for authorised laboratories**, including de-licensing for non-compliance.
- **Admit goods analyses performed by accredited laboratories in EU Member States and/or countries with which Serbia has agreements** on recognition of laboratory analyses, and publish list of these laboratories and their accredited analyses on the web sites of the Ministry of Agriculture and Ministry of Health.

CHALLENGE: Since late 2021, major delays been observed with veterinary health certificates for import of raw materials for the meat processing industry: the time needed to issue these documents has increased from 8 to 10 days in the past to 60 days, which is the maximum statutory waiting time, according to an opinion of the responsible ministry. Moreover, some certificates have been withdrawn without explanation. These delays create issues for Serbian meat processors as they incur warehousing costs and are forced to pay penalties to suppliers, compounding the already difficult position faced by the food industry due to market disturbances caused by the crisis in Ukraine.

RECOMMENDATION: Reinstate timely issuance of veterinary health certificates as seen in the past. These procedures should be simplified by the new information system, which the Ministry of Agriculture has cited as the initial cause of the bottleneck. The frequent occurrence of these delays in the past eight months requires additional efforts to identify and remove their root causes, as well as to subsequently keep monitoring whether these import permits continue to be issued in good time.

CHALLENGE: Some inspections services continue using a rules-based rather than a risk-based approach to selecting shipments for additional sampling or controls. The application of byelaws, annual inspection plans, instructions, and interpretations of regulations means shipments containing certain products are always sampled, regardless of their actual risk, with decisions as to which shipment to sample being made at random and based on the order with which the shipments cross the border rather than risk assessment. In addition, even inspections that partially employ risk assessment do not appropriately account for all risk parameters, which should be broadened to include **importer** risk in addition to product, country, producer, and destination risk.

RECOMMENDATION: Internal quality control systems employed by importers could range from non-existent to highly sophisticated, standardised, and certified, and as such require assessment, appraisal, and risk categorisation. As such, it is neither logical nor efficient to use scant administrative resources for equally frequent controls of both firms that pay close attention to product safety and quality controls and those that lack risk management systems altogether. Comprehensive risk analysis would allow food businesses to be grouped into high- and low-risk categories, which would expedite customs clearance and marketing of products that pose low or negligible risk. Importers whose risk is assessed as low or negligible would be

able to save money and time by having their documents processed more quickly and being required to submit to fewer sampling procedures at the time of importing. Risk assessment would also focus control and administrative resources to where they are most needed and better protect the market from potential entry of non-conforming products. Specific steps ought to include:

- Developing and implementing risk assessment models for goods imports based on European practices and methodology (taking into account businesses' conformity risks, good business practices, and existence of internal quality controls).
- Reviewing current rules and, wherever possible, introduce risk assessment into the control of agricultural and food products for presence of genetically modified organisms (GMOs) and radioactivity (instead of the current practice whereby all products are always sampled).
- Developing and implement risk-based official control plans.
- Assessing options for introducing IT tools for risk assessment and management in frontier controls of goods and developing such tools.
- Ensuring Serbian authorities exchange information about high-risk shipments internally and potentially share this information with foreign bodies.

CHALLENGE: Import, export, and transit of goods continue to be hindered by the high volume of mandatory documents and unnecessary formalities.

RECOMMENDATIONS:

- Either broaden the range of products not requiring veterinary health certificates for import and transit or eliminate these certificates altogether.
- Review current rules and, wherever possible, align actual practice with regulations to formally mandate that product samples do not require veterinary health certificates for import and transit.
- Enhance compliance with international treaties regulating trade in agricultural and food products.
- Align all food export certificates for goods exported to Middle Eastern countries and issue all import and export certificates in a bilingual Serbian and English format.

…BY SHORTENING IMPORT PROCEDURES FOR INDUSTRIAL (NON-FOOD) PRODUCTS

CHALLENGE: The Sanitary Inspection samples an arbitrarily chosen percentage of shipments without considering the risk posed by any single shipment. In addition, there is no electronic communication with this inspection service and the required infrastructural and technical capacity for such communication is lacking.

RECOMMENDATIONS:

- Introduce a risk assessment system to aid in selecting shipments for sampling industrial non-food products from the Sanitary Inspection portfolio and new foods. This should entail identifying and weighting risk assessment criteria and developing a plan to implement risk assessment indicating the resources required (funding, staffing, IT, etc.).
- Consider whether it may be optimal to include the Sanitary Inspection in the National Single Point of Contact information system when the risk assessment module is developed or whether this capacity should be created independently of the Single Point of Contact effort.

CHALLENGE: Major delays with granting, renewing, and approving variations of marketing authorisations for medicines and approval of promotional material, in contravention of statutory time limits. For some variations, the delay amounted to as much as 24 times the legal limit, making the process significantly more expensive and leading either to interruptions in supply or unnecessary stockpiling of medicines. For five years this practice has posed a major obstacle to accessing the medicines market but no improvements have been made. The issue has been identified and recognised in the Action Plan to implement the Health Service Digitalisation Programme, which calls for bringing these procedures back into compliance with statutory time limits by the end of 2023.

RECOMMENDATIONS: Optimising procedures in accordance with EU rules is the prerequisite for ensuring compliance with legal time limits. This requires amending the Medicines Law and developing a digital platform for communication with applicants. Several requirements must be met in this process:

- Amend the Medicines Law to remove the requirement for certificates of pharmaceutical products (CPPs) to be submitted if the medicines in question hold marketing authorisation in the EU granted under the centralised, decentralised, or mutual recognition procedures, as well as to eliminate the requirement for samples to be provided, except at the request of the ALIMS.
- Simplify and shorten accelerated marketing authorisation procedures for medicines holding EU-wide marketing authorisations issued by the European Medicines Agency (EMA) under the centralised procedure.
- Allow approval of variations to marketing authorisations based on European Public Assessment Reports (EPARs), which evaluate medicines that hold marketing authorisation issued under the centralised procedure and comprise all product information available on the EMA website, including approved variations.
- Allow systematic monitoring of existing procedures and compliance with statutory procedural time limits.
- Optimise procedures for approving promotional materials for medicines by introducing notification of the content of promotional materials and ex-post control of promotional materials intended for health professionals.

CHALLENGE: Public authorities fail to accept foreign declarations of conformity in contravention of the European Accreditation Multilateral Agreement (EA MLA) ratified by Serbia.

RECOMMENDATION: Additional training is required for both civil servants and businesses in how to implement the EA MLA in terms of recognising foreign declarations of conformity, especially those issued by notified and designated conformity assessment bodies (those listed in the European Commission NANDO database). This training should specifically clarify requirements for recognition of declarations issued by conformity assessment bodies accredited by EA MLA signatories where such declarations certify conformity with EU technical regulations transposed in Serbia for purposes of marketing products in Serbia, by:

- Entering into international treaties/memorandums of understanding and recognition of declarations issued by accredited laboratories;
- Producing informative leaflets and offer training to all stakeholders on the recognition of foreign declarations of conformity and testing reports, as well as on legally permitted options to issue appropriate Serbian conformity instruments for certified products **without the need for a second conformity assessment,** with possible support from the civil sector (projects, organisations, associations, and the like).

…BY ENSURING INFORMATION CAN BE EXCHANGED ELECTRONICALLY WITH THE CUSTOMS ADMINISTRATION

CHALLENGE: Arrangements for information sharing between the Customs Administration and inspection bodies remain deficient.

> **RECOMMENDATION:** Link the **Customs Administration with inspections bodies** (Border Phytosanitary Inspection at the Plant Protection Directorate; Border Veterinary Inspection at the Directorate for Veterinary Medicine; and Sanitary Inspection) by defining a set of data to be provided to the Customs Administration and establish an online system to exchange these data.

CHALLENGE: Businesses can only communicate with the Customs Administration in writing with regard to payment of customs duties, interest on overdue customs payments, and reposting of incorrectly routed payments. Requiring these written submissions is a major obstacle and increases operating costs.

> **RECOMMENDATION: Allow businesses to communicate electronically with the Customs Administration's Collection Unit** with regard to payment of customs duties, interest on overdue customs payments, reposting of incorrectly routed payments, notices of outstanding payments, and communication with guarantor banks.

OBJECTIVE 2: ENHANCE REGIONAL TRADE CO-OPERATION

…BY PROPERLY IMPLEMENTING OPEN BALKAN AGREEMENTS

CHALLENGE: Achieving an integrated regional market, in particular ensuring the free movement of goods throughout the region, has been a key goal of the Trade Facilitation Committee since its establishment in 2011. Even though a variety of regional initiatives (including CEFTA and the Berlin Process) have had meaningful objectives and could rely on a well-developed institutional framework, they were never fully implemented and never led to tangible benefits for businesses. With that in mind, companies have recognised the importance of the Open Balkans initiative in facilitating trade in goods whilst observing that its success will be predicated on real and palpable benefits of the initiative to businesses, continued focus on the initiative including enhanced implementation of these free trade agreements, and identification of further co-operation priorities.

> **RECOMMENDATIONS:** To address this challenge, AmCham has launched a **project to measure the tangible results of trade agreements signed as part of the Open Balkans initiative** that focuses on measuring time savings from source in one country to market in another, tracking efforts to streamline administrative procedures, and measuring any reduction in direct costs. The objective of this project is to enhance implementation of existing free trade agreements and potentially broaden the list of goods and regulatory measures that require additional streamlining to ensure free movement of goods.