

# REFORMS FOR ECONOMIC GROWTH AND BUSINESS RESILIENCE 2024

TRADE FACILITATION COMMITTEE



AMCHAM SERBIA  
A LEADER IN CHANGE

## TRADE FACILITATION COMMITTEE

### OBJECTIVE 1: ENHANCE EFFICIENCY OF EXPORT AND IMPORT PROCEDURES AND ONLINE COMMUNICATION WITH CUSTOMS AUTHORITIES WITHIN SERBIA

#### ...BY IMPLEMENTING A NATIONAL SINGLE POINT OF CONTACT SYSTEM AND AUTOMATED IMPORT AND EXPORT SYSTEMS (AIS/AES)

##### 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, all border authorities do not control shipments based on risk assessment, with some requiring physical inspections of certain percentage or all shipments of certain goods regardless of any other considerations (such as producer certification, country of origin, importer performance to date as evidenced by results of previous shipment inspections, and the like).

**RECOMMENDATION:** Implement a **National Single Window** 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 for inspections that do not have this module in their current systems**. The National Single Window 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.

In addition, the **Customs Administration** should modify its online resources to allow **automated import and export systems (AIS/AES)** and full-fledged online communication with the Customs Administration. An AIS/AES arrangement, coupled with the National Single Window, ought to ensure the Customs Administration is fully online connected with other government ministries, administrations, agencies, and directorates responsible for issuing trade approvals, permissions, and certificates using the Single Window functionality. This would simplify oversight, reduce red tape, and accelerate import and export procedures.

#### ...BY SHORTENING IMPORT PROCEDURES FOR AGRICULTURAL PRODUCE AND FOOD

**CHALLENGE:** Even though Serbia has made progress in recent years, the efficacy of import procedures for agricultural produce and food remains widely divergent between the various authorities and due to the uneven impact of regional trade facilitation initiatives.

The current system is characterised by a myriad of problems: import procedures for agricultural produce continue to be time-consuming, leading to unnecessary costs, whilst long delays prevent efficient importation and marketing of products with short shelf lives and generate major losses for importers. Lengthy procedures are required once goods are sampled; laboratory findings become available only after long 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, including the introduction of a new information technology management, communications, and control system (ITCM) for the Phytosanitary Inspection; the removal of inspections from border crossing to points further inland, which has shortened the time needed to input data into the variety of previous systems; and the resolution of overcrowding issues at the Tabanovce border crossing point. Laboratories have come under increasing scrutiny, but the findings of these audits must also result in efficiency and not just effectiveness improvements.

As part of the Open Balkans initiative, the Veterinary Inspectorate has removed or reduced fees for goods coming from the region's countries.

However, the Sanitary Inspection has failed to replace its current paper-based system with an online platform.

**RECOMMENDATIONS:** Until the National Single Window 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. (Applies to Border Sanitary Inspection)**
- In cases where imported goods are sampled, permit **random selection of authorised laboratories** able to perform all required analyses that are geographically closer to the border crossing post, have samplers available at the border crossing post or sampling location, and are able to perform the analyses within the required timeframes, so as to reduce time needed for sample analysis. (Applies to Border Sanitary Inspection and Border Veterinary Inspection)
- Ensure that all laboratories are able to **efficiently exchange samples and analysis reports with relevant inspections bodies electronically**. Make the process more transparent and involve third parties – customs agents or importers – since importers initiate and pay for these investigations.
- 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. (Applies to all relevant inspections services)
- **Admit laboratory 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 websites of the Ministry of Agriculture and Ministry of Health. (Applies to all relevant inspections services)

**CHALLENGE:** Since late 2021, major delays have been observed with issuance of **veterinary 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. The restricted validity of the certificates (three months), coupled with limited quantities and uncertain times needed to issue the instruments, especially for firms that import large quantities of materials from the same suppliers, have all caused unduly high costs for companies, even though veterinary health requirements have not changed. 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.

Since no robust solution could be found over the past two years, businesses continue to face intermittent uncertainties in this regard for import of other veterinary products as well. Effectively, these practices are tantamount to quantitative import restrictions, which are in contravention to FTAs, and are generally used only to address short-term disturbances with the supply of limited ranges of foodstuffs.

**RECOMMENDATIONS:** In a short run, reinstate timely issuance of veterinary health certificates as seen prior to 2022. In the medium term, the procedure should be reviewed and contrasted with EU practices, and if still found to be necessary, the authorities should consider streamlining it to reduce scope of products and time needed to issue certificates, including possibly by looking into hiring additional staff to handle applications more quickly. In the longer term abolish these types of certificates.

**CHALLENGE:** Some inspections services continue using an administrative-based rather than a risk-based approach to selecting shipments for additional sampling or controls. Certain bylaws, annual inspection plans, instructions, and interpretations of regulations means shipments containing certain products are always sampled, regardless of their actual risk. 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.

**RECOMMENDATIONS:** Internal quality control systems employed by importers can 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 market placement 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). (Applies to Sanitary Inspection insofar as it should be responsible for developing a comprehensive risk assessment model. Border Phytosanitary Inspection and Border Veterinary Inspection

ought to begin modelling importer risk based on information currently available from ITCM)

- Reviewing current rules and, wherever possible, introducing 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). (Applies to Border Phytosanitary Inspection)
- Developing and implementing risk-based official control plans. (Applies to all inspections services)
- Assessing options for introducing IT tools for risk assessment and management in border controls of goods and developing such tools. (Applies to all inspections services)

### **...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 Window 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:** Although improvements have been observed since the summer of 2023, major delays persist 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.

**RECOMMENDATIONS:** This issue has been recognised by the National Trade Facilitation Body, and internal processes were streamlined in the autumn of 2023 that may result in improvements within the scope of current regulatory procedures. An action plan was also developed to bring these processes back into compliance with statutory time limits which identifies additional capacity development needs, including the requirement to approve and hire more staff to ensure bottlenecks are removed within one year.

In addition, optimising procedures in accordance with EU rules is yet another 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.

### **...BY CONSISTENTLY SEEKING TO FACILITATE TRADE IN THE REGION AND WITH THE EU**

Foreign trade inherently depends on best global or regional practice and is regulated by numerous bilateral and multilateral treaties concluded across a variety of venues. Agreements signed by Serbia with the EU (including the Stabilisation and Association Agreement) and regional initiatives (CEFTA, Open Balkans, and the Berlin Process) identify many areas where trade can be facilitated, but these efforts have been constrained by a variety of economic and non-economic factors. The EU Growth Plan, published in late 2023, envisages allowing countries access to the EU single market, even before they are formally admitted as full-fledged EU members, especially by admitting reports by accredited bodies operating locally in compliance with EU rules.

This section lists the challenges identified with implementing Serbia's trade agreements and the opportunities for addressing those issues.

**CHALLENGE:** Some accredited and authorised laboratories and the Sanitary Inspection have been facing challenges with recognition and application of European and international standards.

**RECOMMENDATION:** Although the Law on Products of General Use allows such products to be subjected to health and safety assessment procedures based on scientific principles and Serbia, European, and international standards, guidelines, and recommendations where this is necessary to safeguard human and environmental health and safety, these documents continue to be rejected as relevant by some accredited and authorised laboratories and departments of the Sanitary Inspection. This practice has led to arbitrary and unjustified discrimination against products marketed in the EU and created concealed barriers to trade. Moreover, doing so contravenes the Serbia-EU Stabilisation and Association Agreement.

**Provide more training to both public administration and accredited and authorised laboratories** so these are able to understand and appropriately apply all relevant available materials in the exercise of their responsibilities, pursuant to EU principles and practice.

Establish an **effective oversight and control mechanism for authorised laboratories**, including de-licensing for non-compliance.

**CHALLENGE:** Despite structural shortcomings, the Open Balkans initiative has achieved some results in facilitating trade. It has demonstrated that political will and compliance with EU rules can lead to mutual recognition of laboratory findings, lower charges and fees, cross-border alignment of inspections' working hours, and the like, and these have greatly increased trade whilst cutting costs. Nevertheless, the measures were not pursued consistently across all Western Balkans and CEFTA markets, which is a major shortcoming.

Additionally, the EU Growth Plan envisages access to the EU's single market that will be conditional by progress with regional co-operation and alignment with EU rules.

**RECOMMENDATION:** Any regional economic integration platform should include an effective mechanism that builds upon previous improvements and prioritises fewer tangible enhancements annually. This mechanism must possess a structure for managing and monitoring any agreed improvements, along with arrangements for addressing business grievances in the event the agreed changes are not properly implemented as agreed. This would allow stakeholders to have a realistic picture of progress with implementation whilst providing clear links to the benefits offered by the EU Growth Plan.

The following measures would be particularly useful:

- Urgently removing any discriminatory measures restricting or hindering goods imports.
- Accepting laboratory results and conformity assessment results for all types of goods where laboratories and quality infrastructure comply with EU rules.
- Enhancing infrastructure and technology at border crossings (with possible EU funding) and opening green lanes significantly removing barriers on the borders with Hungary and Croatia.
- Ensuring mutual recognition of Authorised Economic Operators (AEOs) across the region and with the EU.
- Aligning security, quality, and product labelling requirements.
- Consistently harmonising and reducing fees and charges.

These initiatives should be paralleled by efforts in tandem with the EU to create a clear roadmap for identifying all **technical and administrative preconditions for accelerating the movement of goods across borders**, enter into agreements to recognise AEO status, and ensure **clear rules and procedures are in place for access to the single market in areas cited by the EU Growth Plan** (such as an Agreement on Conformity Assessment and Acceptance, or bilateral Mutual Recognition Agreements).