

## ACTION PLAN OF THE NATIONAL TRADE FACILITATION BODY FOR 2020 and 2021

### II EXPERT WORKING GROUP FOR TECHNICAL BARRIERS AND MEASURES WITH EQUAL EFFECTS IN TRADE

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The Expert Working Group on Technical Barriers and Measures with Equal Effects in Trade deals with issues and proposes initiatives that contribute to the promotion and facilitation of foreign trade in industrial (non-food) products (including, among others, cosmetic products and other items for general use, medicines, medical devices, chemicals, mechanical and technical products of various kinds, toys, etc.). Within the matters and the initiatives considered, the expert working group shall ensure that technical regulations, standards and conformity assessment procedures are enacted and implemented without constituting unnecessary obstacles to trade.

|    | <b>Planned activity</b>  | <b>Measures for implementation of activities</b>  | <b>Competent institutions</b>  | <b>Result indicator</b>  |
|----|--|---|--|--|
| 1. | <b>Develop the analysis</b> of the practice in the region regarding compulsory submission of conformity certificates at the time of import customs clearance with the aim to completely eliminate this type of control | <ul style="list-style-type: none"><li>• Preparation of lists, product groups and required documents of conformity by competent authorities with the indication in which countries of the region or the EU such practice exists, and the reasons for obtaining such documents during import customs clearance</li><li>• With the involvement of the competent institutions and the private sector, the WG will conduct the analysis and develop the set of recommendations in order to reduce the number of products for which</li></ul> | Ministry of Trade, Tourism and Telecommunications, Ministry of Construction, Transport and Infrastructure, Ministry of Mining and Energy, Ministry of Health, Customs Administration | Reduced volume of certain Annexes to the Decision on determining the goods which require certain documents for import, export or transit |

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|----|--|---|---|--|
|    |  | <p>conformity documents are required at the time of import customs clearance</p> <ul style="list-style-type: none"> <li>Updating of the Decision on determining the goods which require certain documents for import, export or transit - Implementation of recommendations</li> </ul>  |   |  |
| 2. | <p>Establishing an <b>efficient system of risk analysis by the Sanitary Inspection</b> in order to reduce barriers and facilitate import for companies with: good business practices, goods that comply with regulatory requirements, and developed internal procedures for safety and quality controls;</p> | <ul style="list-style-type: none"> <li>Analysis of the applicability of the available import risk analysis models (<i>e.g. model developed under WGI for the import of products with short shelf life etc.</i>) to the Sanitary Inspection portfolio in the field of industrial non-food products</li> <li>Identification of the criteria for risk analysis and needs assessment</li> <li>Development of the plan for implementation of risk analysis in the process of import control of goods with necessary resources (financial, personnel, IT, etc.).</li> <li>Adoption and application of measures necessary for implementation of risk analysis</li> </ul> | <p>Ministry of Health Sanitary Inspection</p>                 | <p>Functional risk assessment at the arrival of each consignment at the border, and decision on sampling on the basis of risk assessment</p> |
| 3. | <p><b>Further harmonization of technical regulations with the EU legislation</b></p>   | <ul style="list-style-type: none"> <li>Publication of the complete list of Serbian standards (EU list) in the area of construction products, that is, the list of standards that will accompany the legal act on construction products</li> </ul>   | <p>Ministry of Construction, Transport and Infrastructure</p> | <p>List of standards as prescribed by the Law on Construction Products</p>   |

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|--|------------------|---|--|--|
|  |                  | <ul style="list-style-type: none"> <li>• In the domain of products of general use - adoption and regular updating of regulations in line with changes to the EU legislation, in particular:               <ul style="list-style-type: none"> <li>- Drafting of the by-laws for materials and objects in contact with food, in accordance with the EU legislation</li> <li>- Drafting of the by-laws regulating the regime for tobacco products and accessories, in accordance with the EU legislation</li> <li>- Drafting of by-laws regulating the import regime of detergents, biocides, etc. in accordance with the EU legislation</li> <li>- WG to participate in the public debate, or provide opinion on drafts of these acts (taking into account the EU legislation and the examples of good practice)</li> </ul> </li> </ul> | Sanitary Inspection, Ministry of Health            | Regulations adopted pursuant to the Law on Items of General Use  |
|  |                  | <ul style="list-style-type: none"> <li>• Revoking the obligation to obtain a certificate of conformity issued by the designated conformity assessment body in the field of low voltage electrical equipment, electromagnetic compatibility and machinery (LVD, EMC and MD)</li> </ul>   | Ministry of Economy                                | Amended Regulations (Rulebook on Electrical Equipment Intended for Use within Certain Voltage Limits, Rulebook on Electromagnetic Compatibility, Rulebook on Machine Safety) |
|  |                  | <ul style="list-style-type: none"> <li>• Transposition of the new EU Directive on Radio Devices (RED), prompt publication of the list of</li> </ul>   | Ministry of Trade, Tourism and Telecommunications, | Amended regulations and publication of the Rulebook on   |

|    | Planned activity   | Measures for implementation of activities  | Competent institutions  | Result indicator   |
|----|--|--|---|--|
|    |  | <p>Serbian standards in the field of radio equipment (and telecommunication terminal equipment), revision of the validity period of the certificate of conformity, with the aim of abolishing it.</p> <ul style="list-style-type: none"> <li>• Development of the Instructions / Guide / Interpretation for the Customs Administration, Market Inspectorate and designated conformity assessment bodies regarding the validity of certificates of conformity and training of competent officials and the private sector</li> </ul> | <p>Designated Conformity Assessment Body RATEL, Market Inspection, Designated Conformity Assessment Bodies, Ministry of Economy</p> | <p>Radio Equipment (withdrawal of the Rulebook on Radio and Telecommunications Terminal Equipment)</p> <p>Published updated list of Serbian standards in the field of radio equipment (and telecommunication terminal equipment)</p> <p>Instructions/Guide/Interpretation for the Customs Administration, Market Inspectorate and designated conformity assessment bodies and commercial entities regarding the validity of certificates of conformity</p> |
| 4. | <p><b>Eliminate delays in the registration of new medicines, renewal of registration and approval of promotional material,</b> in accordance with the legal deadline</p> | <ul style="list-style-type: none"> <li>• <b>Modification of regulations in the field of permanent licenses</b> – enable issuing of licenses for medicines that are registered on the market under the old rulebooks, in accordance with the EU regulations</li> <li>• <b>Significant simplification of the procedure for medicines</b></li> </ul>  | <p>Medicines and Medical Devices Agency of Serbia<br/>Ministry of Health</p>  | <p>Issuing of registration for new medicines, and renewal of registration within legal deadline</p> <p>Simplified procedure for promotional materials</p>  |

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|----|---|--|---|--|
|    |   | <p><b>authorized for trade in the entire territory of the EU</b></p> <ul style="list-style-type: none"> <li>• Modification of the regulations related to <b>promotional material</b> - following the example of good practice from the EU, prescribe the obligation of prior approval only for the promotional material intended for lay audiences, while promotional material for professional audiences would be issued on the basis of the rulebook without prior approval, but with the possibility of subsequent control by inspections</li> <li>• Preparation of the annual reports of the Medicines and Medical Devices Agency of Serbia on the time necessary for resolving individual requests for registration, renewal and issuance of promotional materials indicating whether there were breaches of legal deadlines</li> <li>• Analysis of the amount of administrative tariffs of the Medicines and Medical Devices Agency of Serbia (with the help of donor projects and suggestions of member business associations)</li> </ul> |   | <p>Annual report with a positive assessment regarding the elimination or reduction of delays</p> <p>Analysis of the amount of tariffs in terms of the cost of the service provided</p> |
| 5. | <b>Acceptance of foreign certificates of conformity</b> | <ul style="list-style-type: none"> <li>• Further promotion of the procedure for the recognition of foreign</li> </ul>  | Member Institutions of the National Trade Facilitation Body, Market Inspection, | Number of concluded agreements/memoranda on  |

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|--|------------------|--|--|--|
|  |                  | <p>documents of conformity, in particular issued by notified conformity assessment bodies (notified conformity assessment bodies from the NANDO EU database), as well as accepting documents issued by accredited designated conformity assessment bodies from countries signatories of EA MLA (Multilateral Agreement on European Accreditation on Mutual Recognition, signed by the national accreditation bodies of an EA Member), when such a document confirms conformity with an EU technical regulation transposed in the Republic of Serbia for the purpose of placing goods on the market in the Republic of Serbia through:</p> <ul style="list-style-type: none"> <li>- Signing of international agreements / memoranda on cooperation and acceptance of documents issued by accredited laboratories</li> <li>-Development of brochures and organization of trainings for all interested parties on the topic of acceptance of foreign certificates of conformity or test results, as well as regarding the legal possibility of drafting and issuing appropriate national documents of conformity for</li> </ul> | <p>Designated Conformity Assessment Bodies, Accredited Laboratories, Commercial Entities</p> | <p>acceptance of foreign documents of conformity</p> <p>Brochures published</p> <p>Number of trainings held and number of participants attending the trainings</p> |

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|--|------------------|--|------------------------|------------------|
|  |                  | the product concerned <b>without re-conducting the conformity assessment</b> , with possible support from the civil sector (projects, organizations, associations, etc.) |                        |                  |