

Regulatory and Procedural Barriers to Trade in selected UNECE countries

The paper is meant to support the discussion at the 27th Session of the Working Party on Regulatory Cooperation and Standardization Policies, specifically as regards Item 5 in the provisional agenda (Risk management in regulatory systems).

This paper is a first draft of a report that will highlight challenges to setting up risk-based regulatory systems that are fit for purpose for achieving the Sustainable Development Goals (SDGs).

In its current version, it draws on the results of the UNECE's survey-based studies on regulatory and procedural barriers to trade in Albania, Kazakhstan, Kyrgyzstan, Moldova and Tajikistan. It will, when finalized, attempt at more fully reconciling the findings from the reports to risk management best practice developed by the Working Party on "Regulatory cooperation and standardization policies".

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Abbreviations

CABs	Conformity assessment bodi(es)
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
CPA	Consumer Protection Agency (Moldova)
CTRM	Committee for Technical Regulation and Metrology (Kazakhstan)
CU	Customs Union of Kazakhstan, Belarus, Russia, Armenia, and Kyrgyzstan
DPA	General Directorate of Accreditation (Albania)
EA MLA	European Cooperation for Accreditation Multilateral Recognition Agreement
EN(s)	European Standard(s)
ETSI	European Institute for Telecommunications Standards
GDS	General Directorate of Standardization (Albania)
Gosstandart	State Committee for Standardization (Belarus)
IAF MLA	International Accreditation Forum Multilateral Recognition Arrangement
ICSMS	Information and Communication System for Market Surveillance
IEC	International Electrotechnical Commission
ILAC MRA	International Laboratory Accreditation Cooperation Mutual Recognition Arrangement
ISO	International Organization for Standardization
MOLDAC	National Accreditation Centre (Moldova)
MRA(s)	Mutual recognition agreement(s)
MSB(s)	Market Surveillance Bodi(es)
NAC	National Accreditation Centre (Moldova)
NFA	National Food Authority (Albania)
NMI	National Metrology Institute (Moldova)
NSB(s)	National standardization bodi(es)
NSI	National Standardization Institute (Moldova)
RAPEX	Rapid Alert System for dangerous non-food products
RIA(s)	Regulatory impact assessment(s)
RTA(s)	Regional trade agreement(s)
SMEs	Small and medium enterprises
SRAAF	Quick Alert System for Food and Feed
TCS(s)	Technical Committee(s) for Standardization

1. Introduction

The Sustainable Development Goals (SDGs) of the UN Development Agenda set out a compelling direction for policy action, shifting development action towards the achievement of more just, inclusive, resilient and sustainable societies.

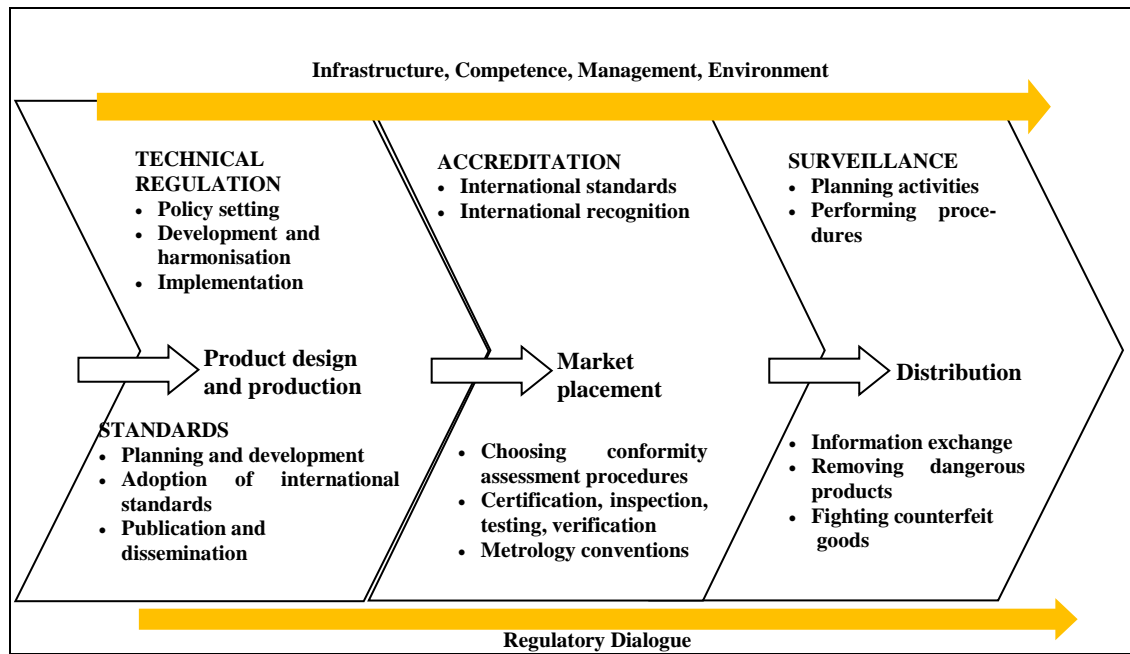
The SDGs should also be seen as regulatory objectives, in other words they are the policy outcomes that regulatory authorities should set out to achieve when planning out regulatory interventions and reforms. These interventions require a careful management of the possible unforeseen events that could prevent their achievement.

This paper is a first draft. In its final version, it will discuss the challenges of implementing the UNECE methodology for risk based and standards based regulatory systems in the countries under review, and how addressing them can support the achievement of SDGs.¹

In its current version, this paper highlights common challenges of regulatory systems as they currently stand, tracing their root causes. These challenges were identified using the product life cycle approach to ascertain capacity shortfalls within the SQAM system. As shown in Figure 1, regulations and institutions are assessed in terms of their impact on product design, its placement on the market and eventual distribution.

¹ This methodology is set out in the UNECE publication “Risk Management in Regulatory Frameworks”¹ and related recommendations which emphasize the importance of taking into account unforeseen events in each phase of policy and regulatory making processes. Its implementation requires a comprehensive risk management approach, including organizational, legislative and procedural guidelines, which should be integrated throughout the national system of standardization, technical regulations, conformity assessment and metrology. This is a complex undertaking, which requires tackling challenges at different levels of government and within different institutions and settings.

Figure 1
Product life cycle and regulatory system processes



This paper is divided in six sections. The introduction is followed in sections 2-6 by an overview of the challenges to implementing a risk-based and standards-based approach to the system of technical regulations, including not only technical regulations, but also standardization conformity assessment and enforcement. Section 6 offers preliminary conclusions and looks at the policy implications of the challenges that have been identified for the achievement of SDGs.

The references for this paper are, on the one hand, the Recommendations and best practice developed by the UNECE Working Party on Regulatory Cooperation and Standardization policies, and on the other the Recommendations of the UNECE's survey-based studies on regulatory and procedural barriers to trade in Albania, Kazakhstan, Kyrgyzstan, Moldova and Tajikistan.²

The recommendations were born out of broad-based discussions with public and private sector stakeholders during national stakeholder validation workshops, and were adopted by the Governments of Albania, Kazakhstan, Kyrgyzstan, Moldova and Tajikistan. The Governments also report to UNECE member States on progress made in implementing the recommendations during the annual sessions of the Steering Committee on Trade Capacity and Standards (previously, the Committee on Trade).³

² The studies are available at: <https://www.unece.org/tradewelcome/studies-on-regulatory-and-procedural-barriers-to-trade.html>. UNECE carried a similar study on Belarus in 2010. The paper does not cover Belarus, as the Government will be briefing the delegates on progress made in the area of risk management under agenda item 5.

³ Progress reports presented during the Steering Committee's annual sessions are available at: <https://www.unece.org/trade/meetings.html#/0/0/0/39818>. Reports presented during the Committee on Trade's annual sessions are available at:

2. SQAM systems

With the exception of Tajikistan, the general management of the SQAM system is assigned to line ministries as regards sectoral policies and the Ministry of Economy (although national denominations differ) as regards horizontal, economy-wide coordination (Table 1). Standard-setting agencies as well as those involved in technical regulations and conformity assessment all work closely with or under the guidance of the line ministries.

Table 1. State agencies responsible for SQAM oversight

SQAM functions	Albania	Kazakhstan	Kyrgyzstan	Moldova	Tajikistan
Overall coordination	Ministry of Finance and Economy	Ministry of national Economy	Ministry of Economy	Ministry of Economy and Infrastructure	Ministry of Economic Development and Trade
Technical regulations	Line Ministries (sectoral regulations) and Ministry of Finance and Economy (horizontal regulations)	Line Ministries (sectoral regulations) and Ministry of national Economy (horizontal regulations)	Line Ministries (sectoral regulations) and Ministry of Economy (horizontal regulations)	Line Ministries (sectoral regulations) and Ministry of Economy and Infrastructure (horizontal regulations)	Tadjikstandart
Standardization	General Directorate of Standardization (DPS)	Committee for Technical Regulation and Metrology (CTRM)	Centre for Standardization and Metrology	National Standardization Institute (NSI)	Tadjikstandart
Conformity assessment	Independent conformity assessment bodies	Institute of Standardization and Certification (KazInSt)	Centre for Standardization and Metrology	Independent conformity assessment bodies	Tadjikstandart
Accreditation	General Directorate of Accreditation (DPA)	National Accreditation Centre	Centre for Accreditation	National Accreditation Centre (MOLDAC)	Tadjikstandart
Metrology	General Directorate of Metrology (DPM)	Kazakhstan Institute of Metrology (KazInMetr)	Centre for Standardization and Metrology	National Metrology Institute (NMI)	Tadjikstandart
Market surveillance	Departments/ Inspectorates of branch ministries; Consumer Protection Commission; National Food Authority; Food Safety and Veterinary Institute; Market Surveillance Inspectorate;	Territorial Departments of the CTRM; Departments/ Inspectorates of branch ministries	State Inspectorate of Environmental and Technical Safety; Departments/ Inspectorates of branch ministries	Consumer Protection Agency; National Food Safety Agency; Departments/ Inspectorates of branch ministries	Trade Inspection of Tajikstandart; Departments/ Inspectorates under line ministries

SQAM func-tions	Albania	Kazakhstan	Kyrgyzstan	Moldova	Tajikistan
	Consumer As-sociations				

The development of the SQAM system is based on multi-year development plans, which are prepared by the the Government. The plans are inspired by a strong drive to harmonize national legislation with the requirements of the WTO-administered multi-lateral trading system as well as the regulatory systems of main trading partners. They are geared to, among others, ensuring public safety; safeguarding the environment; promoting energy efficiency; improving competition; and, supporting regional and global integration.

However, they lack coherence, in that each area is treated on its own right in the absence of a guiding framework. As shown below, risk management is seen as part of the development of technical regulations. Risk management is at best, partial, because it is mostly undertaken as part of regulatory impact assessments (RIA), which by virtue of focusing on specific regulations, offers limited insight into risks.

Moreover, while the specialized agencies work independently, they all rely on the public purse for financing their activities. The agencies income sources are modest, thereby setting the limits to their ability to invest in attracting and maintaining experts and, for conformity assessment bodies, acquire modern laboratory equipment and supplies. Training services, which are critical for human resource development, are mainly provided within the context of donor-funded projects.

In the case of Tajikistan, the dominance of a single agency, namely Tajikstandart, causes conflicts of interests that cast doubts over the effectiveness of technical regulations and services like testing and certification. Tajikstandart, which develops technical regulations and inspects, tests and certifies products against these very same technical regulations, charges testing and certification fees. Tajikstandart also provides conformity assessment services (testing, certification and inspection) and at the same time accredits Tajik conformity assessment bodies. The value of accreditation resides in the independent assessment of conformity assessment bodies, and this is not the case. The Government is taking steps to modernize the entire system so that the functions of standardization, conformity assessment, accreditation, metrology and market surveillance are performed by independent agencies with specialized staff.

All of the countries covered under the UNECE studies on Regulatory and Administrative Barriers to Trade series reported effective cooperation with international organizations, and attached great importance to partnerships with these organizations. As shown in table 2, countries are at different stages of obtaining membership in regional and international organizations and of entering into the European Cooperation for Accreditation Multilateral Recognition Agreement (EA MLA) and the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (ILAC MRA).

Table 2. Participation of the revised countries in the international/regional organizations

N	International/regional organizations	Albania		Kazakhstan	Kyrgyzstan	Moldova	Tajikistan
International organizations							
1	Organization for Standardization (ISO)	CM*		FM	CM	CM	CM
2	International Organization of Legal Metrology (OIML)	FM		FM	n.a.m	CM	n.a.m
3	International Electrotechnical Commission (IEC)	AM		AM	n.a.m	AM	n.a.m
4	International Laboratory Accreditation Cooperation (ILAC)	FM		FM	FM	FM	n.a.m
	• <i>International Laboratory Accreditation Cooperation Mutual Recognition Arrangement</i>	S		S	S	S	n.y.a
5	Bureau International des Poids et Mesures (BIPM)	AM		FM	n.a.m	AM	n.a.m
6	International Accreditation Forum (IAF)	FM		FM	n.a.m	n.a.m	n.a.m
	• <i>International Accreditation Forum Multilateral Recognition Arrangement</i>	n.y.a		S	n.y.a	n.y.a	n.y.a
7	International Measurement Confederation (IMEKO)	FM		FM	n.a.m	n.a.m	n.a.m
Regional organizations							
8	European Association of National Metrology Institutes (EURAMET)	FM		n.a.m	n.a.m	n.a.m	n.a.m
9	European Cooperation for Accreditation (EA)	FM		n.a.m	n.a.m	AM	n.a.m
	• <i>European Cooperation for Accreditation Multilateral Recognition Agreement</i>	S		n.y.a	n.y.a	S	n.y.a
10	European Committee for Standardization (CEN)	AfM		n.a.m	n.a.m	n.a.m	n.a.m
11	European Committee for Electrotechnical Standardization (CENELEC)	AfM		n.a.m	n.a.m	n.a.m	n.a.m
12	CIS Inter-State Council for Standardization, Metrology and Certification (EASC)	n.a.m		FM	FM	FM	FM
13	Euro-Asian Cooperation of National Metrological Institutions (COOMET)	n.a.m		FM	FM	FM	FM

 *FM - full member; AM - associated member; CM - corresponding member; S – signatory; n.a.m - not a member; n.y.a - not yet admitted.

3. The system of technical regulations

In all countries reviewed under the UNECE studies, technical regulations are reportedly aimed at protecting the life and health of consumers, animals and plants in a manner that does not create trade barriers and are elaborated by means of referencing to standards.

The countries all use the “reference to standards” method – as set out in UNECE Recommendation D⁴ - and generally based on the model of the European Union. This involves mentioning only the essential safety requirements (or other requirements of the general interest) in the text of each technical regulation, which is accompanied by a list of the voluntary standards (which, when met, create a presumption of conformity). Meeting

⁴ https://www.unece.org/fileadmin/DAM/trade/wp6/Recommendations/Recommendation_D_en.pdf

the requirements of export markets is high on the agenda of the regulatory agencies of all countries surveyed. (Box.1).

Box 1. Regulatory harmonization in UNECE region

In 2017, the Republic of Moldova was following ambitious plans⁵ to approximate the entire set of EU horizontal Directives⁶ along with 80 sectoral Directives.⁷

Members of the Eurasian Economic Union (EAEU) agreed to adopt common technical regulations for 61 products which are incorporated in the “Single List of Products”.

⁸Existing national technical regulations for products are applicable until the entry of the common regulations into force.

Regulatory impact assessments (RIAs) are seen by all countries surveyed as a critical element to ensure that regulatory requirements are well understood, that the benefits of regulatory intervention are greater than the costs, and that there are no lower cost alternative forms of regulation.

However, all the countries lack the capacity to conduct rigorous RIAs due to high turnover rates and the lack of qualified staff. For Albania and Moldova, these capacity shortfalls come in addition to the recurrent government shuffles that have been disrupting regulatory reform processes. These shortfalls have resulted in many hastened reforms where a drive to approximate regulatory requirements to those of the European Union has resulted in the countries simply transposing corresponding EU directives into national law without proper adaptation.

In a cause-effect relation, the weaknesses in the decision-making process have set the limits to successful implementation. As shown in the remaining sections, there remains a gap in institutional capacities, both in terms methodologies for generating synergies between the different policy areas and in terms of the required procedures for implementing technical regulations. Hence the double challenge for institutionalizing risk management

⁵ See the National Action Plan for the Implementation of the Association Agreement (PNA AA) for 2014-2016 (approved by Governmental Decision No.808 of 7 October 2014 and amended by Decision No.713 of 12 October 2015) which spells out legislative and procedural reforms covering TBT provisions, and the Legislative Programme on implementing the commitments under the AA (Parliament Decision No.146 of 9 July 2015). In late 2016, the Government was preparing a new action plan on implementing Association Agreement for the period 2017-2019.

⁶ EU horizontal directives are established under the EU New Legislative Framework (NFL) for technical harmonization and standardization and the EU Directive 2001/95/EC on general product safety. The NFL principles and rules are set out under EC Regulation 765/2008 (for accreditation and market surveillance) and Decision 768/2008/EC (on a common framework for the marketing of products). EC Regulation 765/2008 and Decision 768/2008/EC are available at: http://ec.europa.eu/growth/single-market/goods/new-legislative-framework/index_en.htm

⁷ The EU sectoral directives define for each product group the essential health and safety requirements and the specific conformity assessment procedures to be followed).

⁸ tba

in regulatory systems, as efforts have to take into account the capacity shortfalls in each area.

4. Standardization

One of the main drivers for the modernization of the standardization system of the countries reviewed in the UNECE studies has been WTO accession. For example, upon accession Tajikistan's authorities pledged to reform the standardization system phasing out "mandatory" standards by 2018, and replacing them with voluntary standards referenced where desirable in technical regulations.⁹ Regional integration efforts have been another factor driving standardization policies and priority is given to harmonizing standards for export-oriented, import-substituting and innovative industries.

Consistent with international best practices,¹⁰ the standards are developed by technical committees that are were structured to ensure the broadest possible participation and create synergy with the development of technical regulations. Kyrgyzstan has established 23 technical committees, Kazakhstan – 51 committees, Albania – 75 committees and Moldova-18 committees. Each committee brings together representatives from producers, traders, business and professional associations, research institutions, consumer associations, market surveillance authorities, testing laboratories, certification bodies and line Ministries, who worked under the guidance of an elected chair.

In practice, all of the countries are standard-takers and adopt harmonized standards as national standards through the cover sheet method. The main benefit of the standard-taker strategy is a quick modernization of local standards. However, this strategy generates significant risks for the local economy. One important shortfall of this approach is that it leads to weak participation in international standards-setting processes and hence insufficient representation of the national interests, and in particular the interests of specific sub-groups – such as SMEs - in international standards under development. Once standards are adopted nationally with little or analysis or adaptation the local industry will be ill prepared to respond adequately.

5.Conformity assessment (accreditation, product certification) and market surveillance

The conformity assessment systems of the countries reviewed in the UNECE studies has been, and continues to be, the subject of targeted reforms.

In the case of Albania and Moldova, reforms have been geared towards institutionalizing the basic principles and rules established under the EU New Legislative Framework

⁹ Regulatory and Procedural Barriers to Trade in the Republic of Tajikistan: Needs Assessment / UNECE, 2014. – 114 p. – P. 51.

¹⁰ See NSI Code of Best Practice (CBP 1-2) of 17 June 2014 on the "Principles and methodology of standardization. The structure and organization of technical standardization committees", which is based on international best practices as established under the provisions of the WTO Code of Good Practice (Annex 3 of the TBT Agreement), ISO/IEC Guide 59:1994 Code of Good Practice for Standardization and the CEN-CENELEC the Guide 20.

(NLF) for technical harmonization and standardization,¹¹ including: the presumption of conformity; demarcation economic operators' responsibilities; protection of CE marking; designated procedures for conformity assessment; and, the separation of accreditation from other quality control and quality assurance functions.

The aim, as emphasized by interviewed officials, is to ensure adherence to safety and quality requirements throughout the product life cycle without creating unnecessary non-tariff barriers. This strategic goal also forms the focus of the remaining countries that are members of the EAEU, which also advances basic principles similar to those of the EU.

However, the results of, as well as the processes of conformity assessment carried out by national CABs are not recognized in the EU, as the accreditation agencies are yet to join the European Cooperation for Accreditation (EA) Multilateral Recognition Arrangement (MLA) and International Laboratory Accreditation Cooperation (ILAC) mutual recognition agreement (MRA). The signing of such agreements requires targeted efforts to strengthen the accreditation centers; address capacity shortfalls within CABs; and, consolidate the country's market surveillance system.

To begin with accreditation bodies operate under binding financial constraints, in some cases. Moreover, the majority of the existing CABs are publically owned, and, given the Government's budget constraints, are unable to afford the accreditation fees, even though the level of these fees is low. The Governments cannot invest in improving the centre's services, even if the costs are modest. This had been the case with ILAC's peer assessments.

Similarly, the Governments are unable to cover the costs for translating the guides and technical documents by specialized international organizations from English into national languages. For example, in Kyrgyzstan, officials reported that the centre has only 3 staff, who are fluent in English, and while they are highly qualified Lead Assessors (1 for laboratories, 1 for certification and 1 for inspection bodies), they cannot possibly attend to the centre's translation needs. The centre is unable to attract qualified staff, since its salary scale is at par with that of the public sector, and could not generate enough income from fees. The fees for accrediting CABs, set at USD 1000 by the Antimonopoly Authority, are too low to allow for achieving any degree of self-sufficiency.

To facilitate trade, all of the countries also seek to establish cooperation arrangements in the field of conformity assessment. The TBT Agreement encourages members to enter into technical equivalence agreements (TEAs) with trading partners. These offer the most efficient tool for harmonization since they imply that products do not have to comply with the regulations of the importing country, assuming that the same objectives are fulfilled by the requirements of both countries. If establishing TEAs proves to be difficult, the Government considers establishing comprehensive mutual recognition agreements (MRAs), which cover several different industries and regulatory issues. All of the re-

¹¹ The NFL principles and rules are set out under EC Regulation 765/2008 (for accreditation and market surveillance) and Decision 768/2008/EC (on a common framework for the marketing of products). EC Regulation 765/2008 and Decision 768/2008/EC are available at: http://ec.europa.eu/growth/single-market/goods/new-legislative-framework/index_en.htm

viewed countries have been opting to establishing MRAs with main trading partners (Box 2)

Box 2. Relevant agencies of Albania's SQAM system has established the cooperation agreements with the SQAM bodies in Azerbaijan, Bosnia Herzegovina, Croatia, Czech Republic, Greece, FYROM, Kosovo, Montenegro, Poland, Romania, the Russian Federation, Sweden, Turkey.¹² Kyrgyzstan had signed mutual recognition agreements with Azerbaijan, Armenia, Belarus, Georgia, Kazakhstan, Moldova, China, Russia, Tajikistan, Turkmenistan, Ukraine and Uzbekistan.¹³ Moldova has established cooperation agreements in the field of the SQAM with Belarus, Bosnia and Herzegovina, Cyprus, Czech Republic, Estonia, Kazakhstan, Kyrgyzstan, Macedonia, Poland, Romania, Slovakia, Turkey and Ukraine.¹⁴

Countries are committed to developing effective market surveillance system. In this regard, authorities approve relevant mid-term programs. In Albania, the National Strategy on Consumer Protection and Market Surveillance for the period 2014-2020 stipulates that the development of the SQAM system is a prerequisite for the efficient market surveillance. The strategy also highlights the urgent need for establishing a national database of non-food products and developing the relevant IT infrastructure to allow for information exchange among different market surveillance agencies, establishing an alert system for dangerous non-food products, and implementing arisk classification and assessment methodology.

Establishing such a system offers better interface with relevant EU systems, i.e. Rapid Alert System for dangerous non-food products (RAPEX) and the Information and Communication System for Market Surveillance (ICSMS).¹⁵

Countries implement market surveillance in the absence of a coherent and risk-based market surveillance strategy In particular, market surveillance authorities lack:

- a risk assessment methodology;
- an overarching policy statement on the principles underpinning market surveillance;
- internal guidelines defining the scope of interagency coordination and procedures for facilitating such coordination.
- food traceability systems as a way for consolidating reliable information on production and business processes throughout the supply chain and, enabling agencies to quickly identify the source of the problem in the event of a food safety incident.

As such systems are product focused and complex to develop, the Government may consider focusing on priority products with high export potential. Kyrgyzstan has applied

¹² Regulatory and Procedural Barriers to Trade in Albania: Needs Assessment / UNECE, 2016. – 149 p. – P. 87.

¹³ Regulatory and Procedural Barriers to Trade in the Republic of Kyrgyzstan: Needs Assessment / UNECE, 2015. – 230 p. – P. 105.

¹⁴ Regulatory and Procedural Barriers to Trade in the Republic of Moldova: Needs Assessment / UNECE, 2017. – 196 p. – P. 62.

¹⁵ Regulatory and Procedural Barriers to Trade in Albania: Needs Assessment / UNECE, 2016. – 149 p. – P. 101-102.

such a progressive approach in the inspection activities of the State Inspectorate of Environmental and Technical Safety (SIETS) (please, see box 3).

Box 3. SIETS inspections are carried out within the context of risk-based planning, and enterprises could address their inquiries to SIETS through a hotline. Inspection plans are prepared based on risk assessments, and submitted to the Ministry of Economy for approval one year in advance. Enterprises that are assessed as posing a high risk (due to shortfalls in the equipment, product, technology and works) are inspected once a year. Enterprises with medium risk levels are inspected once every three years, while those with low risk levels are inspected once every five years.¹⁶

The assessments show that consolidating the country's market surveillance system will not automatically translate into increased compliance with applicable international requirements at the enterprise level. Only a limited segment of the enterprises implements quality management systems. For food producers, the requirements are even more demanding as they have to introduce safety management systems throughout the supply chain (at farm level, slaughterhouses, factories and processing plants) based on the Hazard Analysis and Critical Control Points (HACCP)¹⁷ and the Good Manufacturing Practices (GMP) principles.¹⁸ Just like their counterparts in other South East Europe¹⁹, the majority lack the capacity to operate according to HACCP, which became mandatory in 2010.

¹⁶ Regulatory and Procedural Barriers to Trade in the Republic of Kyrgyzstan: Needs Assessment / UNECE, 2015. – 230 p. – P. 108.

¹⁷ The HACCP system addresses food safety through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product.

¹⁸ Good Manufacturing Practices are those required to conform to guidelines recommended by agencies that control the authorisation and licensing for the manufacture and sale of food, drug products, and active pharmaceutical products. The guidelines provide minimum requirements that a manufacturer must meet to ensure that the products are of high quality and do not pose any risk to the consumer or to the public.

¹⁹ See UNECE (2016) Regulatory and procedural barriers to trade in Albania: An assessment, available at: <https://www.unece.org/tradewelcome/studies-on-regulatory-and-procedural-barriers-to-trade.html>