



Economic Commission for Europe

Steering Committee on Trade Capacity and Standards

**Working Party on Regulatory Cooperation
and Standardization Policies (WP.6)****Thirty-first session**

Geneva, 24–26 November 2021

Item 5 of the provisional agenda

Group of Experts on Risk Management in Regulatory Systems**Recommendation V on Addressing Product Non-Compliance
Risks in International Trade****Submitted by the Bureau***Summary*

The text of the Recommendation is presented to the Working Party for discussion and adoption.

Mandate

The Working Party agreed at its twenty-ninth session on the base text of this recommendation and requested that the Group of Experts on Risk Management in Regulatory Systems (GRM) prepare the document for finalization and presentation for adoption (ECE/CETCS/WP.6/2019/2, Decision 14).

Proposed decision:

Member States approved the new *Recommendation V on Addressing Product Non-Compliance Risks in International Trade*. They mandated the secretariat to report on its implementation. They encourage the donor community to make available resources for capacity-building projects to assist member States in its implementation.

1. The Working Party on Regulatory Cooperation and Standardization Policies,
2. Taking into account the wide range of risks present within an international trade system,
3. Noting that efficient and proportionate management of customs risks as well as risks of product non-compliance with technical regulations and standards associated with incoming shipments is a prerequisite to optimizing border compliance time and costs for importers and for avoiding unnecessary trade disruptions,
4. Stressing the importance of import compliance as a key component of market surveillance and enforcement framework, and its higher efficiency compared to post-market control in providing safety of consumers, society and environment, as well as for achieving fair market competition,
5. Noting that import compliance inspections performed by regulators responsible for compliance with technical regulations and standards have a strong impact and often hamper trade facilitation,
6. Highlighting that management of product non-compliance risk is of particular importance for setting priorities in market surveillance and import compliance with the purpose of removing dangerous and non-compliant products from the market, as described in Recommendation S,
7. Reminding that market surveillance is a necessary component of any regulatory system and that building risk-based regulatory systems that would be proportionate to risks that are relevant to the Sustainable Development Goals (SDGs) and targets is essential for sustainable development, as described in Recommendation T,
8. With the objective of further assisting regulatory authorities in achieving the objectives of the World Trade Organization (WTO) Trade Facilitation Agreement (TFA), Technical Barriers to Trade (TBT) and sanitary and phytosanitary measures (SPS) Agreements, as well as in implementing the integration principles described in the World Customs Organization's Risk Management Compendium,
9. Noting that the efficiency of risk management application at the border depends on
 - (a) individual risk management capacity of each regulatory agency involved in border control in management of non-compliance risks, ensuring correct evaluation of consequences and of the probability of non-compliance associated with each incoming shipment;
 - (b) integration of risk management systems of border control agencies, essential for ensuring involvement of all regulatory agencies in risk management in a cost-effective way,
10. Underlining the central role of the customs authorities in border management and generally high level of data processing infrastructure available at the customs,
11. Keeping in mind that
 - (a) customs regulations cover every incoming shipment, whereas most regulatory authorities are responsible for a limited number of products;
 - (b) customs authorities work according to an international data model;
 - (c) customs authorities often have advanced information system;
 - (d) customs authorities in more than 90 countries are using the United Nations developed IT system ASYCUDA, which contains a module for management of risks,
12. Noting that management of risk of product non-compliance with technical regulations requires different approaches than those for management of customs risks,

Recommends that:

13. Governments develop and implement an integrated risk management strategy to optimize overall border clearance times and costs while maintaining regulatory requirements by the means of systematically addressing all non-compliance risks within border

management procedures, including customs-related and those related to non-compliance of imported products with the requirements of technical regulations and standards.

14. Governments develop harmonized – cross-agency – criteria for the evaluation of non-compliance risk and apply overall border compliance time and costs as evaluation metrics. Risk criteria for evaluation of non-compliance risks are based on the regulatory objectives, which take into account relevant SDGs, as described in Recommendation T.

15. Product regulators develop and implement procedures necessary to explicitly address the risk of product non-compliance within their scope of responsibility, including within import compliance processes at the border, as described in Recommendation S. These processes include

- (a) those required for defining compliance rules and algorithms based on best available data, to allow inspectors focusing on shipments that contain products that are dangerous when non-compliant and have a high probability of non-compliance;
- (b) establishing processes for applying these rules and algorithms at the border upon arrival of a shipment containing products within the scope of responsibility of the product regulator;
- (c) product regulators may apply a reference model of a targeting system described in Annex I for building a profiling system in border control, based on principles of Recommendation S.

16. Governments ensure that processes required for the management of product non-compliance risks are integrated into processes aimed at addressing customs-related and trade disruption risks. In particular, by

- (a) developing guidance documents to facilitate and harmonize a way of how risks are identified and evaluated within an integrated risk management system, as well as how risk treatment strategies are chosen and implemented;
- (b) allowing the customs to provide product regulators with data necessary to determining compliance rules or applying predictive algorithms for profiling the incoming shipments, as described in Recommendation S, as well as for developing an integrated history dataset and analysing correlations among different non-compliance risks;
- (c) sharing IT resources and expertise, as well as encouraging cooperation among regulators in developing and evaluating compliance rules and risk profiles;
- (d) performing an integrated overview of a targeting system (simulations) and harmonizing risk tolerance levels;
- (e) developing integrated approaches for the application of compliance rules of regulators.

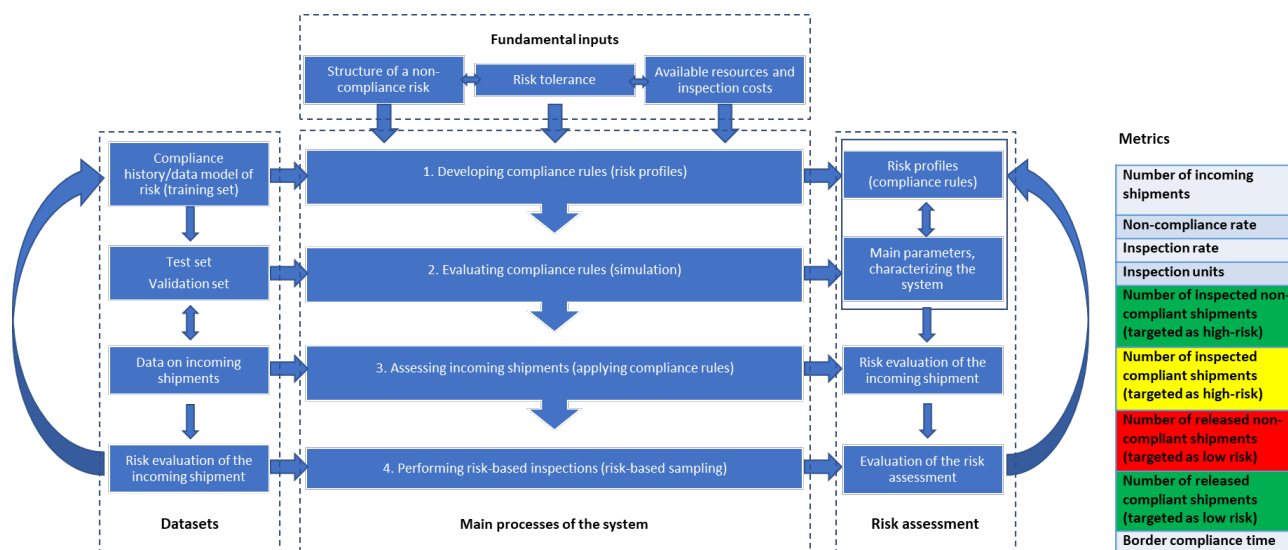
17. In developing integrated approaches for application of compliance rules, Governments establish/strengthen cooperation among product regulators (whose products are involved in international trade) and customs authorities in the assessment of shipment according to product non-compliance risks by allowing the evaluation of the product non-compliance risk associated with the incoming shipments, as well as shipment clearance procedures with respect to this risk, be performed upon shipment's arrival:

- (a) by product regulators based on the data supplied by the customs within product regulator's own IT infrastructure, or
- (b) by product regulators based on the data supplied by the customs within the IT infrastructure of the customs, or
- (c) by the customs according to the compliance rules or algorithms developed by product regulators, as described in Annex II,
- (d) by performing joint inspections on the basis of integrated evaluation of non-compliance risks.

18. Governments strengthen the role of import compliance in market surveillance and ensure that import compliance processes are integrated with other elements of the respective regulatory systems, as described in Recommendation R.

Annex I

Reference model of a system for targeting product non-compliance with technical regulations and standards



Source: UNECE.

1. The left side of the reference model sets out the main processes of the system, outlines their main outcomes and presents a data flow supporting each process.
2. The model presents available resource, risk tolerance and a structure of a non-compliance risk within the responsibility of the regulatory agency as fundamental inputs into the system.
3. The objective of an import compliance system is to bring the level of risk to the tolerable level with minimum resources, and **risk tolerance**¹ constitutes a fundamental input into an import compliance framework and should be proportionate to the available resources and explicitly defined.
4. Depending on the compliance rate and other parameters (described later in the annex), it is possible that the tolerable level of risk cannot be achieved with the **available resources**; in this situation, either risk tolerance or available resources should be increased.
5. The **structure of the non-compliance risk** constitutes a basis for performing risk profiling of the incoming shipments (assessment of the likelihood of non-compliance) and for evaluating the consequences of non-compliance.
6. As risk management is a process that inputs data, the model is structured around the three main elements of a targeting system – a flow of functions, a data flow required to support these functions and a resulting flow of risk evaluations.
7. **Developing risk profiles and compliance rules.** The Structure of non-compliance risk, especially the probability factors, forms the basis for building history datasets that are used for developing risk profiles or compliance rules. This building block of a targeting process can be implemented in many ways; from the simplest, i.e., using expert judgment or non-structured data, to the most sophisticated, such as using predictive algorithms, such as neural networks.
8. **Evaluating compliance rules/risk profiles.** The compliance rules and risk profiles should be evaluated and compared with the risk tolerance of a regulatory authority. For this

¹ This term and other risk management-related terms within this document are based on the terms and definitions defined by ISO 31000 series of standards. See for example, Guide 73:2009, point 3.1.7.3 for risk tolerance. <https://www.iso.org/obp/ui/#iso:std:iso:guide:73:ed-1:v1:en>.

purpose a test and validation datasets should be developed and simulations performed. Results of the simulations – application of compliance rules to the history data, providing information on what would have happened if a regulatory authority had applied the compliance rules in the past, describe the same parameters that are used to define the risk tolerance (the main characteristics of a targeting system described below). In case compliance rules and risk profiles meet the risk tolerance requirement of a regulator and can be implemented using available resources, they become operational.

9. **Applying compliance rules/assessing incoming shipments.** Every incoming shipment is evaluated against the rules; this operation requires data processing that would provide the system with all data that is necessary to implement the rules. The final step of the process is risk-based sampling – performing an inspection according to the risk evaluation or releasing the shipment without an inspection.

10. **Performing risk-based inspections.** In case an inspection is performed, it provides evidence on how good the prediction provided by the targeting system was. In any case, the information on the inspections is added to the history dataset and used to update the compliance rules. Risk-based inspections allow for shifting resources from low-risk shipments to those associated with higher level of risk. When shipments can be categorized in terms of non-compliance risk, regulatory authority can assign the following parameters to each risk group:

- Inspection frequency or inspection rate
- Sample size

11. **Updating the targeting system.** The model shows that a targeting system should be constantly updated. The updates of the system can be categorized as fundamental or operational.

(a) Fundamental changes include those that are related to fundamental inputs to the system. Changes in the risk tolerance of a regulatory authority, as well as in available resources, might require a complete rebuilding of the compliance rules and risk profiles, since the updated regulatory regime would need to meet the new requirements in terms of the number of non-compliant shipments, which release without an inspection can be tolerated by the system. Changes in the structure of the compliance risk – appearance of new cases of non-compliance, and changes in the probability factors also require rebuilding of the targeting process, as such changes require building and processing of new datasets and performing other changes. The system should be reviewed with respect to the required fundamental changes on a systemic basis.

(b) Operational updates of the system should be performed periodically, but on a more regulator basis than fundamental changes. The operational updates allow the targeting system to benefit from the principles of machine learning and include updating the history datasets with the results of the inspections that were performed since the previous update.

12. The right side of the reference model contains a list of the main parameters that characterize any import compliance targeting system. These parameters should be monitored by a regulatory authority on a regular basis for a pre-determined time period (week, month, etc.). They include:

<i>Parameter</i>	<i>Description</i>
Number of incoming shipments	Total number of incoming shipments within the responsibility of a regulatory authority within an analyzed period of time.
Inspection rate	Per cent of shipments (out of total number of incoming shipments) that were inspected.

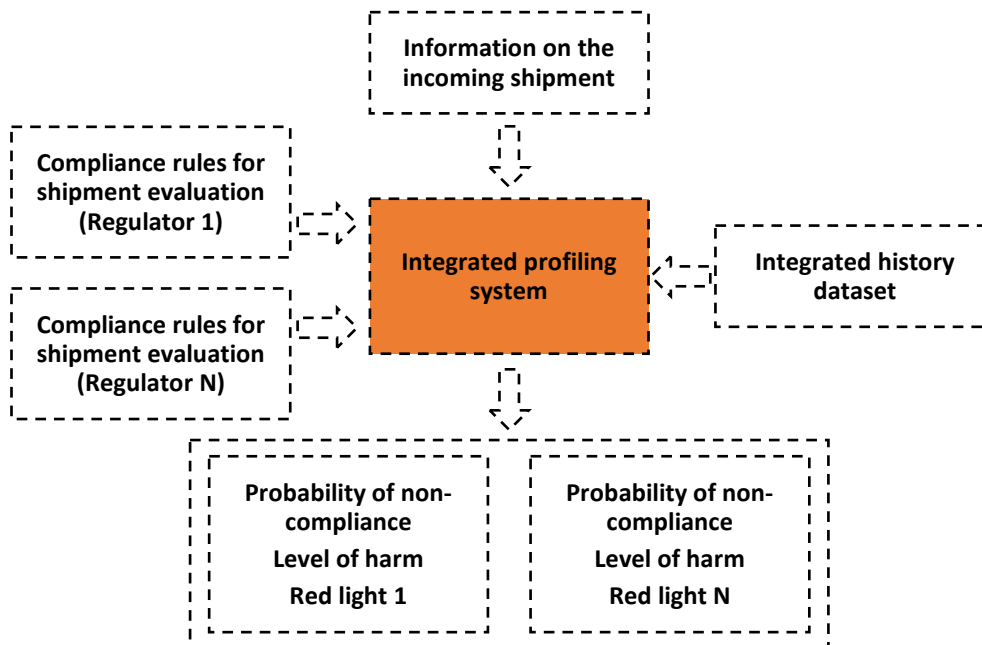
<i>Parameter</i>	<i>Description</i>
Non-compliance rate (interception rate)	Per cent of shipments that were found to be non-compliant with regulatory requirements.
Inspection units	Inspection units allocated per shipment, can be measured in man/hours. Total number of inspection units within a given period of time determine border compliance time.
Number of inspected non-compliant shipments	Number of shipments that were targeted as high-risk by the targeting system and that were found to be non-compliant.
Number of inspected compliant shipments	Number of shipments that were targeted as high-risk but were found to be compliant with regulatory requirements.
Number of released non-compliant shipments	Number of shipments that were targeted as low-risk but were found to be non-compliant with regulatory requirements (e.g., during the later stages of product marketing); the real number is often unknown but the parameter is important for simulation purposes.
Number of compliant shipments released without an inspection	Number of compliant shipments that were targeted as low-risk.

Source: UNECE.

13. Detailed description of the reference model can be found in the UNECE/ITC publication “*Managing risk for post-pandemic trade: Guide for border regulatory agencies*”.

Annex II

A reference model for integrated application of compliance rules at the border



Source: UNECE.

1. The reference model presents an integrated approach for risk targeting at the border. The integrated approach for import compliance implies
 - using one source of data on the incoming shipments, and
 - processing all compliance rules within one information system (e.g. that of the customs).
2. The main steps of the process include the following:
 - Regulatory authorities transfer compliance rules to the integrated profiling system.
 - In order to apply these rules, the system builds an integrated history dataset which includes all risk factors that are used in compliance rules developed by regulatory authorities.
 - When an incoming shipment arrives, the system gets its characteristics from the integrated history dataset.
 - The system applies the conditions of the compliance rules and returns results to regulatory authorities.
3. Detailed description of the reference model can be found in the UNECE/ITC publication “*Managing Risk for Post-Pandemic Trade: Guide for Border Regulatory Agencies*”.