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Item 5(c) of the provisional agenda

Risk management in regulatory systems

Draft Recommendation S on “Applying predictive risk management tools for targeted market surveillance”

Submitted by the Group of Experts on “Managing Risks in Regulatory Systems” (GRM)

Summary

The GRM Group presents for approval by the Working Party the proposed Recommendation S.

The Recommendation aims at providing guidance to market surveillance authorities in planning surveillance activities on the basis of a predictive risk-based assessment of products/businesses within their jurisdiction. It does not aim at replacing existing methodologies. It is instead intended as complementary guidance. It fosters a culture of prevention of accidents on the basis of a structured assessment of risks. The Recommendation has a general part supported by two annexes respectively on: evaluating how dangerous a product is when it is non-compliant with standards and regulations, on evaluating the probability of non-compliance of a product/business entity present on the market.

Proposed decision:

Member States approve Recommendation S on "applying predictive risk management tools for targeted market surveillance". They mandate 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.

I. Introduction

1. The Working Party on Regulatory Cooperation and Standardization Policies,

Emphasizing that achieving absolute safety cannot be the goal of a regulatory system,

Noting that excessively stringent controls can create unnecessary barriers to trade,

Recognizing the importance of ensuring that products on the market (including imported goods), physical infrastructure, commercial and industrial facilities are compliant and safe so as to protect consumers, citizens and the environment

Emphasizing the importance of applying predictive risk assessment tools for planning the activities of market surveillance/compliance authorities at the “before an accident”/“before the non-compliance reported” stage,

Stressing that risk-based surveillance frameworks should help avoiding:

- Excessive controls on low risk products and
- Omitted or insufficient controls on high risk products,

Recognizing that authorities need to efficiently allocate limited resources and that risk-based targeted surveillance on products on the market (as well as on installations and facilities) provide an important means to that end,

Aiming to provide guidance in the use of predictive risk management techniques so as to increase the efficiency of the existing risk assessment tools and data sharing platforms,

Aiming to complement the existing risk assessment tools applied by market surveillance authorities,

Recommends that: Authorities plan surveillance activities on the basis of the evaluation of the non-compliance risk of products/businesses within their jurisdiction. The evaluation of the non-compliance risk should reflect:

- How dangerous a certain product/business entity is when it is non-compliant to standards,
- What is the probability that a non-compliant product of this type is present on the market.

II. Evaluating the non-compliance risk of a product

2. Working Party recommends that national authorities, with due consideration for their individual resources, needs and priorities, develop and implement methodologies and processes that allow for an evaluation of the risk of non-compliance of products/businesses within their jurisdiction to relevant standards and regulations.

3. The approach laid out in Annexes A and B can be used as a basis for the evaluation of the non-compliance risk of a product/business entity. Respectively:

4. Annex A assists in evaluating how dangerous a product is when it is non-compliant with standards and regulations,

and

Annex B assists in evaluating the probability of non-compliance of a product/business entity present on the market.

III. Storing and sharing non-compliance risk related data

5. The Working Party encourages national authorities - with due consideration for their individual resources, needs and priorities - to use, or as necessary develop, data gathering tools for storing data on:

- Results of market surveillance activities related to products (matching them to the evaluation of the probability of non-compliance made during the planning phase);
- Injuries and other accidents related to the use of non-compliant products,

and to use this data continuously improve the evaluation of the non-compliance risk of products.

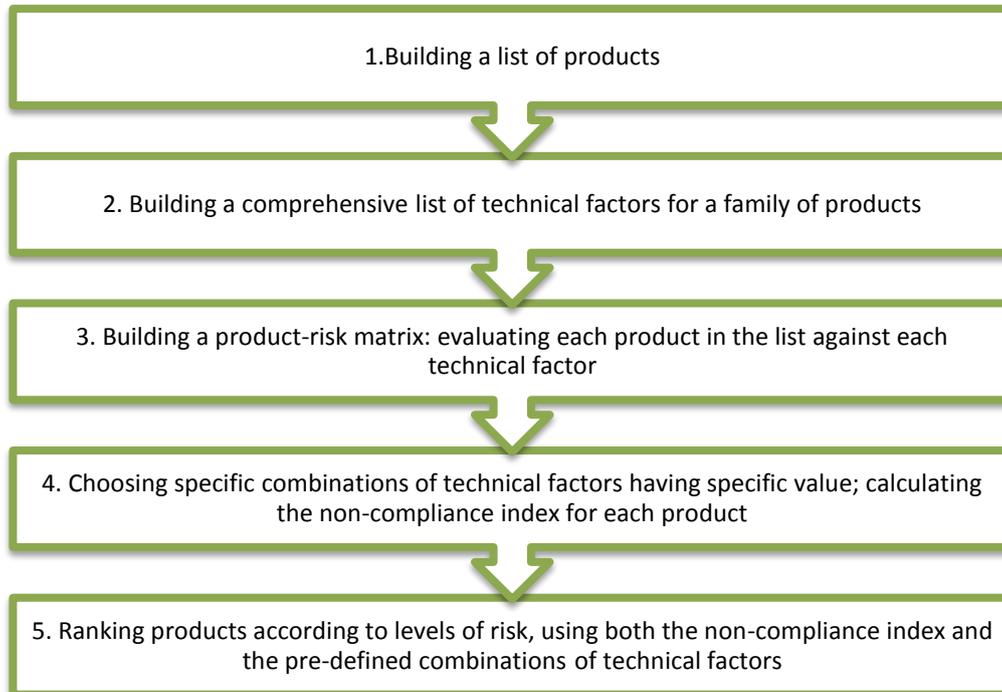
6. Also encourages national authorities to share the non-compliance risk and injuries related data with their international counterparts, so as to increase the efficiency of regulatory intervention and surveillance,

And recommends that resources be earmarked for assisting in the development and implementation of these tools both at the national level and internationally.

Annex A

Evaluating how dangerous a non-compliant product is

Evaluating how dangerous a product is when it doesn't comply with standards requires running the process presented in the picture below systematically for each family of products within the authority's jurisdiction.



Building a list of products for each family of products

Building a comprehensive list of products within the scope of its activities is an essential step in planning the surveillance activities. In performing this task, an authority could refer to international and national standards, and also to the catalogs of producers/importers, as well as to other sources.

Building a list of technical factors for a family of products

A technical factor for a group of products can be defined as a vulnerability that might increase the impact of any of the product-related risks when a product is in the non-compliant mode.

Identification of risks related to each product within a certain family of products is essential for building a list of technical factors. According to international risk management standards, identification of risks (in general and related to products) requires formalizing:

- Risk events,
- Their likelihoods,
- Their impacts,
- Set of related vulnerabilities (risk factors).

Most of the vulnerabilities (risk factors) related to product risks are also product's technical factors: in most cases non-compliance just increases the impact of product's risks. At the same time, list of technical factors should also include specific safety factors, that make a compliant product safer but a non-compliant product more dangerous.

For example, technical factors for the electrical equipment include:

- Product relies on isolation between Low Voltage (LV) and exposed Extra Low Voltage (ELV) parts.
- Product likely to move during or between uses
- Product used in circumstances where the user is not able to readily disconnect with normal physical reaction to electric shock.
- Product relying on guards and barriers to prevent mechanical injury.
- Product likely to be used by unsupervised or lightly supervised children.

(a) Building a product-risk matrix: evaluating each product in the list against each technical factor

The next step in the process is building a product – risk matrix, which fully characterizes a family of products with respect to the relevant technical factors:

	<i>Product 1</i>	<i>Product 2</i>	...	<i>Product n</i>
TF_1	<i>1</i>	<i>0</i>	...	<i>1</i>
TF_2	<i>0</i>	<i>1</i>	...	<i>1</i>
...
TF_m	<i>0</i>	<i>0</i>	...	<i>0</i>

In case a certain technical factor (say – “product likely to be moved during or between uses” is relevant to a product (a product is moved during use), it gets an evaluation of 1, if not (a product is not moved during use) – 0.

(b) Calculating the non-compliance index for each product.

Using the product-risk matrix, authorities can characterize each product with a non-compliance index, which is the sum of all technical factors relevant to the product, and use it in the evaluation of the product non-compliance risk.

Additionally, authorities can define specific combinations of technical factors to have a higher weight in a non-compliance index (for example, a combination of factors “product moved during use” and “product used by unsupervised children” can have a weight higher than 2).

(c) Ranking products according to levels of risk, using both the non-compliance index and the pre-defined combinations of technical factors

When each product is characterized by a combination of technical factors and its non-compliance index, authorities can use different approaches for ranking products. The simplest approach would be to rank products according to their non-compliance indices,

though other approaches can also be applied. For example, an authority can declare all products that are characterized with a certain combination of technical factors being of “high risk”.

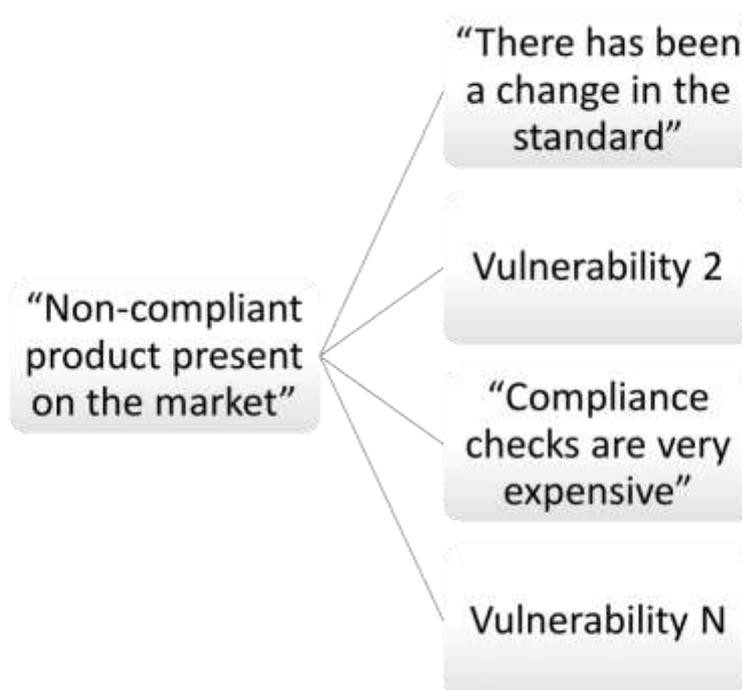
(d) Storing and using relevant data

Authorities store and process data on injuries related to the use of non-compliant products so that they could adjust the weights of the technical factors thus improve the evaluation of the non-compliance risk.

Annex B

Evaluating probability of non-compliance.

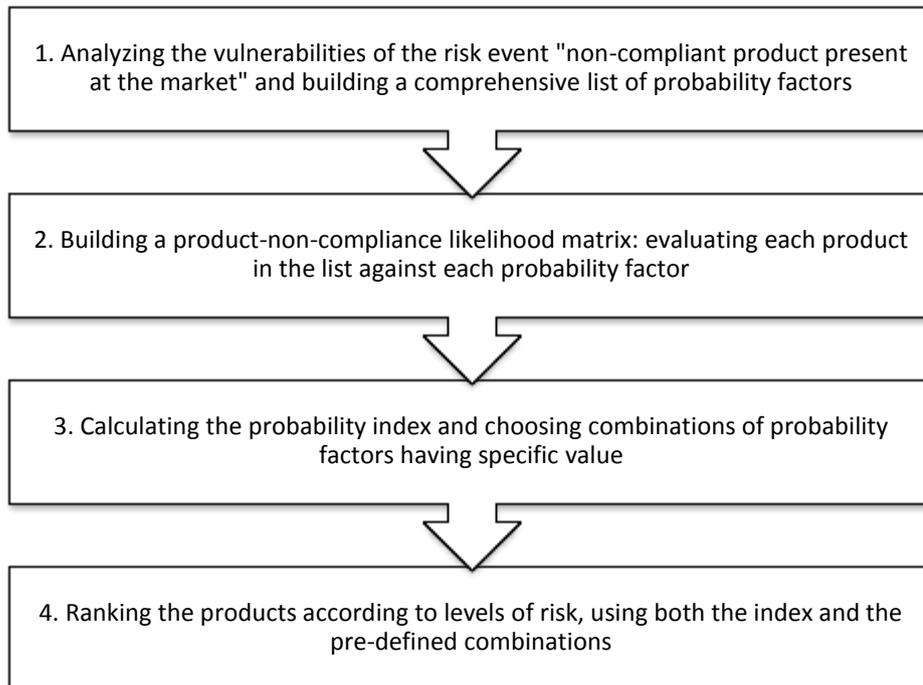
To evaluate the probability of non-compliance, i.e. the probability that a non-compliant product of a certain type can be found on the market, an enforcement authority should determine a list of factors that increase the likelihood of the event “non-compliant products present in the market” for each family of products, as shown in the picture below:



A vulnerability of a risk event “non-compliant product present on the market” can be called a probability factor PF. Other examples of probability factors include:

- There are cost disincentive for compliance
- Compliance with the applicable Standard is complex or technically difficult.

Evaluating the level of probability that a product of certain type can be found to be non-compliant on the market, requires the following process:



The process similar to that described in Annex A, similar approaches for ranking the products according to their probability of non-compliance levels can be applied.

Authorities store data on past surveillance activities so that they could build learning compliance frameworks and thus improve the evaluation of the non-compliance risk related to the product.
