Market surveillance system for products in Europe

1. Market Surveillance

Market surveillance is crucial for the smooth functioning of the single market in Europe. It helps protect:

- Consumers and workers against unsafe products and non-compliance
- Businesses from unfair competition by those who ignore the rules.

EU Market Surveillance legislation

The major objective of the European Commission is to ensure that EU market surveillance legislation provides:

- Clear and uniform rules applying to non-food products and towards economic operators
- Requirements (infrastructure, organisation, legal powers, etc.) to ensure that market surveillance can cope with enforcing EU legislation
- Streamlined market surveillance procedures for controlling products within the EU and at its borders (import controls)
- Tools to coordinate activities carried out by national surveillance bodies across the EU (e.g. discussion forums, IT databases, and common market surveillance campaigns).

The current legal framework:

The Regulation (EC) 765/2008 sets out the requirements for accreditation and market surveillance relating to the marketing of products. The Regulation:

- sets out clear obligations for EU countries to carry out market surveillance and to prohibit or restrict the marketing of dangerous or non-compliant products
- provides market surveillance authorities the powers to obtain all necessary documentation from manufacturers to evaluate product conformity, to enter manufacturers' premises and take samples for testing, and in extreme cases to destroy products
- Includes clear obligations for EU countries to ensure cooperation at national and international level.

Decision 768/2008/EC on "common framework for the marketing of products" contains provisions on market surveillance, obligations of businesses, traceability and safeguard mechanisms. These provisions are being incorporated in sector specific legislation.

Directive 2001/95/EC (the General Product Safety Directive) contains additional market surveillance provisions, notably for non-harmonised consumer products.

Actions under the Single Market Strategy to increase compliance with EU product legislation

The Single Market Strategy adopted on 28 October 2015 emphasised that the growing number of illegal and non-compliant products in the single market distorts competition among businesses and puts consumers at risk.

New regulation on market surveillance and compliance of products

In June 2019 Regulation (EU) 2019/1020 on market surveillance and compliance of products was published, aiming at improving and modernising market surveillance. It will apply to 70 regulations

and directives (listed in its Annex I) that harmonise at EU level requirements on non-food products to protect consumers, health and safety, the environment and other public interests. Regulation (EU) 2019/1020 will replace the market surveillance provisions of Regulation (EC) No 765/2008 as from 16 July 2021, and will improve them in particular by

- preventing non-compliance by providing information to businesses:
  - Single Digital Gateway: product requirements and obligations derived from EU legislation
  - National Product Contact Points: information on national transposition and implementation
- joint activities with businesses
  - Raising awareness, providing guidance
  - Identifying non-compliance: results of joint activities may be used for investigations
- providing more effective enforcement tools to address online sales
- improved cooperation: between EU countries, between market surveillance and customs authorities, and through an EU product compliance network

Market surveillance of products sold online

In July 2017, the Commission issued guidelines to help national market surveillance authorities better control products sold online. These guidelines clarify:

- that any product sold online in the EU has to comply with EU product legislation, even if the producer is based outside the EU
- the obligations of online marketplaces when authorities require them to remove dangerous products through the 'notice and action procedure', as defined in the e-Commerce Directive
- the responsibility of all actors in the supply chain, including fulfilment service providers who receive the order, package and send the product

2. Implementation of market surveillance at national level

European countries must ensure effective surveillance of their markets. They are required to guarantee that:

- products placed on the market are monitored
- the marking and documentation requirements have been respected
- products have been designed and manufactured in accordance with EU harmonisation requirements
- market surveillance authorities have the necessary powers, resources and knowledge to perform their functions
- procedures are put in place for following up complaints and monitoring accidents
- market surveillance programmes are established, implemented and periodically updated
- the functioning of surveillance activities is reviewed and assessed at least every four years

List of national market surveillance authorities:

Contact details of national authorities competent for market surveillance in different areas can be accessed by clicking on below hyperlinks:

- List of national market surveillance authorities by sector
- List of national market surveillance authorities by EU country

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Information exchange and cooperation at EU level:

Effective cross-border cooperation between market surveillance authorities in different EU countries is essential to ensure efficient, comprehensive, and consistent market surveillance.

Regulation (EC) 765/2008, sector specific EU harmonisation legislation aligned to Decision 768/2008/EC, Directive 2001/95/EC and current administrative practice provide tools for the pooling of information and cooperation at EU level. They include:

- **Rapid Information System (RAPEX)** - an alert system that facilitates the rapid exchange of information among EU countries and the European Commission.
- **General information support system** – the **Information and Communication System on Market Surveillance (**ICSMS) system for information exchange will include **best practices**, results of joint actions, details of non-compliant products and information on national market surveillance programmes.
- **Safeguard procedures** - a safeguard procedure which obliges EU countries to communicate any measures they take which restrict the free movement of a product because it presents a risk or is otherwise non-compliant.
- **Administrative Co-operation Groups (AdCos)** - the Commission facilitates discussions within AdCos composed of market surveillance experts. The purpose is to share information and cooperate on practical matters related to the implementation of EU laws.
- **Financing of joint actions** – the Commission finances market surveillance activities jointly carried out by national authorities. The final report of the joint project for market surveillance in the field of measuring is published below under 'Support documents on market surveillance'.
- Regular contacts and policy discussions with national representatives in the Expert Group on the Internal Market for Products

The purpose of cross-border cooperation is to make sure that EU product legislation can be effectively enforced across the Single Market, where goods can move freely from one country to another, despite the fact that the enforcement powers of individual authorities are limited by national boundaries. The need for cross-border cooperation among authorities across the EU can arise for virtually all products falling within the scope of EU harmonisation legislation, including goods supplied on-line. The typical case where cross-border cooperation may be needed is when the market surveillance authority of country A (MSA A) finds a non-compliant product made available by local distributor(s), but where the economic operator responsible for product conformity (i.e. EU importer or manufacturer) is based in country B. The assistance of the authority in country B (MSA B) is necessary to obtain information needed to complete the compliance evaluation carried out by the authority in country A (e.g.; when the economic operator does not reply to MSA A's request for documentation or when MSA A has difficulties in findings the contacts of the relevant economic operator). The legal basis for this type of mutual assistance is set out in Article 24 of Regulation (EC) 765/2008.

A further form of cross-border cooperation can be envisaged when authorities discuss corrective action with businesses. Here there is an increasing need for surveillance authorities to seek 'cross-border voluntary corrective action' from economic operators, i.e. voluntary measures aiming at correcting the noncompliance throughout the Single Market. When the economic operator accepts to

take corrective action, the competent authorities of each Member State will nevertheless need to verify that this has actually taken place on their territory. Moreover, the procedure set out in Article R31 of Decision 768/2008 (and corresponding provisions included in 'aligned' legislation) already provides for cooperation between authorities in the Member States in so far as they are required to follow up compulsory restrictive measures adopted by MSA A to impose restrictive measures in their respective national territories. This further form of cross-border cooperation enables the enforcement of the initial measures across the Single Market. Follow up measures by the authority located in the same country of the economic operator (MSA B) will be particularly important in this regard.

Responsibility for proceedings: When MSA A requests the assistance of MSA B to obtain information necessary to complete its investigation, it keeps responsibility for proceedings, unless both authorities clearly agree among themselves to transfer such responsibility. Only in this latter case should the 'baton passing' functionality be used.

Type of assistance: When mutual assistance is requested, this should relate to tasks that MSA A cannot objectively fulfil due to lack of enforcement powers, unless otherwise agreed by the relevant authorities. MSA B is then expected to provide assistance. However, authorities should agree on what assistance (e.g. supply of information or documentation, carrying out investigations etc.), and how and when it will provided in order to fulfil the requirements of MSA's proceedings. Where there is a disagreement on the approach between MSAs, they could informally seek the advice of the ADCO (e.g. at meetings or simply via-email). If appropriate, for example where the disagreement relates to the interpretation of EU legislation, the Commission should be informed and could provide advice.

Click here for the guidance on cross-border cooperation among EU market surveillance authorities

3. Risk Assessment

According to the provisions of the EU legislation, the Market Surveillance Authority has to carry out a risk assessment (as part of the compliance assessment) as soon as a noncompliant product representing a risk to the health or safety of persons or to other aspects of public interest protection is identified. The Market Surveillance Authority must evaluate the nature and level of that risk and document the result. This is needed to determine the level of risk when notifications are made in both ICSMS and RAPEX where a category for risk must be reported.

The outcome of the risk assessment should determine the level of the risk and provide the relevant information for the Market Surveillance Authority to issue a proportionate measure when the Economic Operator fails to take appropriate action and decide whether a RAPEX procedure is needed.

EU general risk assessment methodology implements Article 20 of Regulation (EC) No 765/2008 and *intended to assist market surveillance authorities when they assess the compliance of products that are subject to Union harmonization legislation*. The methodology builds on the RAPEX Guidelines, developed within the framework of the Directive on General Product Safety (GPSD) and extends them in two respects:

1. to make sure that the broader categories of public risk protected under EU harmonization legislation can be taken into account;
2. to reflect the specific legal requirements on harmonised products.

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The methodology developed in this paper is exclusively for the purpose of market surveillance activities. It should not be used by manufacturers, importers or distributors for the assessment of the risk of the products they intend to make available on the EU market.

For more details, please click here

4. Challenges to the proper functioning of the market surveillance system in EU

Several factors affect the market surveillance authorities' ability to check whether products made available in the EU are manufactured according to EU law:

- Supply chains may be very complex and encompass several countries.
- Economic operators may be located in a country different to those in which products are made available. Often, they are located outside the EU.
- Consumers may purchase products through the internet.

5. Best practices on market surveillance

Market surveillance of vehicle emissions: Best-practice examples with respect to the European Commission's proposed type-approval framework regulation

On January 27, 2016, the European Commission (EC) proposed a new motor vehicle type-approval framework that will, if adopted, make fundamental and far-reaching changes to the existing Framework Directive (Directive 2007/46/EC). Among other improvements, the proposal requires EU member states to establish market surveillance programs.

There are four elements of the proposal that pertain to market surveillance with the aim of strengthening the EU's in-use vehicle compliance program:

1. Require EU member states to perform market surveillance testing of vehicles
2. Grant EU member states the authority to take measures against noncompliant vehicles sold in their own markets
3. Create an EU wide advisory body called the Forum for Exchange of Information on Enforcement
4. Require the EU member states to establish a national fee levied on the manufacturers that would cover the costs of market surveillance activities

Although the proposed framework reflects a desire to improve market surveillance in the EU, in its current form, it lacks detail and offers insufficient guidance to regulators that could reduce its potential impact. The market surveillance requirements in any new type-approval framework should be improved, based on a set of compliance and enforcement best practices developed by the ICCT, in the following ways to ensure a full and comparable implementation in all member states:

1. Implement fleet screening to identify potentially noncompliant vehicle models
2. Specify market surveillance testing scale and protocol
3. Clarify the threshold for failure and requirements for remedial actions
4. Enhance financial sustainability of market surveillance programs
5. Harmonize noncompliance determination and enforcement actions throughout the EU

For more information please click here

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