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GOOD PRACTICE FOR MARKET SURVEILLANCE

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This document reflects good practice in the field of market surveillance and aims to contribute to a better understanding and consistent application of EU rules on market surveillance of non-food products across different sectors. The information provided is of a general nature only and doesn't specifically address any particular individual or entity. Only the text of the Union applicable legislation itself has legal force and only the Court of Justice of the EU has the competence of interpreting EU legislation in a binding manner. The first edition of this guidance document published in January 2017 has been developed by market surveillance experts who were members or Chairpersons of various Administrative Cooperation (AdCo) groups. This document has been taken over by the EUPCN (EU Product Compliance Network) which has been set up by the Regulation (EU) 2019/1020 on Market surveillance and Compliance of Products and revised by an EUPCN Working group consisting of SLO (Single Liaison Office) representing the Member States and ADCO Chairs representing the harmonised sectors.

This document is primarily intended for market surveillance authorities, in sectors falling under the scope of Regulation (EU) 2019/1020 on Market Surveillance and Compliance of Products. However, it can be used, for information, by any other interested parties or for any other sector where market surveillance is required.

As the document reflects the state of the art at the moment of its drafting, it may be subject to later modifications.

1. INTRODUCTION

The document has been prepared in order to develop good practice for market surveillance for products applicable 'horizontally' to different sectors. The document has been developed by an ad hoc working group established by EUPCN.

SCOPE AND TARGET AUDIENCE

The purpose of this document is to provide guidance to Market Surveillance Authorities in the EEA responsible for market surveillance in sectors within the scope of Regulation (EU) 2019/1020[1]. This guidance is also expected to be relevant for Swiss Market Surveillance Authorities competent in sectors within the scope of the EU-Switzerland Mutual Recognition Agreement[2].

It is intended to be a working tool which will help to facilitate effective cross border market surveillance and provide a common understanding of the procedures laid down in applicable EU legislation ensuring a consistent approach to market surveillance.

The document covers:

- the procedural steps described in Regulation (EU) 2019/1020 on market surveillance for products covered by Union harmonisation legislation. The Regulation directly applies to Member States and national authorities.
- where applicable, the market surveillance provisions described in Decision No 768/2008/EC on a common framework for the marketing of products [3] and incorporated in sectoral legislation aligned to it.

The relevant market surveillance provisions are described in Chapter 7 of the Blue Guide[4]. For some legislation, the scope of the Blue Guide is limited. They can be found in Section 1.5 "Scope of the Blue Guide".The document primarily addresses market surveillance carried out in relation to Union harmonisation legislation as listed in Annex I. For chemicals in scope of the REACH Regulation, this document needs to be complemented by specific guidance developed by ECHA and the Forum. The document does not attempt to cover the General Product Safety Regulation (EU) 2023/988[5].

DEFINITION OF MARKET SURVEILLANCE

Market surveillance is defined by Regulation (EU) 2019/1020 as the activities carried out and measures taken by market surveillance authorities to ensure that products comply with the requirements set out in the Union harmonization legislation and and to ensure protection of the public interest covered by that legislation. These applicable requirements are contained in Union harmonisation legislation, laying down rules on marketing products.

One of the fundamental freedoms of the European internal market is the free movement of goods. Economic Operators of non-food goods can placing on the markettheir products to the internal market without needing prior approval by a Market Surveillance Authority.

1 https://eur-lex.europa.eu/eli/reg/2019/1020/oj/eng
2 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=legissum:4350035
3 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32008D0768
4 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2022.247.01.0001.01.ENG
5 https://eur-lex.europa.eu/eli/reg/2023/988/oj/eng

However, they must ensure that the products meet all legal requirements. Market surveillance Authorities verifies this and allows measures restricting the movement of non-compliant products in the EU. By doing so market surveillance guarantees the protection of all aspects of public interests, such as the health and safety of persons or the environment, while also ensuring fair competition.

Market surveillance activities can be carried out proactively, on the Market Surveillance Authority's initiative, or reactively, following accidents, complaints, notifications by customs or other intelligence requiring investigation. Formal market surveillance measures can only be addressed once a product has been placed on the market, put into service or presented to customs with a view to be released for free circulation. However, a Market Surveillance Authority may also encourage compliance by providing information on applicable legislation (e.g. via press releases, dedicated websites or information campaigns) at any stage of the design and production process and carry out checks at trade shows, fairs and exhibitions.

2. KEY PRINCIPLES

Effective market surveillance is based on several key principles which should be considered whether the activities performed are proactive or active.

STRATEGY FOR MARKET SURVEILLANCE

Market surveillance is not about checking every single product on the market but is about working efficiently and intelligently in order to monitor a wide range of products with the available resources. Intelligent market surveillance considers the appropriate targeting of products, the appropriate actions to perform controls, and the most effective follow-up measures. Furthermore, market surveillance can be carried out both proactively and reactively depending on how to most effectively meet objectives.

PROPORTIONALITY

Article 14 (2) of Regulation (EU) 2019/1020 requires Member States to ensure that market surveillance activities are exercised with respect to the principle of proportionality. It requires Market Surveillance Authorities not to go beyond what it is necessary for achieving the expected result. In practice, this means that when deciding on corrective actions Market Surveillance Authorities should consider the level of non-compliance and possible impact e.g. severity of harm and probability of occurrence.

CROSS BORDER COOPERATION

Cooperation between Market Surveillance Authorities from different Member States is essential to effective market surveillance. Articles 22 and 23 of the Regulation (EU) 2019/1020 compel Market Surveillance Authorities to provide assistance or enforcement measures upon request and exchange information and documentation, while Article 34 of Regulation (EU) 2019/1020 establishes a common database to share market surveillance information. Market Surveillance Authorities should also follow up on restrictive measures adopted by other Market Surveillance Authorities to ensure effective enforcement across the single market. Furthermore, they should attend and actively participate in Administrative Cooperation

groups (AdCos[6]) meetings and as far as possible participate in common projects and joint market surveillance actions.

EXCHANGE OF INFORMATION THROUGH IT TOOLS (e.g. ICSMS)

The information exchange between Market Surveillance Authorities is one of the key elements for the functioning of the European Market Surveillance system. IT Tools like the Information and Communication System for Market Surveillance (ICSMS) and other sector specific systems support the exchange of information and contribute to effective cross border cooperation.

ICSMS[7] is the information and communication system on market surveillance provided for in Article 34 (1) of Regulation (EU) 2019/1020, providing a comprehensive platform for communication between the EU market surveillance authorities.

According to Article 34 (4) of Regulation (EU) 2019/1020, Market Surveillance Authorities shall enter into ICSMS information regarding products in the scope of the Market Surveillance Regulation for which an in-depth check of compliance has been carried out as well as for products entering the Union market for which the process for the release for free circulation has been suspended. The ICSMS shall also be used for mutual assistance requests under Article 22 or 23 of Regulation (EU) 2019/1020.

TARGETING THE RELEVANT ECONOMIC OPERATOR

Most of the legislation listed in Annex 1 contains clear obligations for Economic Operators, proportional to the role they are playing in the supply chain. These obligations are described in detail in Chapter 3 of the Blue Guide.

To maximise the effectiveness of market surveillance in the EU, Market Surveillance Authorities should always request corrective actions from the Economic Operator (either the manufacturer or the importer) responsible for placing the non-compliant product on the EU/EEA market. This request should be made before or in parallel to addressing the national distributor (i.e. any person in the supply chain, of the product other than the manufacturer or importer, who makes the product available on the market). Addressing the manufacturer or the importer should ensure that corrective actions are taken at EU/EEA level[8]. For sectors falling under the Mutual Recognition Agreement on Conformity Assessment between the EU and Switzerland, Market Surveillance Authorities should address non-compliance within the EEA as well as Switzerland. Against this background, references to the EU in the rest of this document will need to be interpreted as broader references to the EEA and, if appropriate, to Switzerland.

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6 http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/administrative-cooperation-groups/index_en.htm

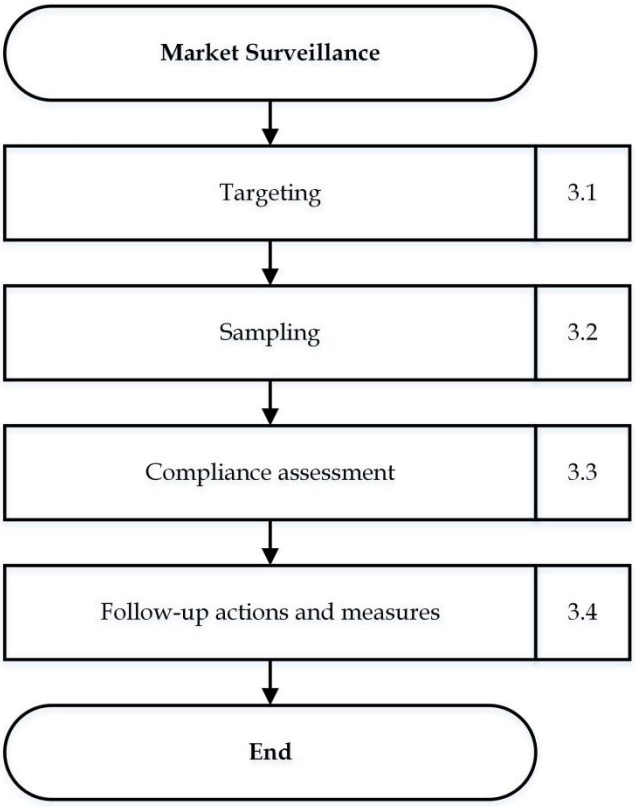
7 https://webgate.ec.europa.eu/single-market-compliance-space/market-surveillance

8 The manufacturer or the importer is responsible for taking necessary corrective measures when informed that a product is non-compliant.

3. MARKET SURVEILLANCE PROCESS / DESCRIPTION

The following flow chart summarises market surveillance activities, detailed descriptions of which can be found in the following sections.

The basic (main) process of market surveillance can be divided into 4 successive steps. Firstly, the Market Surveillance Authority has to determine which products and/or Economic Operator will be targeted to achieve the greatest impact on the market (see "Targeting – 3.1"). The Market Surveillance Authority must then apply its ownstrategy in the field and take samples when relevant (see "Sampling – 3.2"). The Market Surveillance Authority then has to assess compliance which may require requesting more information from the Economic Operator e.g. access to technical documentation (see "Compliance assessment – 3.3"). At the end of the assessment the Market Surveillance Authority is able to draw informed conclusions on the compliance of the type of product. For this stage, and before making a definitive decision, discussion with the relevant Economic Operators is needed (see "Follow-up actions and measures – 3.4"). All information gathered throughout the process is valuable and could be taken into account in future market surveillance activities.



3.1. TARGETING STAGE

Intelligent and resource efficient market surveillance enhances assessing the compliance of products on or entering the market. Market Surveillance Authorities should prioritise resources to ensure that the actions they take contribute effectively to the protection of public interests and fair markets. When planning market surveillance activities, it is important to utilize a risk-based approach – based on the likelihood and potential magnitude of harm posed by noncompliant products to such protected values as consumer safety, consumer rights and fair competition – when deciding which products and on which Economic Operator to focus in order to achieve the greatest possible protection of such public interests as efficiently as possible.

There are two distinct types of market surveillance:

- Proactive market surveillance - planned market surveillance activity
- Reactive market surveillance - in response to an outside event

In both cases, a risk-based approach can make the targeting process more efficient by focusing a market surveillance authority's limited resources on the areas where they can achieve the greatest possible results.

3.1.1 Proactive market surveillance

a) Knowledge of the market

It is recommended that Market Surveillance Authorities perform a market screening exercise to identify which Economic Operators are active in a particular sector; what products are available and where . Market Surveillance Authorities are advised to cooperate with industry to identify supply chains and market share and conduct market research among end users. Third party services may also be used to provide information if it can be established as being reliable. At the end of the market screening exercise the Market Surveillance Authority should have an intelligence led overview of the following information, which is relevant for assessing risk:

- the overall size of the market, i.e. the amount and type of products supplied on the market.
- the names and market share of the Economic Operators supplying given products. Market share is an important risk factor (the more products placed on the market, the greater the potential harm, if it were to occur).
- the type of Economic Operator (e.g. manufacturers, importers, distributors) and main channels of sales (e.g. online or retail premises).
- Information about the market related to product quantities, economic operators, and compliance rates from ICSMS/Kibana.

The Market Surveillance Authority must decide which Economic Operators and products should be targeted to achieve the most effective outcome.

Market surveillance authorities shall follow a risk-based approach in deciding on which

market surveillance checks to perform, on which types of products and on what scale. Application of risk-based approach allows Market Surveillance Authorities to prioritize their activities on those products /product categories considered most likely to pose a risk. In prioritization Market Surveillance Authorities shall take in account a set of factors related to products and relevant economic operators and previous analysis of Member State data. Here, the concept of risk in relation to products is broader than just the traditional health and safety risks. It also includes risks related to occupational health and safety, consumer protection, the environment, public safety, as well as risks related to the protection of other public interests.

Factors to be considered in risk-based market surveillance of products include:

The types of non-compliance and resulting hazards in certain products, their occurrence on the market, the activities and operations performed by the Economic Operator, the Operator's past record of non-compliance, the scope of the Operator's operations (by turnover, number of products, number of customers, market size, etc.) and consumer complaints and other information received from third parties. Nevertheless, random selection may be beneficial where little information is available, e.g. new products, new economic operators.

When targeting products in a given sector, priority should be based on the number and severity of non-compliant products potentially available on the market. To maximise effectiveness and efficiency of market interventions whenever possible the Market Surveillance Authority should focus on targeting products produced in large quantities instead of a single product or targeting products that have the potential to have high impacts on health and safety of consumers, users or the environment. Targeting shipments at ports of entry can also be an efficient use of resources as it can prevent non-compliant products from entering the EU market and avoid more costly actions once the product is in the distribution chain. If products are manufactured in and have been placed on the EU market, targeting products at distributor's sites (in particular wholesalers) is also an efficient and effective way of sampling. Inspecting large or industrial products (which are often supplied individually and may not be assembled until they reach the end user e.g. a factory) may not be fully possible prior to assembly or installation.

Cooperation at an early stage with custom authorities should also be systematic when specific Economic Operators who import the targeted products are identified.

Some Economic Operators might only offer products online, without having them in stock.

b) Planning activities

Proactive market surveillance refers to activities which are specifically planned, organised and implemented by the Market Surveillance Authority.

Proactive market surveillance activities are important because they have the potential to prevent non-compliance and/or the harm that can result from non-compliance from taking place. It is more cost-efficient than reactive market surveillance because the resources and the parameters needed to carry out these activities can be defined in advance. These activities can also include long-term planned actions for specific products, product groups or sectors such as raising awareness through communication activities or with Economic Operators involved in compliance schemes when they exist.

Art. 13 of Regulation (EU) 2019/1020 requires Member States to draw up overarching market surveillance strategies for market surveillance and enforcement and to communicate these strategies to the Commission and to other Member States on regular base. This exchange of information can facilitate cooperation and sharing of resources between Market Surveillance Authorities in different Member States and avoid duplicating activities. It is therefore important that information on planned market surveillance activities is exchanged in the relevant AdCo group.

Proactive market surveillance can relate either to the targeting of Economic Operators or Products, both of which can be conducted as part of a focussed market surveillance campaign based on risk criteria such as

- history of non-compliance,
- results of audits,
- market share,
- distribution of products and / or users.

Once an Economic Operator or a product has been selected the process of inspection in line with national legislation to ensure legal requirements are met can begin.

Where the effects of non-compliance are not immediately identifiable (e.g. toxicological or ergonomic hazards such as chronic health issues or damage to the environment e.g. excessive energy consumption) proactive market surveillance is preferable.

c) Preparing to implement market surveillance campaigns

After having defined scope (e.g. which and how many products or Economic Operators to target) of a specific market surveillance campaign, the Market Surveillance Authority will still need to:

- Define objectives to verify that products are compliant with the applicable legislation in order to guarantee consumer protection and to stop unfair competition
- Define the depth of the compliance evaluation to be carried out[9]
- Determine the period during which the campaign will be performed
- Conduct a feasibility study to evaluate if there is sufficient resource to meet the defined scope and objectives of the campaign.
- Determine which procedures to follow e.g. by developing a code of practice which will enable the effectiveness of a campaign and facilitate the preparation of a standardised report.

During a campaign the Market Surveillance Authority will evaluate the non-compliance and risk and take appropriate follow up action (see chapter 3.4 of the guide).

[9] Market Surveillance Authorities for instance can choose to carry out an *extensive* compliance evaluation involving administrative verification and sampling, technical verification including testing/inspection by (internal or external) laboratory/inspection bodies (where no conflicts of interest exist). Alternatively, they can conduct a *limited* compliance evaluation involving administrative verification and/or sampling and internal testing (visual) of easily feasible requirements for which no or simple equipment is needed (e.g. measuring the reflective surface of visibility clothing or measuring the length of a cord in a toy).

At the end of the campaign the Market Surveillance Authority will produce a report and publish the findings of the campaign to stakeholders (e.g. business, industry, Economic Operators consumers, other Market Surveillance Authorities etc.) via appropriate and accessible media channels (e.g. at AdCo website) and that data protection obligations will be addressed accordingly. It will also perform appropriate follow up measures.

Market surveillance campaigns can be conducted at a national level or jointly with other Member States. Joint market surveillance campaigns are strongly recommended as they improve the effectiveness of national efforts on the Single Market and can reduce costs. Administrative Co-operation Groups (AdCos) can play a key role in the organisation of these campaigns. To encourage joint market surveillance campaigns the European Commission is funding coordinated activities and joint actions.

3.1.2 Reactive market surveillance

Not all market surveillance activities can be planned in advance. Reactive market surveillance is normally triggered by an outside event and in relation to a specific suspected offence. This could include incidents and accidents, notifications from other Market Surveillance Authorities through the Safety Gate Rapid Alert System and ICSMS, notifications from other authorities (e.g. customs, labour inspectorate, police, social inspector, transport authority) or notifications from external sources (e.g., consumer complaints, Economic Operators, Notified Bodies, press releases, consumer reports)[10]. Information received by a Market Surveillance Authority relating to a product suspected to be non-compliant or to present a risk must be followed up in accordance with the principle of proportionality. In order to avoid duplication, a Market Surveillance Authority should check ICSMS and any other appropriate platforms (e.g. national databases) to see if the same product has already been assessed.

Furthermore, a risk-based approach fosters more efficient reactive market surveillance strategies when evaluating information received by a Market Surveillance Authority that relates to such a product. A risk-based approach dictates that information received by a Market Surveillance Authority be considered along with all other available information that may be relevant. Based on the totality of the available information, the Market Surveillance Authority should evaluate the magnitude of the potential harm to health, safety, consumer rights, fair competition, environment or other aspects of public interest (e.g. for Ecodesign, EMC, …) by categorizing the harm to the public interest as irreparable or reparable harm and then further categorizing it according to the number of people potentially affected and the likelihood of such harm occurring (e.g., on a scale of 1 to 4). This approach allows the Market Surveillance Authority to choose from a range of methods from unannounced inspections to written communication with the economic operator, as appropriate based on the level of risk.

Although reactive market surveillance can create a sense of urgency (as the product might be suspected of having caused an accident) and may attract media interest, Market Surveillance Authorities should act proportionately and reach a considered and justifiable decision.

3.2. SAMPLING STAGE

To assess compliance of products Market Surveillance Authorities often need product samples

[10] Article 11 (7), point (a) of Regulation (EU) 2019/1020.

and relevant documentation regarding the products. Articles 11 (3) and 14 (4) of Regulation (EU) 2019/1020 provide the legal basis to ensure that Market Surveillance Authorities may acquire samples and require the documentation and information necessary for carrying out their activities.

During the sampling stage Market Surveillance Authorities need to define the appropriate number of samples and where they will be acquired. The Market Surveillance Authority's approach to sampling is based on the applicable legislation, the type of product, the type of non-compliance being considered, and the number of products on the market.

A primary factor in deciding the sampling strategy is the type of non-compliance being considered. If it is a design or production issue e.g. the lack or wrong type of safety device being fitted, then one model is sufficient. If the Market Surveillance Authority wishes to assess the compliance of a product category in a statistically representative way, setting the sampling strategy will require knowledge of the size of the product population, which may range from one item (e.g. a large industrial machine) to thousands of models being available.

a) When and where to acquire samples

Samples are usually acquire from the Economic Operator if the Market Surveillance Authority has doubts on the compliance of a product, during a market surveillance campaign or as part of reactive or proactive market surveillance inspections.

Samples may be obtained from various locations, either online or directly from the economic operator's physical place of business. Depending on the product the Market Surveillance Authority may consider it appropriate to inspect specific samples at the end-user's premises. This will normally be the case for large industrial products.

It might be efficient to acquire samples and all related necessary documents (e.g. the EU Declaration of Conformity, Instructions for use etc.) from the Economic Operator responsible for placing the product on the market. This should allow faster and more comprehensive measures to be taken to resolve cases of non-compliance.

The Market Surveillance Authority will decide which samples to obtain from those available. Samples are usually acquired without prior announcement to the Economic Operator concerned, mitigating the risk of non-representative samples being supplied and ensuring that the samples correspond with those freely available on the market.

National legislation dictates whether or not the Market Surveillance Authority has to pay for the samples acquired. If national legislation requires the Market Surveillance Authority to pay, the Economic Operator must issue a receipt for the products purchased. If national legislation does not require the Market Surveillance Authority to pay, the samples remain the property of the Economic Operator and the Market Surveillance Authority will issue an official proof of sampling (a sampling document).

b) Number of samples

The number of samples defined in the scope of the campaign must be sufficient for the planned assessment of compliance and testing. It is important to note that the aim of inspection and testing by the Market Surveillance Authority is to check whether a product is compliant or not

with one (or more) specific applicable sectorial legislation.

Where the Market Surveillance Authority inspects the product against the 'Essential Requirements' of the applicable Directive or Regulation, the number of samples requested (acquired) by the Market Surveillance Authority depends upon the complexity of the product and required steps for the testing of the product or by the number of samples defined in the regulation. Harmonized testing procedures (standards or RfU) are useful tools to determine the necessary quantity of samples. This is because some tests may destroy the product and if further tests are necessary more samples of the product will be needed. Also, for legal reasons (depending on national legislation) it may be necessary to have an additional verification sample that is "sealed" and available for independent additional testing if required. Prior exchange of information with the laboratory technicians who will be in charge of the testing is recommended to clarify these aspects.

It is the Market Surveillance Authority`s responsibility to demonstrate the non-compliance of the samples acquired. It is the responsibility of the Economic Operator to demonstrate to the Market Surveillance Authority whether or not only the specific samples and not the entire production series are non-compliant.

For market surveillance it is only necessary to use a statistical approach to sampling if a campaign aims to find a result representative for a certain product group. In this case sampling includes defining the "batch of products" from which the sample is drawn.

c) Handling of the samples

When handling samples, consideration to continuity of evidence is critical and the Market Surveillance Authority must ensure that:

- the samples acquired are packaged and stored in a way that precludes tampering and damage
- the samples are unequivocally identifiable and auditable e.g. through clear labelling and recording system.
- all required information about the samples is collected and recorded properly. A sampling documentshould contain detailed identification of the samples, such as data on the label, the number of samples acquired (based on technical specifications, standards), photographs of the samples, location of sampling, date the samples were acquired, name and signature of the inspector, name and signature of the Economic Operator's representative and any other necessary comments. The sampling document should then be stored in a national database.

It is critical that the samples are correctly handled, appropriately sealed, secured, and are fully traceable at each stage, from taking the sample to testing the sample. Any secure seals if required by national legislation and applied to the samples should only be removed and subsequently recorded, when testing commences.

Consideration should be given to samples of products (e.g. dangerous chemicals, fireworks) for which the transport and storage are regulated. The necessary authorisations or the use of specially habilitated transport / storage service may be needed and should be planned ahead.

d) Sampling of large products

A Market Surveillance Authority might not consider it to be appropriate or cost effective to sample large products or those supplied in low numbers and instead must identify which elements of the product are representative for the products compliance. The Market Surveillance Authority might consider it sufficient to carry out a detailed examination of a specific part of a large product.

In the case of large products, it may also be appropriate to keep and inspect the product at either the Economic Operator's or the end-user's site. This will necessitate the Market Surveillance Authority to use appropriate powers provided under national legislation to obtain access to and seal the product ensuring that the product remains unchanged during the investigation, inspection and testing process.

3.3. COMPLIANCE ASSESSMENT

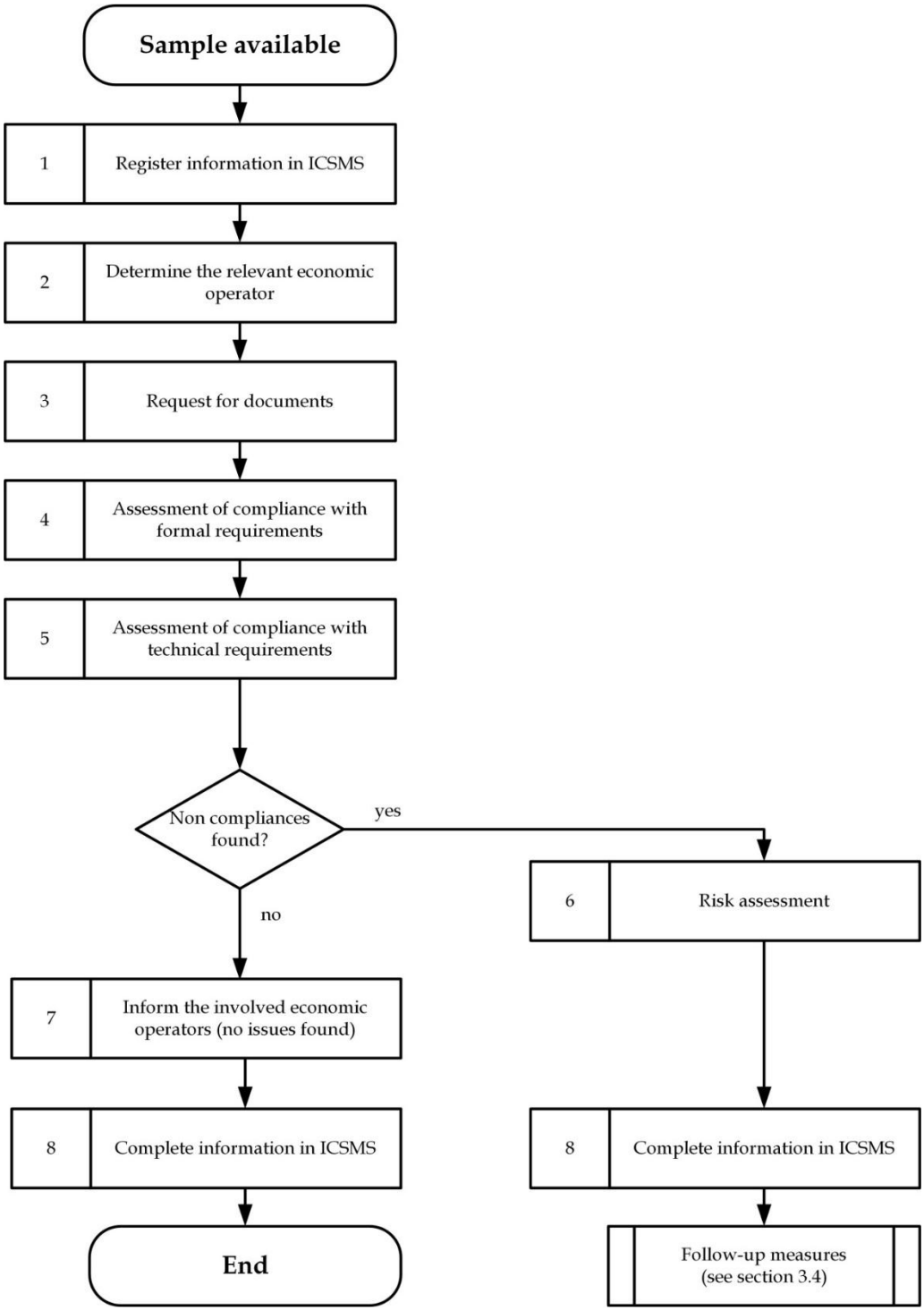
It is the Economic Operators responsibility, according to their respective role in the supply chain, to ensure compliance with all relevant legislation and to fulfil all appropriate conformity assessment obligations.

The task of the Market Surveillance Authority is to verify whether a product complies with the requirements of the applicable legislation. However, the Market Surveillance Authority should not issue a compliance statement or confirmation which could be seen as endorsing a product.

When assessing the compliance of a product, the Market Surveillance Authority may choose to consider all relevant legislative requirements (a *full compliance assessment*) or parts of them (a *partial compliance assessment*). The compliance assessment may be divided between 'Formal' compliance (administrative requirements e.g. documentation, markings, etc.) and 'Technical' compliance **.**

Market Surveillance Authorities should exchange views on how the various requirements are to be assessed to ensure consistency regardless of which Market Surveillance Authority has assessed the product. Therefore, benchmarking exercises could be organised via AdCos whereby members assess the same product to provide comparable outcomes. Common checklists developed by AdCos may be used to facilitate the compliance assessment for specific product groups. For a compliance assessment and risk management to be effective the Market Surveillance Authority should have access to complementary information such as the date the sample was placed on the market (to determine the accuracy of the Economic Operator's conformity assessment) and information on the quantity of products sold in the distribution chain.

The compliance assessment will begin once an inspection has been carried out or a sample or document has been made available. The following flowchart outlines the process between the collection of a sample and the determination of any subsequent follow-up measures. The steps identified in the flowchart presume that the Market Surveillance Authority will carry out a full compliance assessment according to the relevant legislation. It is important to remember that the steps described in the flowchart may vary depending on the product being assessed and the campaign itself.



3.3.1. Step 1: Register information in ICSMS

The Market Surveillance Authority should check whether the product to be assessed is already registered on ICSMS. If so, it might be useful to verify the Product Information (PI) details and to contact the processing Market Surveillance Authority.

If a PI does not already exist, the relevant information about the product should be recorded in ICSMS promptly. This is necessary as other Market Surveillance Authorities should be informed in a timely fashion that the product, which may be available in other Member States,

is being assessed to avoid unnecessary duplication.

In the case of mass products, where a high number of initial checks take place, it may not be feasible to encode in ICSMS information on all investigations carried out. However, encoding should take place at very least when the authority has reason to believe that the same product has also been made available in other Member States or a sample has been taken for examination.

3.3.2. Step 2: Determine the relevant Economic Operator

It is important to quickly determine the manufacturer or importer responsible for placing the product on the market. This enables the Market Surveillance Authority to request information and resolve non-compliance efficiently and in good time.

If there is a manufacturer or importer in the EU, the Market Surveillance Authority should address them directly. If the manufacturer is based outside of the EU, the Market Surveillance Authority should contact its authorised representative, if such exists, or attempt to contact the manufacturer in the third country.

If the manufacturer or importer is not available or cooperative, the Market Surveillance Authority should address the Economic Operators high up in the distribution chain as possible (e.g. the wholesaler or retailer)[11].

It should be noted that a product is non-compliant if the name and address of the manufacturer or importer is not present. In such cases, the Market Surveillance Authority should request that the Economic Operator from whom the product was sampled to provide information (such as lists of deliveries, invoices or orders) regarding where the product was purchased to identify the highest Economic Operator in the EU within the distribution chain.

3.3.3. Step 3: Request for documents

To carry out a comprehensive compliance assessment, the Market Surveillance Authority should have detailed information on the product, which is available in the EU declaration of conformity / declaration of performance[12] and, if necessary, in the technical documentation. Requesting of the declaration of conformity and technical documentation will usually be done via the relevant Economic Operator or via the highest Economic Operator in the supply chain (see section 3.3.2).

In the case of complex industrial products, it may not be cost effective or necessary to request technical documentation in full. In such instances the principle of proportionality would imply that the Market Surveillance Authority would not require the complete technical file but only the technical documentation sufficient to support a compliance assessment.[13]

When the Market Surveillance Authority requests technical documentation from an Economic Operator in a different Member State, it is recommended to inform the Market Surveillance

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[11] Some legislation may foresee additional entities that have obligations to fulfill, as private importer. Directive 2013/53/EU on recreational craft and personal watercraft foresees that a private importer, before putting the product into service, shall ensure that it has been designed and manufactured in accordance with the requirements set out in the relevant legislation. This means that in general, all the requirements for the Economic Operators apply also to the private importer

[12] Most EU legislation requires a Declaration of Conformity; the Construction Products Regulation requires a Declaration of Performance.

[13] See section 7.4 of the Blue Guide for further details.

Authority of the Member State where the Economic Operator is based. If the Market Surveillance Authority is unsuccessful in requesting technical documentation from that Economic Operator, it should then seek the assistance of the Market Surveillance Authority where the Economic Operator is based (by using the "Request for Information" (RFI) procedure within ICSMS). This Market Surveillance Authority should provide adequate assistance e.g. by supplying information or documentation, by carrying out appropriate investigations or any other appropriate measures[14]. Further details on the mutual assistance procedure can be found in Annex 2 (see in particular the proposed general principles and procedure for case 1).

If there is evidence (e.g. identification number on the product and/or the packaging) that a notified body has been involved in the conformity assessment procedure, the Market Surveillance Authority may contact this notified body to ask for more information on its involvement and to obtain information on the conformity assessment procedure.

Another important source of information is the instructions for use and, for some products, (e.g. construction products) information on dangerous substances. These usually have to accompany the product and should be available to users. When a compliance assessment is carried out without a sample, instructions for use may be available online. If necessary, they can be requested from the Economic Operator and must be made available to the Market Surveillance Authority.

3.3.4. Step 4: Assessment of compliance with formal requirements

Assessing compliance with formal requirements normally consists of assessing whether:

- the conformity marking has been affixed on the product and/or on its packaging and is in line with legal requirements
- the EU declaration of conformity or performance is available and drawn up correctly
- the technical documentation is available and complete
- the instructions for use and/or installation are available and comprehensible in the language of the user
- other specific elements required by the relevant EU legislation should be considered

Situations where missing or incomplete information (e.g. safety information for the end-user) might lead to a risk should not be considered as formal non-compliance when deciding on the appropriate follow up action (see also step 11 in section 3.4).

The Market Surveillance Authority should consider whether some of the information required to carry out a formal compliance assessment is available online.

When assessing technical documentation, the Market Surveillance Authority should check:

- that the EU declaration of conformity or performance is available and complete[15]
- the correctness of the conformity assessment procedure carried out by the

[14] The legal basis for this type of mutual assistance is set out in Article 22, point 2-5 of Regulation (EU) 2019/1020.

[15] Assessing the accuracy of the Declaration of Conformity may only be possible in conjunction with other technical documentation

manufacturer;

- the validity of the conformity assessment procedure carried out by the manufacturer at the time of placing the product on the market (e.g. a conformity assessment carried out ten years ago may no longer be valid for products sampled by the Market Surveillance Authority);
- whether all documents necessary to support compliance have been made available;
- checking the completeness and accuracy of the documents.

3.3.5. Step 5: Assessment of compliance with technical requirements

Assessing the compliance with technical requirements will establish whether the product is fulfilling those essential requirements that relate to technical aspects, while other essential requirements — such as labelling and instructions — may not be covered by this assessment. This is achieved by testing the product either by the Market Surveillance Authority or by an independent third party (e.g. test laboratory). Accreditation of the third party is not mandatory in all sectors but does provide a further guarantee as to the competence of the body. For some products (e.g. large or industrial products) the Market Surveillance Authority may identify non-compliance through a simple visual check. Such items are rarely sent to a third party for assessment but if an independent view is needed, an external engineer competent in the aspects being examined could be appointed to give expert evidence on factual aspects of the compliance.

To define which tests to be carried out requires appropriate analysis and depends on numerous variables e.g. the availability of relevant harmonised standards and their application by the manufacturer. Therefore, access to the declaration of conformity and/or the technical documentation, which provides information on the manufacturer's conformity assessment, is essential. It may be necessary to request more information from the manufacturer regarding how to test the product (e.g. to set the product in a test mode).

The results of any test are to be recorded in test reports and the Market Surveillance Authority should also consider the technical documentation when evaluating the results.

Carrying out the compliance assessment will depend on whether a harmonised standard exists and has been used by the manufacturer, if it is by direct reference to the essential requirements, or if the involvement of a notified body is legally required. The following scenarios are therefore possible:

- A harmonised standard exists but it has not been (fully) applied and some other standards have been used;
- A harmonised standard has been applied but it does not cover all essential requirements and/or hazards or the product is not covered adequately by the existing product standard (e.g. new product features or new product category).

It may therefore be possible for a product to comply with a harmonised standard but not the legislation. An effective way of assessing technical compliance is to test the product against a relevant harmonised standard and to evaluate whether compliance with the legislation has been compromised.

The Market Surveillance Authority should also be aware that other standards may be used (e.g. ISO, IEC, national) where harmonised standards do not exist. In the case that no harmonised standard exists, it might be advisable to agree on an appropriate common assessment procedure, either within the AdCos or together with stakeholders (if necessary) in reference of the Rules for Use (RfU) defined by the relevant Notified Bodies in the sectorial Notified Bodies coordination groups.

The Market Surveillance Authority should be aware that the manufacturer is free to choose his own way of demonstrating compliance to the essential requirements. The Market Surveillance Authority should check against the essential requirements, as the use of harmonised standards represents the agreed state of the art testing method.

When a notified body has been involved in the conformity assessment it may be appropriate to ask the notified body the extent of that involvement and the documents on which the assessment was based.**Error! Bookmark not defined.**

3.3.6. Step 6: Risk assessment

According to the provisions of the EU legislation, the Market Surveillance Authority must carry out an appropriate product risk assessment as soon as a product is identified representing a risk (direct or indirect) to the health or safety of persons or to other aspects of public interest . This should not be confused with the risk analysis discussed in section 3.1, which covers risks posed by Economic Operators and their noncompliant products and is conducted during the targeting stage.

The Market Surveillance Authority must evaluate the nature and level of risk, in terms of both the severity of potential harm and the likelihood of such harm occurring, and document the result[16]. Detailed risk information is needed when Safety Gate Rapid Alert System notifications are prepared and when information regarding in-depth checks of compliance is entered into the ICSMS system. Exemptions are risks posed by a product which shall be presumed as a serious risk according to Annex II of Commission Delegated Regulation (EU) 2024/3173 Annex II.

The outcome of the product risk assessment should determine the level of the risk and provide the relevant information for the Market Surveillance Authority to choose the risk management strategy that will most effectively prevent harm from occurring, such as issuing a proportionate measure when the Economic Operator fails to take appropriate action and deciding whether a Safety Gate Rapid Alert System notification is needed.

The Commission Delegated Regulation (EU) 2024/3173[17], concerning the functioning of the Safety Gate Rapid Alert System, outlines the criteria for assessing the risk levels posed by products. This Regulation specifies the criteria for evaluating health and safety risks to consumers for products under Regulation (EU) 2023/988, as well as health and safety risks to end-users for products under Regulation (EU) 2019/1020. Additionally, it addresses risks to other public interests for products covered by Regulation (EU) 2019/1020.

[16] There are other systematic approaches of risk assessment that consider a broader definition of the term risk. including the non-conformity associated with the product and the possible damage caused by the product in general.

[17] https://eur-lex.europa.eu/eli/reg_del/2024/3173/oj/eng

However, given the specific nature of those other public interests protected by Union harmonisation legislation, the criteria for assessing (direct or indirect) risk levels should align with the objectives and requirements of the applicable legislation, which may differ from health and safety risk criteria. AdCos play a key role in facilitating sector-specific product evaluations, including risk assessments and publishing risk profiles.

3.3.7. Step 7: Inform the involved Economic Operators (no issues found)

If the Economic Operators are aware that their product is being assessed, it is good practice to inform them of the result in writing , even if no issues have been found. However, care must be taken to ensure that the Economic Operator does not misuse this communication as an endorsement or compliance certificate. The communication should never indicate that the product is compliant because the Market Surveillance Authority has not fully assessed the product and the manufacturing process.

3.3.8. Step 8: Complete information in ICSMS

To avoid duplicating investigations it is necessary to provide other Market Surveillance Authorities with relevant information and results of the assessment carried out, the documents received from the Economic Operator and other relevant information via ICSMS as soon as possible.

3.4. ENFORCEMENT AND FOLLOW-UP MEASURES

Where market surveillance authorities find out that the product compromises aspects of public interest mentioned above, or is not conform to applicable Union harmonisation legislation they shall without delay require the manufacturer or the importer responsible for placing the product on the market (the relevant economic operator), to take corrective actions within a reasonable time limit (unless immediate action is required to address a serious safety or environmental risk) in accordance with their obligations (e.g. bringing the product into compliance or other corrective action). This should take place before or at least simultaneously to addressing the distributor allowing for corrective actions to be taken at the highest possible level of the product placing in the single market.

In the first instance the relevant Economic Operator should undertake corrective actions voluntarily in order to resolve the problem[18]. Corrective actions should be proportional to the risks involved and should aim to resolve the non-compliance for products supplied into all Member States, not only in the Member State where the non-compliance was first discovered[19].

This section explains the relevant steps for a Market Surveillance Process in line with the model provisions (notably model Articles 31 to 34) of Decision No 768/2008/EC on a Common Framework for the Marketing of Products that have been incorporated in all new European harmonisation directives and regulations.

[18] A voluntary action is that undertaken by the Economic Operator before the Market Surveillance Authority requires specific corrective measures. Model Articles R2 (8), R4 (7) and R5 (4) of Decision No 768/2008 (obliges manufacturers, importers and distributors to take corrective measures if aware that products they made available are non-compliant.

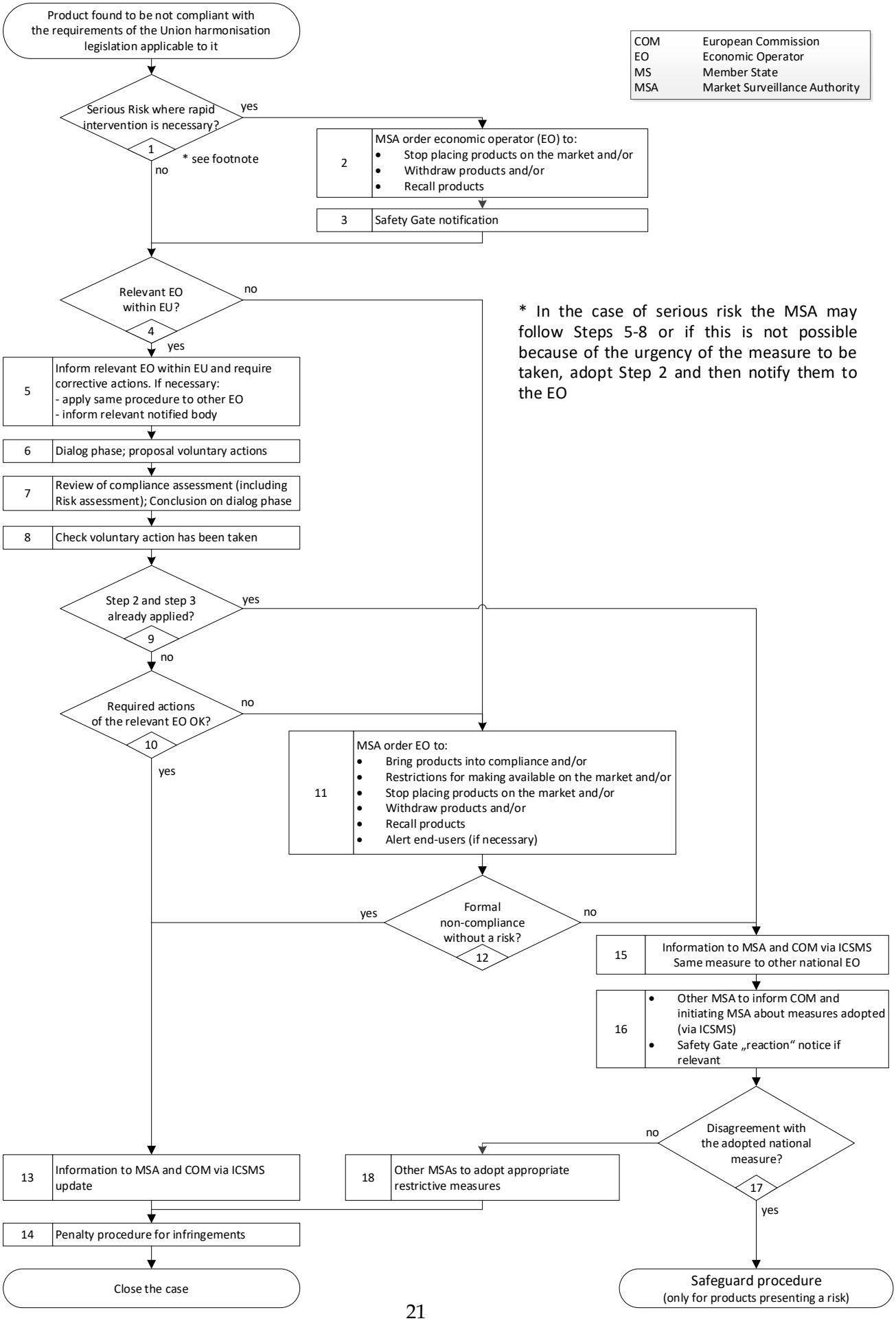
[19] Article R31(3) of Decision No 768/2008 and corresponding provisions in EU harmonisation legislation obliges the Economic Operator to ensure that appropriate corrective action is taken in respect of all the products concerned that it has made available on the EU market.

3.4.1. Dealing with non-compliant products

The role of the Market Surveillance Authority is to communicate the nature of the non-compliance to the Economic Operator and ensure that the actions taken are appropriate and carried out in full. Depending on the nature of the non-compliance, the risk involved and the actions of the Economic Operator, it may be necessary to take formal proportionate enforcement action.

Where an Economic Operator does not take voluntary action, or if voluntary action is considered not suitable to solve the problem, or a serious risk is identified, the Market Surveillance Authority shall take all appropriate action according to Article 16 (5) Regulation (EU) 2019/1020 and notify them to the European Commission and other Market Surveillance Authorities unless the non-compliance is restricted only to their own territory. The purpose of the notification is to inform all national Market Surveillance Authorities about non-compliant products presenting a risk, and to have the necessary restrictions extended to all Member States in order to ensure an equivalent level of protection throughout the EU.

The following flowchart explains this process and the necessary steps to be taken when dealing with non-compliant products:


Product found to be not compliant with the requirements of the Union harmonisation legislation applicable to it
COM European Commission
EO Economic Operator
MS Member State
MSA Market Surveillance Authority
Serious Risk where rapid intervention is necessary?
1
yes
no
* see footnote
2
MSA order economic operator (EO) to:
• Stop placing products on the market and/or
• Withdraw products and/or
• Recall products
3
Safety Gate notification
Relevant EO within EU?
4
no
yes
* In the case of serious risk the MSA may follow Steps 5-8 or if this is not possible because of the urgency of the measure to be taken, adopt Step 2 and then notify them to the EO
5
Inform relevant EO within EU and require corrective actions. If necessary:
- apply same procedure to other EO
- inform relevant notified body
6
Dialog phase; proposal voluntary actions
7
Review of compliance assessment (including Risk assessment); Conclusion on dialog phase
8
Check voluntary action has been taken
Step 2 and step 3 already applied?
9
yes
no
Required actions of the relevant EO OK?
10
no
yes
11
MSA order EO to:
• Bring products into compliance and/or
• Restrictions for making available on the market and/or
• Stop placing products on the market and/or
• Withdraw products and/or
• Recall products
• Alert end-users (if necessary)
Formal non-compliance without a risk?
12
yes
no
15
Information to MSA and COM via ICSMS
Same measure to other national EO
16
• Other MSA to inform COM and initiating MSA about measures adopted (via ICSMS)
• Safety Gate „reaction“ notice if relevant
Disagreement with the adopted national measure?
17
no
yes
13
Information to MSA and COM via ICSMS update
18
Other MSAs to adopt appropriate restrictive measures
14
Penalty procedure for infringements
Close the case
Safeguard procedure
(only for products presenting a risk)

Step 1: After the compliance and risk assessment has been carried out the Market Surveillance Authority must decide upon the appropriate follow up measure which will be determined by the seriousness of the risk.

Step 2: Where the product presents a serious risk requiring rapid intervention, including where the effects of the risk are not immediate, the Market Surveillance Authority shall ensure that such products are recalled, withdrawn, their availability on the market prohibited or restricted or that the Economic Operator takes other appropriate corrective action.

If immediate voluntary measures cannot be agreed and undertaken in a timely manner by the Economic Operator, then formal mandatory action will be required. In case of urgency, it may also be appropriate to take action prior to giving the Economic Operator the opportunity to make their views known. In this situation the Economic Operator shall be given the opportunity to make their case as soon as possible and the action taken shall be subsequently reviewed.

Step 3: Measures taken against products presenting a serious risk require a notification via the Safety Gate Rapid Alert System which was established under Article 25 of Regulation (EU) 2023/988 (on General Product Safety) and extended to all harmonised products by Regulation (EU) 2019/1020[20].

Step 4: If no relevant Economic Operator within the EU has been established, the Market Surveillance Authority should try to contact the Economic Operator in the third country to solve the non-compliance (go to step 11).

Step 5: Where the product does not present a serious risk (or where rapid corrective actions have been taken nationally to resolve a non-compliant product presenting a serious risk) the Market Surveillance Authority shall immediately inform the Economic Operator about the non-compliance of the product. The Market Surveillance Authority will seek to understand the reasons for non-compliance and commit the Economic Operator to take all appropriate corrective actions to either bring the product into compliance, to withdraw the product from the market, or to recall it within a reasonable period. It is essential that the Economic Operator is requested to reply in a specified reasonable time. The Market Surveillance Authority must consider whether it is also necessary to inform relevant notified body(s) and notifying authorities.

The Market Surveillance Authority should contact (if possible) the relevant Economic Operator in the Union even if they are not located in their own jurisdiction, requiring that necessary voluntary corrective actions are taken.

Step 6: The Economic Operator (both European and national) should be given appropriate time to respond[21] and can provide an explanation concerning the Market Surveillance Authority's findings or suggest corrective actions which may have already started.

Step 7: The Market Surveillance Authority must use the information received from the Economic Operator to review the compliance and risk assessment that was carried out. The

[20] A Safety Gate contact point is available in and can provide advice to all Member States via https://ec.europa.eu/safety-gate/#/screen/pages/contacts

[21] Article 18 (3) of Regulation (EU) 2019/1020.

information may mitigate the original result or could lead to a less or more serious result. It is essential that the Market Surveillance Authority subsequently evaluates the suggested actions of the Economic Operator requiring more comprehensive corrective actions to be taken when necessary.

Step 8: In accordance with Article 11 (7) of Regulation (EU) 2019/1020 the Market Surveillance Authority must assess whether the Economic Operator has carried out the agreed voluntary actions in full. Successful completion of these actions should ensure that the issue of non-compliance has been resolved and that further products placed on or entering the market will be compliant.

Step 9: If steps 2 and 3 of the follow up procedures have already been taken then the Market Surveillance Authority will move to step 15, if not to step 10.

Step 10: Following an assessment of the voluntary actions taken by the Economic Operator the Market Surveillance Authority will decide whether further corrective action is needed or whether the case can be closed.

Step 11: The Market Surveillance Authority can adopt restrictive measures in its national territory if the Economic operator does not cooperate or require further corrective actions to be taken where voluntary actions are not sufficient to prevent non-compliant products being placed on the market or to mitigate the risks of non-compliant products already placed on the market.

Further corrective actions will be based on specific European and national legislation as well as those defined in Regulation (EU) 2019/1020 which includes:

- restrictions for placing products on the market or
- bringing products into compliance;
- stopping products being placed on the market;
- withdrawal of products;
- recall of products.

These measures can be required from the Economic Operator regardless of their location but can only be enforced when there is an offence in the Market Surveillance Authority's own jurisdiction. Cross-border cooperation may be necessary in cases where the Economic Operator is not located within the Market Surveillance Authority's Member State. The Request for Information (RFI) or the Request for Enforcement Measures (RFEM) of ICSMS should be used for Cross-boarder cooperation.

Step 12: A non-compliance can be considered as "formal without risk" when it is limited to formal requirements only (for instance if information on traceability and markings is missing or affixed incorrectly as regards its design, size visibility or legibility *and* that there are no other reasons to believe that the product presents a risk[22]). In this case the Market Surveillance Authority, after taking appropriate measures to restrict the marketing of the product, will

[22] In cases where the CE marking or other required markings are missing the Market Surveillance Authority has reasons to believe that the non-compliance goes beyond this formal requirement and the product presents a risk. Therefore, it will move to step 14. See also section 7.4.2.2 of the Blue Guide.

inform other Member States and the European Commission by uploading all available information on ICSMS (see step 15).

Step 13: If the voluntary measures taken by the Economic Operator in step 8 are satisfactory and resolve the issue, the Market Surveillance Authority will make this clear via ICSMS.

Step 14: The Market Surveillance Authority will assess whether it is appropriate and proportionate to impose sanctions (penalties according to national law) following the Economic Operator's corrective actions.

Step 15: If the product presents a risk to the health or safety of persons or to other aspects of public interest protection covered by the legislation on which the assessment is based and is not restricted to their national territory, the Market Surveillance Authority will immediately inform the European Commission and other Member States via ICSMS about the measures in place to prohibit or restrict the product being made available on their national market, to withdraw the product from that market or to recall it (Safeguard Notification). If the product is sold in different Member States, the Market Surveillance Authority shall extend the adopted measures to other national Economic Operators. If it appears that the product presents a serious risk, the Market Surveillance Authority shall issue a Safety Gate Rapid Alert System notification.

Step 16: Information on measures taken by MSA against other Economic Operators regarding the same product should be uploaded to ICSMS to ensure a comprehensive exchange of information between the initiating MSA, other MSA and the COM. If the product presents a serious risk other Market Surveillance Authorities should have issued a Safety Gate Rapid Alert System reaction as a follow up to the measures initially notified in the system.

Step 17: If the product does present a risk, and objections are raised against the measures adopted by the initiating Market Surveillance Authority, the case shall be assessed by the European Commission under the Union Safeguard Procedure.

Step 18: If no objections are raised the measures are deemed to be valid and should be enforced by all other Market Surveillance Authorities where the product was made available.

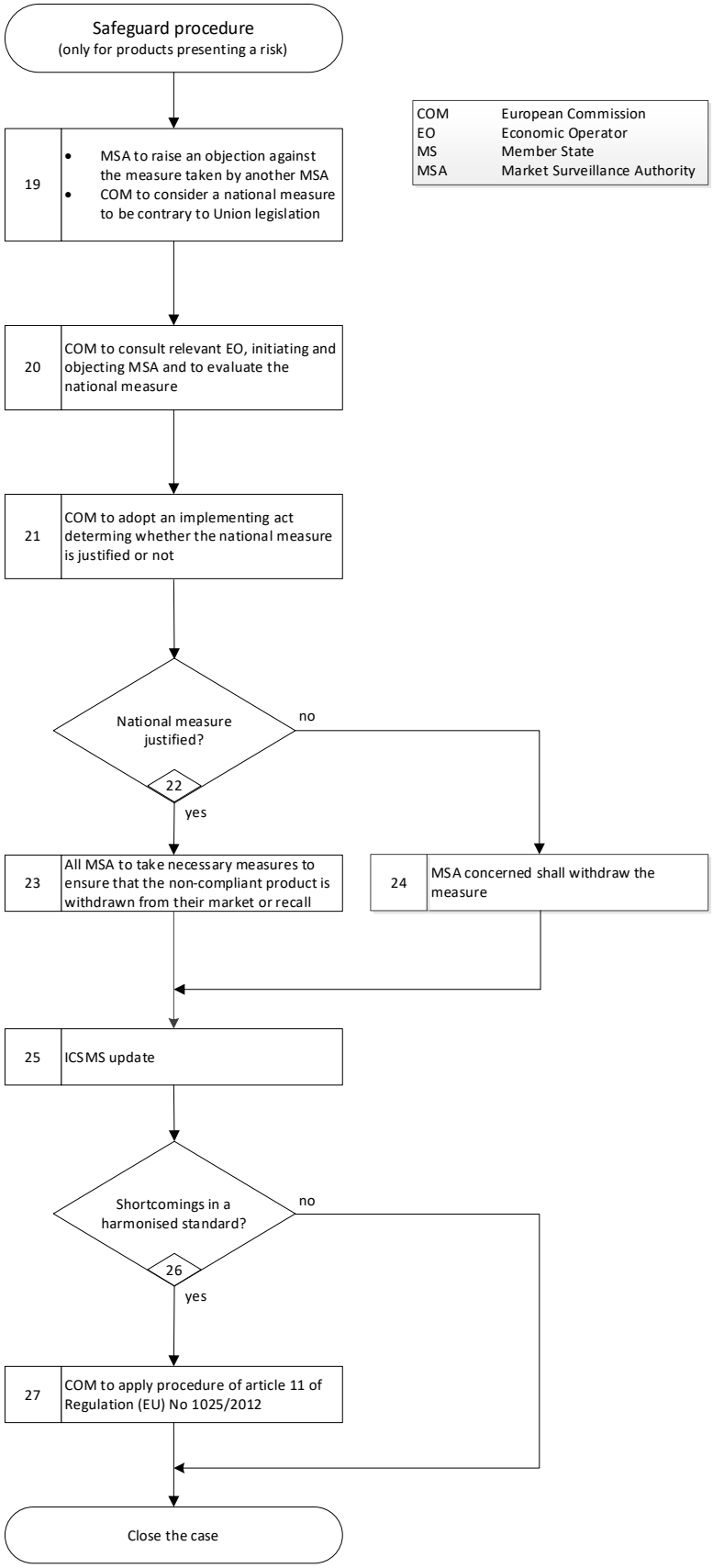
3.4.2 Union Safeguard Procedure

Decision No 768/2008/EC provides a model for a Union Safeguard Procedure[23] applicable when an objection is raised by either a Member State or the Commission in respect of a restrictive measure taken by a Member State. This model has been implemented in all NLF aligned harmonization legislation.

The Safeguard Procedure is designed to allow the European Commission to take a position on national measures restricting the free movement of products with a view to ensuring the functioning of the internal market and that proportionate and appropriate measures are taken when non-compliant products are found on the market.

The following flowchart explains the Safeguard Procedure and the necessary steps to be taken:

[23] The following procedure is only relevant for sector legislation aligned to the model set out in Decision No 768/2008/EC. Sector legislation not yet harmonised with Decision 768/2008 will have a different procedure



Step 19: The Safeguard Procedure is initiated if an objection from another Market Surveillance

Authority is made via ICSMS within three months[24] from the notification by the initiating Market Surveillance Authority or if within the same period the European Commission informs the Market Surveillance Authority, through ICSMS, that the measure might be contrary to EU law.

Step 20: The European Commission shall:

- consult with all Market Surveillance Authorities and relevant Economic Operators without delay, via suitable means, in writing to ensure that the Market Surveillance Authority is kept informed of any responses from the Economic Operator.
- evaluate the national measure taking into account the consultations held with the Market Surveillance Authority and the Economic Operator.
- adopt an implementing act determining whether the national measure is justified or not based on the results of the evaluation,

Step 21: The European Commission will adopt and communicate its decision (implementing act) to all Market Surveillance Authorities and the Economic Operator and update ICSMS accordingly.

Step 22: The European Commission informs the Market Surveillance Authority if the measure is considered to be justified or if the Market Surveillance Authority has to withdraw the measure.

Step 23: If the measure is considered justified, all Market Surveillance Authorities must take the necessary measures to ensure that the non-compliant product is withdrawn from the market or recalled from the end-user and inform the European Commission accordingly.

Step 24: If the measure is considered unjustified, the initiating Market Surveillance Authority must withdraw the measure and any associated Safety Gate Rapid Alert System notifications.

Step 25: The Market Surveillance Authority should upload any information about national measures (whether upheld or withdrawn) to ICSMS.

Step 26: The European Commission shall assess whether a measure is attributed to shortcomings in a harmonised standard.

Step 27: Where the national measure is considered justified and the non-compliance of the product is attributed to shortcomings in the harmonised standards, the European Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012 concerning the formal objection to harmonised standard.

4. COOPERATION WITH BORDER CONTROL AUTHORITIES (CUSTOMS)

Articles 25 to 28 of Regulation (EU) 2019/1020 on Market Surveillance and Compliance of Products (Chapter VII) establish obligations to carry out controls on products entering the EU market and provide the legal basis for the cooperation between authorities designated for such

[24] Unless otherwise specified in sector-specific EU harmonisation legislation

controls (usually customs authorities[25]) and Market Surveillance Authorities.

While the provisions of Regulation (EU) 2019/1020 relating to market surveillance apply to products subject to EU harmonisation legislation, as initially listed in Annex I, it is important to note that Articles 25 to 28 have a broader scope: they apply to all products covered by EU law, in so far as there are no specific provisions relating to the organisation of controls on products entering the EU market in EU law (*lex specialis* principle).

Controls at EU (and EEA) external borders are an effective way to carry out market surveillance on products before they enter the Single Market. Customs, in cooperation with Market Surveillance Authorities, can set up risk profiles (e.g. based on product type, name of importer, etc.) according to the Combined Nomenclature codes[26] used in the EU customs database TARIC[27].

In all Member States, cooperation between Customs (which can control goods entering the EU and suspend the release for free circulation of those suspected to be non-compliant or to present a serious risk) and Market Surveillance Authorities (which can assess the compliance of products and require appropriate corrective action) is essential to ensure that both authorities' respective activities are complementary and effective.

Article 34 (7) of Regulation (EU) 2019/1020 describes the task of the Commission to develop an electronic interface that can be used for the transmission of data between Customs Authorities and ICSMS.

The notification can be made electronically via the EU Customs Single Window – CERTEX (EU CSW-CERTEX) once it is operational. The use of the electronic interface is not mandatory but is strongly recommended to ensure effective and timely communication, as well as the automated collection of data on compliance controls with respect to products entering the EU.

In order for cooperation to be effective, the Market Surveillance Authority should provide customs officers with training and tools (e.g. checklists) to detect product-specific non-compliance. Market Surveillance Authorities can ask Customs to set up risk profiles, with relevant criteria (e.g. name of importer, product type etc.) on specific products.[28]

It is paramount to note that, whereas the requirement by a Market Surveillance Authority not to release a product for free circulation creates an obligation for customs to not release the product, an approval by Market Surveillance Authorities to release a product for free circulation or a no reply within 4 working days is not binding on customs: customs may still

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[25] In accordance with Article 25 (1) of Regulation 2019/1020, Member States designate customs authorities, one or more market surveillance authorities or any other authority as the authorities in charge of the control on products entering the EU market. Most Member States designated their customs authorities to this effect; a few Member States also designated specific market surveillance or other authorities in addition to customs due to the specificities of their national organisation.

[26] Further information on Combined Nomenclature codes can be found via https://taxation-customs.ec.europa.eu/customs-4/calculation-customs-duties/customs-tariff/combined-nomenclature_en

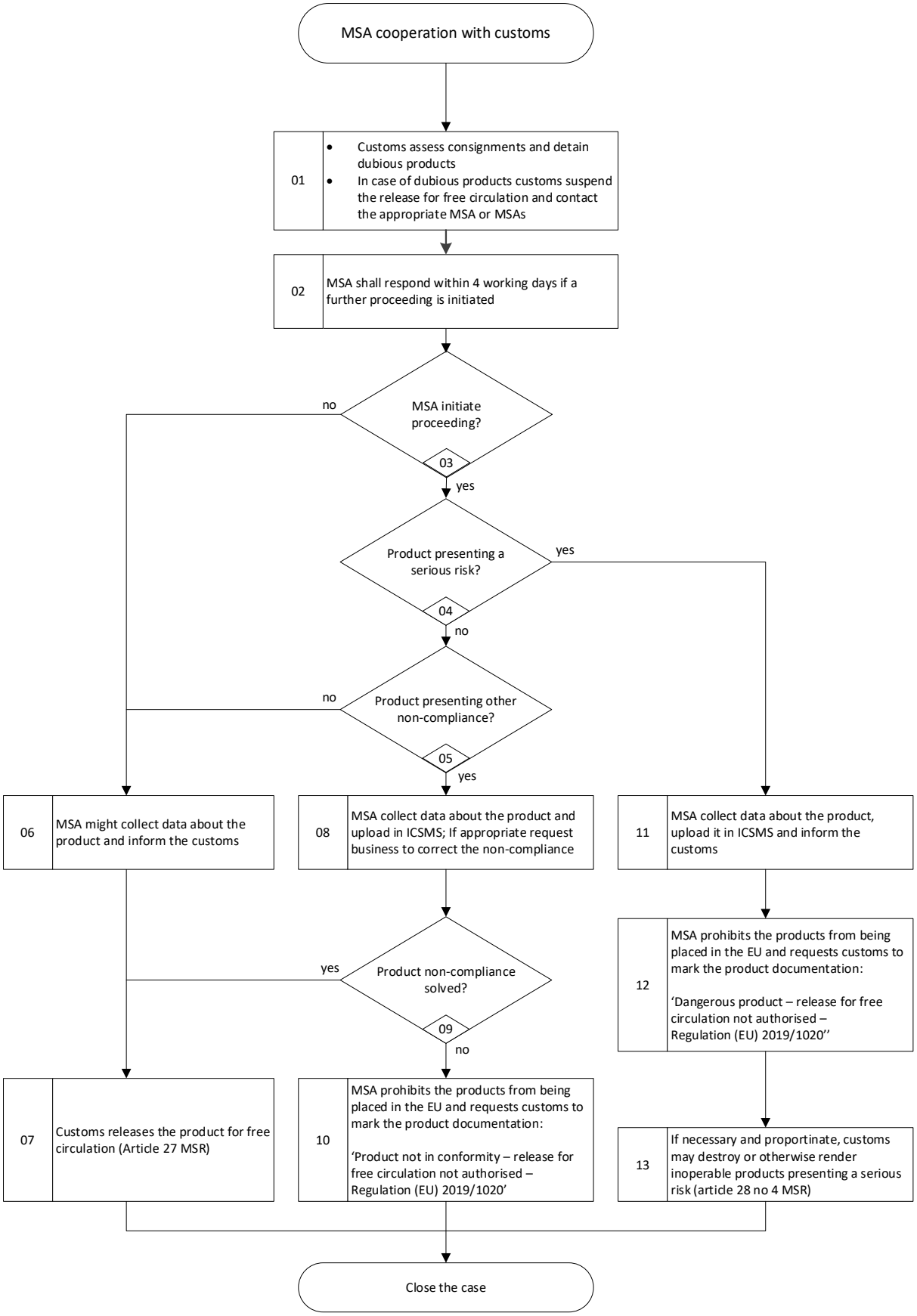
[27] TARIC, the integrated Tariff of the European Union, is a multilingual database in which are integrated all measures relating to EU customs tariff, commercial and agricultural measures and Prohibitions and restrictions to import and export. By integrating and coding these measures, the TARIC secures their uniform application by all Member States and gives all Economic Operators a clear view of all measures to be undertaken when importing into the EU or exporting goods from the EU. It also makes it possible to collect EU-wide statistics for the measures concerned. Further information on TARIC can be found via https://taxation-customs.ec.europa.eu/customs-4/calculation-customs-duties/customs-tariff/eu-customs-tariff-taric_en

[28] See the document "Cooperation between Customs and Market Surveillance Authorities on risk management in the area of product safety and compliance controls on imported goods" final version of 11 November 2015. Market surveillance and customs officers can obtain a copy of the document via their national representatives at "Customs 2020 project group on product safety and compliance controls on imported goods" managed by DG TAXUD.

refuse the release for free circulation in view of their own powers or other issues with the product. In addition, the release for free circulation of a product is no proof of its compliance with Union law.

The following flowchart explains the process and the necessary steps to be taken pursuant to Articles 25-28 of Regulation (EU) 2019/1020 when cooperating with Customs.[29]

[29] This flowchart and the accompanying description provide an illustrative overview of the cooperation process. Only the provisions of Regulation (EU) 2019/1020 have legal force.


MSA cooperation with customs
01
Customs assess consignments and detain dubious products
In case of dubious products customs suspend the release for free circulation and contact the appropriate MSA or MSAs
02
MSA shall respond within 4 working days if a further proceeding is initiated
MSA initiate proceeding?
03
no
yes
Product presenting a serious risk?
04
yes
no
Product presenting other non-compliance?
05
no
yes
06
MSA might collect data about the product and inform the customs
08
MSA collect data about the product and upload in ICSMS; If appropriate request business to correct the non-compliance
11
MSA collect data about the product, upload it in ICSMS and inform the customs
Product non-compliance solved?
09
yes
no
12
MSA prohibits the products from being placed in the EU and requests customs to mark the product documentation:
'Dangerous product – release for free circulation not authorised – Regulation (EU) 2019/1020''
07
Customs releases the product for free circulation (Article 27 MSR)
10
MSA prohibits the products from being placed in the EU and requests customs to mark the product documentation:
'Product not in conformity – release for free circulation not authorised – Regulation (EU) 2019/1020'
13
If necessary and proportinate, customs may destroy or otherwise render inoperable products presenting a serious risk (article 28 no 4 MSR)
Close the case

Step 1: Customs authorities carry out risk-based controls on products entering the EU. They do so on the basis of risk analysis in accordance with the Union Customs Code and, where relevant, on the basis on the basis of specific risk profiles established in cooperation with Market Surveillance authorities.

If customs authorities have reasons to consider that a product does not comply with EU legislation or presents a serious risk, they suspend the release for free circulation and immediately notify the relevant Market Surveillance Authorities.

Market surveillance authorities also have the ability to request the suspension of a specific product if they have reasonable reasons to believe that it is dangerous or non-compliant. The electronic interface can also be used to this effect[30].

Steps 2 – 3: Although the Market Surveillance Authority does not need to make an immediate decision regarding the compliance of the product they shall assess (Risk analyses) whether the product is non-compliant or presents a serious risk and should respond within 4 working days to inform Customs. Market Surveillance Authority may:

1) **Request customs to maintain the suspension**, for instance to request documentation or to carry out further investigations or laboratory testing. There is no additional deadline after the suspension has been maintained but Market Surveillance Authorities are expected to conclude their assessment as quickly as possible;

2) **Approve the release for free circulation** of the product. If the Market Surveillance Authority approves the release for free circulation or does not respond within 4 days, Article 27 of Regulation (EU) No 2019/1020 states that Customs shall release the product.

   Market surveillance authorities are urged to respond accordingly within four days. Failure to reply to customs will result in the product being released for free circulation.. To valorise customs efforts and ensure the protection of the Single Market, Market Surveillance authorities are called upon to make best efforts provide a reply to customs authorities within 4 working days or request to maintain the suspension if they need more time to conclude.

Step 4: The Market Surveillance Authority assesses whether the product presents a serious risk (Risk analyses).

Step 5: The Market Surveillance Authority assesses whether the product presents other non-compliances.

Step 6: It can be useful for Market Surveillance Authorities to collect data on products in order to identify trends and patterns on which to base future proactive market surveillance activities.

Step 7: If a Market Surveillance Authority does not identify non-compliance or if non-compliance identified has been solved by means of appropriate corrective action Customs shall release the product for free circulation.

[30] If MSAs consider that specific products or product categories are likely to be non-compliant and should therefore be controlled when they are declared at the external borders, the appropriate procedure is to request the creation of a customs risk profile and to establish it in cooperation with customs by providing all available information on the risk indicators, such as description of the products, countries of origin, economic operators involved, etc.

Step 8: Where the Market Surveillance Authority finds that a product does not comply with EU harmonisation legislation they shall take appropriate action to ensure the product is brought into conformity or, if necessary, to prohibit placing on the market.

However, non-compliant products under the customs procedure 'release for free circulation' are in exceptional cases possible to be brought into conformity without changing customs procedure, and if considered possible, both the customs and MSAs must agree on the actions to be taken. Normally corrective actions usually requires that the product must be placed under a different customs procedure, such as customs warehousing, and the corrective actions must be both legally allowed and practically effective. Reprocessing at this stage should be a last option. Economic operators should not rely on corrective measures after customs clearance, as this may weaken enforcement.

Referring to Article 28 (2) of Regulation (EU) 2019/1020, Market surveillance authorities shall enter information about products found during border controls that does not comply with EU harmonisation legislation in **ICSMS** (product information and case information) until the interface between CERTEX and ICSMS is established (foreseen until end of 2025).

Step 9: If the product is brought into compliance from the Economic Operator (if possible, some requirements can only be brought into compliance by the manufacturer i.e. CE mark), then it is possible to release the product for free circulation (see Step 7).

Step 10: Where placing on the market is prohibited, the Market Surveillance Authority shall require Customs in charge of external border controls not to release the product for free circulation and to include the following endorsement on the commercial invoice accompanying the product and on any other relevant accompanying document or, where data processing is carried out electronically, in the data-processing system itself:

> **'Product not in conformity – release for free circulation not authorised – Regulation (EU) 2019/1020'** [31]

Step 11: Referring to Article 28 (1), Market surveillance authorities shall immediately enter information about products found during border controls that present a serious risk in **ICSMS** (product information and case information). Products presenting a serious risk should also be notified in the Safety Gate.

Step 12: Where the Market Surveillance Authority finds that a product presents a serious risk, they shall take measures to prohibit that product from being placed on the market and shall require the authorities in charge of external border controls to include the following endorsement on the commercial invoice accompanying the product and on any other relevant accompanying document or, where data processing is carried out electronically, in the data-processing system itself:

[31] Market Surveillance Authorities may conclude that the product does not comply with EU legislation and presents a serious risk. If so, they shall inform customs authorities accordingly, requiring the inclusion of both of notices by customs authorities.

'Dangerous product – release for free circulation not authorised – Regulation (EU) 2019/1020' [32]

Step 13: When Market Surveillance Authorities request customs authorities not to release the product for free circulation, they also have the possibility to indicate:

- Whether and why they consider that the product should be destroyed or otherwise rendered inoperable. Nevertheless, the final decision to destroy the product or to render it inoperable, as well as its execution, are the responsibility of the customs authorities.
- That they object to the product being subsequently declared for a customs procedure other than release for free circulation. This will make it impossible for the product to enter the EU through another customs procedure, for instance to bring the product into compliance, and it will thus require its re-exportation outside the EU (unless the product is destroyed).

Referring to Article 28 (4) of Regulation (EU) 2019/1020, authorities designated under Article 25 (1) of Regulation (EU) 2019/1020 may destroy or otherwise render inoperable a product which presents a risk to the health and safety of end users where the authority in question considers that it is necessary and proportionate to do so. The cost of such measure shall be borne by the natural or legal person declaring the product for free circulation.

[32] Market Surveillance Authorities may conclude that the product does not comply with EU legislation and presents a serious risk. If so, they shall inform customs authorities accordingly, requiring the inclusion of both of notices by customs authorities.

ANNEX 1: List of sectorial legislation.

Sectorial harmonisation legislations in the scope of Market Surveillance Regulation are undergoing a continuously amendment, a link to the latest list of sectorial harmonisation legislations, can be found below.

Aligned legislation:
https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en

List of harmonisation legislation subject to Regulation (EU) 2019/1020:

https://webgate.ec.europa.eu/circabc-ewpp/d/d/workspace/SpacesStore/54a3b610-ade7-4442-9304-a776770c184a/file.bin

ANNEX 2: Other available Guidelines related to Market Surveillance

The 'Blue Guide' on the implementation of EU product rules 2022
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2022.247.01.0001.01.ENG

Multi-annual action plan for the surveillance of products in the EU :
http://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A52013DC0076

NANDO:
https://webgate.ec.europa.eu/single-market-compliance-space/notified-bodies

Application of Regulation (EU) 2019/515

https://ec.europa.eu/docsroom/documents/45593

Market surveillance of products sold online
https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1503381110390&uri=CELEX%3A52017XC0801%2801%29

The application of the mutual recognition regulation - Train the trainers - Training material
https://ec.europa.eu/docsroom/documents/45186

Guide to the application of Treaty provisions governing the free movement of goods
http://publications.europa.eu/en/publication-detail/-/publication/a5396a42-cbc8-4cd9-8b12-b769140091cd

Commission Notice on the market surveillance of products sold online (Text with EEA relevance)
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52017XC0801(01)

OECD Best Practice Principles - Enforcement and Inspections
https://www.oecd.org/en/publications/oecd-regulatory-enforcement-and-inspections-toolkit_9789264303959-en.html

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on consumer product safety and repealing Council Directive 87/357/EEC and Directive 2001/95/EC
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013PC0078

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE A vision for the internal market for industrial products
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52014DC0025

Single Market Act Twelve levers to boost growth and strengthen confidence "Working together to create new growth"
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52011DC0206

Overview of responses to the public consultation on the Communication 'Towards a Single Market Act'
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52011SC0467

Consultation on the Single Market Act All Responses
https://ec.europa.eu/docsroom/documents/16482/attachments/3/translations

Key Actions
https://ec.europa.eu/docsroom/documents/15502/attachments/2/translations

Single Market Act II Together for new growth
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52012DC0573

Notification of Member States penalties provisions pursuant to Article 41 of Regulation (EU) 2019/1020
https://ec.europa.eu/docsroom/documents/63816

Guide on Articles 34-36 of the Treaty on the Functioning of the European Union (TFEU)
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021XC0323(03)

Identifying and addressing barriers to the Single Market
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020SC0054

Development of cross-border e-commerce through parcel delivery
https://data.europa.eu/doi/10.2873/931558

Business Handbook on Due Diligence in the Cocoa Sector. Addressing Child Labour and Forced Labour
https://www.oecd-ilibrary.org/finance-and-investment/business-handbook-on-due-diligence-in-the-cocoa-sector_79812d6f-en

Safety Gate SAFER PRODUCTS FOR ALL 2022 RESULTS
https://op.europa.eu/en/publication-detail/-/publication/17a111d4-d42a-11ed-a05c-01aa75ed71a1/language-en

INJURY AND ACCIDENT DATA COLLECTION IN SUPPORT OF CONSUMER PRODUCT SAFETY AND MARKET SURVEILLANCE (CPS-IAData project)
https://ec.europa.eu/safety-gate/#/screen/home

CASP2022 Final Report - Communication booster
https://op.europa.eu/en/publication-detail/-/publication/dcbc4a9f-7d35-11ee-99ba-01aa75ed71a1/language-en/format-PDF/source-309502972

Art 9 Joint activities
https://ec.europa.eu/docsroom/documents/48334

Article 4 EU 2019/1020
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC0323(01)

Guide on Articles 34-36 TFEU
https://ec.europa.eu/docsroom/documents/44906

European Commission, Directorate-General for Enterprise and Industry, Free movement of goods – Guide to the application of Treaty provisions governing the free movement of goods, Publications Office, 2010
https://data.europa.eu/doi/10.2769/24937

The application of the mutual recognition regulation to food supplements - Training material for authorities
https://ec.europa.eu/docsroom/documents/45185

Market surveillance for effective consumer protection in the EU - The role of Market Surveillance Authorities and their cross-border cooperation

https://www.europarl.europa.eu/RegData/etudes/STUD/2023/754190/IPOL_STU(2023)754190_EN.pdf

PROSAFE Best Practice Techniques in Market Surveillance
https://ec.europa.eu/docsroom/documents/13249/attachments/1/translations

OECD Regulatory Enforcement and Inspections Toolkit
https://www.oecd.org/en/publications/oecd-regulatory-enforcement-and-inspections-toolkit_9789264303959-en.html

Good Practice in Market Surveillance Activities related to Non-Food Consumer Products sold Online Report
https://ec.europa.eu/docsroom/documents/8723/attachments/1/translations

20 actions for safer and compliant products for Europe: a multi-annual action plan for the surveillance of products in the EU
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013DC0076

Delivering the Single Market Act: State of Play
https://ec.europa.eu/docsroom/documents/15498/attachments/1/translations

SINGLE MARKET ACT : PUBLIC CONSULTATION – FIRST OVERVIEW OF RESPONSES
https://ec.europa.eu/docsroom/documents/16482/attachments/2/translations

Conclusions on the Single Market Act 3057th COMPETITIVENESS (Internal Market, Industry, Research and Space) Council meeting Brussels, 10 December 2010
https://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/intm/118409.pdf

Conclusions on the priorities for relaunching the Single Market 3094th COMPETITIVENESS (Internal Market, Industry, Research and Space) Council meeting Brussels, 30 May 2011
https://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/intm/122331.pdf

Guidelines for economic operators and market surveillance authorities on the practical implementation of Article 4 of Regulation (EU) 2019/1020 on market surveillance and compliance of products
https://ec.europa.eu/docsroom/documents/46171

Guidance document for the application of Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008
https://ec.europa.eu/docsroom/documents/45593

Guide to the implementation of directives based on the new approach and the global approach
https://op.europa.eu/en/publication-detail/-/publication/4f6721ee-8008-4fd7-acf7-9d03448d49e5

A guide to good practice. Principles and practices in product regulation and market surveillance. ISO
https://casco.iso.org/files/live/sites/cascoregulators/files/PDF/casco_guide.pdf

Market surveillance for effective consumer protection in the EU The role of Market Surveillance Authorities and their cross-border cooperation.

https://www.europarl.europa.eu/thinktank/en/document/IPOL_STU(2023)754190

OECD, Recommendation of the Council on Consumer Product Safety, OECD/LEGAL/0459
https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0459

Guidance on relationship between GPSD 2001/95/EC and market surveillance provisions of Regulation (EC) No 765/2008
https://ec.europa.eu/safety-gate/#/screen/home

Product Safety Pledge +
https://commission.europa.eu/document/download/9b900172-b2a9-4d92-a43d-ff02b4b28031_en?filename=Pledge%2B_final_new.pdf

CASP 2022, Coordinated activities on the safety of products – Risk assessment and management – Final report
https://op.europa.eu/en/publication-detail/-/publication/b206e47b-8509-11ee-99ba-01aa75ed71a1/language-en

A vision for the internal market for industrial products:
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV%3A240302_4

AdCo administrative cooperation groups, including their guides (documents from AdCos):
https://single-market-economy.ec.europa.eu/single-market/goods/building-blocks/market-surveillance/organisation/adcos_en

Combined nomenclature:
https://taxation-customs.ec.europa.eu/customs-4/calculation-customs-duties/customs-tariff/combined-nomenclature_en

New legislative framework (Regulation 765/2008, Decision 768/2008 and aligned legislation):
https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en

OECD Best Practice Principles for Regulatory Policy: Regulatory Enforcement and Inspections:
http://www.oecd.org/gov/regulatory-policy/enforcement-inspections.htm

Prosafe best practices techniques in market surveillance:
http://www.prosafe.org/library/knowledgebase/item/best-practices-techniques-in-market-surveillance

Good Practice in Market Surveillance Activities related to Non-Food Consumer Products sold Online:
http://ec.europa.eu/DocsRoom/documents/8724?locale=nl

Guidelines for import controls in the area of product safety and compliance:
https://ec.europa.eu/taxation_customs/sites/taxation/files/docs/body/guidelines_en.pdf

Harmonised standards:
https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards_en

Recreational craft:
https://ec.europa.eu/growth/sectors/maritime/recreational-crafts_en

Rules on access to and operation of the Safety Gate Rapid Alert System, information to be entered in that System, notification requirements and the criteria for assessment of the level of risk: https://eur-lex.europa.eu/eli/reg_del/2024/3173/oj/eng

Taric database:
https://taxation-customs.ec.europa.eu/customs-4/calculation-customs-duties/customs-tariff/eu-customs-tariff-taric_en

Toys:

https://ec.europa.eu/growth/sectors/toys_en

Treaty guidance:
http://ec.europa.eu/growth/single-market/goods/building-blocks/

United Nations Economic Commission for Europe (UNECE) Advisory Group on Market Surveillance (MARS):
http://www.unece.org/trade/wp6/sectoralinitiatives/mars/mars.html

WELMEC European cooperation in legal metrology guides:
http://www.welmec.org/latest/guides/

ANNEX 3: Glossary

Term / Abbreviation	Definition	Source
Accreditation	An attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity.	Article 2 (10) of Regulation (EC) No 765/2008
ADCO	An administrative cooperation group established for the uniform application of Union harmonisation legislation. ADCO shall be composed of representatives of the national market surveillance authorities and, if appropriate, representatives of the single liaison offices. ADCOs meetings are intended only for representatives of market surveillance authorities and the Commission.	Article 30 (2) of Regulation (EU)2019/1020
ATEX	ATEX is an abbreviation for "ATmosphere EXplosive". ATEX is also the abbreviated name of the European Directive 2014/34/EC concerning the placing on the market of explosion-proof electrical and mechanical equipment, components and protective systems.	Directive 2014/34/EU
Authorised representative	Any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on its behalf in relation to specified tasks with regard to the manufacturer's obligations under the relevant Union harmonisation legislation or under the requirements of Regulation 2019/1020 and Regulation 2013/988.	Article 3 (13) of Regulation 2019/1020 and Article 3 (9) of Regulation (EU) 2023/988

Term / Abbreviation	Definition	Source
Blue Guide	A non-binding document published by the European Commission on the implementation of the EU product rules. The Guide is meant for a better understanding of EU product rules and facilitation of their uniform application across sectors throughout the Single Market.	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:C:2022:247:TOC
CE marking	A marking by which a manufacturer indicates that the product is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing.	Article 2 (20) of Regulation (EC) No 765/2008
CN	Combined nomenclature. The Combined Nomenclature (CN) is a tool for classifying goods, set up to meet the requirements both of the Common Customs Tariff and of the EU's external trade statistics. The CN is also used in intra-EU trade statistics.	Regulation (EEC) No 2658/87 Regulation (EU) 2024/2522
Compliance assessment	The procedure followed by a market surveillance authority to verify if a product complies with the applicable requirements of the Union harmonisation legislation.	https://prosafe.org/images/publications/EMARS_Book_of_Best_Practices_Annexes.pdf
Conformity assessment	The process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled.	Article 2 (12) of Regulation (EC) No 765/2008
Conformity assessment body	A body that performs conformity assessment activities including calibration, testing, certification and inspection.	Article 2 (13) of Regulation (EC) No 765/2008
Corrective action	Any action taken by an economic operator to bring any non-compliance to an end where required by a market surveillance authority or on the economic operator's own initiative.	Article 3 (16) of Regulation (EU)2019/1020

Term / Abbreviation	Definition	Source
Distributor	Any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market.	Article 3 (6) of Regulation (EU)2019/1020
EEA	The European Economic Area.	
EO	Economic operator. The manufacturer, the authorised representative, the importer, the distributor, the fulfilment service provider or any other natural or legal person who is subject to obligations in relation to the manufacture of products, making them available on the market or putting them into service in accordance with the relevant Union harmonisation legislation.	Article 3 (13) of Regulation (EU)2019/1020
EU	The European Union.	
EU type examination	The part of a conformity assessment procedure in which a notified body examines the technical design of a product and verifies and attests that the technical design of the product meets the requirements of the legislative instrument that apply to it.	Annex II of Decision No 768/2008/EC

Term / Abbreviation	Definition	Source
Formal non-compliance	Unless there are reasons to believe that the product presents a risk, one of the following non-compliances with a number of administrative or formal requirements are defined as formal non-compliance by Union harmonisation legislation: (a) the CE marking or other markings required by Union harmonisation legislation have not been affixed or have been affixed incorrectly; (b) the EU declaration of conformity, where required, has not been drawn up or has been drawn up incorrectly; (c) the technical documentation is incomplete or unavailable; (d) the required labelling or instructions for use are incomplete or missing: (e) any other formal requirement describes in the harmonise legislation (i.e. Article 4 of Regulation (EU) 2019/1020).	Article R34 of Decision No 768/2008/EC and corresponding provisions in Union harmonisation legislation, Blue Guide
Harmonised standard	A standard adopted by one of the European standardisation organisations listed in Annex I of Regulation (EU) No 1025/2012 upon a request made by the European Commission for the application of Union harmonisation legislation.	Article 2 of Regulation (EC) No 765/2008, Blue Guide
ICSMS	Information and Communication System for the pan-European Market Surveillance. A general information support system set up by the European Commission for the exchange of information between market surveillance authorities.	Article 34 of Regulation (EU) 2019/1020
Importer	Any natural or legal person established within the Union who places a product from a third country on the Union market;	Article 3 (9) of Regulation (EU) 2019/1020

Term / Abbreviation	Definition	Source
Making available on the market	Any supply of a product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.	Article 3 (1) of Regulation (EU) 2019/1020
Market surveillance	The activities carried out and measures taken by market surveillance authorities to ensure that products comply with the requirements set out in the applicable Union harmonisation legislation and to ensure protection of the public interest covered by that legislation.	Article 3 (3) of Regulation (EU) 2019/1020
Manufacturer	Means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark.	Article 3 (8) of Regulation (EU) 2019/1020
Measures	Appropriate and proportionate corrective action (preventive, corrective or restrictive) taken by market surveillance authorities to bring the non-compliance (for product subject to Union harmonisation legislation, when used in accordance with its intended purpose or under conditions which can be reasonably foreseen and when properly installed and maintained is liable to compromise the health or safety of users, or does not conform to applicable Union harmonisation legislation) to an end or to eliminate the risk within a specified period.	Article 16 of Regulation (EU) 2019/1020
National accreditation body	The sole body in a Member State that performs accreditation with authority derived from the State.	Article 2 (11) of Regulation (EC) No 765/2008
Notified Body	A conformity assessment body which is notified by the Member States to the European Commission.	Decision No 768/2008/EC

Term / Abbreviation	Definition	Source
Placing on the market	The first making available of a product on the Union market;	Article 3 (2) of Regulation (EU) 2019/1020
Recall	Any measure aimed at achieving the return of a product that has already been made available to the end user/consumer.	Article 3 (22) of Regulation (EU) 2019/1020 Article 3 (25) of Regulation (EU) 2023/988
Release for free circulation	The procedure which confers on non-Union goods the customs status of Union goods, entailing application of commercial policy measures, completion of the formalities laid down in respect of the import of the goods, and the collection of any duty legally due. The act whereby the customs authorities, or other persons on their behalf, make goods available for the purposes specified for the customs procedure under which they are intended to be placed.	Article 3 (25) of Regulation (EU) 2019/1020 Article 5 (26) of Regulation (EU) 952/2013
Recommendation for Use (RfU)	A "Recommendation for Use" (RfU) is a document developed by Notified Bodies (NoBos) in specific sectors (e.g., Machinery, Personal Protective Equipment) to provide guidance and a unified interpretation for applying EU legislation and technical standards during conformity assessment. RfUs clarify complex legal provisions or technical requirements, ensuring consistent application by all NoBos across Europe. They are not mandatory legislation but are strongly encouraged for stakeholders to use and support the harmonized implementation of regulations.	Section 5.2.4 of Blue Guide Information by the European Coordination of Notified Bodies

Term / Abbreviation	Definition	Source
SAFETY GATE	Safety Gate rapid alert system (The previously Rapid Alert System "RAPEX"). The EU rapid alert system for dangerous non-food products. For external communication reasons, the RAPEX website was renamed (according to annex of the Commission Implementing Decision (EU) 2019/417 of 8 November 2018, Article 3.4.5.1) and upgraded to 'Safety Gate' (article 25 of the General Product Safety Regulation). It enables a quick exchange of information between EU Member States and the European Commission about dangerous non-food products and the related measures.	Article 25 of Regulation (EU) 2023/988
Single market	The Union market, where people, goods, services and capital can move around as freely as within a single country. Also called the internal market.	https://single-market-economy.ec.europa.eu/single-market_en https://european-union.europa.eu/priorities-and-actions/actions-topic/single-market_en
State of the art	Developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience	EN 45020
TARIC code	A code from the Integrated Tariff of the European Union.	Interactive Terminology for Europe database (iate.europa.eu)
TAXUD	Directorate-General for Taxation and Customs Union.	Interactive Terminology for Europe database (iate.europa.eu)

Term / Abbreviation	Definition	Source
Technical specification	Document that prescribes technical requirements to be fulfilled by a product, process or service. It may be a standard, a part of a standard or independent of a standard.	Article 2 (8) of Regulation (EC) No 765/2008, EN 45020
Third country	A country that is not a Member State of the European Union as well as a country or territory whose citizens do not enjoy the European Union right to free movement.	Interactive Terminology for Europe database (iate.europa.eu) Article 2 (5) of the Regulation (EU) 2016/399 (Schengen Borders Code).
Union	The European Union.	
Union harmonisation legislation	Union legislation listed in Annex I to Regulation (EU) 2019/1020 and any other Union legislation harmonising the conditions for the marketing of products to which General Product Safety Regulation applies	Article 2 and Annex I of Regulation (EU)2019/1020 Article 3 (27) of Regulation (EU) 2023/988
Union Safeguard clause procedures	Specific procedures establishing whether or not a national measure restricting the free movement of a product is justified. Those procedures apply following the exchange of information on measures with regards to products presenting a risk to the health and safety of persons or to other aspects of public interest protection.	Chapter R5 of Decision No 768/2008/EC and Chapter 7.6.2 of Blue Guide
Voluntary measure	A corrective action where not required by a market surveillance authority. Comment: these voluntary measures should not be mixed up with corresponding measures requested by Market Surveillance Authorities if the product is assessed as non-compliant/unsafe.	Article 3 (17) of Regulation (EU)2019/1020

Term / Abbreviation	Definition	Source
Withdrawal	Any measure aimed at preventing a product in the supply chain from being made available on the market.	Article 3 (23) of Regulation (EU) 2019/1020 Article 3 (26) of Regulation (EU) 2023/988