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Revised Glossary of Market Surveillance Terms

Submitted by the subgroup Chair

Summary

This trilingual glossary provides a comprehensive list of terms used in legislative practice related to market surveillance in English, French and Russian. Market surveillance policies have a strong impact on business competitiveness, international trade and economic development. To build an effective market surveillance system requires cooperation among the system stakeholders, both nationally and internationally. For this purpose, a common terminology is a prerequisite.

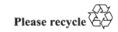
A first multilingual glossary of market surveillance terms was published by the Working Party on Regulatory Cooperation and Standardization Policies (WP.6) in 2011. Since then, there have been new terms and procedures that have come into effect. This revision integrates terms such as "conformity rate", "information society service provider", "online interface", "corrective action". This revision also proposes modification to some terms such as "market surveillance", "withdrawal", "technical regulation", "technical specification".

Mandate

The Programme of work of WP.6 for 2022 (ECE/CTCS/WP.6/2021/10), paragraph 11d foresees the finalization of the revision of the *Glossary of Market Surveillance Terms* (ECE/TRADE/389).

Proposed decision

"The Working Party endorses the revised *Glossary of Market Surveillance Terms* and encourages member States to provide extra-budgetary funding in order to make this available through an electronic database."





I. Introduction

- 1. What is market surveillance? Who is responsible for carrying out market surveillance activities? If a non-conforming product is found on the market, or causes harm to a consumer or worker, who is liable for consequences?
- 2. As a body with global reach, the United Nations Economic Commission for Europe (ECE) Working Party on Regulatory Cooperation and Standardization Policies (WP.6), started work on Market Surveillance in the late 1990s. WP.6 has found over the span of over twenty years work advising its membership that different institutions use different definitions of market surveillance, of the different tasks that underlie market surveillance, as well as of the stakeholders and processes involved.
- 3. ECE WP.6 experts are well aware that in this area, there cannot be a one-size-fits-all approach, and that countries at different levels of development may find that a variety of options can be found to suit the needs of stakeholders.
- 4. This document therefore does not aim to provide mandatory definitions of market surveillance terms, nor to present best practice in this field. It merely presents the terms and their definitions as they appear in widely referred to documents and legislative texts.

II. Mandate and background

- 5. At its eighteenth session, WP.6 noted that different definitions were being used for the term "market surveillance".
- 6. Some members used a narrow definition, i.e. the responsibility of governmental authorities to ensure that products placed on the market comply with legislation. Others wished to further include counterfeit and dangerous products. Elsewhere, the term "market surveillance" was used in a much wider sense, e.g. to include services and the voluntary sphere.
- 7. WP.6 resolved that work on common definitions and terminology for market surveillance should be continued. A first edition of this glossary, published in 2011, was the result of this work.
- 8. This second edition includes adapted and new terms related to new regulatory and institutional developments about market surveillance.
- 9. The glossary contains terms and definitions relevant to market surveillance and post-market surveillance of non-food products. It is intended for promoting a common understanding and harmonization of the terms and definitions used in national legislation.
- 10. The terms have been taken (and sometimes adapted) from the World Trade Organization Technical Barriers to Trade (WTO/TBT) Agreement, European Commission (EC) legislative instruments and the International Organization for Standardization (ISO) guides and standards. Although ISO guides and standards are not mandatory, some terms and definitions from these publications are widely accepted.
- 11. Users are invited to submit additional terms that they believe should be included in future editions of this glossary and any deviating definition from their national legislation of the terms listed. The latter may foster a better understanding of the differences in legislation and market surveillance responsibilities and activities among ECE members States.

III. A glossary to support work of the United Nations Economic Commission for Europe in market surveillance

12. The "United Nations Guidelines for Consumer Protection" adopted by the General Assembly of the United Nations in 1999, encourages Governments to further international cooperation in the field of consumer protection.

- 13. In pursuit of this mandate, WP.6 has developed a body of best practice in addressing the challenges caused by the proliferation of dangerous and counterfeit goods on consumer markets. Hazardous children's toys, contaminated milk, falsified spare parts for cars, appearing on the market, have caused public outcry all over the world.
- 14. These incidents pose a serious threat to human health and to the natural environment. They also undermine local industry, which is frequently unable to compete against a massive inflow of cheap and inferior-quality goods. Market surveillance is one important regulatory response to ensure that products placed on the market, whether imported or produced locally, conform to national or regional technical regulations and are not counterfeit or pirated.
- 15. The development of a global market enables businesses to produce and assemble goods in different places and to export them to many markets. Diversification of production has also increased the number of different goods available to consumers.
- 16. In this context, effective enforcement of regulations will require developing an efficient market surveillance system:
 - (a) To remove illegal and unsafe products from the market. When no conformity assessment is conducted before products are placed on the market, or when only a fraction of products are tested, public authorities have a responsibility to monitor products available to buyers.
 - (b) To ensure that market conditions are fair: suppliers who follow the rules and bear the related administrative costs and delays should not be at a disadvantage vis-àvis those who do not.
- 17. The United Nations has the responsibility of guiding and supporting governments' efforts towards these goals.
- 18. This glossary is therefore a step in this direction, as it sets out to establish common ground and facilitate regional and international efforts to cooperate towards stronger enforcement of technical regulations. The end goal of WP.6 remains that of protecting consumers and workers, ensuring a level playing field for compliant business, and minimizing the strain caused by audits and inspections on companies.

IV. Terms

- 19. Authority: Central or local government body, or non-governmental body empowered by Government to perform public tasks.
- 20. Authorized representative¹: Any natural or legal person established within a country who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks with regard to the latter's obligations under the relevant legislation.
- 21. Conformity assessment²: The process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled.³
- 22. Conformity rate: The percentage of products on the market that conform to all relevant technical and administrative requirements laid down in the technical regulation(s), i.e. the probability that a consumer will purchase a product from the market that is conforming.
- 23. Corrective action⁴: 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.
- 24. Country: Territory occupied by a nation under a central Government.⁵

¹ Adapted from 2019/1020/EU, Art. 3 (12).

² ISO/IEC 17000:2020, 4.1.

³ Conformity assessment includes activities such as testing, inspection, or verification.

⁴ 2019/1020 EU, Art. 3 (16).

⁵ In the case of a treaty establishing a free trade area, "country" may refer to the combined territory occupied by the States that have acceded to the treaty.

- 25. Customs authorities: The government-appointed organization(s) responsible for regulating the flow of goods into and out of a market/country, at the border, including the collection of revenue.
- 26. Distributor⁶: Any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market.
- 27. E-commerce: Activity of agreeing the supply of products or online services via the Internet, when the parties are remote from each other.⁷
- 28. Economic operators⁸: The manufacturer, the authorized representative, the importer, the fulfilment service provider and the distributor.
- 29. End user⁹: Any natural or legal person who receives the benefit of a product or service.
- 30. Fulfilment service provider¹⁰: Any natural or legal person offering, in the course of commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching, without having ownership of the products involved.
- 31. Government body (central —)¹¹: Central Government, its ministries and departments and any body subject to the control of the central Government in respect of the activity in question.
- 32. Government body (local -)¹²: Government other than a central Government (e.g. States, provinces, Länder, cantons, municipalities), its ministries or departments or any body subject to the control of such a Government in respect of the activity in question.
- 33. Governmental body (non —) 13 : Body other than a central government body or a local government body.
- 34. Hazard¹⁴: Potential source of harm.¹⁵
- 35. Importer¹⁶: Any natural or legal person established within a country who places a product from another country on the market.
- 36. Information society service provider¹⁷: The legal entity providing any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services.
- 37. Inspection¹⁸: Examination of an object of conformity assessment and determination of its conformity with detailed requirements or, on the basis of professional judgement, with general requirements.
- 38. Jurisdiction: The territory within which an authority can exercise power.
- 39. Manufacturer¹⁹: 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.

^{6 2019/1020/}EU, Art. 3 (10).

⁷ E-commerce includes transactions involving businesses or other parties in law, e.g. consumers.

⁸ Adapted from 2019/1020/EU, Art. 3 (13).

⁹ Adapted from 2019/1020/EU art. 3 (21).

 $^{^{10}\,}$ Adapted from 2019/1020/EU art. 3.

¹¹ WTO/TBT/Annex 1, 6.

¹² WTO/TBT 7 Annex 1, 7.

 $^{^{\}rm 13}~$ Adapted from WTO/TBT Annex 1, 8.

¹⁴ ISO Guide 51:1999, 3.5.

¹⁵ The term hazard can be qualified in order to define its origin or the nature of the expected harm (e.g. electric shock hazard, crushing hazard, cutting hazard, toxic hazard, fire hazard, drowning hazard).

¹⁶ Adapted from 2019/1020/EU, Art.3 (9).

¹⁷ Adapted from 2015/1535/EU, Art. 1.

¹⁸ ISO/IEC 17000:2020, 6.3.

¹⁹ 2019/1020/EU, Art.3 (8).

- 40. Market (making available on the —) 20 : Any supply of a product for distribution, consumption or use on the market in the course of a commercial activity, whether in return for payment or free of charge.
- 41. Market (placing on the -)²¹: The first making available of a product on the market.
- 42. Market Surveillance²²: The activities carried out and measures taken by designated authorities to ensure that products comply with the requirements set out in the relevant legislation and to ensure protection of the public interest covered by that legislation.²³
- 43. Market surveillance authority²⁴: Authority responsible for carrying out market surveillance within its jurisdiction.
- 44. Market survey: Investigation of administrative or technical properties of products that have been placed on the market to assess whether they conform to the applicable requirements as laid down in legislation and standards. This includes but is not limited to inspection of marking and instructions, examination of technical documentation and testing of products.
- 45. Online interface²⁵: Any software, including a website, part of a website or an application, that is operated by or on behalf of an economic operator, and which serves to give users access to the economic operator's products.
- 46. Operational sampling: The non-statistical selection of one or more samples of a product for the purpose of assessment against legal requirements.²⁶
- 47. Pre-emptive testing (or in general assessment): Performing the assessments or, in most cases the tests, according to a test plan until a non-conformity has been detected.
- 48. Procedure²⁷: Specified way to carry out an activity or a process.
- 49. Producer:28
 - (a) The manufacturer of the product and any other person presenting themself as the manufacturer by affixing to the product their name, trademark or other distinctive mark, or the person who reconditions the product;
 - (b) The manufacturer's representative, when the manufacturer is not established in the country or, if there is no representative established in the country, the importer of the product;
 - (c) Other professionals in the supply chain insofar as their activities may affect the safety properties of a product.
- 50. Product²⁹: Output of an organization that can be produced without any transaction taking place between the organization and the customer.
- 51. Product (consumer —)³⁰: Any product including in the context of providing a service which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether

²⁰ Adapted from 2019/1020/EU, Art.3 (1).

²¹ Adapted from 2019/1020EU, Art.3 (2).

²² Adapted from 2019/1020/EU, Art.3 (3).

Activities carried out to ensure that a compliant measuring instrument has been properly adjusted and is being used correctly while in service are not themselves market surveillance, but they may be regarded as market surveillance if they are carried out by persons who can identify a non-compliant product and initiate further market surveillance actions. Activities which take place before a product is placed on the market, e.g. activities like conformity to type, are not included. However, activities where Customs Authorities and Market Surveillance Authorities are involved, are included.

²⁴ Adapted from 2019/1020/EU, Art.3 (4).

²⁵ 2019/1020/ EU, Art. 15.

²⁶ Frameworks that require multiple samples may require a retained reference sample in case of dispute.

²⁷ ISO/IEC 17000:2020, 5.2.

²⁸ 2001/95/EC.

²⁹ ISO 9000:2015, 3.7.6.

³⁰ 2001/95/EC Art. 2 (a).

for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned.³¹

- 52. Product (safe —):³² Any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the following points in particular:
 - (a) The characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;
 - (b) The effect on other products, where it is reasonably foreseeable that it will be used with other products,
 - (c) The presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product;
 - (d) The categories or consumers at risk when using the product, in particular children and the elderly. 33
- 53. Prospective sampling³⁴: Initial sampling procedure to define market intelligence when developing a market surveillance strategy or an annual market surveillance plan and while using a suboptimal statistical relevant approach.³⁵
- 54. Recall³⁶: Any measure aimed at achieving the return of a non-complying product that has already been made available on the market.
- 55. Risk³⁷: Combination of the probability of an event and its consequence.³⁸
- 56. Risk (serious —)³⁹: Any risk, including those the effects of which are not immediate, requiring rapid intervention by the public authorities.
- 57. Risk assessment⁴⁰: Overall process of risk analysis and risk evaluation.
- 58. Risk communication⁴¹: Exchange or sharing of information about risk between the decision-maker and other stakeholders.⁴²
- 59. Risk control⁴³: Actions implementing risk management decisions.
- 60. Risk management⁴⁴: Coordinated activities to direct and control an organization with regard to risk.⁴⁵

This definition shall not apply to second-hand products supplied as antiques or as products to be repaired or reconditioned prior to being used, provided that the supplier clearly informs the person to whom he supplies the product to that effect.

³² 2001/95/EC Art. 2 (b).

³³ The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product to be "dangerous".

³⁴ Adapted from American dictionary of psychology, APA (American Psychological Association).

³⁵ Sampling, within a prospective study, which starts with the present and follows conformity of products with regulations forward in time to examine trends, predictions, and outcomes.

³⁶ Adapted from 2001/95/EC, Art. 2 (g).

³⁷ ISO Guide 73:2002, 3.1.1.

³⁸ The term "risk" is generally used only when there is at least the possibility of negative consequences.

³⁹ Adapted from 2001/95/EC, Art.2 (d).

⁴⁰ ISO Guide 73:2002, 3.1.1.

⁴¹ ISO Guide 73:2002, 3.2.4.

⁴² The information can relate to the existence, nature, form, probability, security, acceptability, treatment or other aspects of risk.

⁴³ ISO Guide 73:2002, 3.4.2.

⁴⁴ ISO Guide 73:2002, 3.1.7.

⁴⁵ Risk management generally includes risk assessment, risk treatment, risk acceptance and risk communication.

- 61. Safety⁴⁶: Absence from unacceptable risk.
- 62. Sampling⁴⁷: Selection and/or collection of material or data regarding an object of conformity assessment.
- 63. Standard⁴⁸: Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.⁴⁹
- 64. Statistical relevance: The allowed deviation from the true probability of an event or series of events, which is caused by the allowed error and the set confidence level of the analysis.⁵⁰
- 65. Statistically relevant market survey action: Providing best level of intelligence on certain products groups in the market with given resources.
- 66. Technical regulation⁵¹: Technical specifications and other requirements or rules on services, including the relevant administrative provisions, the observance of which is compulsory, de jure or de facto, in the case of marketing, provision of a service, establishment of a service operator or use, as well as laws, regulations or administrative provisions, prohibiting the manufacture, importation, marketing or use of a product or prohibiting the provision or use of a service, or establishment as a service provider.
- 67. Technical specification⁵²: A specification contained in a document which lays down the characteristics required of a product such as levels of quality, performance, safety or dimensions, including the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures.
- 68. Test⁵³: Determination of one or more characteristics of an object of conformity assessment, according to a procedure.
- 69. Use (intended -)⁵⁴: Use of a product, process or service in accordance with information provided by the supplier.
- 70. Use (reasonably foreseeable mis-—)⁵⁵: Use of a product, process or service in a way not intended by the supplier, but which may result from readily predictable human behaviour.
- 71. Voluntary measure⁵⁶: Means a corrective action where not required by a market surveillance authority.
- 72. Withdrawal⁵⁷: Any measure aimed at preventing a product in the supply chain from being made available on the market.

⁴⁶ ISO Guide 51:1999, 3.1.

⁴⁷ ISO/IEC 17000:2020, 6.1.

⁴⁸ WTO/TBT 2 Annex 1, Definition 2.

⁴⁹ Although the international standardization community generally prepared standards based on consensus, the WTO/TBT Agreement also covers documents that are not based on consensus.

⁵⁰ Statistical relevance is a complex concept and expert advice should be sought.

⁵¹ Adapted from Directive (EU) 2015/1535 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (codification).

Directive (EU) 2015/1535 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (codification).

⁵³ ISO/IEC 17000:2020, 6.2.

⁵⁴ ISO Guide 51:1999, 3.13.

⁵⁵ ISO Guide 51:1999, 3.14.

⁵⁶ 2019/1020/EU, Art. 17.

⁵⁷ Adapted from 2019/1020/EU, Art. 2 (23).