

# UNECE WP on Regulatory Cooperation and Standardisation Policies

## **Market Surveillance glossary update**

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# 1. Introduction

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- ✓ Title: Common definitions and terminology in Market Surveillance
- ✓ Current version dates of 2011
- ✓ Scope: Market surveillance of non-food products including internet sales.

# 1. Introduction

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- ✓ Decision to rework the 2011 glossary taken in 2018
- ✓ New terms and changes of terms of the 2011 edition discussed during the Moscow meeting of July 2019
- ✓ Edited 2011 (draft 1) glossary document sent to members of a small working group in Nov. 2019
- ✓ A reformatted draft 2 provided to UNECE members on 6 July 2021
  - ✓ Comments received from OIML and BRML (Romania)

## 2. Why review the document?

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- ✓ Challenge of internet sales and new actors (supply chain) on the market to put products on the market.
- ✓ Increased market surveillance actions worldwide to counter existence of non-conform (counterfeited) products on the market.
- ✓ More advanced concepts of market surveillance needed to increase effectiveness.
  - ✓ Better approach for identifying products which may cause serious risk by identifying the spread of uncertainty of sub-injury scenarios is needed. This would imply adding relevant statistical terms.
- ✓ To incorporate latest changes of terms/definitions coming from basic/other standards and regulatory documents. (e.g. ISO/IEC 17000 latest 2020 version)

### 3. Objective of the document

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- ✓ To provide a global, harmonized set of terms and definitions to be used as a reference when drafting regulations, standards and other documents, with respect to market surveillance of non-food products placed or made available on the market.
- ✓ To be in compliance with the WTO/TBT agreement.
- ✓ To consider international regulations and other guidance documents (new MS regulation 2019/1020/EU published on 25/6/2019).

## 4. Proposed changes

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Changes to the 2011 glossary edition can be broken down into 2 levels:

- New terms
- Changed terms

For each of the terms in the glossary is provided:

- A definition
- The reference document (source document)
- Comments (informal) to the definition

## 4. Proposed changes

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### 16# New terms (see end of the glossary doc.)

- ✓ Market survey

- ✓ Assessment of administrative or technical properties of products to assess whether they comply with 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.

- ✓ Conformity rate

- ✓ The conformity rate is the fraction of products on the market that conform to legal requirements.

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## 4. Proposed changes

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### Other new terms

- ✓ Information society service provider
- ✓ Fulfillment service provider
- ✓ Online interface
- ✓ Non-compliance
- ✓ Customs authorities
- ✓ Products entering the country
- ✓ Release for free circulation
- .../...

## 4. Proposed changes

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### Other new terms

- ✓ End user
- ✓ Corrective action
- ✓ Voluntary measure
- ✓ Products presenting a risk
- ✓ Products presenting a serious risk
- ✓ Statistically relevant market survey action
- ✓ Different sampling procedures: prospective or survey sampling, system level sampling, operational sampling

## 4. Proposed changes

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### Changed terms

#### ✓ Market Surveillance

- ✓ **Comment OIML:** “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.”

#### ✓ Economic operator (fulfillment service provider now included)

#### ✓ Withdrawal

- ✓ **Comment BRML:** “any measure aimed at preventing a product in the supply chain from being made available on the market”

## 4. Proposed changes

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### Change of terms

#### ✓ Technical regulation

- ✓ **Comment BRML:** “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.” (from 2015/1535/EC)

## 4. Proposed changes

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### Change of terms

#### ✓ Technical specification

- ✓ **Comment BRML:** “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.”  
(from 2015/1535/EC)
- ✓ Existing text in glossary was: “A document that prescribes technical requirements to be fulfilled by a product, process or service.”

## 4. Proposed changes

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### Other changes

- ✓ Update introduction of the document
  - ✓ Add history
  - ✓ Purpose of the document
- ✓ Update list of documents used

## 5. Proposal for a guide to clarify terms in the glossary

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### **Uncertainty of risk assessment results**

#### Section 5.3.6 of ISO 31010 Risk Management – Risk Assessment Techniques:

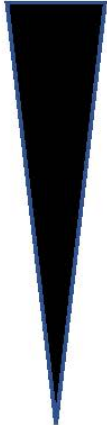
*“There are often considerable uncertainties associated with the analysis of risk. An understanding of uncertainties is necessary to interpret and communicate risk analysis results effectively.”*

*“Uncertainty analysis involves the determination of the variation or imprecision in the results, resulting from the collective variation in the parameters and assumptions (scenarios) used to define the results.”*

*“The completeness and accuracy of the risk analysis should be stated as fully as possible. Sources of uncertainty should be identified where possible...”*

# 5. Proposal for a guide to clarify terms in the glossary

Risk assessment is highly sensitive to variations in the initial assumptions (different expert opinion) and can shift a product from one risk level to another.

Probability of occurrence of the harm scenario during the foreseeable lifetime of the product		Severity of injury					
		1	2	3	4		
	High	> 50 %	High risk	Serious risk	Serious risk	Serious risk	Serious risk
	> 1/10	Medium risk	Serious risk	Serious risk	Serious risk	Serious risk	
	> 1/100	Medium risk	Serious risk	Serious risk	Serious risk	Serious risk	
	> 1/1.000	Low risk	High risk	Serious risk	Serious risk	Serious risk	
	> 1/10.000	Low risk	Medium risk	High risk	Serious risk	Serious risk	
	> 1/100.000	Low risk	Low risk	Medium risk	High risk	Serious risk	
	> 1/1.000.000	Low risk	Low risk	Low risk	Medium risk	High risk	
	Low	> 1/10.000.000	Low risk	Low risk	Low risk	Low risk	Medium risk
> 1/10.000.000	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	



## 5. Proposal for a guide to clarify terms in the glossary

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- Risk analysis is very sensitive with respect to
  - Probabilities within scenarios
  - Completeness and correctness of scenarios
- Easily, with slight change in the assumptions (in the experts opinion) one product can go from one to another risk level.
- The use of software based on the Monte Carlo method is adequate tool for studying, analysing and verifying scenarios.

## 5. Proposal for a guide to clarify terms in the glossary

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- Risk assessment procedures should be revised to provide guidelines and methodology for evaluation of the RA uncertainty.
- New template for risk assessment should be developed.
- Methodology (z-score) should be created for comparison of risk assessment results delivered by different authorities.

## 6. Preliminary conclusions & way forward

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- ✓ To integrate new/changed terms of latest ISO/IEC 17000:2020, ISO 9000:2015 and 2019/1020/EU in existing UNECE glossary document
- ✓ To study comments of OIML and BRML (legal metrology) if they can be integrated in glossary draft 2.
- ✓ **Need for a guide to explain terms in glossary such as e.g.:**
  - ✓ **Precision and uncertainty definition plays large role in assessing (serious) risk cases and therefore statistic terms need to be added to the market surveillance glossary document**
  - ✓ **Liaise with other similar initiatives e.g., EU project EMPIR Casoft (2018-2020)**

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Thank you