



Ministry of Economy and Industry  
Foreign Trade Administration

# Guide to the EU Market Surveillance Regulation

EU-based representative required?



**Foreign Trade Administration** | Your Connection to Israeli Innovation

# EU Single Market for Goods

- Legislation on single market for goods aims to ensure that products placed on the EU market meet high health, safety and environmental requirements.
- Products allowed to be sold in the EU can circulate without barriers to trade and with a minimum of administrative burden.
- Free movement in harmonised (common EU-rules) and non-harmonized (national rules) sectors.

## The Goods Package includes two Regulations:

- Regulation(EU) 2019/515 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008
- Regulation (EU) 2019/1020 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011

# EU's objective

Growing number of illegal and non-compliant products in the single market distorts competition among businesses and puts consumers at risk.

*Example: Unsafe chargers on Chinese web shops*

Goods Package aims to reinforce trust in the Single Market by:

- Improving and facilitating mutual recognition for goods  
-> Mutual Recognition Regulation
- Ensuring compliance with, and enforcement of product legislation  
-> **Market Surveillance Regulation**

# Market Surveillance in the EU

Market surveillance protects EU consumers.

Market Surveillance Authorities in each EU country:

- Control products and take measures, such as: product withdrawals, recalls and sanctions
- Close cooperation with customs

# The new Market Surveillance Regulation

Regulation (EU) 2019/1020 will replace the market surveillance provisions of Regulation (EC) No 765/2008 as from 16 July 2021, and will improve them in particular by:

- preventing non-compliance by providing information to and joint activities with businesses
- improved cooperation: between EU countries, between market surveillance and customs authorities, and through an EU product compliance network
- providing more effective enforcement tools to address **online sales**

# Greatest Impact on Online Sales

Currently, for B2C sales from businesses outside EU to consumer in EU:  
Consumers considered as 'importers', responsible for compliance.

This will change. Non-EU vendors required to have a representative in the EU, and fulfilment service provider responsible when there is no representative.

# Timeline

- December 2017: 'Goods Package' proposal by European Commission
- July 2019: Entry into force of Market Surveillance Regulation
- February 2020: Publication of Draft Guidelines on Article 4 and stakeholder meeting. Final version expected in September.
- July 16, 2021: The regulation will apply except for the setting up of the Union Product Compliance Network, which has to be established by January 1, 2021.



## Zooming in on Article 4

Article 4 of the regulation specifies that, for certain product categories, there should be an economic operator (= **responsible person**) in the EU that can provide information to, and cooperate with the market surveillance authorities.

**No economic operator in the EU after 16 July, 2021  
-> Goods not allowed to enter the EU**

# When is an EU responsible person required?

1. The product falls into the scope of one or more of the Directives or Regulations that are listed in paragraph 5 of Article 4.
2. The product is placed on the EU market

*Products offered for sale online, or through other distance sales means, are presumed to be made available on the EU market if the economic operator directs its activities to a Member State by any means.*

## Which goods are covered by Article 4?

- The new Regulation covers the market surveillance of **industrial products** (non-food products) and applies to all the products listed in Annex I of the Regulation
- **Article 4 only covers a limited subset of the Regulations in Annex I. Products with higher risk.**
- CE - Marking
- New rules shall not replace the market surveillance aspects specifically regulated in the relevant product legislation, for instance in the Cosmetics Regulation, Medical Devices Regulation and In-Vitro Diagnostics Regulation.

# Which goods are covered by Article 4?

- **Construction products**
- **Personal protective equipment** HS Code 6307
- **Appliances burning gaseous fuels** HS Codes 7321 and 8416
- **Noise emission in the environment by equipment for use outdoors** HS Codes 8467 and 8433
- **Machinery** HS Code 8468
- **Safety of toys**
- **Eco-design requirements for energy-related products**
- **Certain hazardous substances in electrical and electronic equipment** HS Code 8535
- **Recreational craft and personal watercraft** HS Codes 8902 and 8903
- **Simple pressure vessels** HS Code 8419
- **Electromagnetic compatibility** HS Code 8505
- **Non-automatic weighing instruments** HS Code 8423
- **Measuring instruments** HS Code 9031
- **Equipment and protective systems intended for use in potentially explosive atmospheres** HS Code 8511
- **Electrical equipment designed for use within certain voltage limits** HS Code 8536
- **Radio equipment** HS Code 8525
- **Pressure equipment** HS Code 8419
- **Pyrotechnic articles**

# Which goods are covered by Article 4?

- [Noise - equipment for use outdoors – Directive 2000/14/EC](#)
- [Machinery – Directive 2006/42/EC](#)
- [Toy Safety - Directive 2009/48/EU](#)
- [Eco-design requirements for energy-related products - Directive 2009/125/EC](#)
- [Restriction of Hazardous Substances in Electrical and Electronic Equipment - Directive 2011/65/EU](#)
- [Construction products - Regulation \(EU\) No 305/2011](#)
- [Pyrotechnic Articles - Directive 2013/29/EU](#)
- [Recreational craft and personal watercraft - Directive 2013/53/EU](#)
- [Simple Pressure Vessels - Directive 2014/29/EU](#)
- [Electromagnetic Compatibility - Directive 2014/30/EU](#)
- [Non-automatic Weighing Instruments - Directive 2014/31/EU](#)
- [Measuring Instruments - Directive 2014/32/EU](#)
- [ATEX - Directive 2014/34/EU](#)
- [Radio equipment - Directive 2014/53/EU](#)
- [Low Voltage - Directive 2014/35/EU](#)
- [Pressure equipment - Directive 2014/68/EU](#)
- [Personal protective equipment - Regulation \(EU\) 2016/425](#)
- [Gas appliances - Regulation \(EU\) 2016/426](#)

# Tasks of the responsible person

An economic operator **must be established in the EU** in order to:

- Ensure the availability of the conformity documentation
- Cooperate with market surveillance authorities
- Inform authorities when they have reasons to believe that a product presents a risk

## Who can be the EU responsible person?

Type of economic operators that can be the responsible person

The way they become the responsible person

The way they obtain the means to fulfil their duties as responsible person

**Manufacturers in the EU**

Through their establishment in the EU

As a result of their obligations under sector-specific legislation

## Who can be the EU responsible person?

Type of economic operators that can be the responsible person	The way they become the responsible person	The way they obtain the means to fulfil their duties as responsible person
Manufacturers in the EU	Through their establishment in the EU	As a result of their obligations under sector-specific legislation
<b>Importers in the EU</b>	By placing a product on the EU market: through selling it to a distributor or offering it for sale to end users	As a result of their obligations under sector-specific legislation



# Importers in the EU

Products from manufacturers outside the EU that are sold:

- **In physical stores in the EU** (products already placed on the EU market by an importer)
- **online** (or through other distance sales) with a conventional supply chain **with an importer** and distributor(s)

The importer is the responsible person. The manufacturer may also have appointed an authorized representative in the EU.

**No additional action is required.**

## Who can be the EU responsible person?

Type of economic operators that can be the responsible person	The way they become the responsible person	The way they obtain the means to fulfil their duties as responsible person
Manufacturers in the EU	Through their establishment in the EU	As a result of their obligations under sector-specific legislation
Importers in the EU	By placing a product on the EU market: through selling it to a distributor or offering it for sale to end users	As a result of their obligations under sector-specific legislation
<b>Authorized representatives in the EU</b>	<b>Through appointment by the manufacturer</b>	<b>Through their mandate</b>

# Authorized Representative in the EU

If the product is shipped from outside the EU directly to the end-user:

**The manufacturer needs to appoint (written mandate) an authorized representative in the EU**, which will be the responsible person.

If the manufacturer has not appointed such authorized representative, the product cannot be offered for sale to EU end-users.

## Who can be the EU responsible person?

Type of economic operators that can be the responsible person	The way they become the responsible person	The way they obtain the means to fulfil their duties as responsible person
Manufacturers in the EU	Through their establishment in the EU	As a result of their obligations under sector-specific legislation
Importers in the EU	By placing a product on the EU market: through selling it to a distributor or offering it for sale to end users	As a result of their obligations under sector-specific legislation
Authorized representatives in the EU	Through appointment by the manufacturer	Through their mandate
<b>Fulfilment service providers in the EU</b>	<b>Only if there is none of the other three types of economic operators in the EU: by handling the product</b>	<b>As a result of Article 4 of Regulation (EU) 2019/1020</b>

# Fulfilment Service Provider in the EU

Person or company offering at least two of the following services:

- Warehousing
- Packaging
- Addressing
- Dispatching

without having ownership of the products involved  
(courier and postal companies are specifically excluded)

Examples: Shipwire, Fulfilment By Amazon (FBA)

# Fulfilment Service Provider in the EU

If a fulfilment service provider in the EU handles the product:  
The fulfilment service provider is the responsible person,  
unless the manufacturer has appointed an EU authorized representative.

**Assess relationship with Fulfilment Service Provider**, because there is no automatic connection with the manufacturer in order to fulfil the tasks of responsible person.

# Fulfilment Service Provider in the EU

Before accepting to provide the fulfilment service, the fulfilment service provider needs to receive the means to fulfil its obligations:

- Declaration of conformity or performance for the products concerned.
- Assurances that the manufacturer will cooperate to ensure that other tasks can be fulfilled, such as providing technical documentation or undertaking corrective action when requested by the authorities.

## How to prepare?

Companies placing these products on the EU market, who do not yet identify a responsible person established in the EU, or who rely on an economic operator established in the United Kingdom, should assess their obligations and take the necessary steps.

1. Is your product covered by any of the legislations referred to in Article 4?
2. Is your product being sold online (or through other methods of distance selling)?
3. Assess your supply chain: importer, authorized representative or fulfilment service provider?



# Labelling Requirements

The name, registered trade name or registered trade mark, and contact details, including the postal address of the responsible person have to be indicated on at least one of the following:

- the product
- its packaging: sales packaging (primary packaging) or grouped packaging (secondary packaging)
- the parcel: transport packaging (tertiary packaging)
- an accompanying document

## Practical example

### **Selling toys directly to EU customers on Etsy (no intermediary)**

1. Identify relevant legislation
2. Check the scope
3. Product covered? Take action!



# Identify relevant legislation

- Noise - equipment for use outdoors – Directive 2000/14/EC
- Machinery – Directive 2006/42/EC
- Toy Safety - Directive 2009/48/EU
- Eco-design requirements for energy-related products - Directive 2009/125/EC
- Restriction of Hazardous Substances in Electrical and Electronic Equipment - Directive 2011/65/EU
- Construction products - Regulation (EU) No 305/2011
- Pyrotechnic Articles - Directive 2013/29/EU
- Recreational craft and personal watercraft - Directive 2013/53/EU
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- ATEX - Directive 2014/34/EU
- Radio equipment - Directive 2014/53/EU
- Low Voltage - Directive 2014/35/EU
- Pressure equipment - Directive 2014/68/EU
- Personal protective equipment - Regulation (EU) 2016/425
- Gas appliances - Regulation (EU) 2016/426

# Check the scope

## Article 2 of the Toy Safety - Directive 2009/48/EU

### *Article 2*

#### **Scope**

1. This Directive shall apply to products designed or intended, whether or not exclusively, for use in play by children under 14 years of age (hereinafter referred to as toys).

The products listed in Annex I shall not be considered as toys within the meaning of this Directive.

2. This Directive shall not apply to the following toys:

- (a) playground equipment intended for public use;
- (b) automatic playing machines, whether coin operated or not, intended for public use;
- (c) toy vehicles equipped with combustion engines;
- (d) toy steam engines; and
- (e) slings and catapults.

# Product is covered. Take action!

- Online direct sale to EU end-customer.
- No intermediary (no importer, no fulfilment service provider). Shipping from Israel.
- **Appointing an authorized representative in the EU is required!**

# Tips

- If your products requires CE-marking, chances are high it will be covered by the new Regulation.
- Practically all electronics are covered by the Low Voltage Directive.
- Multiple legislations may be applicable to one product!
- Don't forget to label your product (packaging) with the information on the responsible person.

# Conclusion

1. If you are selling directly to EU consumers without an intermediary in the EU
2. And your products fall within the scope of the Regulation (which might be the case if your product requires CE-marking)

You will need to appoint an authorized representative in order to continue selling to the EU, or you will need to contact your fulfilment service provider. Other options would be to find an importer in the EU, or to establish a subsidiary in the EU.

# Additional Information

- Draft Guidelines (available upon request)
- Israel Trade [Blog Post](#)
- '[Blue Guide](#)' on the implementation of EU product rules  
-> will be updated in the near future to reflect most recent changes
- Regulation (EU) [2019/515](#) (mutual recognition)
- Regulation (EU) [2019/1020](#) (market surveillance and compliance)





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# Thank You

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