



# **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**



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# 01





# INTRODUCTION

Regulation (EU) 2019/1020 on market surveillance and compliance of products<sup>1</sup> ('the Regulation') introduces a comprehensive framework to protect consumers from unsafe and non-compliant products and to provide a level playing field for economic operators.

The EU single market gives economic operators access to consumers and other end-users in all the Member States, provided they and their products meet EU legal requirements aimed at delivering safety, environmental performance and other public interests. Market surveillance authorities and the authorities in charge of controls on products entering the EU market<sup>2</sup> ('border authorities') have to verify and enforce those requirements. This can be challenging, especially for distance sales.

The new rules on market surveillance and product compliance should ensure compliance with the requirements. They help to create a level playing field, i.e. protect businesses manufacturing compliant products from unfair competition. They also spare market surveillance authorities from incurring undue costs in their investigations.

These guidelines concern the implementation of a key provision of the Regulation: Article 4 on the 'tasks of economic operators regarding products subject to certain Union harmonisation legislation' (see section 6). Article 4 requires in essence that for certain products placed on the EU market there must be an economic operator in the EU who on request provides the authorities with information or takes certain action. This will apply as from 16 July 2021 (Article 44 of the Regulation).

These guidelines provide guidance on how economic operators should implement Article 4:

- Section 2 explains its **scope** and **which economic operator** should act as the economic operator referred to in Article 4 for a given product;
- Section 3 clarifies the **tasks** of the economic operator referred to in Article 4; and

- Section 4 provides more detail on the **practical application** of Article 4 according to the type of economic operator acting as the economic operator referred to in Article 4.
- Further, as the aim of Article 4 is to facilitate the work of the **market surveillance and border authorities**, Section 5 sets out how the authorities can make use of this requirement in practice.

The guidelines are designed to help economic operators and authorities and facilitate consistent implementation. They concern the implementation of Article 4 only and do not apply to EU product legislation not covered by it, which may impose similar but different requirements<sup>3</sup>. They refer to requirements under EU harmonisation legislation as they apply at the date of adoption of this guidance. Comprehensive guidance on EU harmonisation legislation is available in the *Blue Guide*, to which these guidelines refer<sup>4</sup>. The Commission will update this guidance in the light of further legislative developments in other areas, like for instance the Digital Services Act<sup>5</sup>.

This document is purely for guidance — only the text of the Regulation itself has legal force. The guidelines reflect the views of the European Commission and as such are not legally binding. The binding interpretation of EU legislation is the exclusive competence of the Court of Justice of the European Union. The views expressed here cannot prejudice the position that the Commission might take before the Court of Justice. Neither the Commission nor anyone acting on its behalf is responsible for the use that might be made of the following information..

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<sup>1</sup> Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1).

<sup>2</sup> i.e. the authorities designated by Member States under Article 25(1) of the Regulation.

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<sup>3</sup> e.g. Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment (OJ L 257, 28.8.2014, p. 146), which requires in its Article 13 manufacturers not located in the EU to appoint an authorised representative, and Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59), which requires in its Article 4 the designation of a responsible person in the EU. These are not covered by Article 4 or by these guidelines.

<sup>4</sup> *Blue Guide on the implementation of EU product rules 2016* (OJ C 2016, 26.7.2016, p. 1) or its successor document.

<sup>5</sup> Proposal for a Regulation of the European Parliament and of the Council on a Single Market For Digital Services (Digital Services Act) and amending Directive 2000/31/EC – COM(2020)825 of 15.12.2020.

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# SCOPE AND APPLICATION

## 2.1 Scope

An economic operator referred to in Article 4 is required when a product:

- *falls within the scope of one or more of the Directives or Regulations listed in Article 4(5) or other legislation that makes explicit reference to Article 4.* This ‘sector-specific legislation’ covers the safety of toys, electrical equipment, radio equipment, electromagnetic compatibility, restricting hazardous substances in electrical and electronic equipment (‘RoHS’), energy-related products (‘ecodesign’), gas appliances, construction products, machinery, outdoor equipment (‘outdoor noise’), equipment for use in potentially explosive atmospheres (ATEX), pressure equipment, simple pressure vessels, pyrotechnic articles, recreational craft, measuring instruments, non-automatic weighing instruments, personal protective equipment and unmanned aircraft systems<sup>6</sup> (‘drones’)<sup>7</sup>; and
- *is placed on the EU market<sup>8</sup> – i.e. made available (supplied for distribution, consumption or use on the EU market in the course of a commercial activity, whether in return for payment or free of charge) for the first time on the Union market<sup>9</sup> – on or after 16 July 2021 (Article 4(1) and Article 44 of the Regulation).* Products offered for sale online, or through other means of distance sale, are considered to be made available on the market if the offer is targeted at end-users in the EU. An offer for sale is considered to be targeted at end users in the EU if the relevant economic operator directs, by any means, its activities to a Member State (Article 6 of the Regulation) (this is determined case by case in the light of relevant factors such as the geographical areas to which

dispatch is possible, the language(s) used for the offer or for ordering, means of payment, etc.<sup>10</sup>).

Thus, an economic operator who intends to place on the EU market on or after 16 July 2021 a product covered by Article 4 has first to ensure that there is an economic operator referred to in Article 4 in the EU. Otherwise, such products cannot be placed on the EU market on or after 16 July 2021.

## 2.2 Determination of the economic operator referred to in Article 4

Four types of economic operator can act as the economic operator referred to in Article 4:

- A manufacturer<sup>11</sup> established in the EU
- An importer<sup>12</sup> (by definition established in the EU), where the manufacturer is not established in the Union
- An authorised representative<sup>13</sup> (by definition established in the EU) who has a written mandate from the manufacturer designating the authorised representative to perform the tasks set out in Article 4(3) on the manufacturer’s behalf
- A fulfilment service provider<sup>14</sup> established in the EU where there is no manufacturer, importer or authorised representative established in the Union

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<sup>6</sup> As specified in Article 5(3) of Commission Delegated Regulation (EU) 2019/945 of 12 March 2019 on unmanned aircraft systems and on third-country operators of unmanned aircraft systems (OJ L 152, 11.6.2019, p. 1)

<sup>7</sup> Information on which Directives or Regulations might apply to a given product is available through YourEurope; [https://europa.eu/youreurope/business/product/product-rules-specifications/index\\_en.htm](https://europa.eu/youreurope/business/product/product-rules-specifications/index_en.htm)

<sup>8</sup> The geographical scope may be extended, e.g. once the Regulation is included in the annexes to the Agreement on the European Economic Area, it will include Iceland, Liechtenstein and Norway.

<sup>9</sup> See definitions (1) and (2) in Article 3 of the Regulation.

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<sup>10</sup> Recital 15 of the Regulation. See the Blue Guide for more detail on placing on the market (e.g. as regards timing, including for products for which manufacturing has not yet been completed at the time of the offer, and products for trade fairs).

<sup>11</sup> Defined in Article 3(8) of the Regulation as ‘any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under its name or trademark’.

<sup>12</sup> Defined in Article 3(9) of the Regulation as ‘any natural or legal person established within the Union who places a product from a third country on the Union market’.

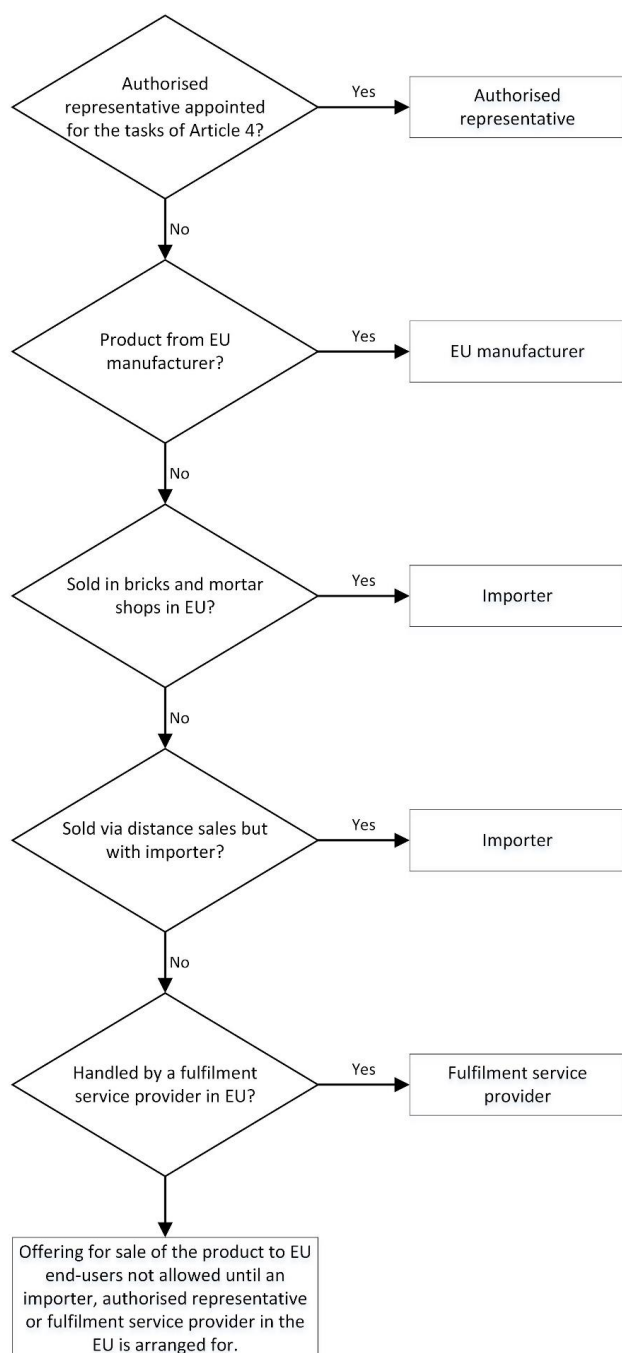
<sup>13</sup> Defined in Article 3(12) of the Regulation as ‘any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on its behalf in relation to specified tasks with regard to the manufacturer’s obligations under the relevant Union harmonisation legislation or under the requirements of this Regulation’.

<sup>14</sup> Defined in Article 3(11) of the Regulation as ‘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, excluding postal services as defined in point 1 of Article 2 of Directive 97/67/EC of the European Parliament and of the Council, parcel delivery services as defined in point 2 of Article 2 of Regulation (EU) 2018/644 of the European Parliament and of the Council, and any other postal services or freight transport services’.

Section 4 contains detail on these economic operators' role under sector-specific legislation and how this relates to their tasks under Article 4.

What economic operator acts as the economic operator referred to in Article 4 depends in particular on the supply chain. Box 1 provides a short guide on this and is followed by further explanation.

### Box 1: The economic operator referred to in Article 4 in different supply chains



Step 1: If the manufacturer (whether or not established in the EU) has mandated in writing an **authorised representative** to carry out the specific tasks under Article 4, that representative is the

economic operator referred to in Article 4. In other cases, it depends on the supply chain.

Step 2: Products from manufacturers established in the EU, whether sold online or in 'bricks and mortar' shops, are in general placed on the market by the EU manufacturer<sup>15</sup>. For such products, the **EU manufacturer** is the economic operator referred to in Article 4 (unless it has appointed an authorised representative for the tasks under Article 4).

Step 3: Products from manufacturers established outside the EU that are sold in 'bricks and mortar' shops in the EU are in principle placed on the EU market by an importer<sup>16</sup>. For such products, the **importer** is the economic operator referred to in Article 4 (unless the manufacturer has appointed an authorised representative for the tasks under Article 4). Section 4.2 explains what happens if there are multiple importers for the same type of product.

Step 4: For products from manufacturers established outside the EU offered for sale online (or through other distance sales), there may also be an importer, e.g. offering the product for sale online itself or selling it to a distributor who does so.

Step 5: If there is no importer but *a fulfilment service provider established in the EU is handling the product*, the **fulfilment service provider** is the economic operator referred to in Article 4 (unless the manufacturer has appointed an authorised representative for the tasks under Article 4). Unlike importers and authorised representatives, fulfilment service providers do not automatically have a formal connection with the manufacturer enabling them to fulfil the tasks of the economic operator referred to in Article 4. Therefore, they will need to make arrangements with economic operators to whom they are providing fulfilment services ('clients') to ensure

<sup>15</sup> The manufacturer is defined by Article 3 of the Regulation as "any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under its name or trademark". The importer is defined as "any natural or legal person established within the Union who places a product from a third country on the Union market". This implies that if the product is manufactured outside the EU, but a company located in the EU markets it under its name or trademark, that company is considered to be the manufacturer. And if that manufacturer places the product on the EU market, even if actual importation is done by another company, there is no 'importer' within the meaning of the Regulation.

<sup>16</sup> Except where the manufacturing takes place in the EU, while the manufacturer is not established in the EU. In such case, there is no manufacturer in the EU, nor an importer thus leaving only the options of authorised representative or fulfilment service provider as economic operator referred to in Article 4.

that they first receive from the client, or directly from the manufacturer, the means to fulfil their obligations as the economic operator referred to in Article 4 (see Section 4.4);

Step 6: Where *the product is being shipped from outside the EU directly to an end-user in the EU*, if an **authorised representative** has been mandated in writing for the specific tasks under Article 4, it is the economic operator referred to in Article 4. If the manufacturer has not appointed an authorised representative, the product may not be offered for sale to EU end-users. The economic operator planning to offer the product for sale<sup>17</sup> to EU end-users will need to ensure that the manufacturer appoints an authorised representative for that product (see Box 2).

**Box 2: The perspective of an economic operator based outside the EU who plans to offer products for sale online to EU consumers or other end-users: How do I arrange for an economic operator referred to in Article 4? (example)**

- First, verify that the products are meant for the EU market and comply with EU legislation. If in doubt, contact the manufacturer.
- If this is in order, check with the manufacturer whether it has already appointed an authorised representative for these products.
- If so, make sure the authorised representative's name and contact details are indicated as required (see Section 2.3).
- If not, explore (in cooperation with the manufacturer) the following avenues:
  - if you intend to offer the products for sale on an online marketplace (see Section 2.4), does that marketplace offer authorised representative or fulfilment services?
  - if you already sell products for which an authorised representative in the EU or similar entity is required (e.g. cosmetics, medical devices and marine equipment), would that entity be interested to be an authorised representative for your products covered by Article 4?
  - are there relevant trade associations that (could) have access to information on existing authorised representatives (as a number of manufacturers of

products covered by Article 4 may already have an authorised representative in the EU)?

- When you have found a potential authorised representative, make sure that the manufacturer authorises it to perform the required tasks (see Sections 3 and 4.3). Then make sure the representative's name and contact details are indicated as required (see Section 2.3).
- Where a fulfilment service provider is to act as economic operator referred to in Article 4, make practical arrangements, in particular ensuring that it receives the declaration of conformity/performance for the products in question. Then make sure its name and contact details are indicated as required (see Section 2.3)

**2.3 Information on the economic operator referred to in Article 4**

The **name** (or registered trade name/trademark) **and contact details** (including postal address) of the economic operator referred to in Article 4 must be indicated on at least one of the following (Article 4(4) of the Regulation):

- the product;
- its packaging, i.e. the sales packaging;
- the parcel, i.e. packaging to facilitate handling and transport;
- an accompanying document, e.g. declaration of conformity/performance<sup>18</sup>.

NB: If the economic operator referred to in Article 4 is an EU manufacturer or an importer, this information is normally already required under sector-specific legislation (see Section 4). Those requirements may be more restrictive as to the place where the information is indicated, and have to be complied with.

A **website address** may be given in addition to, but not instead of, a postal address (normally made up of a street/postbox, building number, postcode and town). Also, it is useful to include an email address and/or phone number to facilitate swift contacts with the relevant authorities.

It is possible that **multiple economic operators'** names and contact details are indicated on or with the

<sup>17</sup> Not be confused with an entity merely hosting the offer for sale online; for those, see Section 2.4.

<sup>18</sup> An indication in the (electronic) customs declaration is not sufficient, as this does not physically accompany the product.



product. While there may be no explicit requirement that these be preceded by 'manufactured by', 'imported by', 'represented by' or 'fulfilled by', the information should not mislead the market surveillance authorities. Where the operators' roles are not specified, the authorities will have to determine them themselves. Each economic operator should be able to prove its role. There is no obligation to translate the English terms 'manufactured by', 'imported by', 'represented by' or 'fulfilled by'; these English terms are considered easily understandable throughout the EU.

The name and contact details of the economic operator referred to in Article 4 have to be present when the product is declared for free circulation at **customs** (Article 26(1)(d) of the Regulation). Therefore, in case the product is aimed for release for free circulation in the EU and no further processing on the product is foreseen after its shipment<sup>19</sup>, economic operators outside the EU offering products for sale should make sure that they are indicated in the way described above, adding them (or having them added) prior to shipping if necessary.

## 2.4 Products sold through online marketplaces

An online marketplace is a type of e-commerce service where products are offered for sale by multiple economic operators<sup>20</sup>. It allows economic operators on the one side, and end users on the other side, to conclude sales transactions of products.

Article 4 applies to products sold through online marketplaces.

It places no specific obligation on the online marketplaces where they are merely providing

intermediary services to third-party sellers and fall within the scope of Article 2(b) of Directive 2000/31<sup>21</sup>. In the situation where an online marketplace intermediates the offer for sale to the EU end users of a product covered by Article 4 for which there is no economic operator referred to in Article 4<sup>22</sup> and obtains actual knowledge or awareness of illegal content (e.g. by means of a sufficiently precise and adequately substantiated notice from a market surveillance authority), that online marketplace can only rely on the liability exemption laid down in Article 14(1) of Directive 2000/31/EC, if upon obtaining such knowledge or awareness, it acts expeditiously to remove or to disable access to the illegal content in question.

Where an online marketplace is also a manufacturer, importer, authorised representative or fulfilment service provider, it could be the economic operator referred to in Article 4.



<sup>19</sup> Recital 53 of the Regulation reminds that Articles 220, 254, 256, 257 and 258 of Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1) provide that products entering the EU market that require further processing in order to be in compliance with the applicable EU harmonisation legislation shall be placed under the appropriate customs procedure allowing such processing by the importer.

<sup>20</sup> Article 4(1)(f) of Regulation (EU) No 524/2013 of the European Parliament and of the Council of 21 May 2013 on online dispute resolution for consumer disputes and amending Regulation (EC) No 2006/2004 and Directive 2009/22/EC (Regulation on consumer ODR) (OJ L 165, 18.6.2013, p. 1–12) defines an 'online marketplace' as follows: 'a service provider, as defined in point (b) of Article 2 of Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce'), which allows consumers and traders to conclude online sales and service contracts on the online marketplace's website'.

<sup>21</sup> Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (OJ L 178, 17.7.2000, p. 1).

<sup>22</sup> This falls under 'illegal activity or information' referred to in Article 14(1)(a) of Directive 2000/31/EC, because it does comply with Article 4 of the Regulation.

03



# TASKS OF THE ECONOMIC OPERATOR REFERRED TO IN ARTICLE 4

This section categorises and provides guidance on the tasks of the economic operator referred to in Article 4. That economic operator, especially if it is an EU manufacturer or importer, may already have obligations under sector-specific legislation (depending on how it is classified) that fully or partly cover those tasks (see Section 4).



First, in accordance with Article 4(3)(a), the economic operator referred to in Article 4 has to perform a number of tasks when it **takes up its duties** or when **a new product** is added to its portfolio:

- verify that the declaration of conformity/performance has been drawn up and keep it – all sector-specific legislation covered by Article 4 requires such declarations<sup>23</sup>. As specified in the legislation covered by Article 4, they have to be kept for 10 years after the product has been placed on the market<sup>24</sup>. Where more than one legislative act applies to a product, a single declaration conformity is drawn up for all applicable acts together<sup>25</sup>; and
- verify that the technical documentation has been drawn up<sup>26</sup> and ensure that it can be made available to market surveillance authorities on

request – where the economic operator referred to in Article 4 does not keep the documentation itself, this implies checking that the documentation exists and obtaining assurances from the manufacturer that it will share it on request, either with the economic operator referred to in Article 4 or with the market surveillance authorities directly (see below).

Second, in accordance with Article 4(3)(c) and (d), where the economic operator referred to in Article 4 has reason to believe that a product presents a **risk**<sup>27</sup>, it must:

- inform the relevant market surveillance authorities. It should do this in each Member State in which the product has been made available<sup>28</sup>; it is also important to inform them of the corrective action that has been or will be taken; and
- make sure that the necessary corrective action is taken immediately to remedy any case of non-compliance or, if that is not possible, to mitigate the risk (see below).

Finally, in accordance with Article 4(3)(a), (b) and (d), the economic operator referred to in Article 4 must take certain action **when asked** to do so by a market surveillance authority:

- provide that authority with the declaration of conformity/performance;
- provide the authority with the technical documentation or, where the economic operator referred to in Article 4 does not keep this

<sup>23</sup> The declaration of performance for construction products; the declaration of conformity for others.

<sup>24</sup> Legislation on outdoor noise, machinery, and ecodesign specify 10 years from the last date of manufacture.

<sup>25</sup> Article 5 of Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products (OJ L 218, 13.8.2008).

<sup>26</sup> All the legislation covered by Article 4 requires the manufacturer to draw up the technical documentation.

<sup>27</sup> Article 3(19) of the Regulation defines 'product presenting a risk' as 'a product having the potential to affect adversely health and safety of persons in general, health and safety in the workplace, protection of consumers, the environment, public security and other public interests, protected by the applicable Union harmonisation legislation, to a degree which goes beyond that considered reasonable and acceptable in relation to its intended purpose or under the normal or reasonably foreseeable conditions of use of the product concerned, including the duration of use and, where applicable, its putting into service, installation and maintenance requirements'.

<sup>28</sup> For contact information, see:

[https://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation\\_en](https://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation_en)



documentation, ensure that the technical documentation is provided to the authority (in particular by the manufacturer);

- provide other information and documentation to demonstrate the conformity of the product (this may include e.g. certificates and decisions from a notified body) in a language that can be easily understood by the authority (to be negotiated with the authority – this could be a language other than the national language(s));
- cooperate with the authority. The action required will depend on the authority's request, which has to be in accordance with the principle of proportionality (Article 14(2) of the Regulation); and
- make sure that the necessary corrective action is taken immediately to remedy any non-compliance with the EU harmonisation legislation applicable to the product in question or, if that is not possible, to mitigate the risks presented by the product. The action could involve bringing the product into conformity, withdrawing it or recalling it, as appropriate<sup>29</sup>. The economic operator referred to in Article 4 does not have to take corrective action or mitigate the risk itself if that economic operator is not obliged to do so under the sector-specific legislation, but must ensure that action is taken, e.g. by asking the manufacturer to respond to the request and verifying that it has done so.

The economic operator referred to in Article 4 should act within a **reasonable timeframe** or within any deadline set by the market surveillance authorities. It should provide the declaration of conformity/performance without delay and other documents within a reasonable period of time<sup>30</sup>.

If the economic operator referred to in Article 4 finds that it **cannot fulfil one or more of its tasks** due to a problem in its relations with the manufacturer<sup>31</sup> (e.g. the manufacturer does not respond to a request), an appropriate follow-up would be to remind the manufacturer of its obligations under EU legislation. If the problem persists, the logical consequence could be

for it to take the necessary measures to cease being the economic operator referred to in Article 4 for the products in question, on the basis that it is unable to carry out its tasks under Article 4. In other words, in the case of:

- *an importer* – it could no longer place the products on the market;
- *an authorised representative* – it could try to end its relationship with the manufacturer;
- *a fulfilment service provider* – it could no longer handle the products, i.e. not dispatch them to end-users.



The economic operator referred to in Article 4 can be **sanctioned**<sup>32</sup> if it does not fulfil its tasks under Article 4. Any penalties must be effective, proportionate and dissuasive (Article 41(2) of the Regulation). The manufacturer remains responsible for the compliance of the product with sector-specific legislation and (like other actors in the supply chain) retains any legal obligations it has as regards products, guarantees, liability for defective products, etc. Article 4 does not impose additional legal obligations *vis-à-vis* consumers or other end-users.

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<sup>29</sup> These options are specifically referred to in most sector-specific legislation for the manufacturer and importer; further potential corrective actions are listed in Article 16 of the Regulation.

<sup>30</sup> Some sector-specific legislation (e.g. on toy safety and ecodesign) contains more detailed provisions on the timeliness with which certain economic operators are to provide the market surveillance authorities with certain documentation. These continue to apply.

<sup>31</sup> Or if a fulfilment service provider is hampered by a problem with its client or between its client and the manufacturer.

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<sup>32</sup> Article 41(1) of the Regulation requires Member States to lay down rules on penalties in relation to this and certain other provisions of the Regulation.

04



# PRACTICAL IMPLICATIONS FOR ECONOMIC OPERATORS

The tasks of the economic operator referred to in Article 4 (as described in Article 4) are the same regardless of what type of economic operator is performing them, but the extent to which they overlap with the economic operator's other tasks under sector-specific legislation differs. All the 'Article 4 obligations' apply, regardless of what the sector-specific legislation requires of the economic operator in question. There are some sectoral differences, but most of the legislation closely follows the model legal provisions on economic operators' obligations<sup>33</sup>. This section highlights differences that affect the implementation of Article 4.

## 4.1 Manufacturers established in the EU

A manufacturer is a natural or legal person that manufactures a product or has a product designed or manufactured, and markets that product under its name or trademark (Article 3 of the Regulation)<sup>34</sup>. If established in the EU, it is in principle the economic operator referred to in Article 4, unless it has appointed an authorised representative for the specific tasks under Article 4.

Manufacturers established in the EU already have responsibilities under sector-specific legislation that in general overlap with and go beyond the obligations under Article 4(3). An exception is that – unlike Article 4 – EU legislation on outdoor noise, machinery and ecodesign does not explicitly require them to inform the market surveillance authorities where they have reason to believe that a product covered by such legislation presents a risk. Manufacturers established in the EU and who are the economic operator referred to in Article 4 will however have to do this for the products covered by these legislative acts.

Most sector-specific legislation requires that the manufacturer's name/trademark and address are indicated on the product; however:

- for some sectors, that information can in certain circumstances be indicated on the packaging or in an accompanying document instead;
- ecodesign legislation contains no such requirement;
- the legislation on outdoor noise and machinery requires instead that the name and address be indicated in the declaration of conformity<sup>35</sup> (or in the declaration of incorporation, in the case of partly completed machinery<sup>36</sup>) and that the declaration accompany the product<sup>37</sup>.

Therefore, in the exceptional case of a product covered by ecodesign legislation but not by the other sector-specific legislation covered by Article 4, Article 4 requires manufacturers established in the EU and who are the economic operator referred to in Article 4 to take the additional action of indicating their name and contact details.

## 4.2 Importers

An importer is a natural or legal person established in the EU that places a product from a third country on the EU market (Article 3 of the Regulation). If there is an importer in the EU, it is in principle the economic operator referred to in Article 4, unless the manufacturer has appointed an authorised representative for the specific tasks under Article 4.

Sector-specific legislation in general imposes on the importer obligations that overlap with and go beyond the obligations laid down in Article 4(3)<sup>38</sup>. Again, an exception is that – unlike Article 4 – EU legislation on outdoor noise, machinery and ecodesign does not

<sup>33</sup> As laid down in Decision No 768/2008/EC; the *Blue Guide* provides further guidance on economic operators' obligations.

<sup>34</sup> Some sector-specific legislation contains a different definition of manufacturer. In particular, Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products (OJ L 285, 31.10.2009, p. 10) omits the 'or has a product designed or manufactured'.

<sup>35</sup> Annex II to Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors (OJ L 162, 3.7.2000, p. 1) and Part I.A.1 of Annex II to Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery (OJ L 157, 9.6.2006, p. 24), respectively.

<sup>36</sup> Part I.B.1 of Annex II to Directive 2006/42/EC

<sup>37</sup> Article 4(1) of Directive 2000/14/EC and Article 5(1)(e) of Directive 2006/42/EC, respectively.

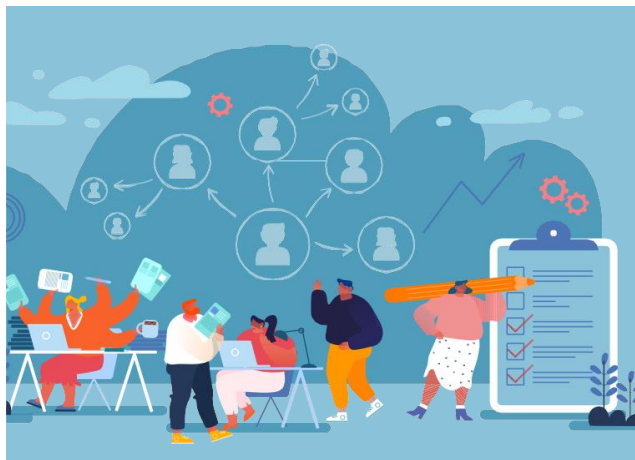
<sup>38</sup> EU legislation on outdoor noise (Article 4(2) of Directive 2000/14/EC) and machinery (Article 2(i) of Directive 2006/42/EC) does not use the term 'importer', but refers to 'any [other] person placing [the product] on the market'.



explicitly require importers to inform the market surveillance authorities where they have reason to believe that a product covered by such legislation presents a risk. Importers of products falling under that legislation and who are the economic operator referred to in Article 4 will however have to do this for the products covered by these legislative acts.

The sector-specific provisions on indicating the importer's name and contact details on or with the product are largely the same as for the manufacturer (see above). Therefore, only in exceptional cases does Article 4 require the importer who is the economic operator referred to in Article 4 to take the additional action of indicating its name and contact details.

Where multiple importers handle the same type of product, each is the economic operator referred to in Article 4 for the units it has placed on the EU market and will have to ensure that its name appears on or with those units, as required. This is already the case under sector-specific legislation where there are multiple importers for the same type of product. An individual product should thus in principle only bear the name of the relevant importer.



### 4.3 Authorised representatives

An authorised representative is a natural or legal person established in the EU that 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 (EU) 2019/1020 (Article 3 of the Regulation). If a manufacturer wants an authorised representative to act as the economic operator referred to in Article 4, it must ensure that the mandate includes all the tasks listed in Article 4(3). The authorised representative must have the appropriate means to be able to fulfil its tasks (Article 5(3) of the Regulation).

Sector-specific legislation often allows for the appointment of an authorised representative<sup>39</sup>. Where that option is taken up, it generally requires that the representative be mandated to do at least the following:

- keep the declaration of conformity/performance and the technical documentation at the disposal of the national market surveillance authorities for a specified period (in general 10 years in the case of the sector-specific legislation covered by Article 4);
- following a reasoned request, provide a competent national authority with all the information and documentation needed to demonstrate the conformity of a product; and
- cooperate with the competent national authorities, at their request, on any action to eliminate the risks posed by products<sup>40</sup> covered by its mandate.

Exceptions to this can be found in the legislation on outdoor noise, machinery and ecodesign, under which the authorised representative has different tasks, closer to those of the manufacturer.

Where a manufacturer has appointed an authorised representative under sector-specific legislation and wants it to act as the economic operator referred to in Article 4, it will therefore have to review its mandate to ensure that it includes all the tasks listed in Article 4(3). In particular, it may have to add tasks to be performed where the representative has reason to believe that a product presents a risk.

Similarly, where a manufacturer is planning to appoint an authorised representative with a view to facilitating compliance with Article 4, and where it wants to appoint an authorised representative within the framework of the sector-specific legislation, it will have to check the applicable sector-specific legislation for possible tasks in addition to those required by Article 4.

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<sup>39</sup> Except that for pyrotechnic articles. However, by virtue of Articles 4 and 5 of the Regulation, an authorised representative can be appointed for pyrotechnic articles; in that case its tasks will be those listed in Article 4.

<sup>40</sup> In the case of legislation on RoHS, on any action taken to ensure compliance (Article 8(b) of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011)), and in the case of legislation on drones, on any action to eliminate the non-conformity or the safety risks (Article 7(2)(c) of Commission Delegated Regulation (EU) 2019/945 of 12 March 2019 on unmanned aircraft systems and on third-country operators of unmanned aircraft systems (OJ L 152, 11.6.2019, p. 1)

In addition to the tasks listed in Article 4(3), the authorised representative must also, on request, provide a market surveillance authority with a copy of its mandate in an EU language determined by the authority (Article 5(2) of the Regulation).

The legislation on outdoor noise, machinery and construction products requires that the authorised representative's name and contact details be indicated in the declaration of conformity/performance<sup>41</sup> that has to accompany these products<sup>42</sup>. In many other sectors, the legislation requires the manufacturer to indicate a contact address on or with the product; that address could be that of the authorised representative. Where the name and contact details of an authorised representative who is the economic operator referred to in Article 4 are not yet indicated on or with the product, the economic operator placing the product on the EU market should make sure these are added as required (for a smoother process, it could ask the manufacturer to do this systematically).

#### 4.4 Fulfilment service providers established in the EU



A fulfilment service provider is a natural or legal person offering at least two of the following services in the course of commercial activity, without having ownership of the products involved:

- warehousing;
- packaging
- addressing; and
- dispatching.

The qualifying services do not include postal services<sup>43</sup>, parcel delivery services<sup>44</sup> or any other postal or freight transport services (Article 3 of the Regulation).

Fulfilment service providers normally warehouse products in the EU, so that they can be swiftly delivered to EU consumers or other end-users as soon as they are ordered online. Thus, they provide services to other economic operators. On receiving an order, they package the product (unless it is already properly packaged for transport), affix the delivery address and dispatch it, either handing it over to a postal, parcel or transport service or delivering it themselves.

There is a wide range of operating scenarios for fulfilment services, but as described here they go beyond those of postal/parcel service providers (i.e. clearance and the sorting, transport and delivery of parcels). Where a natural or legal person offers both fulfilment services and postal/parcel delivery or freight transport services, Article 4 could be of relevance only in respect of the products handled by its fulfilment services.

Fulfilment service providers established in the EU are the economic operator referred to in Article 4 for products they handle in cases where there is no manufacturer, importer or authorised representative in the EU for those products. Therefore, before agreeing to provide the fulfilment service for a product covered by Article 4, they should verify with their client whether there is already one of the other types of economic operator in the EU for that product. If not, they will be the economic operator referred to in Article 4.

The sector-specific legislation does not refer to fulfilment service providers. Therefore, when acting as the economic operator referred to in Article 4, they will need to make arrangements with their clients to ensure that, before agreeing to provide the service, they receive from the client, or directly from the manufacturer, the means to fulfil the obligations, in particular:

- the declaration of conformity/performance for the products in question; and

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<sup>41</sup> Annex II to Directive 2000/14/EC, Part 1.A.1 of Annex II to Directive 2006/42/EC, and Annex III to Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products (OJ L 88, 4.4.2011, p. 5), respectively.

<sup>42</sup> Article 4(1) of Directive 2000/14/EC, Article 5(1)(e) of Directive 2006/42/EC, and Article 7 of Regulation (EU) No 305/2011, respectively.

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<sup>43</sup> As defined in Article 2(1) of Directive 97/67/EC of the European Parliament and of the Council of 15 December 1997 on common rules for the development of the internal market of Community postal services and the improvement of quality of service (OJ L 15, 21.1.1998, p. 14).

<sup>44</sup> As defined in Article 2(2) of Regulation (EU) 2018/644 of the European Parliament and of the Council of 18 April 2018 on cross-border parcel delivery services (OJ L 112, 2.5.2018, p. 19).

- assurances of cooperation to help them carry out other tasks, such as:
  - providing technical documentation; and
  - taking corrective action when requested by the authorities.

The client should make sure that the service provider's name and contact details are indicated on or with the product, unless the manufacturer has already done so. The client can do this itself or have someone do it for them before the product is declared for free circulation at customs (see Section 2.3).

As with importers, there can be multiple fulfilment service providers for a given type of product. Each is the economic operator referred to in Article 4 for, and will have to have its name and contact details on or with, the units that it handles.

The manufacturer can appoint a fulfilment service provider as its authorised representative. In such cases, the parts of these guidelines concerning authorised representatives are relevant instead.



### **Box 3: I am a fulfilment service provider in the EU – what do I do? (example)**

A practical checklist would include the following:

- make existing and potential clients aware that, if any products covered by Article 4 they are selling must be linked to an economic operator referred to in Article 4. Point them to Article 4 and these guidelines;
- indicate to clients that you will be the economic operator referred to in Article 4 if there is no manufacturer, importer or authorised representative established in the EU (or, if you do not want to, make this clear and indicate that they cannot use your fulfilment services for those products unless there is a manufacturer, importer or authorised representative in the EU);
- if clients want you to act as the economic operator

referred to in Article 4, check whether you are already performing this role for the same type of product for another client – if so, you already have everything you need; if not, decide the extent to which you will arrange what you need and the extent to which you want the client to do this for you;

- tell clients who want you to act as the economic operator referred to in Article 4 what they have to do before they can start using your fulfilment services, e.g. provide the manufacturer's contact details, declarations of conformity/performance, etc.;
- inform the clients once all arrangements have been made for you to act as the economic operator referred to in Article 4, so that they can start offering the products for sale.



05



# MARKET SURVEILLANCE AND CONTROLS ON PRODUCTS ENTERING THE EU MARKET

## 5.1 Market surveillance

Market surveillance authorities have to perform appropriate checks on the characteristics of products on an adequate scale (Article 11(3) of the Regulation). In deciding what checks to perform, on which types of product and on what scale, they have to follow a risk-based approach (Ibid.) designed to achieve the greatest impact on the market.

After deciding what products to check, they may need to ask for **compliance documentation**. The economic operator referred to in Article 4 helps them obtain this information by facilitating their contact and cooperation with the manufacturer. Market surveillance authorities can contact the economic operator referred to in Article 4 directly even if it is located in another Member State<sup>45</sup>. They should be specific about the type of documents they need and the products for which they need them.

In the case of online or other distance sales where market surveillance authorities want to check compliance documentation without or before checking the product, they may not have the name and contact details of the economic operator referred to in Article 4. In such cases, they can contact the economic operator (as defined in Article 3 of the Regulation) offering the product for sale to ask for this<sup>46</sup>.

The economic operator referred to in Article 4 will serve as a contact to resolve **questions or problems** that go beyond documentation (Article 4(3)(d) of the Regulation). In such cases, the authorities should make it clear what they expect of it.

The market surveillance authorities could contact the economic operator referred to in Article 4 on an issue

that is relevant to the manufacturer whose product(s) are dealt with by it, but that does not specifically fall within the scope of Article 4, i.e. an issue that concerns legislation or products not covered by Article 4. Although Article 4 does not specifically provide for such requests, the economic operator referred to in Article 4 is encouraged to facilitate contacts between the authorities and manufacturers for these purposes.

## 5.2 Controls on products entering the EU market

Border authorities have a duty to control products entering the EU. They do so on the basis of risk analysis. When they perform physical checks on products covered by Article 4, it is recommended that they verify whether the name and contact details of the economic operator referred to in Article 4 are indicated on the product, the packaging, the parcel or any accompanying document (Article 4(4) of the Regulation). If this is not the case or they have cause to believe that for another reason the product does not comply with Article 4<sup>47</sup>, they should suspend the release for free circulation, notify the market surveillance authorities (Article 26 of the Regulation) and await their reaction.

## 5.3 Non-compliance with Article 4



Given that the aim of Article 4 is mainly to facilitate checks on compliance documents, the absence of the name and contact details of the economic operator referred to in Article 4 is problematic, as it hampers

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<sup>45</sup> If a market surveillance authority has difficulty in doing so, it can request assistance from an authority in the other Member State through the procedures and under the conditions laid down in Chapter VI of the Regulation.

<sup>46</sup> In accordance with Article 7(1) of the Regulation, economic operators (as defined in Article 3) have an obligation to cooperate with market surveillance authorities regarding certain actions. Recital 24 of the Regulation states that this includes providing the contact information of the economic operator with tasks regarding products subject to certain Union harmonisation legislation where requested by authorities and where this information is available to them.

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<sup>47</sup> For example, where the name and contact details of the economic operator referred to in Article 4 are indicated on or with a product, but they find, in the course of their control, that these are false, e.g. the address does not exist or no such operator exists at the address.

market surveillance. It is also an indication that the product may not be meant for the EU market and/or may not comply with EU rules.

Therefore, where market surveillance authorities find, in the course of their investigations, that the name and contact details of the economic operator referred to in Article 4 are missing, they should require the relevant economic operator<sup>48</sup> to take corrective action. They also have the power to impose penalties (Article 14(4)(i) of the Regulation).

The same applies where the name and contact details of the economic operator referred to in Article 4 are indicated on or with a product, but the authorities find, in the course of their investigation, that these are false, e.g. the address does not exist or no such operator exists at the address.

The requirement to indicate the name and contact details of the economic operator referred to in Article 4 is not intended as the main object of an investigation. However, market surveillance authorities could take specific action in this area in the context of awareness-raising on it, possibly through EU-wide joint actions.

As mentioned in Section 3, the economic operator referred in Article 4 itself can be sanctioned if it does not comply with its obligations, and in particular if it does not cooperate (Article 41(1) of the Regulation). Any penalties have to be effective, proportionate and dissuasive (Article 41(2) of the Regulation).

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<sup>48</sup> Normally, the manufacturer (unless, for example, the manufacturer did not intend for the products to be placed on the EU market, but another economic operator nevertheless did so). This will be possible only if the manufacturer can be identified, along with its contact information.



06



# TEXT OF THE PROVISION

## 'ARTICLE 4

### **Tasks of economic operators regarding products subject to certain Union harmonisation legislation**

1. Notwithstanding any obligations set out in applicable Union harmonisation legislation, a product subject to legislation referred to in paragraph 5 may be placed on the market only if there is an economic operator established in the Union who is responsible for the tasks set out in paragraph 3 in respect of that product.
2. For the purposes of this Article, the economic operator referred to in paragraph 1 means any of the following:
  - (a) a manufacturer established in the Union;
  - (b) an importer, where the manufacturer is not established in the Union;
  - (c) an authorised representative who has a written mandate from the manufacturer designating the authorised representative to perform the tasks set out in paragraph 3 on the manufacturer's behalf;
  - (d) a fulfilment service provider established in the Union with respect to the products it handles, where no other economic operator as mentioned in points (a), (b) and (c) is established in the Union.
3. Without prejudice to any obligations of economic operators under the applicable Union harmonisation legislation, the economic operator referred to in paragraph 1 shall perform the following tasks:
  - (a) if the Union harmonisation legislation applicable to the product provides for an EU declaration of conformity or declaration of performance and technical documentation, verifying that the EU declaration of conformity or declaration of performance and technical documentation have been drawn up, keeping the declaration of conformity or declaration of performance at the disposal of market surveillance authorities for the period required by that legislation and ensuring that the technical documentation can be made available to those authorities upon request;
  - (b) further to a reasoned request from a market surveillance authority, providing that authority with all information and documentation necessary to demonstrate the conformity of the product in a language which can be easily understood by that authority;
  - (c) when having reason to believe that a product in question presents a risk, informing the market surveillance authorities thereof;
  - (d) cooperating with the market surveillance authorities, including following a reasoned request making sure that the immediate, necessary, corrective action is taken to remedy any case of non-compliance with the requirements set out in Union harmonisation legislation applicable to the product in question, or, if that is not possible, to mitigate the risks presented by that product, when required to do so by the market surveillance authorities or on its own initiative, where the economic operator referred to in paragraph 1 considers or has reason to believe that the product in question presents a risk.
4. Without prejudice to the respective obligations of economic operators under the applicable Union harmonisation legislation, the name, registered trade name or registered trademark, and contact details, including the postal address, of the economic operator referred to in paragraph 1 shall be indicated on the product or on its packaging, the parcel or an accompanying document.
5. This Article only applies in relation to products that are subject to Regulations (EU) No 305/2011, (EU) 2016/425 and (EU) 2016/426 of the European Parliament and of the Council, and Directives 2000/14/EC, 2006/42/EC, 2009/48/EC, 2009/125/EC, 2011/65/EU, 2013/29/EU, 2013/53/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and 2014/68/EU of the European Parliament and of the Council.'

