



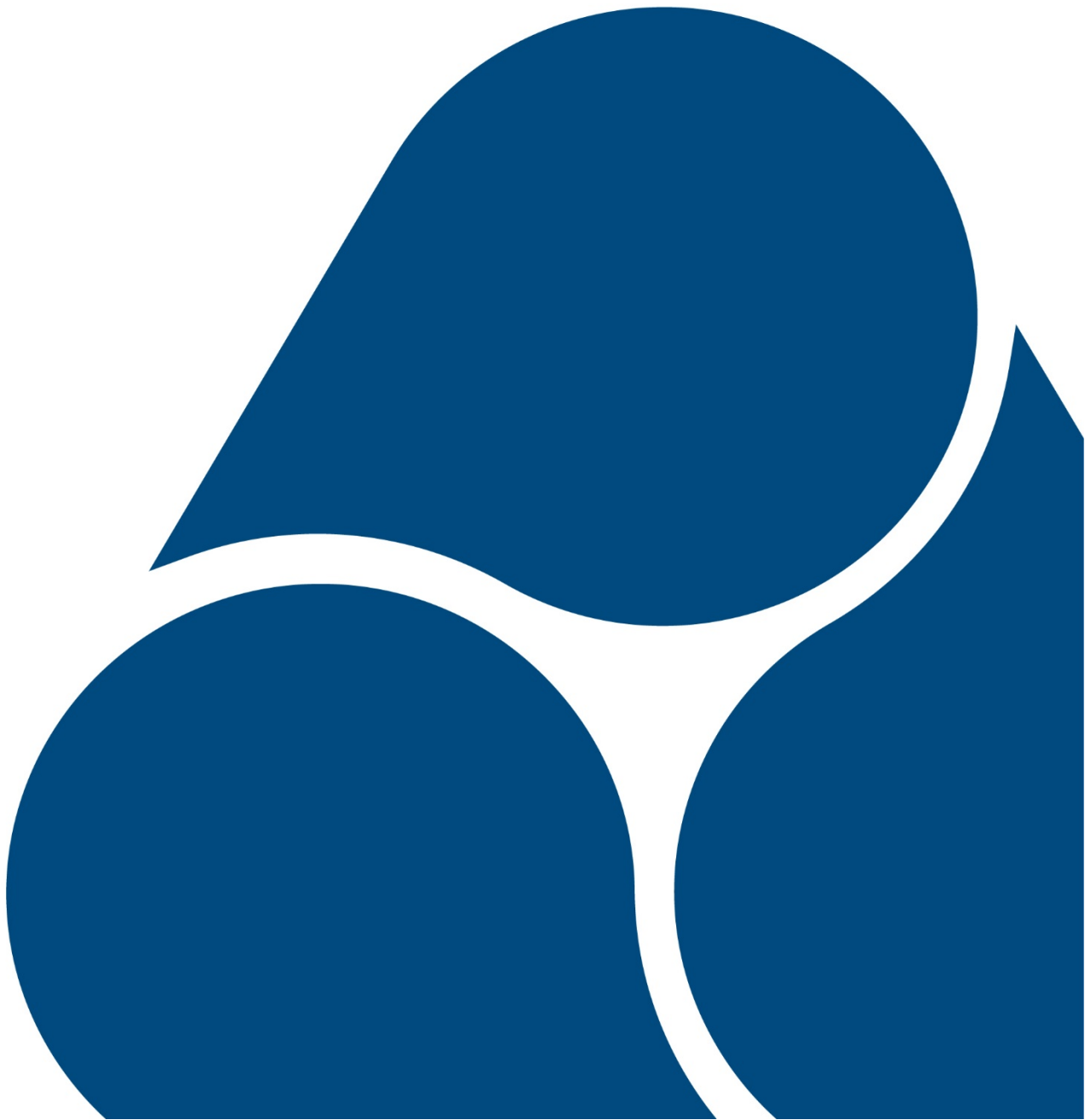
Office for Product
Safety & Standards

EU Regulation on Market Surveillance and Compliance of Products (2019/1020)

Having a responsible economic operator for compliance
(Article 4)

**Guidance for businesses who place certain products on
the Northern Ireland market from 16 July 2021**

June 2021



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Guidance

1. Introduction

From 16 July 2021, the EU Regulation on Market Surveillance and Compliance of Products 2019/1020 (EU Regulation on Market Surveillance) applies in EU Member States. It replaces the market surveillance provisions in the Regulation on Accreditation and Market Surveillance 765/2008 (RAMS)¹.

For the duration of the Northern Ireland Protocol² ('the Protocol'), EU rules relating to goods will apply in Northern Ireland (NI), including the EU Regulation on Market Surveillance. Although it is a new Regulation, it replaces an existing obligation which forms part of the Protocol. It does not apply in Great Britain (GB) where RAMS (as retained in UK law and applicable in GB) continues to apply.

Article 4 of the EU Regulation on Market Surveillance requires that for certain products to be placed on the EU market, there must be an economic operator based in the EU responsible for compliance tasks. Otherwise these products cannot be placed on the EU market. For the duration of the Protocol, Article 4 applies to the NI market.

This guidance sets out how Article 4 applies to the NI market. There are various ways to meet the requirements of Article 4, and most UK businesses will likely have sufficient arrangements in place. If adjustments are needed, this guidance outlines what to do.

This guidance is particularly relevant to those who sell products online directly to consumers in NI (rather than via bricks and mortar shops).

The European Commission has also published [guidelines on the practical implementation of Article 4 in the EU](#).

Enforcement of the EU Regulation on Market Surveillance will continue to be proportionate, risk-based and intelligence-led, minimising disruption to business. Regulatory checks on goods entering NI will continue to take place by exception, and only where there is a high level of risk. The vast majority of regulatory activity will continue to take place away from points of entry after goods have been placed on the market.

2. What businesses need to do

Article 4 sets out that certain products can only be placed on the NI market if there is a responsible economic operator established in NI (or the EU) to fulfil certain compliance tasks.

There are various ways to meet the requirements of Article 4, and most UK businesses will likely have sufficient arrangements in place.

¹ The accreditation provisions in RAMS continue to directly apply in NI.

² The Protocol on Ireland/Northern Ireland (also known as 'The Northern Ireland Protocol' and referred to in this document as 'the Protocol').

2.1 When does Article 4 apply?

Article 4 applies to products subject to regulations for the following³:

- ATEX
- Construction products
- Eco-design
- Electromagnetic capability
- Gas appliances
- Low voltage electrical equipment
- Machinery
- Measuring instruments
- Non-automatic weighing instruments
- Outdoor machinery ('outdoor noise')
- Personal Protective Equipment
- Pressure equipment
- Pyrotechnics
- Radio equipment
- Recreational craft
- Restricting hazardous substances in electrical and electronic equipment ('RoHS')
- Simple pressure vessels
- Toys

A product is placed on the market when it is made available on the NI or EU market for the first time. In practice, this means a written or verbal agreement (or offer of an agreement) to transfer ownership or possession or other rights to the product is made. This refers to each individual product, not to a model or type of product, and does not require physical transfer of the good. This transfer could be for payment or free of charge.

Where a product is sold online, it is considered placed on the NI (or EU) market if it is targeted at NI (or EU) consumers⁴.

Article 4 applies to products first placed on the market after 16 July 2021. It does not apply to products already in circulation⁵.

2.2 Who can be a responsible economic operator?

The responsible economic operator can be the manufacturer, an importer, an authorised representative, or a fulfilment service provider⁶ who is established in NI (or the EU).

³ See Annex I of this guidance for list of regulations.

⁴ An offer for sale should be considered targeted at end users if the economic operator directs its activities towards end users in that state, for example by the language or currency offered, or where the product can be delivered.

⁵ In the case of a product where the model or type has been placed on the market before 16 July 2021, those individual products/units already on the market are not subject to Article 4. However, where new individual products/units in that model/type are first placed on the market after 16 July 2021, they need to comply with Article 4.

⁶ Article 3.11 of the EU Regulation on Market Surveillance defines fulfilment service provider and the definition of 'economic operator' includes fulfilment service providers. This only applies in relation to the obligations of economic operators in the EU Regulation on Market Surveillance – it does not affect the definition of economic operator in other legislation.

'Established' means having a physical presence in NI or the EU – it cannot simply be a postal address. For a business, this can be your registered office, headquarters or your permanent place of business (head office) in that country. For an individual, this can be the place where you are resident.

The responsible economic operator can be any one of:

- **The manufacturer:** A natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under its name or trademark.
- **An importer, when the manufacturer is not established in NI (or the EU):** A natural or legal person established in the NI (or EU) who first places a product from a country outside the EU on the NI (or EU) market.
- **An authorised representative:** A natural or legal person established in the NI (or EU) who is appointed by the manufacturer to act on their behalf to fulfil certain legal duties. A written mandate must be in place, and duties are limited to certain administrative tasks.
- **A fulfilment service provider:** A 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. This does not include postal, parcel or freight services⁷.

Note:

- If a manufacturer has mandated an authorised representative to carry out the compliance tasks in Article 4, the authorised representative is the responsible economic operator (even if there is a manufacturer, importer, or fulfilment service established in NI or EU for that product).
- If there is no manufacturer, importer, or authorised representative established in NI or in the EU, but there is a fulfilment service provider, the fulfilment service provider will automatically be considered the responsible economic operator and expected to fulfil compliance tasks.

Where there is no responsible economic operator established in NI (or the EU) already, the manufacturer placing the product on the market should take steps to ensure someone is in place to undertake those compliance tasks or the product cannot be placed on the market.

For information on enforcement, please see section 4.

2.3 What does the responsible economic operator need to do?

Under Article 4, the responsible economic operator has responsibility for these compliance tasks:

⁷ This is a new legal definition in Article 3.11 Article 3 of the EU Regulation on Market Surveillance. It applies to businesses established in NI or the EU who meet the definition.

1. **Keep documentation:** Verify that the EU declaration of conformity or declaration of performance and technical documentation have been drawn up, keep the declaration of conformity or declaration of performance at the disposal of Market Surveillance Authorities for the period required by that legislation (usually 10 years from the date the product is placed on the market unless explicitly stated otherwise), and ensure that the technical documentation can be made available to those authorities upon request.
2. **Provide documentation:** If a reasoned request is made by a Market Surveillance Authority, provide them with all information and documentation necessary to demonstrate the conformity of the product.
3. **Notify risk:** If there is reason to believe a product presents a risk, inform the Market Surveillance Authority.
4. **Cooperate and take necessary action:** Cooperate with Market Surveillance Authorities, including requests to take appropriate corrective action to remedy non-compliance. If it is not possible, and the economic operator has reason to believe the product presents a risk, take corrective action to mitigate the risks presented by the product, at their own initiative or at the request of Market Surveillance Authorities.

2.4 How to comply with Article 4

For a product in scope of Article 4 to be placed on the NI (or EU) market, one of the economic operators below must be in place in the supply chain and they must fulfil the compliance duties in section 2.3. Most UK businesses will likely have sufficient arrangements in place.

- **A manufacturer established in NI** (or the EU)
- **An importer established in NI** (or the EU), when the manufacturer is not established in NI (or the EU).
- **An authorised representative established in NI** (or the EU). The manufacturer must ensure a written mandate is in place which includes the tasks of Article 4⁸, and that the authorised representative has the appropriate means to fulfil their tasks (e.g. the required compliance documentation). An authorised representative established in NI is sufficient for the EU market, and vice versa.
- **A fulfilment service provider established in NI** (or the EU). The manufacturer should confirm with them that they will perform this role and that they understand their responsibilities. The manufacturer should provide anything necessary for them to fulfil their role (e.g. the required compliance documentation)

Where there is no responsible economic operator established in NI (or the EU) already, the manufacturer placing the product on the market should take steps to ensure one is in place.

⁸ Note that Market Surveillance Authorities can request to see the written mandate.

The name, registered trade name or registered trademark, and contact details (including the postal address) of the responsible economic operator must be indicated on the product, or on its packaging, the parcel or an accompanying document.⁹

What is an authorised representative?

Authorised representatives are a natural or legal person that a manufacturer appoints to represent them and carry out certain duties on their behalf. Sector legislation specifies what those duties can and can't be, but they are mainly administrative in nature, for example keeping conformity and technical documentation. Some sector legislation may permit them to carry out additional tasks, such as affixing the CE marking.

If a manufacturer appoints an authorised representative, there must be a written mandate in place specifying the tasks that the authorised representative agrees to and is authorised to carry out on the manufacturer's behalf. The authorised representative must also be based in the EU (or NI).

Appointing an authorised representative with a mandate to carry out the compliance tasks in Article 4 is one option traders can use to meet the requirements of Article 4.

The name, registered trade name or registered trademark, and contact details (including the postal address) of the responsible economic operator must be indicated on the product or on its packaging, the parcel or an accompanying document.

What is a fulfilment service provider?

Fulfilment service providers typically provide services such as storage, packaging and delivery, and businesses use them to dispatch their products. In the EU Regulation on Market Surveillance they are defined as:

A 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. (Article 3.13)

Under Article 4, fulfilment service providers can be a responsible economic operator so using a fulfilment service provider is another option traders can use to meet the obligations of Article 4. Manufacturers should confirm with the fulfilment service provider that they will perform this role, that they understand their tasks and the manufacturer will provide anything necessary for them to fulfil them (such as the required compliance documentation).

The name, registered trade name or registered trademark, and contact details (including the postal address) of the responsible economic operator must be indicated on the product or on its packaging, the parcel or an accompanying document.

⁹ In the case of the manufacturer or importer, their name and contact details usually already accompany the product.

3. Movement of goods from NI to GB

The EU Regulation on Market Surveillance does not apply in GB, but there are [existing rules for placing goods on the GB market](#).

There is also [sector specific guidance](#) that outlines requirements for placing certain products on the GB and NI markets.

NI businesses will continue to benefit from unfettered access to the GB market, in line with the rules for qualifying NI goods. For more information, see the [guidance on moving qualifying goods from Northern Ireland to the rest of the UK](#).

4. Enforcement

The UK approach to enforcement of goods placed on the NI market is unchanged and in line with the [Regulator's Code](#). Enforcement continues to be proportionate, risk-based and intelligence led, minimising disruption to UK businesses. Authorities continue to have an initial focus on providing effective advice and support for UK businesses, helping them to understand any new obligations they may have, and applying their discretion as businesses adapt.

In line with the approach in existing legislation, Market Surveillance Authorities must require corrective action to address non-compliance or risks to health and safety, for example, through compliance, withdrawal or recall notices. A breach of the EU Regulation on Market Surveillance by economic operators is an offence which may lead to a conviction, for example where it is not addressed through the use of notices or there is a deliberate or persistent breach.¹⁰ Where there are specific provisions with the same objective in product-specific legislation; the provisions and offences in that product-specific legislation will apply and take precedence over the general provisions in the EU Regulation on Market Surveillance.

5. Further support and advice

If you have queries or need further guidance, please contact OPSS.enquiries@beis.gov.uk.

This guidance will be reviewed and updated as necessary.

6. Examples of how this applies to businesses in different parts of the supply chain

¹⁰ A conviction may give rise to a fine, up to a maximum of £5,000.

6.1 I'm a UK manufacturer placing products on the NI (or EU) market

Do you manufacture a product in scope of Article 4 (see Annex 1) and offer it for sale to NI (or EU) consumers?

No

Your products are not in scope, you don't need to do anything.

Yes ▼

Are you a manufacturer established in NI (or the EU)?

Yes

In almost all cases, your existing obligations as a manufacturer meet the requirements of Article 4. The manufacturer's details need to be on or accompany the product.¹¹

No ▼

Do you have an importer based in NI (or the EU)?

Yes

In almost all cases, existing importer obligations meet the requirements of Article 4 and their details should be on or with the product anyway.¹²

No ▼

Do you have an authorised representative established in NI (or the EU)?

Yes

You can amend their mandate to include the compliance tasks of Article 4. You need to make sure they understand their duties and have appropriate means, and any documentation they may need, to fulfil their compliance tasks.

No ▼

Do you use a fulfilment service provider established in NI (or the EU)?

Yes

They can be the responsible economic operator. You should ensure you agree with them that they will take on the role, that they understand their role and responsibilities, and that you provide them with the documentation necessary for them to fulfil the compliance tasks in Article 4 (eg. EU Declaration of Conformity).

No ▼

If you do not have an authorised representative, importer, or fulfilment service provider already you should ensure one is in place if you place products on the NI (or EU) market. They need to understand their obligations and have the required product documentation necessary to fulfil them.

The responsible economic operator can be established in NI and this will be sufficient to meet obligations to place on the EU market too.

Once agreed, the contact details of the responsible economic operator must be indicated on the product or on its packaging, the parcel, or an accompanying document.

¹¹ Always check product specific legislation that applies for your product. In the rare case that there are specific provisions in Article 4 that are not present in the product-specific legislation, these will apply in addition to the product-specific requirements.

¹² Ibid.

6.2 I run an online shop and sell products to UK consumers, including those in NI

Your responsibilities in relation to Article 4 depend on whether you are established in NI or GB and whether, for the purposes of the NI market, you are the manufacturer, distributor or importer.

If you are established in GB and selling to end users in NI or the EU¹³

- If you are the **manufacturer** of the products you sell, there must be a responsible economic operator established in NI or in the EU to fulfil the compliance tasks of Article 4. (See Section 2.4)
- If you are selling products made by a manufacturer established in NI or the EU and already placed on the NI or EU market, you are a **distributor** for the NI and EU market and do not need to do anything additional for Article 4. Note the existing distributor duty of due care applies as well as any other obligations you may already have in the product-specific legislation.
- If you are selling products made by a manufacturer established outside NI or the EU (for example GB, or a non-EU country) and directly selling them to NI consumers, there must be a responsible economic operator established in NI or the EU to fulfil the compliance tasks of Article 4. (See section 2.4)

If you are established in NI and selling to end users in NI or the EU

- If you are the **manufacturer** of the products you sell, your manufacturer obligations will almost always meet the requirements of Article 4¹⁴.
- If you sell products made by a manufacturer established in NI or the EU and already placed on the NI or EU market, you are a **distributor** for the NI (and EU) market. You do not have responsibilities under Article 4, but the existing distributor duty of due care applies as well as any other obligations you may already have in the product-specific legislation.
- If you sell products made by a manufacturer established outside NI or the EU, but buy products from an importer established in NI or the EU, you do not have responsibilities under Article 4, as these will likely be fulfilled by the importer, but the existing distributor duty of due care applies and any obligations you may have in the product-specific legislation.
- If you sell products made by a manufacturer established outside NI or the EU (for example GB, or a non-EU country) and place them on the NI market for the first time, you are the **importer**. Your existing obligations as an importer will almost always meet the requirements of Article 4¹⁵.

¹³ 'End user' means any natural or legal person residing or established in the EU (or NI), to whom a product has been made available either as a consumer outside of any trade, business, craft or profession or as a professional end user in the course of its industrial or professional activities.

¹⁴ You should always check product specific guidance and legislation that applies for your product. In the rare case that there are specific provisions in Article 4 that are not present in the product-specific legislation, these will apply in addition to the product-specific requirements.

¹⁵ You should always check product specific guidance and legislation that applies for your product. In the rare case that there are specific provisions in Article 4 that are not present in the product-specific legislation, these will apply in addition to the product-specific requirements.

6.3 I'm a fulfilment service provider established in NI

If your business model fits this description, you are a fulfilment service provider:

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. (This excludes postal, parcel and freight services)¹⁶.

If there is no manufacturer, importer or authorised representative established in NI (or the EU) who is responsible for the compliance tasks listed in Article 4, you (as fulfilment service provider) are responsible by default. As you can be considered responsible for compliance tasks in relation to the products you handle, you may wish to:

- Make existing and potential clients aware that, if any products they sell are in scope of Article 4, there needs to be an economic operator established in NI (or EU).
- Make clients aware that if there is no manufacturer, importer or authorised representative established in NI or the EU, you will be the responsible economic operator.
 - If you do not want to fulfil this role, 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 NI or the EU.
 - If clients want you to act as the responsible economic operator, check whether you are already performing this role for the same product for another client – if so, you will likely have everything you need (eg. compliance documentation). If not, decide the extent to which you will arrange what you need and the extent to which you want the client to arrange what you need.
- If clients want you to act as the responsible economic operator, tell them what they have to do before they can start using your fulfilment service provider, e.g. provide the appropriate compliance documentation.
- Once all the appropriate arrangements have been made, inform clients so that they can start offering the products for sale.

6.4 Our business includes providing service and repairs which may require replacing parts. Do we have to do anything to comply with Article 4?

Article 4 applies when a product is placed on the market. If you are repairing a product using spare parts, you are not placing those component parts on the market – they will have been placed on the market already, purchased, and you are using them. Therefore Article 4 is not applicable. However, note that:

- If you are repairing a product in NI or the EU, any component parts you use must be compliant with relevant EU legislation.

¹⁶ This is a new legal definition in Article 3.11 Article 3 of the EU Regulation on Market Surveillance and Compliance of Products 1020/2019. It applies to businesses established in NI or the EU who meet the definition.

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If you repair a product, you should check that the repairs have not made a material change to the product which may require re-certification. You'll need to do this for each product on a case-by-case basis. If the repairs have not substantially changed the product, it will not be considered "placing on the market" and Article 4 will not apply. For further guidance about repairs see the EU Blue Guide.

Annex I – Products in scope of Article 4

Products subject to this EU legislation are in scope of Article 4:

- Appliances burning gaseous fuels (Regulation 2016/426)
- Construction products (Regulation 305/2011)
- Personal protective equipment (Regulation 2016/425)
- Ecodesign requirements for energy-related products (Directive 2009/125/EC)
- Electrical equipment designed for use within certain voltage limits (Directive 2014/35/EU)
- Electromagnetic compatibility (Directive 2014/30/EU)
- Equipment and protective systems intended for use in potentially explosive atmospheres (Directive 2014/34/EU)
- Machinery (Directive 2006/42/EC)
- Measuring instruments (Directive 2014/32/EU)
- Noise emission in the environment by equipment for use outdoors (Directive 2000/14/EC)
- Non-automatic weighing instruments (Directive 2014/31/EU)
- Pressure equipment (Directive 2014/68/EU)
- Pyrotechnics (Directive 2013/29/EU)
- Radio equipment and telecommunications terminal equipment (Directive 2014/53/EU)
- Recreational craft (Directive 2013/53/EU)
- Simple pressure vessels (Directive 2014/29/EU)
- The restriction of the use of certain hazardous substances in electrical and electronic equipment (Directive 2011/65/EU)
- Toys' safety (Directive 2009/48/EC)

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