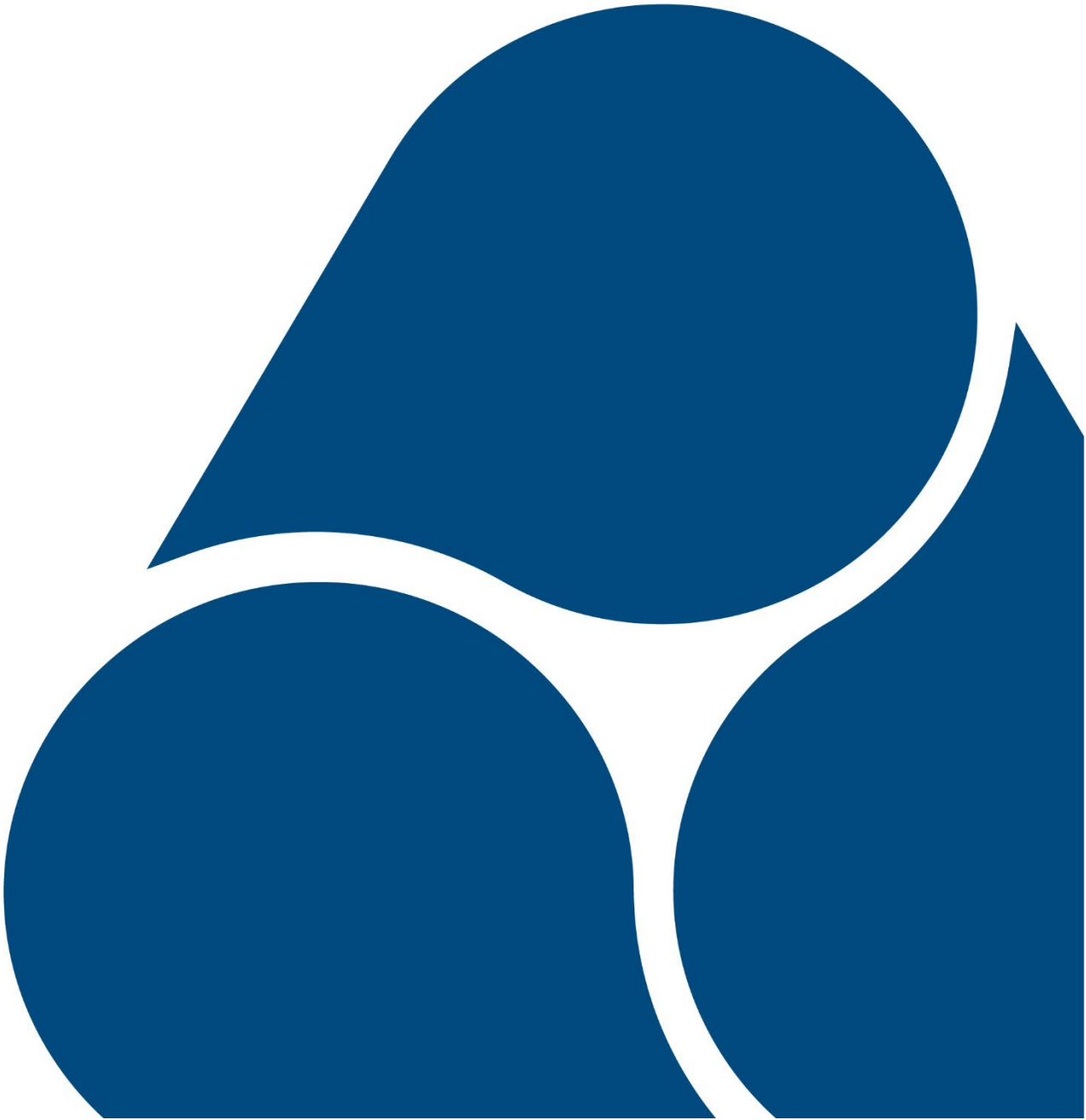
Office for Product Safety & Standards

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

Guidance for Market Surveillance Authorities applying in respect of Northern Ireland from 16 July 2021

June 2021



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1. Introduction

1.1 This guidance primarily relates to the EU Regulation on Market Surveillance and Compliance of Products 2019/1020 (EU Regulation on Market Surveillance). This Regulation applies from 16 July 2021 in EU Member States.

1.2 For as long as the Ireland/Northern Ireland Protocol applies ('the Protocol'), the EU Regulation on Market Surveillance will need to be observed in respect of Northern Ireland (NI).

1.3 The EU Regulation on Market Surveillance replaces the market surveillance provisions in EU Regulation for Accreditation and Market Surveillance 765/2008 (RAMS). The provisions on accreditation (Chapter II, Articles 3-14) and CE marking (Article 30) are unchanged and continue to apply alongside the general and financing provisions.

1.4 This guidance provides an overview of the Regulation and is primarily for Market Surveillance Authorities operating in Northern Ireland[1].

Read guidance for businesses about their responsibilities under the EU Regulation on Market Surveillance.

For details about the accreditation provisions in RAMS which continue to directly apply, see point 1.8-1.9.

1.5 This guidance replaces "EU Regulation for Accreditation and Market Surveillance 765/2008 applying in respect of Northern Ireland from 1 January 2021" published in December 2020.

Legislative framework

1.6 For as long as the Protocol applies, the EU legislative framework for manufactured goods continues to apply in Northern Ireland. The framework consists of 'general' requirements that apply to all harmonised goods, and 'specific' requirements (which, if they are more detailed and specific, may supersede the general requirements) that apply to a number of individual product categories – for example, electrical goods and toys. Further information relating to placing manufactured goods on the market can be found in general guidance and product specific guidance.

1.7 The EU Regulation on Market Surveillance replaces only the market surveillance provisions in RAMS. It sets out requirements for market surveillance relating to the marketing of products subject to EU harmonised legislation.

1.8 The accreditation provisions in RAMS (Chapter II, Articles 3-14) remain unchanged and continue to directly apply in Northern Ireland. UKAS remains the UK's appointed sole national accreditation body. Its role in accrediting UK approved bodies is unchanged. See further information on accreditation and conformity assessment.

[1] 'Market Surveillance Authorities' include those Authorities designated in legislation as Market Surveillance Authorities, whose responsibility includes the NI market. It also includes Authorities designated as 'enforcers' in respect of Northern Ireland that are otherwise expected to dispense a market surveillance function.

1.9 The marking provisions in RAMS (Article 30) remain unchanged and continue to directly apply in NI. See further information on conformity marking.

1.10 While EU legislation does apply, Northern Ireland continues to be a key part of the UK product safety system. The Office for Product Safety and Standards (OPSS) continues to coordinate the application of UK and EU market surveillance legislation and provide support to Authorities and their sponsoring Government Departments across the whole UK. A version of RAMS is retained in UK law which applies in respect of Great Britain – read further guidance.

Overall approach to market surveillance in Northern Ireland

1.11 The same Market Surveillance Authorities will retain responsibility for regulating the Northern Ireland market, where most EU single market rules for goods continue to apply[2]. This includes any Authorities whose responsibility covers the whole UK market including Northern Ireland, even if they are based in Great Britain.

1.12 The EU Regulation on Market Surveillance does not change the principles which originated from RAMS. It continues to require that Market Surveillance Authorities make “appropriate checks” on “an adequate scale”, on the basis of risk assessment, of goods placed on the market in Northern Ireland. This includes goods manufactured in Northern Ireland in addition to those manufactured elsewhere. Authorities who have a UK-wide scope will need to ensure that the obligations in respect of Northern Ireland are fulfilled.

1.13 The majority of market surveillance activity by Authorities will continue to take place after goods have been made available on the Northern Ireland market. Authorities will continue totake a proportionate, risk-based and intelligence-led approach to regulating the Northern Ireland market, prioritising unsafe products. In line with the Regulators’ Code, Authorities are encouraged to provide advice, support and reassurance to help businesses understand any new obligations, and to avoid non-compliance.

1.14 Authorities acting in respect of Northern Ireland should continue to refer to the most recent and available version of the European Commission ‘Blue Guide’ for guidance on the application of EU goods legislation.

[2] A full list of these regulations is provided in Annex II of the Northern Ireland Protocol: https://www.gov.uk/government/publications/new-protocol-on-irelandnorthern-ireland-and-political-declaration

2. Key provisions

Definitions and scope

2.1 The EU Regulation on Market Surveillance applies to all products subject to EU harmonised legislation, in so far as there are no specific provisions with the same objective in sector legislation which regulate in a more specific way in relation to market surveillance.

2.2 Most definitions are consistent with existing definitions in EU harmonised legislation or are included to add clarity.

2.3 Notable definitions which were not in RAMS include:

- **'Fulfilment service provider' (Article 3.11)** means 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. This excludes postal services, parcel delivery services and any other freight transport services.

  For the purposes of the EU Regulation on Market Surveillance, fulfilment services are included as a type of economic operator and subject to any requirements placed on economic operators by the Regulation[3]. Under Article 4, fulfilment services can be responsible for certain compliance activities (See point 2.7)

  Note also that the definition of 'economic operator' (Article 3.13), for the purposes of the EU Regulation on Market Surveillance, is slightly broader than in other pieces of sector legislation and includes anyone who is subject to obligations in relation to manufacture of products, making them available, or putting them into service[4].

- **'Information society service provider' (Article 3.14)** means a provider of a service as defined in the EU Directive on Information Society Services[5].

  In practice, this means a natural or legal person who carries out an economic activity purely online with no physical delivery of the service. This includes entities such as online webshops, online marketplaces, and internet service providers[6]. (See point 2.10 about what this means in practice for market surveillance).

- **'Online interface' (Article 3.15)** means any software, including a website, part of a website or an application, that is operated by or on behalf of an economic operator, and which serves to give end users access to the economic operator's products.

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3 This only applies in relation to obligations placed on economic operators in the EU Regulation on Market Surveillance – in other pieces of harmonised legislation, 'economic operator' does not include fulfilment services.

4 Article 13.3: ''the manufacturer, the authorised representative, the importer, the distributor, the fulfilment service provider or any other natural or legal person who is subject to obligations in relation to the manufacture of products, making them available on the market or putting them into service in accordance with the relevant Union harmonised legislation'. This only applies in relation to obligations placed on economic operators in the EU Regulation on Market Surveillance– in other pieces of harmonised legislation, this definition does not apply.

5 Point (b) of Article 1(1) the Council Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services

6 This is only in relation to the online activity – while the sale of goods online is covered, the physical delivery of goods is not.

Business requirements

2.4 There are some new requirements for businesses to enable better traceability of products, particularly those sold online. Under the terms of the Northern Ireland Protocol, these also apply to products placed on the Northern Ireland market.

2.5 **Article 4** requires that for certain products to be placed on the EU (or NI) market, an economic operator responsible for compliance must be established in the EU (or NI) to fulfil certain compliance tasks. (See Annex I of this guidance for a list of products in scope) The responsible economic operator can be any one of a manufacturer, importer, authorised representative, or a fulfilment service provider but in all cases must be established in the EU (or NI).

2.6 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.[7] [8]

2.7 The economic operator responsible for compliance must:

- **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 unless specified otherwise) and ensure that the technical documentation can be made available to those Authorities upon request.
- **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.
- **Notify risk:** If there is reason to believe a product presents a risk, inform the Market Surveillance Authority.
- **Cooperate:** Cooperate with Market Surveillance Authorities, including requests to take appropriate corrective action. If that is not possible, the responsible economic operator must mitigate the risks presented by the product when they believe the product presents a risk or are requested to do so by the Market Surveillance Authorities.

2.8 Read further guidance on how Article 4 applies to UK businesses. The European Commission has also published guidance on the practical implementation of Article 4 in the EU.

2.9 **Article 6** clarifies that if a product is targeted[9] at end users in the EU (or NI), it is considered placed on the market in that state and must comply with the relevant legislation.

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7 A website address may be given in addition to, but not instead of, a postal address. It can be useful to include an email address and/or phone number to facilitate swift contact.

8 Where the manufacturer or importer is fulfilling this role, their details should already accompany the product.

9 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.

2.10 **Article 7.2** outlines that information society service providers (defined in point 2.3) must cooperate with a request from Market Surveillance Authorities to facilitate action to eliminate or mitigate risk. This provision, together with the Article 14.4(k) (the power for Market Surveillance Authority to require the removal of content or that access to content is restricted when there are no other means available to mitigate serious risk), operate to add legal clarity to how Market Surveillance Authorities and information society service providers interact when a product presents a risk[10].

Enforcement

2.11 Market Surveillance Authorities should continue to apply a targeted and risk-based approach, prioritising unsafe products. In line with the Regulators' Code, Authorities should 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.

2.12 As the EU Regulation on Market Surveillance includes obligations on businesses, there will be an enforcement regime in place, given effect through secondary legislation. See Section 3 for further details.

Market Surveillance

Organisation

2.13 The EU Regulation on Market Surveillance does not fundamentally alter how market surveillance is organised and delivered but there are small operational changes.

2.14 **Article 10** of the Regulation requires a Single Liaison Office (SLO) to be established to represent the coordinated position of Market Surveillance Authorities and border control authorities in the UK, and to assist in the cooperation between Market Surveillance Authorities in different countries.

2.15 The UK Single Liaison Office is the Office for Product Safety and Standards (OPSS) who will fulfil the required functions[11].

2.16 **Article 13** requires a 4-year national market surveillance strategy to be drawn up which Authorities should take into account when conducting their activities. As SLO, OPSS is responsible for coordinating this.

2.17 As SLO, OPSS will also support coordination with Authorities in EU Member States or the EU Commission as required, including passing on information or requests as appropriate to the relevant Market Surveillance Authorities. The contact details are opss-slo@businessandtrade.gov.uk.

Market surveillance activities

2.18 Market surveillance is the set of activities taken by public authorities that ensure the safety and compliance of products placed on the market (with the exception of food, feed, living plants and animals, products of human origin and products of plants and animals relating to their reproduction).

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[10] This is in line with the provisions of the eCommerce Directive and does not alter the way the current liability regime works.

[11] Note that OPSS is also the UK Product Safety Contact Point. This is an operational function, primarily in relation to the notification of unsafe products and sharing of such information, and one that operates across the UK and internationally. The SLO has a more strategic function and includes some cooperation and coordination functions.

2.19 The key principles of RAMS are unchanged including conducting appropriate checks on an adequate scale, based on risk, impartially and proportionately. Whilst the EU Regulation on Market Surveillance is more explicit about what is meant by these terms and what is expected of market Surveillance Authorities, this reflects existing operational practice. Market Surveillance Authorities should continue to apply a targeted and risk-based approach, prioritising unsafe products. In line with the Regulators' Code, Authorities should 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.

2.20 **Article 11** sets out the activities of Market Surveillance Authorities to ensure that products conform to relevant legislation and to ensure the protection of public interest covered by that legislation. These include requiring relevant Authorities to:

- Carry out their duties and exercise powers independently, impartially and without bias.
- Carry out effective market surveillance of products made available online and offline.
- Perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks based on adequate samples, prioritising their resources and actions to ensure effective market surveillance and taking into account the national market surveillance strategy referred to in Article 13 (see point 4.16).
- In deciding on which checks to perform, on which types of products and on what scale, Authorities must follow a risk-based intelligence led approach (this means taking into account possible hazards and non-compliance associated with the product, activities under the control of the economic operator and their past record of non-compliance, relevant risk profiling by Authorities, consumer complaints and other sources of information that might indicate non-compliance).
- Ensure economic operators take appropriate and proportionate corrective action to ensure compliance with the relevant legislation, and take appropriate and proportionate action where the economic operator fails to take action.
- Ensure that products which present a serious risk requiring rapid intervention, including a serious risk where the effects are not immediate, are recalled, withdrawn or prohibited from being placed on the market and the EU Commission is notified.
- Work in collaboration with other authorities to prevent unsafe and non-compliant products entering the market (see point 2.24-26)

Powers of Market Surveillance Authorities

2.21 **Article 14** outlines a minimum set of powers that Market Surveillance Authorities must have and how they should exercise them.

2.22 These are broadly equivalent to powers in existing legislation but add specificity or clarity to reflect modern supply chains and products. Secondary legislation will ensure that these powers are given legal effect and available to those Market Surveillance Authorities operating in Northern Ireland for use in respect of the Northern Ireland market.

2.23 In summary, the powers in Article 14.4 are to:

a) Require economic operators to provide relevant documentation and information, including access to embedded software as far as that is necessary to assess product compliance, in any form or format and irrespective of medium of storage.

b) Require economic operators to provide relevant information on the supply chain.

c) Require economic operators to provide relevant information required for the purpose of ascertaining the ownership of websites.

d) Carry out unannounced on-site inspections and physical checks of products.

e) Enter any premises, land or means of transport that the economic operator in question uses related to their business in order to identify non-compliance and obtain evidence.

f) Start investigations to identify non-compliances and bring them to an end.

g) Require economic operators to take appropriate action to bring an instance of non-compliance to an end or eliminate risk.

h) Take appropriate measures where an economic operator fails to take appropriate corrective action or where the non-compliance or the risk persists, including the power to prohibit or restrict the making available of a product on the market or to order that the product is withdrawn or recalled.

i) Impose effective, proportionate and dissuasive penalties as outlined in the enforcement regime for the EU Regulation on Market Surveillance.

j) Acquire product samples, including under a cover identity, to inspect those samples and to reverse-engineer them in order to identify non-compliance and to obtain evidence.

k) Where no other means are available to eliminate a serious risk:

(i) require the removal of content referring to the related products from an online interface or to require the explicit display of a warning to end users when they access an online interface; or

(ii) where a request according to point (i) has not been complied with, to require information society service providers to restrict access to the online interface, including by requesting a relevant third party to implement such measures.

Control of Products Entering Northern Ireland

Detaining unsafe and non-compliant products

2.24 In relation to the control of products entering Northern Ireland, Market Surveillance Authorities, Border Force and HMRC work together. Operational arrangements are in place which set out their roles and responsibilities.

2.25 Border Force officers should continue to detain products if they are suspected of being unsafe or non-compliant, and refer these consignments to the relevant Market Surveillance Authority, via the Office for Product Safety and Standards.

2.26 The Office for Product Safety and Standards will continue to:

- identify consignments of consumer products that could pose a risk to the public (and facilitate this for other manufactured goods within scope of the EU Regulation on Market Surveillance)
- refer these consignments to the relevant Market Surveillance Authority

2.27 Where a Market Surveillance Authority has reasonable grounds to believe a product does not comply with applicable law or presents a risk, it should be denied release into free circulation by the authorities in charge of control of products entering the Northern Ireland market.

Products entering the EU/NI

2.28 Articles 25 – 28 of the EU Regulation on Market Surveillance deal with controls on products entering the EU market, and for the purposes of the Northern Ireland Protocol, the EU market includes Northern Ireland.

2.29 Products entering the market that are subject to a 'release for free circulation' customs procedures may be subject to certain controls performed by border authorities. These provisions apply to all products covered by European Union law, not just harmonised products, provided there are no specific rules about these controls elsewhere in Union law. This applies to most goods entering Northern Ireland from non-EU countries. Controls must be performed on the basis of risk analysis (rather than routine checks), and close cooperation between customs authorities and Market Surveillance Authorities is encouraged.

2.30 Customs authorities at the first point of entry to the Union or NI, who have reason to believe there is non-compliance of products entering the market that are in temporary storage, or placed under a different customs procedure than "release for free circulation", must share all relevant information with the customs authority at the intended destination of the goods.

2.31 Movements of goods directly from the Republic of Ireland and other EU countries into Northern Ireland are out of scope of this section of the EU Regulation on Market Surveillance.

Reporting requirements

2.32 Reporting obligations for Market Surveillance Authorities acting in respect of Northern Ireland continue to apply with some operational changes.

2.33 **Articles 19 and 20** require Market Surveillance Authorities to report products presenting a serious risk to the EU Commission, including measures or voluntary measures taken (noting their duration and nature), data necessary for the identification of the product, the origin and supply chain of the product, the related risk, and any other available details. Under forthcoming EU implementing legislation, there will also be more specific reporting requirements in respect of controls on products entering the EU and NI markets. Further information will be provided in due course.

2.34 **Article 34** requires Authorities to report all relevant information (including results of testing, identification of risks) and measures taken where an in-depth compliance check has taken place, including where the product is judged to be compliant. This is wider than the previous RAMS requirement to report all relevant information for products presenting a risk.

2.35 For information on how Authorities operating in Northern Ireland should report the relevant information and how UK Product Safety Database, and the EU databases RAPEX and ICSMS should be used, see the guidance on notifying unsafe and non-compliant products.

2.36 If a Market Surveillance Authority acting in respect of Northern Ireland suspects that a non-compliant or unsafe product is also available on the Great Britain market – and would be unlikely to meet regulatory requirements that apply in Great Britain – they should make the relevant Market Surveillance Authority in Great Britain aware of the product, while ensuring that any information obtained from EU databases and systems is not shared.

Cooperation with EU Member States and their Market Surveillance Authorities

2.37 The EU Regulation on Market Surveillance outlines ways in which the EU Commission, EU Member States and their Authorities should communicate, collaborate and exchange information with each other in relation to market surveillance. Market Surveillance Authorities operating in Northern Ireland will communicate and collaborate with non-UK bodies in the manner envisaged under the Northern Ireland Protocol.

2.38 **Articles 22 – 24** outline the procedures that Market Surveillance Authorities can use to request information, mutual assistance, or enforcement by a Market Surveillance Authority in an EU Member State. In the first instance, Authorities responsible for Northern Ireland with access to ICSMS should use this to contact Authorities in EU Member States. Where this is not possible, OPSS (as the SLO) is available to facilitate communication and cooperation between Market Surveillance Authorities and those in EU Member States to support efficient and effective market surveillance. If, as the SLO, OPSS receives requests for information, assistance or issues of mutual interest from Market Surveillance Authorities in an EU Member State, OPSS will liaise with Market Surveillance Authorities operating in NI as appropriate.

3. Enforcement

3.1 Market surveillance should continue to take a proportionate, risk-based and intelligence-led approach to regulating the Northern Ireland market, prioritising unsafe products.

3.2 Enforcement should be in line with the Regulators' Code, including supporting businesses to understand and comply with their obligations.

3.3 A range of enforcement measures are available to Market Surveillance Authorities responsible for regulating the compliance of products in Northern Ireland to exercise proportionately.

3.4 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 and may lead to a conviction for example where they are not addressed through the use of notices or there is a deliberate or persistent breach.[12] 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 these general provisions.

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

4. Further information

4.1 Authorities with queries on the application of the EU Regulation on Market Surveillance or related legislation can contact OPSS as the SLO using the following contact details: opss-slo@businessandtrade.gov.uk.

Annex 1 – 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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