

Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (Text with EEA relevance)

REGULATION (EC) No 765/2008 OF THE
EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 9 July 2008

setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 95 and 133 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee⁽¹⁾,

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁽²⁾,

Whereas:

- (1) It is necessary to ensure that products benefiting from the free movement of goods within the Community fulfil requirements providing a high level of protection of public interests such as health and safety in general, health and safety at the workplace, protection of consumers, protection of the environment and security, while ensuring that the free movement of products is not restricted to any extent greater than that which is allowed under Community harmonisation legislation or any other relevant Community rules. Provision should, therefore, be made for rules on accreditation, market surveillance, controls of products from third countries and the CE marking.
- (2) It is necessary to establish an overall framework of rules and principles in relation to accreditation and market surveillance. That framework should not affect the substantive rules of existing legislation setting out the provisions to be observed for the purpose of protecting public interests such as health, safety and protection of consumers and of the environment, but should aim at enhancing their operation.
- (3) This Regulation should be seen as complementary to 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⁽³⁾.
- (4) It is very difficult to adopt Community legislation for every product which exists or which may be developed; there is a need for a broad-based, legislative framework of

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a horizontal nature to deal with such products, to cover lacunae, in particular pending revision of existing specific legislation, and to complement provisions in existing or future specific legislation, in particular with a view to ensuring a high level of protection of health, safety, the environment and consumers, as required by Article 95 of the Treaty.

- (5) The framework for market surveillance established by this Regulation should complement and strengthen existing provisions in Community harmonisation legislation relating to market surveillance and the enforcement of such provisions. However, in accordance with the principle of *lex specialis*, this Regulation should apply only in so far as there are no specific provisions with the same objective, nature or effect in other existing or future rules of Community harmonisation legislation. Examples can be found in the following sectors: drug precursors, medical devices, medicinal products for human and veterinary use, motor vehicles and aviation. The corresponding provisions of this Regulation should not therefore apply in the areas covered by such specific provisions.
- (6) Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety⁽⁴⁾ established rules to ensure the safety of consumer products. Market surveillance authorities should have the possibility of taking the more specific measures available to them under that Directive.
- (7) However, in order to achieve a higher level of safety for consumer products, the market surveillance mechanisms provided for in Directive 2001/95/EC should be reinforced as regards products presenting a serious risk, in accordance with the principles established by this Regulation. Directive 2001/95/EC should therefore be amended accordingly.
- (8) Accreditation is part of an overall system, including conformity assessment and market surveillance, designed to assess and ensure conformity with the applicable requirements.
- (9) The particular value of accreditation lies in the fact that it provides an authoritative statement of the technical competence of bodies whose task is to ensure conformity with the applicable requirements.
- (10) Accreditation, though so far not regulated at Community level, is carried out in all Member States. The lack of common rules for that activity has resulted in different approaches and differing systems throughout the Community, with the result that the degree of rigour applied in the performance of accreditation has varied between Member States. It is therefore necessary to develop a comprehensive framework for accreditation and to lay down at Community level the principles for its operation and organisation.
- (11) The establishment of a uniform national accreditation body should be without prejudice to the allocation of functions within Member States.
- (12) Where Community harmonisation legislation provides for the selection of conformity assessment bodies for its implementation, transparent accreditation, as provided for in this Regulation, ensuring the necessary level of confidence in conformity certificates, should be considered by the national public authorities throughout the Community the preferred means of demonstrating the technical competence of those bodies. However,

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national authorities may consider that they possess the appropriate means of carrying out this evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.

- (13) A system of accreditation which functions by reference to binding rules helps to strengthen mutual confidence between Member States as regards the competence of conformity assessment bodies and consequently the certificates and test reports issued by them. It thereby enhances the principle of mutual recognition and therefore the provisions of this Regulation on accreditation should apply in relation to bodies carrying out conformity assessments in both the regulated and the non-regulated areas. The issue at stake is the quality of certificates and test reports irrespective of whether they fall within the regulated or the non-regulated area, and no distinction should therefore be made between those areas.
- (14) For the purposes of this Regulation, not-for-profit operation by a national accreditation body should be understood as an activity that is not intended to add any gain to the resources of the body's owners or members. While national accreditation bodies do not have the objective of maximising or distributing profits, they may provide services in return for payment, or receive income. Any excess revenue that results from such services may be used for investment to develop their activities further, as long as it is in line with their main activities. It should accordingly be emphasised that the primary objective of national accreditation bodies should be to support or engage actively in activities that are not intended to produce any gain.
- (15) Since the purpose of accreditation is to provide an authoritative statement of the competence of a body to perform conformity assessment activities, Member States should not maintain more than one national accreditation body and should ensure that that body is organised in such a way as to safeguard the objectivity and impartiality of its activities. Such national accreditation bodies should operate independently of commercial conformity assessment activities. It is therefore appropriate to provide that Member States ensure that, in the performance of their tasks, national accreditation bodies are deemed to exercise public authority, irrespective of their legal status.
- (16) For the assessment and continued monitoring of the competence of a conformity assessment body, it is essential to determine its technological knowledge and experience and its ability to carry out assessment. It is therefore necessary that the national accreditation body possess the relevant knowledge, competence and means for the proper performance of its tasks.
- (17) Accreditation should in principle be operated as a self-supporting activity. Member States should ensure that financial support exists for the fulfilment of special tasks.
- (18) In those cases where it is not economically meaningful or sustainable for a Member State to establish a national accreditation body, that Member State should have recourse to the national accreditation body of another Member State and should be encouraged to have such recourse to the fullest extent possible.

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- (19) Competition between national accreditation bodies could lead to the commercialisation of their activity, which would be incompatible with their role as the last level of control in the conformity assessment chain. The objective of this Regulation is to ensure that, within the European Union, one accreditation certificate is sufficient for the whole territory of the Union, and to avoid multiple accreditation, which is added cost without added value. National accreditation bodies may find themselves in competition on the markets of third countries, but that must have no effect on their activities inside the Community, or on the cooperation and peer evaluation activities organised by the body recognised under this Regulation.
- (20) In order to avoid multiple accreditation, to enhance acceptance and recognition of accreditation certificates and to carry out effective monitoring of accredited conformity assessment bodies, conformity assessment bodies should request accreditation by the national accreditation body of the Member State in which they are established. Nevertheless, it is necessary to ensure that a conformity assessment body is able to request accreditation in another Member State in the event that there is no national accreditation body in its own Member State or where the national accreditation body is not competent to provide the accreditation services requested. In such cases, appropriate cooperation and exchange of information between national accreditation bodies should be established.
- (21) In order to ensure that national accreditation bodies fulfil the requirements and obligations provided for in this Regulation, it is important that Member States support the proper functioning of the accreditation system, monitor their national accreditation bodies regularly and take appropriate corrective measures within a reasonable timeframe where necessary.
- (22) In order to ensure the equivalence of the level of competence of conformity assessment bodies, to facilitate mutual recognition and to promote the overall acceptance of accreditation certificates and conformity assessment results issued by accredited bodies, it is necessary that national accreditation bodies operate a rigorous and transparent peer evaluation system and regularly undergo such evaluation.
- (23) This Regulation should provide for the recognition of a single organisation at European level in respect of certain functions in the field of accreditation. The European cooperation for Accreditation (the EA), whose main mission is to promote a transparent and quality-led system for the evaluation of the competence of conformity assessment bodies throughout Europe, manages a peer evaluation system among national accreditation bodies from the Member States and other European countries. That system has proved to be efficient and to provide mutual confidence. The EA should, therefore, be the first body recognised under this Regulation and Member States should ensure that their national accreditation bodies seek and maintain membership of the EA for as long as it is so recognised. At the same time, the possibility of changing the relevant body recognised under this Regulation should be provided for, in case there is a need for it in the future.
- (24) Effective cooperation among national accreditation bodies is essential for the proper implementation of peer evaluation and with regard to cross-border accreditation. In

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the interests of transparency, it is, therefore, necessary to provide for an obligation on national accreditation bodies to exchange information among themselves and to provide the national authorities and the Commission with relevant information. Updated and accurate information concerning the availability of accreditation activities operated by national accreditation bodies should also be made public and, therefore, accessible, in particular to conformity assessment bodies.

- (25) Sectoral accreditation schemes should cover the fields of activity where general requirements for the competence of conformity assessment bodies are not sufficient to ensure the necessary level of protection where specific detailed technology or health and safety-related requirements are imposed. Given the fact that the EA has at its disposal a broad range of technical expertise, it should be requested to develop such schemes, especially for areas covered by Community legislation.
- (26) For the purpose of ensuring the equivalent and consistent enforcement of Community harmonisation legislation, this Regulation introduces a Community market surveillance framework, defining minimum requirements against the background of the objectives to be achieved by Member States and a framework for administrative cooperation including the exchange of information among Member States.
- (27) In the case of economic operators in possession of test reports or certificates attesting conformity issued by an accredited conformity assessment body, where the relevant Community harmonisation legislation does not require such reports or certificates, market surveillance authorities should take due account of them when performing checks on product characteristics.
- (28) Cooperation between competent authorities at national level and across borders in exchanging information, investigating infringements and taking action to bring about their cessation, even before the placing on the market of dangerous products, by reinforcing measures to identify them, mainly in seaports, is essential to the protection of health and safety and to guaranteeing the smooth functioning of the internal market. National consumer protection authorities should cooperate, at national level, with national market surveillance authorities and should exchange information with them relating to products which they suspect present a risk.
- (29) Risk assessment should take all relevant data into account, including, where available, data on risks that have materialised with respect to the product in question. Account should also be taken of any measures that may have been taken by the economic operators concerned to alleviate the risks.
- (30) Situations of serious risk posed by a product require rapid intervention, which may entail the withdrawal of the product, its recall or the prohibition of its being made available on the market. In those situations it is necessary to have access to a system of rapid exchange of information between Member States and the Commission. The system provided for in Article 12 of Directive 2001/95/EC has proved its effectiveness and efficiency in the field of consumer products. To avoid unnecessary duplication, that system should be used for the purposes of this Regulation. Moreover, coherent market surveillance throughout the Community requires a comprehensive exchange of information on national activities in this context which goes beyond this system.

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- (31) Information exchanged between competent authorities should be subject to the strictest guarantees of confidentiality and professional secrecy and be handled in accordance with rules on confidentiality pursuant to the applicable national law or, as regards the Commission, Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents⁽⁵⁾, in order to ensure that investigations are not compromised and that the reputations of economic operators are not prejudiced. Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data⁽⁶⁾ and Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data⁽⁷⁾ apply in the context of this Regulation.
- (32) Community harmonisation legislation provides for specific procedures establishing whether or not a national measure restricting the free movement of a product is justified (safeguard clause procedures). Those procedures apply following a rapid exchange of information on products presenting a serious risk.
- (33) Points of entry at the external borders are well placed to detect unsafe non-conforming products or products to which the CE marking has been affixed falsely or in a misleading manner even before they are placed on the market. An obligation on authorities in charge of the control of products entering the Community market to execute checks on an adequate scale can therefore contribute to a safer market place. In order to increase the effectiveness of such checks, those authorities should receive all the necessary information concerning dangerous non-conforming products from the market surveillance authorities well in advance.
- (34) Council Regulation (EEC) No 339/93 of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries⁽⁸⁾ lays down rules regarding the suspension of the release of products by customs authorities and provides for further measures including the involvement of market surveillance authorities. It is therefore appropriate that those provisions, including the involvement of market surveillance authorities, be incorporated in this Regulation.
- (35) Experience has shown that products which are not released are often re-exported and subsequently enter the Community market at other points of entry, thus undermining the customs authorities' efforts. Market surveillance authorities should therefore be given the means of proceeding with the destruction of products if they deem it appropriate.
- (36) Within one year of the publication of this Regulation in the *Official Journal of the European Union*, the Commission should present an in-depth analysis in the realm of consumer safety markings, followed by legislative proposals where necessary.
- (37) The CE marking, indicating the conformity of a product, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking should be set out in this Regulation so as to make them immediately applicable and to simplify future legislation.

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- (38) The CE marking should be the only marking of conformity indicating that a product is in conformity with Community harmonisation legislation. However, other markings may be used as long as they contribute to the improvement of consumer protection and are not covered by Community harmonisation legislation.
- (39) It is necessary for Member States to provide for appropriate means of redress in the competent courts and tribunals in respect of measures taken by the competent authorities which restrict the placing on the market of a product or which require its withdrawal or recall.
- (40) Member States may find it useful to establish cooperation with the stakeholders concerned, including sectoral professional organisations and consumer organisations, in order to take advantage of available market intelligence when establishing, implementing and updating market surveillance programmes.
- (41) The Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive and could be increased if the relevant economic operator has previously committed a similar infringement of the provisions of this Regulation.
- (42) In order to achieve the objectives of this Regulation, it is necessary for the Community to contribute to the financing of activities required to implement policies in the field of accreditation and market surveillance. Financing should be provided in the form of grants to the body recognised under this Regulation without a call for proposals, in the form of grants after a call for proposals, or by the award of contracts to that or to other bodies, depending on the nature of the activity to be financed and in accordance with Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities⁽⁹⁾ (the Financial Regulation).
- (43) For some specialised tasks, such as the production and revision of sectoral accreditation schemes, and for other tasks related to the verification of the technical competence and the facilities of laboratories and certification or inspection bodies, the EA should initially be eligible for Community financing, since it is well adapted to providing the necessary technical expertise in this respect.
- (44) Given the role of the body recognised under this Regulation in the peer evaluation of accreditation bodies and its ability to assist the Member States with the management of that peer evaluation, the Commission should be in a position to provide grants for the functioning of the secretariat of the body recognised under this Regulation, which should provide ongoing support for accreditation activities at Community level.
- (45) A partnership agreement should be signed, in accordance with the provisions of the Financial Regulation, between the Commission and the body recognised under this Regulation in order to fix the administrative and financial rules on the financing of accreditation activities.

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- (46) In addition, financing should also be available to bodies other than the body recognised under this Regulation for other activities in the field of conformity assessment, metrology, accreditation and market surveillance, such as the drawing-up and updating of guidelines, inter-comparison activities linked to the operation of safeguard clauses, preliminary or ancillary activities in connection with the implementation of Community legislation in those areas and programmes of technical assistance and cooperation with third countries as well as the enhancement of policies in those areas at Community and international level.
- (47) This Regulation respects the fundamental rights and observes the principles reflected in the Charter of Fundamental Rights of the European Union.
- (48) Since the objective of this Regulation, namely to ensure that products on the market covered by Community legislation fulfil requirements providing a high level of protection of health and safety and other public interests while guaranteeing the functioning of the internal market by providing a framework for accreditation and market surveillance, cannot be sufficiently achieved by the Member States and can therefore, by reason of its scale and effects, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter and scope

1 This Regulation lays down rules on the organisation and operation of accreditation of conformity assessment bodies performing conformity assessment activities.

2 This Regulation provides a framework for the market surveillance of products to ensure that those products fulfil requirements providing a high level of protection of public interests, such as health and safety in general, health and safety at the workplace, the protection of consumers, protection of the environment and security.

3 This Regulation provides a framework for controls on products [^{F1}entering the market of Great Britain].

[^{F2}4 This Regulation provides the requirements as to the form of the UK marking.]

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Textual Amendments

- F1** Words in [Art. 1\(3\)](#) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, [Sch. 33 para. 2\(a\)](#) (as amended by S.I. 2020/1460, reg. 1(4), [Sch. 3 para. 22\(2\)](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F2** [Art. 1\(4\)](#) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, [Sch. 33 para. 2\(b\)](#); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

Article 2

Definitions

For the purposes of this Regulation the following definitions ^{F3}... apply:

1. ‘making available on the market’ [^{F4}means] any supply of a product for distribution, consumption or use on the [^{F5}market of Great Britain] in the course of a commercial activity, whether in return for payment or free of charge [^{F6}and related expressions must be construed accordingly];
2. ‘placing on the market’ [^{F4}means] the first making available of a product on the [^{F7}market of Great Britain] [^{F8}and related expressions must be construed accordingly];
3. ‘manufacturer’ [^{F4}means] any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark;
4. [^{F9}“authorised representative” means a person who—
 - a is established in the United Kingdom; and
 - b has received a written mandate from a manufacturer to act on that manufacturer's behalf in relation to specified task with regard to the manufacturer's obligation under any relevant enactment;]
5. [^{F10}“importer” means any person established in the United Kingdom who places a product from a country outside of the United Kingdom on the market;]
6. ‘distributor’ [^{F11}means] any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market;
7. ‘economic operators’ [^{F12}means] the manufacturer, the authorised representative, the importer and the distributor;
8. ^{F13}
9. ^{F13}
10. [^{F14}“accreditation” means an attestation by a national accreditation body conveying formal recognition that a conformity assessment body is competent to carry out a specific conformity assessment activity;]
11. [^{F15}“UK national accreditation body” means the body appointed by the Secretary of State in accordance with Article 4;]

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12.

‘conformity assessment’ [^{F16}means] the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled;
13.

‘conformity assessment body’ [^{F16}means] a body that performs conformity assessment activities including calibration, testing, certification and inspection;
14.

‘recall’ [^{F16}means] any measure aimed at achieving the return of a product that has already been made available to the end user;
15.

‘withdrawal’ [^{F16}means] any measure aimed at preventing a product in the supply chain from being made available on the market;
16.

^{F17}
17.

‘market surveillance’ [^{F18}means] the activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in [^{F19}any relevant enactment] and do not endanger health, safety or any other aspect of public interest protection;
18.

[^{F20}“market surveillance authority” means an authority responsible for carrying out market surveillance in the United Kingdom;]
19.

[^{F21}“the free circulation procedure” means the procedure set out in Schedule 1 to the Taxation (Cross-border Trade) Act 2018;]
20.

[^{F22}“conformity marking” means a marking, such as the UK marking, by which the manufacturer indicates that a product is in conformity with the applicable requirements of any enactment providing for the affixing such a marking;]
21.

[^{F23}“relevant enactment” means any retained EU law, as it applies in Great Britain, derived from an EU instrument harmonising the conditions for the marketing of products in the EU;]
- 22

[^{F24}“UK marking” means the marking in the form set out in Annex 2.]

Textual Amendments	
F3	Word in Art. 2 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 3(a); 2020 c. 1, Sch. 5 para. 1(1)
F4	Word in art. 2(1)-(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 3(b); 2020 c. 1, Sch. 5 para. 1(1)
F5	Word in Art. 2(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 3(c)(i) (as substituted by S.I. 2020/1460, reg. 1(4), Sch. 3 para. 22(3)(a)); 2020 c. 1, Sch. 5 para. 1(1)
F6	Words in Art. 2(1) inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 3(c)(ii); 2020 c. 1, Sch. 5 para. 1(1)
F7	Word in Art. 2(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 3(d)(i) (as substituted by S.I. 2020/1460, reg. 1(4), Sch. 3 para. 22(3)(b)); 2020 c. 1, Sch. 5 para. 1(1)
F8	Words in Art. 2(2) inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 3(d)(ii); 2020 c. 1, Sch. 5 para. 1(1)
F9	Art. 2(4) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(2), Sch. 5 para. 1(5)

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- F10** Art. 2(5) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 3(f)**; 2020 c. 1, Sch. 5 para. 1(1)
- F11** Word in Art. 2(6) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 3(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F12** Word in Art. 2(7) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 3(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F13** Art. 2(8)(9) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 3(g)**; 2020 c. 1, Sch. 5 para. 1(1)
- F14** Art. 2(10) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 3(h)**; 2020 c. 1, Sch. 5 para. 1(1)
- F15** Art. 2(11) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 3(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F16** Word in art. 2(12)-(15) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 3(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F17** Art. 2(16) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 3(j)**; 2020 c. 1, Sch. 5 para. 1(1)
- F18** Word in Art. 2(17) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 3(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F19** Words in Art. 2(17) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 3(k)**; 2020 c. 1, Sch. 5 para. 1(1)
- F20** Art. 2(18) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 3(l)**; 2020 c. 1, Sch. 5 para. 1(1)
- F21** Art. 2(19) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 3(m)**; 2020 c. 1, Sch. 5 para. 1(1)
- F22** Art. 2(20) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 3(n)**; 2020 c. 1, Sch. 5 para. 1(1)
- F23** Art. 2(21) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 3(o)** (as amended by S.I. 2020/1460, reg. 1(4), **Sch. 3 para. 22(3)(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F24** Art. 2(22) inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 3(p)**; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER II

ACCREDITATION

Article 3

Scope

This Chapter [^{F25}applies] to accreditation, used on a compulsory or voluntary basis, relating to conformity assessment, whether that assessment is compulsory or not, and irrespective of the legal status of the body performing the accreditation.

Changes to legislation: There are outstanding changes not yet made to Regulation (EC) No 765/2008 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Textual Amendments

F25 Word in [Art. 3](#) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 33 para. 4](#); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

f^{F26} Article 4

UK national accreditation body

1 The Secretary of State must by regulations appoint a single UK national accreditation body.

2 The appointment of the UK national accreditation body under regulation 3 of the Accreditation Regulations 2009 is to be treated on and after IP completion day as having been made in pursuance of the duty on the Secretary of State to appoint a UK national accreditation body set out in paragraph 1.

3 The UK national accreditation body must perform its functions in accordance with the provisions of this Chapter.

4 Regulations made under this Article may—

- a terminate the appointment of a UK national accreditation body; and
- b appoint a different body as the UK national accreditation body

where the Secretary of State considers that a UK national accreditation body is not performing its functions in accordance with this Chapter.

5 Regulations made under this Article must establish procedures for the resolution of appeals against accreditation decisions made by the appointed UK national accreditation body.

6 Regulation 5 of the Accreditation Regulations 2009 is to be treated as meeting the requirements of paragraph 5.

7 The UK national accreditation body must operate on a not-for-profit basis.

8 The UK national accreditation body must not—

- a offer or provide any activities or services that are provided by conformity assessment bodies,
- b provide consultancy services; and
- c own shares in, or otherwise have any financial or managerial interest in, a conformity assessment body.

9 The UK national accreditation body must establish and maintain appropriate structures to ensure—

- a consultation on its activities with interested parties; and
- b responses of interested parties to consultation are adequately taken into account.

10 The Secretary of State must ensure that the UK national accreditation body has the appropriate financial and personnel resources for the proper fulfilment of its tasks, including—

- a the fulfilment of special tasks such as activities related to international accreditation cooperation; and
- b activities that are required to support public policy and which are not self-financing.

11 Regulations made under this Article must be made by statutory instrument.

Changes to legislation: There are outstanding changes not yet made to Regulation (EC) No 765/2008 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

- 12 Regulations made under this Article may make such transitional, transitory, consequential or saving provision as the Secretary of State considers appropriate.
- 13 A statutory instrument containing regulations made under this Article is subject to annulment in pursuance of a resolution of either House of Parliament.]

Textual Amendments

F26 Art. 4 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 5 (as amended by S.I. 2020/852, regs. 2(2), 4(2), Sch. 1 para. 1(s)(ii); S.I. 2020/1460, reg. 1(4), Sch. 3 para. 22(4)); 2020 c. 1, Sch. 5 para. 1(1)

- Article 5
- Operation of accreditation
- 1 [F27The UK national accreditation body must], when requested by a conformity assessment body, evaluate whether that conformity assessment body is competent to carry out a specific conformity assessment activity. Where it is found to be competent, [F28the UK national accreditation body must] issue an accreditation certificate to that effect.
- F292
- 3 [F30The UK national accreditation body must] monitor the conformity assessment bodies to which [F31it has] issued an accreditation certificate.
- 4 Where [F32the UK national accreditation body] ascertains that a conformity assessment body which has received an accreditation certificate is no longer competent to carry out a specific conformity assessment activity or has committed a serious breach of its obligations, [F33the UK national accreditation body must] take all appropriate measures within a reasonable timeframe to restrict, suspend or withdraw the accreditation certificate.
- F345

Textual Amendments

F27 Words in Art. 5(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 6(a)(i); 2020 c. 1, Sch. 5 para. 1(1)

F28 Words in Art. 5(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 6(a)(ii); 2020 c. 1, Sch. 5 para. 1(1)

F29 Art. 5(2) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 6(b); 2020 c. 1, Sch. 5 para. 1(1)

F30 Words in Art. 5(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 6(c)(i); 2020 c. 1, Sch. 5 para. 1(1)

F31 Words in Art. 5(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 6(c)(ii); 2020 c. 1, Sch. 5 para. 1(1)

F32 Words in Art. 5(4) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 6(d)(i); 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: There are outstanding changes not yet made to Regulation (EC) No 765/2008 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

- F33

Words in Art. 5(4) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 6(d)(ii); 2020 c. 1, Sch. 5 para. 1(1)
- F34

Art. 5(5) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 6(e); 2020 c. 1, Sch. 5 para. 1(1)

Article 6

Principle of non-competition

- 1

[^{F35}The UK national accreditation body must] not compete with conformity assessment bodies.
- F362

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- F363

.....

Textual Amendments

F35

Words in Art. 6(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 7(a); 2020 c. 1, Sch. 5 para. 1(1)

F36

Art. 6(2)(3) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 7(b); 2020 c. 1, Sch. 5 para. 1(1)

^{F37}Article 7

Cross-border accreditation

.....

Textual Amendments

F37

Art. 7 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 8; 2020 c. 1, Sch. 5 para. 1(1)

Article 8

Requirements for [^{F38}the UK national accreditation body]

- [^{F39}The UK national accreditation body must] fulfil the following requirements:
1.

it [^{F40}must] be organised in such a manner as to make it independent of the conformity assessment bodies it assesses and of commercial pressures, and to ensure that no conflicts of interest with conformity assessment bodies occur;
2.

it [^{F40}must] be organised and operated so as to safeguard the objectivity and impartiality of its activities;

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3. it [^{F40}must] ensure that each decision relating to the attestation of competence is taken by competent persons different from those who carried out the assessment;
4. it [^{F40}must] have adequate arrangements to safeguard the confidentiality of the information obtained;
5. it [^{F40}must] identify the conformity assessment activities for which it is competent to perform accreditation, referring, where appropriate, to [^{F41}any enactment] and standards;
6. it [^{F40}must] set up the procedures necessary to ensure efficient management and appropriate internal controls;
7. it [^{F40}must] have a number of competent personnel at its disposal sufficient for the proper performance of its tasks;
8. it [^{F40}must] document the duties, responsibilities and authorities of personnel who could affect the quality of the assessment and of the attestation of competence;
9. it [^{F40}must] establish, implement and maintain procedures for monitoring the performance and competence of the personnel involved;
10. it [^{F40}must] verify that conformity assessments are carried out in an appropriate manner, meaning that unnecessary burdens are not imposed on undertakings and that due account is taken of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process;
11. it [^{F40}must] publish audited annual accounts prepared in accordance with generally accepted accounting principles.

Textual Amendments

- F38** Words in Art. 8 heading substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 9(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F39** Words in Art. 8 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 9(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F40** Word in Art. 8 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 9(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F41** Words in Art. 8(5) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 9(d)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 9

Compliance with requirements

1 Where [^{F42}the UK national accreditation body] does not meet the requirements of this Regulation or fails to fulfil its obligations hereunder, the [^{F43}Secretary of State must] take appropriate corrective action or [^{F44}must ensure] that such corrective action is taken ^{F45}...

Changes to legislation: There are outstanding changes not yet made to Regulation (EC) No 765/2008 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

2 [F46The Secretary of State must] monitor [F47the UK national accreditation body] at regular intervals in order to ensure that [F48it fulfils] the requirements laid down in Article 8 on a continuing basis.

F493

4 [F50The UK national accreditation body must] have in place the necessary procedures to deal with complaints against the conformity assessment bodies [F51it has] accredited.

Textual Amendments

- F42** Words in Art. 9(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 10(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F43** Words in Art. 9(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 10(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F44** Words in Art. 9(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 10(a)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F45** Words in Art. 9(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 10(a)(iv)**; 2020 c. 1, Sch. 5 para. 1(1)
- F46** Words in Art. 9(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 10(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F47** Words in Art. 9(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 10(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F48** Words in Art. 9(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 10(b)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F49** Art. 9(3) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 10(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F50** Words in Art. 9(4) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 10(d)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F51** Words in Art. 9(4) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 10(d)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

[F52] Article 10

Peer evaluation

- 1 The UK national accreditation body must—
- ensure that it is evaluated in accordance with the requirements of this Article by a body which is approved by the Secretary of State;
 - set out the results of the evaluation in a report;
 - make that report publicly available; and
 - provide a copy of that report to the Secretary of State.

Changes to legislation: There are outstanding changes not yet made to Regulation (EC) No 765/2008 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

- 2 The evaluation referred to in paragraph 1(a) must—
a be based on evaluation criteria and procedures—
 i) agreed between the national accreditation body and the body undertaking the evaluation; and
 ii) approved by the Secretary of State; and
b evaluate whether the UK national accreditation body meets the requirements of Article 8.
- 3 The procedures referred to in paragraph 2(a) must include provision for appeal by the UK national accreditation body against the results of the evaluation.
- 4 The report paragraph (1)(c) must include the evaluation criteria and procedures referred to in paragraph (2)(a).
- 5 The first report under paragraph (1) must be made publicly available before the end of the period of five years beginning on IP completion day.
- 6 After the first report, reports made under this Article are to be made publicly available at intervals not exceeding five years]

Textual Amendments
F52 Art. 10 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 11** (as amended by S.I. 2019/1246, regs. 1(3), 17; S.I. 2020/852, regs. 2(2), 4(2), **Sch. 1 para. 1(s)(iii)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F53 Article 11

Presumption of conformity for national accreditation bodies

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Textual Amendments
F53 Arts. 11-14 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 12**; 2020 c. 1, Sch. 5 para. 1(1)

F53 Article 12

Information obligation

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Textual Amendments
F53 Arts. 11-14 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 12**; 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: There are outstanding changes not yet made to Regulation (EC) No 765/2008 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

F53Article 13

Requests to the body recognised under Article 14

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Textual Amendments

F53Arts. 11-14 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 12; 2020 c. 1, Sch. 5 para. 1(1)

F53Article 14

European accreditation infrastructure

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Textual Amendments

F53Arts. 11-14 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 12; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER III

F54... MARKET SURVEILLANCE FRAMEWORK AND CONTROLS
OF PRODUCTS ENTERING THE [F55MARKET OF GREAT BRITAIN]

SECTION 1

General provisions

Article 15

Scope

- 1Articles 16 to [F5622 and] 26 F57... apply to products covered by [F58any relevant enactment].
- 2Each of the provisions of Articles 16 to [F5922 and] 26 [F60applies] in so far as there are no specific provisions with the same objective in [F61any relevant enactment].
- 3The application of this Regulation [F62does] not prevent market surveillance authorities from taking more specific measures as provided for in [F63the General Product Safety Regulations 2005].
- 4For the purposes of Articles 16 to [F6422 and] 26, a ‘product’ [F65means] a substance, preparation or good produced through a manufacturing process other than food, feed, living

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plants and animals, products of human origin and products of plants and animals relating directly to their future reproduction.

5 Articles 27, 28 and 29^{F66} ... apply to all products covered by [^{F67}any relevant enactment] in so far as other [^{F68}enactments do] not contain specific provisions relating to the organisation of border controls.

Textual Amendments

- F56** Words in Art. 15(1) inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 14(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F57** Word in Art. 15(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 14(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F58** Words in Art. 15(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 14(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F59** Words in Art. 15(2) inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 14(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F60** Word in Art. 15(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 14(d)**; 2020 c. 1, Sch. 5 para. 1(1)
- F61** Words in Art. 15(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 14(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F62** Word in Art. 15(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 14(e)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F63** Words in Art. 15(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 14(e)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F64** Words in Art. 15(4) inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 14(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F65** Word in Art. 15(4) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 14(f)**; 2020 c. 1, Sch. 5 para. 1(1)
- F66** Word in Art. 15(5) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 14(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F67** Words in Art. 15(5) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 14(g)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F68** Words in Art. 15(5) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 14(g)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 16

General requirements

^{F69}1

Changes to legislation: There are outstanding changes not yet made to Regulation (EC) No 765/2008 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

2 Market surveillance [^{F70}authorities][^{F71}must] ensure that products covered by [^{F72}any relevant enactment] which, when used in accordance with their intended purpose or under conditions which can be reasonably foreseen and when properly installed and maintained, are liable to compromise the health or safety of users, or which otherwise do not conform to applicable requirements set out in [^{F72}any relevant enactment] are withdrawn or their being made available on the market is prohibited or restricted and that the public [^{F73}and the Secretary of State] are informed accordingly.

[^{F74}3 The Secretary of State must ensure that there is a national market surveillance infrastructure and programme so that effective measures may be taken in relation to any product subject to any relevant enactment.]

4 Market surveillance [^{F75}must] cover products assembled or manufactured for the manufacturer's own use where [^{F76}any relevant enactment] provides that its provisions ^{F77}... apply to such products.

Textual Amendments

- F69** Art. 16(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 15(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F70** Word in Art. 16(2) inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 15(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F71** Word in Art. 16(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 15(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F72** Words in Art. 16(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 15(b)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F73** Words in Art. 16(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 15(b)(iv)**; 2020 c. 1, Sch. 5 para. 1(1)
- F74** Art. 16(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 15(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F75** Word in Art. 16(4) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 15(d)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F76** Words in Art. 16(4) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 15(d)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F77** Word in Art. 16(4) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 15(d)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

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SECTION 2

[^{F78}Market] surveillance framework

Article 17

Information obligations

^{F79}1

2 [^{F80}The Secretary of State must take appropriate measures to] ensure that the public is aware of the existence, responsibilities and identity of national market surveillance authorities, and of how those authorities may be contacted.

Textual Amendments

F79 Art. 17(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 17(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F80 Words in Art. 17(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 17(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 18

Obligations ^{F81}... as regards organisation

^{F82}1

2 [^{F83}The Secretary of State must] establish adequate procedures in order to:

- a follow up complaints or reports on issues relating to risks arising in connection with products subject to [^{F84}any relevant enactment];
- b monitor accidents and harm to health which are suspected to have been caused by those products;
- c verify that corrective action has been taken; and
- d follow up scientific and technical knowledge concerning safety issues.

[^{F85}3 The Secretary of State may by regulations make such provision as the Secretary of State considers appropriate to ensure that market surveillance authorities have the powers necessary for the proper performance of their duties.

The Secretary of State must entrust market surveillance authorities with the resources and knowledge necessary for the proper performance of their duties.

Regulations made under this paragraph must be made by statutory instrument.

A statutory instrument containing regulations under this paragraph may not be made unless a draft of the instrument has been laid before, and approved by a resolution of, each House of Parliament.]

[^{F86}4 Market surveillance authorities must exercise their powers proportionately.]

[^{F87}5 The Secretary of State must establish, implement and periodically update the United Kingdom's market surveillance programme setting out the principles as to how market

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surveillance is to be organised and covering the sectors in which market surveillance is conducted in the United Kingdom. The Secretary of State must make this programme available to the public by way of electronic communication and, where appropriate, by other means.]

6 ^{F88}The Secretary of State^{F89} must periodically review and assess the functioning of ^{F90}... surveillance activities ^{F91}by market surveillance authorities]. Such reviews and assessments ^{F89}must be carried out at least every fourth year and the results thereof ^{F89}must^{F92}... be made available to the public, by way of electronic communication and, where appropriate, by other means.

Textual Amendments

- F81** Words in Art. 18 heading omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 18(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F82** Art. 18(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 18(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F83** Words in Art. 18(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 18(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F84** Words in Art. 18(2)(a) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 18(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F85** Art. 18(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 18(d)**; 2020 c. 1, Sch. 5 para. 1(1)
- F86** Art. 18(4) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 18(e)**; 2020 c. 1, Sch. 5 para. 1(1)
- F87** Art. 18(5) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 18(f)**; 2020 c. 1, Sch. 5 para. 1(1)
- F88** Words in Art. 18(6) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 18(g)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F89** Word in Art. 18(6) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 18(g)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F90** Word in Art. 18(6) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 18(g)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F91** Words in Art. 18(6) inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 18(g)(iv)**; 2020 c. 1, Sch. 5 para. 1(1)
- F92** Words in Art. 18(6) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 18(g)(v)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 19

Market surveillance measures

1 Market surveillance authorities ^{F93}must perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks on the basis of adequate samples. When doing so

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they ^{F93}must] take account of established principles of risk assessment, complaints and other information.

Market surveillance authorities may require economic operators to make such documentation and information available as appear to them to be necessary for the purpose of carrying out their activities, and, where it is necessary and justified, enter the premises of economic operators and take the necessary samples of products. They may destroy or otherwise render inoperable products presenting a serious risk where they deem it necessary.

Where economic operators present test reports or certificates attesting conformity issued by an accredited conformity assessment body, market surveillance authorities ^{F93}must] take due account of such reports or certificates.

2 Market surveillance authorities ^{F94}must] take appropriate measures to alert users ^{F95}... within an adequate timeframe of hazards they have identified relating to any product so as to reduce the risk of injury or other damage.

They ^{F94}must] cooperate with economic operators regarding actions which could prevent or reduce risks caused by products made available by those operators.

^{F96} Where a market surveillance authority decides to withdraw a product manufactured in the United Kingdom, it must inform the economic operator concerned at the address indicated on the product in question or in the documentation accompanying the product.]

4 Market surveillance authorities ^{F97}must] carry out their duties independently, impartially and without bias.

^{F98}5 Market surveillance authorities must observe confidentiality where necessary in order to protect commercial secrets or to preserve personal data pursuant to national legislation, subject to the requirements that:

- a) information be made public under this Regulation to the fullest extent necessary in order to protect the users in the United Kingdom;
- b) the protection of confidentiality shall not prevent the dissemination to market surveillance authorities of information relevant to ensuring the effectiveness of market surveillance activities.]

Textual Amendments

- F93** Word in [Art. 19\(1\)](#) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 33 para. 19\(a\)](#); 2020 c. 1, Sch. 5 para. 1(1)
- F94** Word in [Art. 19\(2\)](#) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 33 para. 19\(a\)](#); 2020 c. 1, Sch. 5 para. 1(1)
- F95** Words in [Art. 19\(2\)](#) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 33 para. 19\(b\)](#); 2020 c. 1, Sch. 5 para. 1(1)
- F96** [Art. 19\(3\)](#) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 33 para. 19\(c\)](#); 2020 c. 1, Sch. 5 para. 1(1)
- F97** Word in [Art. 19\(4\)](#) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 33 para. 19\(a\)](#); 2020 c. 1, Sch. 5 para. 1(1)

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F98 Art. 19(5) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 19(d)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 20

Products presenting a serious risk

1 [F99Market surveillance authorities must] ensure that products which present a serious risk requiring rapid intervention, including a serious risk the effects of which are not immediate, are recalled, withdrawn or that their being made available on [F100the] market is prohibited, and that the [F101Secretary of State] is informed without delay thereof, in accordance with Article 22.

2 The decision whether or not a product represents a serious risk [F102must] be based on an appropriate risk assessment which takes account of the nature of the hazard and the likelihood of its occurrence. The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk [F103does] not constitute grounds for considering that a product presents a serious risk.

Textual Amendments

- F99** Words in Art. 20(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 20(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F100** Word in Art. 20(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 20(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F101** Words in Art. 20(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 20(a)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F102** Word in Art. 20(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 20(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F103** Word in Art. 20(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 20(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 21

Restrictive measures

1 [F104Market surveillance authorities must] ensure that any measure taken, pursuant to [F105any relevant enactment], to prohibit or restrict the product's being made available on the market, to withdraw it from the market or to recall it, is proportionate and states the exact grounds on which it is based.

2 Such measures [F106must] be communicated without delay to the relevant economic operator, which [F106must] at the same time be informed of the [F107legal] remedies available F108 ... and of the time limits to which such remedies are subject.

3 Prior to the adoption of a measure referred to in paragraph 1, the economic operator concerned [F109must] be given the opportunity to be heard within an appropriate period of not

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less than 10 days, unless such consultation is not possible because of the urgency of the measure to be taken, as justified by health or safety requirements or other grounds relating to the public interests covered by ^{F110}any of the relevant enactments]. If action has been taken without the operator's being heard, the operator ^{F109}must] be given the opportunity to be heard as soon as possible and the action taken ^{F109}must] be reviewed promptly thereafter.

4 Any measure referred to in paragraph 1 ^{F111}must] be promptly withdrawn or amended upon the economic operator's demonstrating that he has taken effective action.

Textual Amendments

- F104** Words in Art. 21(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 21(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F105** Words in Art. 21(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 21(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F106** Word in Art. 21(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 21(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F107** Word in Art. 21(2) inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 21(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F108** Words in Art. 21(2) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 21(b)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F109** Word in Art. 21(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 21(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F110** Words in Art. 21(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 21(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F111** Word in Art. 21(4) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 21(d)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 22

^{F112}Notification of serious risk]

^{F113}1 Where a market surveillance authority takes or intends to take a measure in accordance with Article 20 it must immediately notify the Secretary of State of that measure.]

2 If a product presenting a serious risk has been made available on the market, ^{F114}the market surveillance authority]^{F115}must] notify the ^{F116}the Secretary of State] of any voluntary measures taken and communicated by an economic operator.

3 The information provided in accordance with paragraphs 1 and 2 ^{F117}must] include all available details, in particular the data necessary for the identification of the product, the origin and the supply chain of the product, the related risk, the nature and the duration of the ^{F118}... measure taken and any voluntary measures taken by economic operators.

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4 For the purposes of paragraphs 1, 2 and 3, the market surveillance [^{F119}authority must notify the Secretary of State through the database containing information relating to market surveillance and product safety established by regulation 33(A1) of the General Product Safety Regulations 2005].

Textual Amendments

F112 Art. 22 heading substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 22(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F113 Art. 22(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 22(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F114 Words in Art. 22(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 22(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F115 Word in Art. 22(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 22(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F116 Words in Art. 22(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 22(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F117 Word in Art. 22(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 22(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F118 Word in Art. 22(3) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 22(d)**; 2020 c. 1, Sch. 5 para. 1(1)

F119 Words in Art. 22(4) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 22(e)**; 2020 c. 1, Sch. 5 para. 1(1)

^{F120}Article 23

General information support system

.....

Textual Amendments

F120 Arts. 23-25 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 23**; 2020 c. 1, Sch. 5 para. 1(1)

^{F120}Article 24

Principles of cooperation between the Member States and the Commission

.....

Changes to legislation: There are outstanding changes not yet made to Regulation (EC) No 765/2008 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Textual Amendments

F120 Arts. 23-25 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 23; 2020 c. 1, Sch. 5 para. 1(1)

F120Article 25

Sharing of resources

Textual Amendments

F120 Arts. 23-25 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 23; 2020 c. 1, Sch. 5 para. 1(1)

Article 26

Cooperation with the competent authorities of third countries

1 Market surveillance authorities may cooperate with the competent authorities of third countries with a view to exchanging information and technical support^{F121}... and promoting activities relating to conformity assessment, market surveillance and accreditation.

F122 ...

F1232

Textual Amendments

F121 Words in Art. 26(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 24(a)(i); 2020 c. 1, Sch. 5 para. 1(1)

F122 Words in Art. 26(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 24(a)(ii); 2020 c. 1, Sch. 5 para. 1(1)

F123 Art. 26(2) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 24(b); 2020 c. 1, Sch. 5 para. 1(1)

Textual Amendments

F78 Word in Ch. 3 s. 2 heading substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 16; 2020 c. 1, Sch. 5 para. 1(1)

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SECTION 3

Controls of [F124imported] products F125...

Article 27

[F126Controls of imported products]

[F1271 The authorities in charge of the control of products entering Great Britain must carry out appropriate checks on the characteristics of products on an adequate scale, in accordance with the principles set out in Article 19(1), before those products are discharged from the free-circulation procedure.]

2 Where F128... more than one authority is responsible for market surveillance or external border controls, those authorities [F129must] cooperate with each other, by sharing information relevant to their functions and otherwise as appropriate.

3 The authorities in charge of external border controls [F130must] suspend [F131the discharge of a product from the free-circulation procedure] when any of the following findings are made in the course of the checks referred to in paragraph 1:

- a the product displays characteristics which give cause to believe that the product, when properly installed, maintained and used, presents a serious risk to health, safety, the environment or any other public interest referred to in Article 1;
- b the product is not accompanied by the written or electronic documentation required by [F132any relevant enactment] or is not marked in accordance with that legislation;
- c [F133a conformity] marking has been affixed to the product in a false or misleading manner.

The authorities in charge of external border controls [F130must] immediately notify the market surveillance authorities of any such suspension.

4 In the case of perishable products, the authorities in charge of external border controls [F134must], as far as possible, seek to ensure that any requirements they may impose with regard to the storage of products or the parking of vehicles used for transport are not incompatible with the preservation of those products.

F1355

Textual Amendments	
F126	Art. 27 heading substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 26(a); 2020 c. 1, Sch. 5 para. 1(1)
F127	Art. 27(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 26(a) (as amended by S.I. 2020/1460, reg. 1(4), Sch. 3 para. 22(6)); 2020 c. 1, Sch. 5 para. 1(1)
F128	Words in Art. 27(2) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 26(b)(i); 2020 c. 1, Sch. 5 para. 1(1)
F129	Word in Art. 27(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 26(b)(ii); 2020 c. 1, Sch. 5 para. 1(1)
F130	Word in Art. 27(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 26(c)(i); 2020 c. 1, Sch. 5 para. 1(1)

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- F131** Words in Art. 27(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 26(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F132** Words in Art. 27(3)(b) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 26(c)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F133** Words in Art. 27(3)(c) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 26(c)(iv)**; 2020 c. 1, Sch. 5 para. 1(1)
- F134** Word in Art. 27(4) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 26(d)**; 2020 c. 1, Sch. 5 para. 1(1)
- F135** Art. 27(5) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 26(e)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 28

[^{F136}Discharge] of products

1 A product the [^{F137}discharge] of which has been suspended by the authorities in charge of external border controls pursuant to Article 27 [^{F138}must] be [^{F139}discharged from the free-circulation procedure] if, within three working days of the suspension of [^{F137}discharge], those authorities have not been notified of any action taken by the market surveillance authorities, and provided that all the other requirements and formalities pertaining to such [^{F137}discharge] have been fulfilled.

2 Where the market surveillance authorities find that the product in question does not present a serious risk to health and safety or cannot be regarded as being in breach of [^{F140}any relevant enactment], that product [^{F141}must be discharged from the free-circulation procedure], provided that all the other requirements and formalities pertaining to such [^{F142}discharge] have been fulfilled.

Textual Amendments

- F136** Word in Art. 28 heading substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 27(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F137** Word in Art. 28(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 27(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F138** Word in Art. 28(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 27(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F139** Words in Art. 28(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 27(b)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F140** Words in Art. 28(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 27(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F141** Words in Art. 28(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 27(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

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F142 Word in Art. 28(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 27(c)(iii); 2020 c. 1, Sch. 5 para. 1(1)

Article 29

National measures

1 Where ^{F143}a market surveillance authority finds] that a product presents a serious risk, ^{F144}it] ^{F145}must] take measures to prohibit that product from being placed on the market and ^{F145}must] require the authorities in charge of external border controls to include the following endorsement on the commercial invoice accompanying the product and on any other relevant accompanying document or, where data processing is carried out electronically, in the data-processing system itself:

Dangerous product — ^{F146}discharge from the free-circulation procedure] not authorised — Regulation (EC) No 765/2008.

2 Where ^{F147}a market surveillance authority finds] that a product does not comply with ^{F148}any relevant enactment], ^{F149}it] ^{F150}must] take appropriate action, which may, if necessary, include prohibiting the product's being placed on the market.

Where placing on the market is prohibited pursuant to the first subparagraph, the market surveillance ^{F151}authority] ^{F150}must] require the authorities in charge of external border controls not to ^{F152}discharge the product from the free-circulation procedure] and to include the following endorsement on the commercial invoice accompanying the product and on any other relevant accompanying document or, where data processing is carried out electronically, in the data-processing system itself:

Product not in conformity — ^{F153}discharge from the free-circulation procedure] not authorised — Regulation (EC) No 765/2008.

3 Where that product is subsequently declared for a customs procedure other than ^{F154}the free-circulation procedure] and provided that the market surveillance authorities do not object, the endorsements set out in paragraphs 1 and 2 ^{F155}must] also be included, under the same conditions, on the documents used in connection with that procedure.

4 ^{F156}Market surveillance] authorities may destroy or otherwise render inoperable products presenting a serious risk where they deem it necessary and proportionate.

5 Market surveillance authorities ^{F157}must] provide authorities in charge of external border controls with information on product categories in which a serious risk or non-compliance within the meaning of paragraphs 1 and 2 has been identified.

Textual Amendments

F143 Words in Art. 29(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 28(a)(i); 2020 c. 1, Sch. 5 para. 1(1)

F144 Word in Art. 29(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 28(a)(ii); 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: There are outstanding changes not yet made to Regulation (EC) No 765/2008 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

- F145** Word in Art. 29(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 28(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F146** Words in Art. 29(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 28(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F147** Words in Art. 29(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 28(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F148** Words in Art. 29(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 28(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F149** Word in Art. 29(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 28(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F150** Word in Art. 29(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 28(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F151** Word in Art. 29(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 28(c)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F152** Words in Art. 29(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 28(c)(iv)**; 2020 c. 1, Sch. 5 para. 1(1)
- F153** Words in Art. 29(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 28(c)(v)**; 2020 c. 1, Sch. 5 para. 1(1)
- F154** Words in Art. 29(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 28(d)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F155** Word in Art. 29(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 28(d)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F156** Words in Art. 29(4) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 28(e)**; 2020 c. 1, Sch. 5 para. 1(1)
- F157** Word in Art. 29(5) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 28(f)**; 2020 c. 1, Sch. 5 para. 1(1)

Textual Amendments

- F124** Word in Ch. 3 s. 3 heading inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 25(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F125** Words in Ch. 3 s. 3 heading omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 25(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: There are outstanding changes not yet made to Regulation (EC) No 765/2008 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Textual Amendments

F54 Word in [Ch. 3](#) heading omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 33 para. 13(a)** (as amended by [S.I. 2020/676](#), regs. 1(1), 3); 2020 c. 1, Sch. 5 para. 1(1)

F55 Words in [Ch. 3](#) heading substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 33 para. 13(b)** (as substituted by [S.I. 2020/1460](#), reg. 1(4), **Sch. 3 para. 22(5)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[^{F158}CHAPTER 4

UK MARKING

Article 30

- 1 The Secretary of State must publish the form of the UK marking as set out in Annex 2 on the Gov.uk website (<https://www.gov.uk>).

2 Annex 2 has effect.

3 Any reference to the UK marking in any enactment is a reference to the UK marking in the form set out in Annex 2 and published in accordance with paragraph 1.

4 A requirement in any enactment to affix the UK marking is a requirement to affix the UK marking in accordance with the requirements in Annex 2.

5 The UK marking must not be affixed to a product unless an enactment provides for its affixing.

6 An economic operator must not affix any other marking, sign or inscription which is likely to mislead any person as to the meaning or form of the UK marking.

7 An economic operator must not affix any other marking if the visibility, legibility and meaning of the UK marking would be impaired as a result.

8 Where the UK marking is affixed to a product in breach of paragraph 4, the UK marking is affixed in a false or misleading manner and Article 27(3)(c) applies.]

Textual Amendments

F158 [Ch. 4](#) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 33 para. 29**; 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: There are outstanding changes not yet made to Regulation (EC) No 765/2008 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

^{F159}CHAPTER V

COMMUNITY FINANCING

Article 31

Body pursuing an aim of general European interest

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Article 32

Activities eligible for Community financing

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Article 33

Bodies eligible for Community financing

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Article 34

Financing

.....

Article 35

Financing arrangements

.....

Article 36

Management and monitoring

.....

Article 37

Protection of the Community's financial interests

.....

Changes to legislation: There are outstanding changes not yet made to Regulation (EC) No 765/2008 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Textual Amendments

F159 Ch. 5 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, [Sch. 33 para. 30](#); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

CHAPTER VI

FINAL PROVISIONS

^{F160} Article 38

Technical guidelines

Textual Amendments

F160 Art. 38 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, [Sch. 33 para. 31](#); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

Article 39

Transitional provision

Accreditation certificates issued before 1 January 2010 may remain valid until the date of their expiry, but no later than 31 December 2014. This Regulation shall, however, apply in the case of their extension or renewal.

^{F161} Article 40

Review and reporting

Textual Amendments

F161 Art. 40 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, [Sch. 33 para. 32](#); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

^{F162} Article 41

Penalties

Changes to legislation: There are outstanding changes not yet made to Regulation (EC) No 765/2008 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Textual Amendments

F162 Art. 41 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 33**; 2020 c. 1, Sch. 5 para. 1(1)

F163 Article 42

Amendment to Directive 2001/95/EC

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Textual Amendments

F163 Art. 42 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 34**; 2020 c. 1, Sch. 5 para. 1(1)

Article 43

Repeal

Regulation (EEC) No 339/93 is hereby repealed with effect from 1 January 2010.

F164

Textual Amendments

F164 Words in Art. 43 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 35**; 2020 c. 1, Sch. 5 para. 1(1)

F165 Article 44

Entry into force

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Textual Amendments

F165 Art. 44 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 36**; 2020 c. 1, Sch. 5 para. 1(1)

F166 ...

Changes to legislation: There are outstanding changes not yet made to Regulation (EC) No 765/2008 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

Textual Amendments

F166 Words in Signature omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 33 para. 37**; 2020 c. 1, **Sch. 5 para. 1(1)**

Changes to legislation: There are outstanding changes not yet made to Regulation (EC) No 765/2008 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

F167 ANNEX I

Textual Amendments

F167 Annex 1 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 38**; 2020 c. 1, Sch. 5 para. 1(1)

F168 ANNEX 2

UK marking

Textual Amendments

F168 Annex 2 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 39**; 2020 c. 1, Sch. 5 para. 1(1)

1. The UK marking consists of the initials “UKCA” taking the following form—



2. Where the UK marking is reduced or enlarged, the proportions given in the graduated drawing in paragraph 1 must be respected.
3. Where an enactment does not require specific dimensions, the UK marking must be at least 5 millimetres high.]

Changes to legislation: There are outstanding changes not yet made to Regulation (EC) No 765/2008 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

- (1) [OJ C 120, 16.5.2008, p. 1.](#)
- (2) Opinion of the European Parliament of 21 February 2008 (not yet published in the Official Journal) and Council Decision of 23 June 2008.
- (3) See page 82 of this Official Journal.
- (4) [OJ L 11, 15.1.2002, p. 4.](#)
- (5) [OJ L 145, 31.5.2001, p. 43.](#)
- (6) [OJ L 281, 23.11.1995, p. 31.](#) Directive as amended by Regulation (EC) No 1882/2003 ([OJ L 284, 31.10.2003, p. 1](#)).
- (7) [OJ L 8, 12.1.2001, p. 1.](#)
- (8) [OJ L 40, 17.2.1993, p. 1.](#) Regulation as last amended by Regulation (EC) No 1791/2006 ([OJ L 363, 20.12.2006, p. 1](#)).
- (9) [OJ L 248, 16.9.2002, p. 1.](#) Regulation as last amended by Regulation (EC) No 1525/2007 ([OJ L 343, 27.12.2007, p. 9](#)).

Changes to legislation:

There are outstanding changes not yet made to Regulation (EC) No 765/2008 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.

View outstanding changes

Changes and effects yet to be applied to :

- Ch. 3 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3 heading words substituted by [S.I. 2019/696 Sch. 33 para. 13\(b\)](#) (This amendment not applied to legislation.gov.uk. Sch. 33 para. 13(b) substituted immediately before IP completion day by virtue of S.I. 2020/1460, reg. 1(4), Sch. 3 para. 22(5))
- Regulation applied (with modifications) by [S.I. 2023/959 reg. 4\(a\)Sch. 1](#)
- Title replacement by [EUR 2019/1020 Regulation](#)
- Art. 1 para. 3 repeal by [EUR 2019/1020 Regulation](#)
- Art. 1 para. 2 repeal by [EUR 2019/1020 Regulation](#)
- Art. 2 Point 1 repeal by [EUR 2019/1020 Regulation](#)
- Art. 2 Point 19 repeal by [EUR 2019/1020 Regulation](#)
- Art. 2 Point 18 repeal by [EUR 2019/1020 Regulation](#)
- Art. 2 Point 14 repeal by [EUR 2019/1020 Regulation](#)
- Art. 2 Point 17 repeal by [EUR 2019/1020 Regulation](#)
- Art. 2 Point 15 repeal by [EUR 2019/1020 Regulation](#)
- Art. 2 Point 2 repeal by [EUR 2019/1020 Regulation](#)
- Art. 30 applied by [S.I. 2020/1359 reg. 4\(1\)\(b\)](#)
- Art. 32 para. 1 Point (d) repeal by [EUR 2019/1020 Regulation](#)
- Art. 32 para. 1 Point (e) repeal by [EUR 2019/1020 Regulation](#)
- Art. 32 para. 1 Point (g) replacement by [EUR 2019/1020 Regulation](#)
- Art. 32 para. 1 Point (f) replacement by [EUR 2019/1020 Regulation](#)
- Art. 32 para. 1 Point (c) replacement by [EUR 2019/1020 Regulation](#)

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Ch. 3Art. 27 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3Art. 23 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3Art. 16 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3Art. 29 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3Art. 19 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3Art. 17 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3Art. 22 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3Art. 21 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3Art. 15 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3Art. 24 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3Art. 28 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3Art. 26 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3Art. 20 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3Art. 18 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3Art. 25 repeal by [EUR 2019/1020 Regulation](#)
- Art. 2(1) words substituted by [S.I. 2019/696 Sch. 33 para. 3\(c\)\(i\)](#) (This amendment not applied to legislation.gov.uk. Sch. 33 para. 3(c)(i) substituted immediately before IP completion day by virtue of S.I. 2020/1460, reg. 1(4), Sch. 3 para. 22(3)(a))
- Art. 2(2) words substituted by [S.I. 2019/696 Sch. 33 para. 3\(d\)\(i\)](#) (This amendment not applied to legislation.gov.uk. Sch. 33 para. 3(d)(i) substituted immediately before IP completion day by virtue of S.I. 2020/1460, reg. 1(4), Sch. 3 para. 22(3)(b))

- Art. 2(4) substituted by [S.I. 2019/696 Sch. 33 para. 3\(e\)](#) (This amendment not applied to legislation.gov.uk. Sch. 33 para. 3(e) omitted immediately before IP completion day by virtue of S.I. 2020/1460, reg. 1(4), Sch. 3 para. 3)
- Art. 2(4) words substituted in earlier amending provision S.I. 2019/696, Sch. 33 para. 3(e) by [S.I. 2020/852 reg. 4\(2\) Sch. 1 para. 1\(s\)\(i\)](#) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 1(s)(i) omitted immediately before it comes into force by virtue of S.I. 2020/1460, regs. 1(3), Sch. 4 para. 1(3))