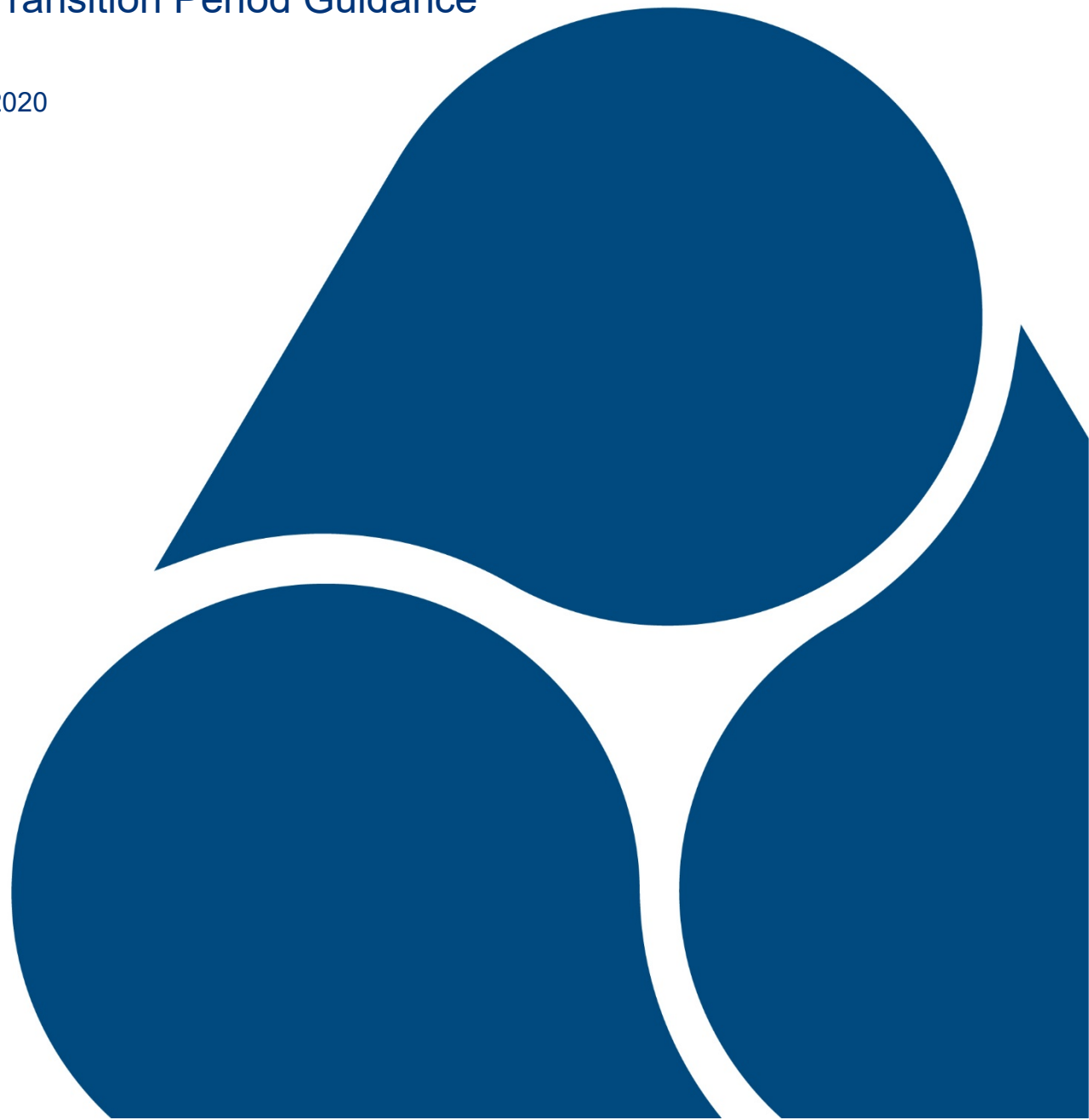
Office for Product Safety & Standards

Changes to Regulation 765/2008 on Accreditation and Market Surveillance applying in Great Britain from 1 January 2021

End of Transition Period Guidance

December 2020



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Guidance

1 What is changing? A summary of the key changes

1.1 This guidance relates to Regulation on Accreditation and Market Surveillance (765/2008) as it has effect in Great Britain ('GB RAMS'), which is an amended version of the EU Regulation on Accreditation and Market Surveillance (765/2008) ('EU RAMS') and forms part of the law applicable in Great Britain (GB) at the end of the Transition Period. GB RAMS will only have effect in Great Britain, EU RAMS will continue to apply in Northern Ireland.

GB RAMs sets out provisions on accreditation and market surveillance of products available on or entering the market in Great Britain.

This guidance highlights the changes relevant to Market Surveillance Authorities and enforcement authorities operating in GB. It is also relevant to other operational partners with an interest in product safety such as Border Force.

1.2 EU RAMS 765/2008 will cease to apply in Great Britain after the Transition Period ends on 31 December 2020, and will be amended by GB RAMS**,** which will be applicable 1 January 2021. GB RAMS retains largely the same framework. The overarching purpose of the legislation remains that all products - intended for or likely to be placed on the market and used by consumers or other end users - are compliant with safety provisions. From 1 January 2021, products entering GB from EU member states will be subject to border import controls and may be subject to checks in accordance with the UK's risk-based intelligence-led approach to market surveillance.

The powers available to market surveillance and enforcement authorities are unchanged. Other UK regulations implementing product-specific EU legislation, and UK domestic legislation including the General Product Safety Regulations, are being updated to reflect the end of the Transition Period, ensuring an appropriate set of enforcement powers are in place.

1.3 EU RAMS 765/2008 will continue to apply directly in Northern Ireland and is the subject of separate guidance.

1.4 GB RAMS introduces a number of changes and amendments to accreditation, market surveillance and UK conformity marking requirements.

Accreditation

1.5 GB RAMS introduces some changes related to accreditation to reflect the Great Britain context. For the most part this means adjusting general provisions for national accreditation bodies to the specifics of the UK national accreditation body (NAB). The more significant changes are to Article 4 (which introduces provisions for the UK national accreditation body), Article 7 (which is removed altogether) and Article 10 (which introduces provisions on evaluation of the national accreditation body). The United Kingdom Accreditation Service (UKAS) remains as the sole UK NAB for voluntary and mandatory accreditation, as appointed by the Accreditation Regulations 2009 (Statutory Instrument 2009/3155).

1.6 Related guidance is available on conformity assessment and placing products on the GB market. Specific guidance for business and Government Departments will be made available.

Market Surveillance

1.7 Market Surveillance Authorities operating in Great Britain continue to have responsibility for identifying and removing unsafe and non-compliant products from the market after the end of the Transition Period. Some responsibilities will change because of the UK leaving the EU. Market Surveillance Authorities and operational partners must continue to take a risk-based and intelligence-led approach to their activities.

1.8 The Office for Product Safety & Standards has responsibility for coordinating the application of UK market surveillance policy and legislation to provide national policy coherence and support Market Surveillance Authorities and their sponsoring Government Departments across the whole UK.

2. Market Surveillance: GB RAMS Articles 15 - 29

What is Market Surveillance?

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

GB RAMS sets out obligations for Market Surveillance Authorities to ensure that products are safe and conform to relevant legislation. These include requiring Market Surveillance Authorities to:

- carry out risk-based assessments;
- seek such information and documentation from economic operators that appears to be necessary for the purpose of carrying out their functions;
- ensure that products conform to applicable requirements set out in relevant sector specific legislation;
- ensure that products which present a serious risk requiring rapid intervention, including a serious risk where the effects are not immediate, are recalled, withdrawn or prohibited from being placed on the market and the Secretary of State is notified without delay.
- work in collaboration with other authorities to prevent unsafe and non-compliant products entering the market.

Overall approach to market surveillance in Great Britain

2.2 The majority of market surveillance activity will continue to take place when goods are on the market in Great Britain. Market surveillance activity will also take place before goods are released into free circulation. This will take place at border ports (i.e. points of entry). Authorities must continue to take a risk-based, intelligence-led approach so they make ‘’appropriate checks’’ on an ‘’adequate scale’’ of goods placed on the GB market.

GB RAMS Market surveillance changes

Many of the provisions in GB RAMS are largely the same and maintain rules and obligations as EU RAMS it amends. The changes take account of the UK’s exit from the European Union, and these include for example removal of references to the European Union, its institutions and laws, and their replacement with references to specific UK bodies, processes and laws.

2.3 Article 15 - Scope

There has been minimal amendment to the general provisions on scope (articles 16 to 22 and 26). Articles 23, 24 and 25 (on EU specific issues) have not been taken forward in GB RAMS. This means that references now relate to UK law and remove references to EU law. These will only apply for as long as there are no more specific provisions with the same objective in any relevant enactment.

2.3 Article 16 - General requirements

This article remains largely the same. Article 16.1 introduces a new specific reporting obligation on Market Surveillance Authorities. They must now advise the Secretary of State and public (previously this was the EU Commission, Member States and public) of any products covered by any relevant enactments which are liable to compromise health or safety of users or do not conform to applicable requirements and which have been withdrawn, prohibited or restricted from being placed on the market.

2.4 Article 19 - Market surveillance measures

This article remains largely the same. The provision in Article 19.5 which requires Market Surveillance Authorities to observe confidentiality (where necessary to protect commercial secrets or to preserve personal data pursuant to national legislation) will continue. This obligation is now subject to two qualifications, namely that:

- information should be made public to the fullest extent necessary to protect users of products in the UK, and
- the protection of confidentiality will not prevent dissemination to Market Surveillance Authorities of information relevant to ensuring the effectiveness of market surveillance activities.

2.5 Article 20 – Products presenting a serious risk

This Article places an obligation on Market Surveillance Authorities to ensure that products that present a serious risk must be recalled, withdrawn or prohibited from being made available on the UK market. Previously this obligation applied to Member States. The duty of the UK (as the Member State) to inform the European Commission has changed. This is now replaced with a duty on Market Surveillance Authorities to inform the Secretary of State, without delay and in accordance with Article 22, which sets out the procedure for reporting serious risks. The Product Safety Database (PSD) has been established to perform this function in place of RAPEX.

2.6 Article 22 – Exchange of information

Obligations in Articles 22.1 and 22.2, that previously required Member States to notify the Commission of serious risks associated with products, now places an obligation on Market Surveillance Authorities. They must now notify the Secretary of State immediately and in accordance with article 22.4. These notifications are required to be made using the Product Safety Database, in accordance with regulation 33(A1) of the General Product Safety Regulations 2005.

2.8 Article 29 – National measures

Where a product entering the market presents a serious risk or is not compliant, the authorities in charge of the control on products entering the market must endorse that product’s accompanying commercial invoice (or other relevant document or where data processing is carried out in the data processing system itself) with specific text.

Market Surveillance Authorities should note that the text of those endorsements has changed as follows:

Where a product is deemed to present a serious risk, the endorsement must be: Dangerous product - discharge from the free-circulation procedure not authorised – Regulation (EC) No 765/2008

Where a product is deemed to be not compliant, the endorsement must be: Product not in conformity - discharge from the free-circulation procedure not authorised – Regulation (EC) No 765/2008

3. UK Conformity Marking under GB RAMS

3.1 The requirements for marking of products has changed. These are set out in Annex 2 to GB RAMS.

The UKCA (UK Conformity Assessed) marking is a new UK product marking that will be used for goods being placed on the market in Great Britain (England, Wales and Scotland). It covers most goods that previously required the CE marking.

The UKCA mark may be used from 1 January 2021. To allow businesses to make the appropriate arrangements to adjust to the requirements, most goods can continue to be CE marked until 1 January 2022.

There is further guidance available on placing goods on the Great Britain market at:

https://www.gov.uk/guidance/placing-manufactured-goods-on-the-market-in-great-britain-from-1-january-2021

For guidance on the use of the UKCA mark from January 2021 please refer to the published guidance at:

https://www.gov.uk/guidance/using-the-ukca-mark-from-1-january-2021#check-whether-you-will-need-to-use-the-new-ukca-marking

Market Surveillance Authorities should be aware that from 1 January 2021, Northern Ireland businesses will continue to benefit from unfettered access to the rest of the United Kingdom, meaning these goods will not be subject to additional processes or procedures when moved from Northern Ireland to Great Britain.

Northern Ireland businesses will continue to be able to place qualifying Northern Ireland goods on the market in Great Britain using EU conformity markings (such as the CE marking or the new UKNI marking). This will be the case even if there are changes between the EU rules that the Northern Ireland Protocol applies and the rules in Great Britain. This is part of the government's commitment for Northern Ireland businesses to have unfettered access to the rest of the UK market.

For further information see:

https://www.gov.uk/guidance/moving-qualifying-goods-from-northern-ireland-to-the-rest-of-the-uk

https://www.gov.uk/guidance/placing-manufactured-goods-on-the-market-in-great-britain-from-1-january-2021

https://www.gov.uk/government/collections/moving-goods-into-out-of-or-through-northern-ireland-from-1-january-2021

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