

**IMPLEMENTATION OF THE
RESTRICTION OF HAZARDOUS
SUBSTANCES IN ELECTRICAL
AND ELECTRONIC EQUIPMENT
(ROHS) DIRECTIVE 2011/65/EU**

Consultation

APRIL 2012

Contents

Contents	2
Implementing the RoHS Directive	3
Executive Summary	4
Issues and questions	5
Introduction	5
Aims of the RoHS Directive	5
Main changes	6
Proposed Regulations.....	12
Detailed aspects of the draft Regulations	14
Impact Assessment.....	17
Government Guidance Notes	18
Annex 1 – Summary of consultation questions	20
Annex 2: Draft government guidance notes	21
Annex 3: Explanation of transposition and copy out	34
Annex 4: Draft Regulations	37

Implementing the RoHS Directive

This consultation seeks views on the implementation policy, draft Regulations and UK's draft guidance notes. This will inform the transposition process taking the Directive into UK law.

Issued: 12 April 2012

Respond by: 6 July 2012

Enquiries to: Mr Peter Askew
Environmental Regulation Unit
Green Economy Team
Department for Business, Innovation and Skills
1 Victoria Street
LONDON
SW1H 0ET

++ 44 (0)20 7215 5000

peter.askew@bis.gsi.gov.uk

This consultation is relevant to: all businesses making and/or placing products with any electrical and electronic function on the market, wholesalers and distributors of these products. and trade associations in the electronics and ICT sector.

When responding please state whether you are doing so as a business, an individual or representing the views of an organisation. If you are responding on behalf of an organisation, please make it clear who the organisation represents and, where applicable, how the views of members were assembled.

Information provided in response to this consultation, including personal information, may be subject to publication or release to other parties or to disclosure in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004). If you want information, including personal data that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence.

In view of this, please explain to us why you consider the information you have provided is confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be considered binding on the Department.

Executive Summary

Overview

The RoHS Directive primarily aims to ensure that EU Member States apply common restrictions on the levels of six hazardous substances that may be present in a wide range of electrical and electronic equipment, as well as minimising the end of life environmental impact of that equipment. It is a single European market measure and implementation is made by one law covering the whole of the UK.

The original Directive published in 2002 was implemented through *The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2006*, (SI 2006 No. 1463) which came into force on 1 July 2006. It was subsequently replaced by SI 2008 No. 37 following revision.

The new *RoHS Directive 2011/65/EU*¹ was published on 1 July 2011. It has a different scope and obligations on those placing products on the market. This consultation seeks views on the implementation policy, draft regulations, consultation impact assessment and draft UK guidance notes. It is expected that additional, more detailed guidance will be made available by the European Commission later this year, as the UK is contributing to drafting work in this area.

Main issues

The original policy of the RoHS Directive to protect human health and the environment across the European single market remains the same. However, the new Directive brings forward changes to:

- Broaden the scope of products covered
- Require the "CE" and other marking of compliant products and new conformity assessment procedures
- Provide for new exclusions from scope
- Provide for new criteria for the application and duration of exemptions
- Introduces an end date after which non-compliant product cannot be made available.

Next steps

After the consultation has closed, we aim to publish a government response within 3 months. The final version of the Regulations will be made and laid before Parliament to come into force from 2 January 2013 and the old Regulations will be revoked. We will aim to publish the UK Government guidance notes for the new Regulations at least 10 weeks before that date.

¹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:174:0088:0110:EN:PDF>

Issues and questions

Introduction

1. The original RoHS Directive places an obligation on the European Commission to review the measures in that Directive to take account of any relevant new scientific evidence. In particular, it calls on the Commission to present proposals to the European Parliament and the Council for the inclusion of both remaining categories of EEE (contained within the WEEE Directive 2002/96/EC) that were not within its original scope. These are category 8 medical devices and category 9 monitoring and control instruments.
2. Between 2005 and 2008, the Commission consultants undertook a number of research projects into various aspects of the RoHS Directive.
3. The results of those studies can be downloaded from the EC's Europa website at http://ec.europa.eu/environment/waste/rohs_eee/studies_rohs2_en.htm. In addition, the Commission formally asked interested stakeholders on two separate occasions for their opinions and comments. The results of those two exercises can be found at http://ec.europa.eu/environment/waste/rohs_eee/studies_rohs2_en.htm.
4. In December 2008, the Commission published its proposals for a recast RoHS Directive, which can be downloaded from http://ec.europa.eu/environment/waste/rohs_eee/index_en.htm.
5. In April 2009 the UK held a public consultation on these Commission proposals. This was a joint consultation covering both proposals on the WEEE and RoHS Directives and was used to inform the UK policy line in the negotiations. Although it was appropriate to consult on both proposals at the same time, the responses were considered separately as they dealt with different negotiations.
6. Following negotiations between the Council and European Parliament, a final Directive was agreed and subsequently published on 1 July 2011. A consultation stage impact assessment² has been produced by BIS based on the final Directive.
7. In this consultation, we welcome comments on the implementation policy, draft regulations, consultation impact assessment and draft UK guidance notes.

Aims of the RoHS Directive

8. Both the current and new RoHS Directive's aim to minimise the amount of potentially hazardous substances ending up in landfill sites and present in recycling processes, by restricting the use of six of those substances in the manufacture of a wide range of electrical and electronic equipment (EEE) placed on the EU market. The restricted substances are lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE). These are listed in Annex II of the new

² BIS Consultation Stage Impact Assessment no. BIS0333 (URN 12/586)
<http://www.bis.gov.uk/assets/biscore/business-sectors/docs/c/12-586-consultation-stage-impact-assessment-recast-rohs-directive.pdf>

Directive. The parts and components of the specified EEE must not contain more than the specified concentrations of these substances.

Main changes

9. The main features of the new Directive, together with issues that we feel need to be addressed in this consultation exercise are listed below. Although we have highlighted these issues in order to assist you in responding, you are free to offer comment on any other areas of the Directive in terms of how we implement the Directive in UK Regulations. **This consultation does not seek views on the provisions of the Directive itself but on our proposed implementation of it.**
10. A copy of the draft Regulations can be found in Annex 4 and the consultation impact assessment can be downloaded from the BIS website³.

Scope and Review

11. The scope of the 2011 RoHS Directive is now defined completely in the Directive itself. This is a change from the original 2002 RoHS Directive which took its scope from the categories listed in the WEEE Directive (2002/96/EC). As a result no assumptions on scope can be made in the context of the WEEE Directive, and indeed products considered EEE under RoHS may differ to those considered EEE under the WEEE Directive.
12. The original categories 1-7 and 10, continue to cover the same products as the original Directive although there is no list of example products. As confirmed by Article 2(2) of the 2011 RoHS Directive, additional items now falling into these categories following the changes to the definition of “dependent” in the context of “electrical function”, are considered outside of scope until 8 years after entry into force (until 22 July 2019). The European Commission has stated that the same rule applies to products considered out of scope now and being brought into scope by the provisions of the new Directive – whatever the reason. A list of the categories can be found in Annex I of the Directive.
13. Two categories of the original WEEE Directive which were excluded from the scope of the original RoHS Directive (category 8 medical devices and category 9 monitoring and control instruments) are now brought into scope. However, the new Directive provides for this to be phased in over a period up to 22 July 2016 and a new annex of exemptions has been included specifically for these two categories. In addition, Industrial monitoring and control instruments are also brought into scope but this is deferred until 22 July 2017.
14. The new category 11 provides for any product with any electrical function to be brought into scope from 23 July 2019. The Directive defines this as “to fulfil at least one intended function”, rather than a main or primary electrical function. This is likely to mean a broad range of products not normally considered electrical or electronic are brought into the scope of the Directive (from 23 July 2019), for example a gas cooker with an electric clock or light. The BIS impact assessment has examined possible items coming into the broader scope. There may be other items not shown, for which respondents to the consultation are invited to provide more details.

³ <http://www.bis.gov.uk/assets/biscore/business-sectors/docs/c/12-586-consultation-stage-impact-assessment-recast-rohs-directive.pdf>

15. In addition to the new categories, the scope also now confirms that cables and two-wheeled vehicles which are not type approved are within the scope of the Directive, although certain exemptions apply to certain cables and spare parts until those categories come into scope. There is no exemption however for spare parts for items falling in category 11.
16. More generally, the Commission interprets Article 2(2) as meaning that EEE which was outside the scope of Directive 2002/95/EC, but which would be covered by the new Directive (2011/65/EU), does not need to comply with the requirements of the new Directive during a transitional period of eight years i.e. until July 2019. EEE which was outside the scope of Directive 2002/95/EC, but which would be covered by the new Directive, includes among others EEE covered by:
- the new category 11;
 - the new definition of "dependent";
 - "cables" mentioned in Article 4 and the related definition in Article 3(5);
 - two-wheel vehicles which are not type-approved.

During the transitional period, in the Commission's interpretation, it follows that Member States are obliged to allow EEE which was outside the scope of Directive 2002/95/EC, but which would be covered by the new Directive, to continue to be made available on their market.

17. A second key change resulting from this Article is that from 22 July 2019 there is a 'hard stop' in that products that were outside the scope of the old Directive but that are already placed on the market will no longer be able to be made available if they are non-compliant.
18. A further impact of the change in scope, taking into account new exclusions, are products which may now fall out of scope, which were in the scope of the original Directive. At present, BIS has identified only certain non-road mobile machinery which are in scope now but may be out of scope under the new Directive but we would welcome input from stakeholders of further examples which might be relevant as a result of changes to existing and new definitions.
19. There is no immediate change to the list of restricted substances specified by the current RoHS Directive. These are specified in Annex II of the recast Directive, along with the existing permitted maximum concentration values that can be tolerated by weight in each homogeneous material within the equipment. Article 6 provides for a review of the list of substances to take place by 22 July 2014. This will be for the Commission to implement.
20. It has been agreed that as the negotiations were concluded without the Commission being able to complete a full impact assessment a review will be made within three years. The Commission are currently consulting stakeholders as they produce their own impact assessment based on the final text⁴. This could lead to further legislative proposals from the Commission to make further changes to the scope of the Directive. This means that some products which appear to come into scope after 22 July 2019 may not ever come into scope, as the Commission could make proposals to exclude them.

⁴ <http://rohs.biois.com/>

21. It is anticipated that the Directive will be adopted across the EEA.

Summary of changes to scope	
i.	from 22 July 2014, Medical devices into scope.
ii.	from 22 July 2016, In vitro medical devices into scope.
iii.	from 22 July 2014, Monitoring and control instruments into scope.
iv.	from 22 July 2017, Industrial monitoring and control instruments into scope.
v.	until 1 July 2016, Reuse of spare parts (recovered from EEE placed on the market before 1 July 2016) in auditable closed loop systems exempt.
vi.	after 22 July 2019: <ul style="list-style-type: none"> i) any product with an electrical function is brought into scope. This is subject to an impact assessment due to be carried out by the Commission in the next 3 years; ii) two wheel vehicles which are not type approved enter into scope; iii) any items not in the scope of the original Directive yet falling into categories 1-7 and 10 and now covered by the new Directive enter into scope.

Exclusions

22. A list of exclusions to scope is provided in Article 2 of the Directive. This includes a number of new types of equipment being brought out of scope or subject to a formal exclusion for the first time. These may require further guidance or interpretation.

23. For example, exemption 4(c) refers to “specifically designed” equipment. One interpretation of this would, for example, consider that car radios designed to fit a DIN standard box in a vehicle would be considered within scope, whereas those only able to be fitted to a specific vehicle i.e. integral to the dashboard, would be subject to the exclusion and therefore fall outside of scope.

24. For products which aren't subject to content restrictions, they don't need to comply with obligations around CE marking etc.

25. Many of the exclusions here are further defined in Article 3 of the Directive (see below).

Definitions

26. There is no change to the definition of EEE, however the definition of “dependent” has been added which defines this as “needing electrical currents or electromagnetic fields to fulfil at least one intended function”. This is a significant change as the original Directive only considered products falling into scope which had a primary electrical function. For example, a gas cooker was not considered electrical as it was primarily a gas powered device even though it had an electrical function such as light or clock. Under the new definition, the fact that it has an electrical ignition or timer places the item within the scope of RoHS.

27. There are new definitions included in the new Directive which relate directly to the exclusions list. Care will be needed when making use of an exclusion to cross-reference to Article 3. For example non-road mobile machinery needs to be made available exclusively for professional use and have an onboard power source in order to be excluded from scope; Non-road mobile machinery without an onboard power source is in scope.

28. There is little clarity on the term “large-scale” within the text of the Directive to determine when an item is within scope of the terms large-scale fixed installation and large-scale stationary industrial tool. This will need to be explored through further guidance developed by the Commission.

29. There is a change to the definition of homogeneous material, which is now considered to be “a material, consisting of a combination of materials”. This differs from the original Directive and has implications for determining the makeup of materials in RoHS products.

Derogation for certain cables and spare parts of products in categories 8, 9 or products which have benefited from an exemption

30. There is a broad exclusion for cables and spare parts of products falling into some of the new categories coming into the scope of new RoHS for the first time, with the exception of category 11. Cables and spare parts under existing categories remain in scope.

31. One specific element of this is for EEE which benefited from an exemption and which was placed on the market before that exemption expired as far as that specific exemption is concerned. We have taken this to apply to specific products which have made specific use of an exemption provided for in the Annexes III and IV of the Directive, before that exemption reached its end date.

Summary of exemption from scope for cables and spare parts

- i. EEE placed on the market before 1 July 2006
- ii. medical devices placed on the market before 22 July 2014
- iii. In vitro medical devices into scope placed on the market before 22 July 2016
- iv. Monitoring and control instruments placed on the market before 22 July 2014
- v. Industrial monitoring and control instruments placed on the market before 22 July 2017
- vi. EEE which benefited from an exemption and which was placed on the market before that exemption expired as far as that specific exemption is concerned.

Technical exemptions

32. A list of exemptions is given in Annex III of the Directive. Exemptions specific to all types of medical devices and both groups of monitoring and control instruments are given in Annex IV of the Directive.
33. The new Article 5 sets out the process for exemptions to be granted on the grounds that such inclusion doesn't weaken the environmental and health protection of Regulation EC 1907/2006, and
- their elimination or substitution via changes which do not require use of items listed in Annex II is scientifically or technically impracticable.
 - the reliability of substitutes is not ensured
 - the total negative environmental, health and consumer safety impacts caused by substitution are enough to outweigh the total benefits of these.
34. The requirements for what must be submitted in an application for an exemption is contained in Annex V of the Directive.
35. The Commission has proposed a significant change to the current procedure by introducing a four-year maximum validity period for all exemptions. Although exemptions can be renewed, Article 5(2) provides that these will be valid for a maximum of five years for most categories, but a maximum 7 years for category 8 and 9. The length of exemption will be decided on a case-by-case basis.

New Legislative Framework

36. Changes have been made to align the proposed Directive with Decision No 768/2008/EC on a common framework for the marketing of products, which was adopted in July 2008 as part of (what has become known as) the “Goods Package”⁵ with a view to introducing greater legislative consistency among EC harmonising measures, and in particular among the increasing number of members of the “New Approach” family of legislation setting harmonised requirements for a range of products.
37. This means key changes for the RoHS Directive and some specific changes to obligations. These changes include the introduction of common definitions and specification of the obligations of economic operators at different stages in the supply chain (manufacturers, importers, distributors) in relation to the placing and making available on the market of EEE.

New obligations

38. Amongst the changes to the Directive are new obligations:

- i. on manufacturers, importers and distributors in respect of non-compliant EEE placed on the market (Articles 7(i), 9 (c), (f), 10(b) and (c)). Manufacturers, importers and distributors must take corrective measures and inform the market surveillance authority if they are aware of non-conformity of EEE. It is proposed that failure to do so will be an offence under UK law. It will be the responsibility of companies to notify the National Measurement Office in such cases of what the problem is and any corrective measures that have been taken.
- ii. on manufacturers and importers, to provide information and documents demonstrating conformity (Articles 7(j) and 9(h)) in a language easily understood by the authority.
- iii. on manufacturers and importers to keep a register of non-conforming EEE and product recalls (Articles 7(f) and 9(e)), and to mark EEE with certain information (Articles 7(c), (g), (h), and 9(d)).
- iv. on distributors to verify that EEE bears CE marking and is accompanied by required documentation in a language which can be easily understood by end-users and consumers, and to provide all the information to the enforcement body.
- v. that declarations of conformity be translated into the language or languages specified by the Member State in which the product is placed or made available (Article 13(2)). BIS proposes that the language be English. This change means that it will no longer be acceptable to provide reports in other languages.

⁵ <http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/new-legislative-framework/>

39. Furthermore, certain obligations don't necessarily arise at time of placing on market (for example register of recalled products) but might apply subsequently.

CE marking

40. The Directive also provides for manufacturers to self-certify the conformity of their products with the requirements of the Directive, to prepare an "EU declaration of conformity" and to affix the "CE marking". In addition, reference is made to Regulation No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products. The Directive's Annex VI sets out the requirements for the declaration of conformity.
41. It is important to note that a product can now be considered non-compliant because it fails to meet procedural, as well as substance, requirements.
42. It is likely that some products not currently CE marked under other legislation will require CE marking under RoHS. It is important for companies to understand these changes and where necessary seek advice from trade associations and review the guidance from the National Measurement Office.
43. Requirements will come into place on the Directive implementation date (2 January 2013) as no transition period is provided for. The government has few options here, as products must be compliant from this date. We expect the Commission to issue guidance to the effect that where EEE falling within the scope of 2011/65/EU and meeting the substance restrictions, procedural requirements and other requirements is placed on the market on or after the Directive's entry into force date (21 July 2011), it may be CE marked and include RoHS on its Declaration of Conformity even if the substance restrictions do not yet apply.

Commission FAQ/Guidance

44. The Commission publication "*Frequently Asked Questions on Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) and Directive 2002/96/EC on Waste Electrical and Electronic Equipment Directive (WEEE)*"⁶ is not considered to apply to the new Directive. This will mean that until guidance is issued by the Commission on the new Directive it can be assumed that items considered out of scope under the current FAQ will fall into scope.

Proposed Regulations

45. A transposition note outlining the main departures from copy out is in Annex 3. A copy of the draft Regulations can be found in Annex 4.
46. In line with Coalition government policy, these are intended to implement only that which is necessary to meet the essential requirements of the Directive. It is government policy that the majority of European legislation be implemented on a copy-out basis, rather than interpreting the text into a more traditional UK structure. This has the benefit of being clear

⁶ http://ec.europa.eu/environment/waste/wEEE/pdf/faq_wEEE.pdf

and unambiguous against the European text. It is proposed that the majority of the Articles for the RoHS Directive be transposed on a copy-out basis, where the text of the Directive would be directly placed into UK Regulation.

47. Where this is not possible, for example in order to provide legal certainty or implement provisions for enforcement, it is justified to make the text clearer or provide the necessary terminology for enforcement powers. These changes have been kept to what is considered necessary to meet the obligations of the Directive both in its obligations and the obligation to provide an enforcement regime.
48. An approach using alternatives to Regulation was investigated. However we are obliged by the Directive to transpose it into UK law and would be subject to infraction proceedings if we did not. Further the Directive has a single market treaty base, and thus provides certainty to the market from its adoption by all Member States. The intention is to ensure a consistent and harmonised approach and, as a result, little discretion is left to Member States as to the manner of implementation.
49. An alternative to regulation considered was providing guidance to manufacturers in order to allow them to pursue voluntary agreements to comply with restriction of hazardous substances to additional product categories. However, this was not considered a viable option because this is likely to raise the rate of non-compliance and lead to an uneven playing field between manufacturers, whereby those who do not comply do not incur any transitional costs from re-designing products etc. There would be a high risk that unscrupulous importers would endanger the environment and undermine the competitiveness of British companies. In addition, it would limit the benefits that would otherwise materialise from the internal market in products included within the scope of RoHS. This would have a detrimental impact on the competitiveness of UK manufacturers, assuming other member states complied under European legislation. In addition the environmental and health benefits from the reduction in use of hazardous substances would not be as significant, due to lower levels of compliance under a voluntary agreement scheme. A voluntary agreement or guidance was not therefore considered a viable option.
50. Regulations are therefore considered a proportionate way to ensure that the UK framework is robust and enforceable, ensuring the requirements have a formal legal base.
51. The proposed Regulations provide for a statutory review, as agreed in the core Coalition principles for new regulations. The Directive requires the Commission to submit a report on the implementation of the Directive to the European Parliament and to the Council by 22 July 2014. The Commission also has an obligation to produce an impact assessment on the open scope. The UK Review will need to take account both of these reports and impact assessment.
52. The Directive entered into force on 21 July 2011, (20 days after its publication in the Official Journal). The Directive requires that transposition take place no later than 2 January 2013. We will propose that the commencement date for the UK new RoHS Regulations be 2 January 2013.
53. A summary of all the questions in the consultation can be found at Annex 1.

Detailed aspects of the draft Regulations

Transitional arrangements

54. The new Regulations apply to EEE placed on the market on or after 2nd January 2013.
55. The existing Regulations apply to EEE which was placed on the market before 2nd January 2013 in relation to the obligations that arose at the time of placing on the market. Obligations that arose under those Regulations can be enforced under Schedules 2 and 3 of the new Regulations. In addition, however, from 2 January 2013 the new obligations on the supply chain that arise after placing on the market, as set out in the new Regulations, also apply. This does not affect liability under the 2008 Regulations for any offences committed before 2 January 2013.

Definitions

56. Where definitions are taken from the Directive they are essentially copied out, with some additional definitions added largely for the purposes of the enforcement regime. For the most part these are listed at the start of the Regulations, but terms specific to particular sections or regulations have been placed in those sections.

Article 2.2

57. Article 2(2) of the new Directive allows EEE that was outside the scope of Directive 2002/95/EC, but which would not comply with the new Directive, to continue to be made available on the market until 22 July 2019. This applies unless there are restrictions under Articles 4(3) and 4(4).
58. We have transposed this Article into the Regulations, with the following implications:
- Firstly products newly coming into scope don't have to comply with the requirements of the Directive until 2019, regardless of which category they fall into. Member states may have slightly different interpretations of the scope of 2002/95/EC.
 - To some extent, category 8 and 9 products (medical devices and monitoring and control instruments) also benefit from this provision, although they are mentioned in Articles 4(3) and 4(4). Although there is no transitional phase for the DoC and CE marking, category 8 and 9 products do not have to comply with these requirements before the date for the substance limit values as specified in Article 4(3).
 - After 22 July 2019, product that isn't compliant cannot continue to be made available on the market. The Commission has indicated that this term includes the first placing on the market as well as all secondary market operations, e.g. resale. The implication of this is that the distribution chain must be "clean" of non-compliant product after that date, as product cannot be made available for distribution, consumption or use in the course of commercial activity whether in return for payment or even given away free.
 - o Although categories 8 and 9 products benefit from a later date of coming into scope of the Directive, Article 2(2) impacts on categories 8 and 9 too because by 22 July 2019, the supply chain within the EU must be clear of non-compliant

category 8 and 9 products that have been placed on the market after 2 January 2013 (between 3 Jan 2013 and 22 July 2014/16/17) as well.

- EEE already placed on the market is subject to some of the obligations of the new Directive. This includes any product still in the distribution chain. Obligations include those on distributors set out in Article 10 of the Directive.

Homogeneous materials

59. The definition of “homogeneous material” in Article 3(20) has a direct impact on the scope of the Directive as the maximum concentration values by weight apply to homogenous materials (Article 4.2). The maximum concentration values for the restricted substances set in the Directive are currently restricted to below 0.1% by weight in homogeneous materials, except Cadmium which must be below 0.01%. The Directive provides for the Commission to make delegated acts regarding the rules for compliance with the maximum concentration values for the substance restrictions set out in Article 4.2. The Commission will therefore need to adopt rules for complying with these values, especially relating to the surface coatings.
60. In January 2012, the Commission asked the consultants BIOS to make a study⁷ to inform the process. As the consultation will not close until April 2012, it is unlikely any decision will have been made and published as a legislative change before the UK will have adopted new RoHS Regulations to transpose the Directive. An amendment will therefore be made if necessary to update the UK RoHS Regulations once the Commission has published these new rules.

CE marking of components, spare parts and products benefiting from an exemption

61. The new obligations for CE marking are not clarified in the Directive and at first appear to apply to all EEE. However for spare parts Article 3 draws a distinction between EEE (Article 3(1)) and spare parts (Article 3(27)). Article 4 requires EEE and spare parts to comply with the substance restrictions but the requirements for affixing CE marks under Article 15 only apply to finished EEE. Therefore we interpret this to mean that spare parts that are not EEE (Article 3(1)) do not have to be CE marked or have a Declaration of Conformity.
62. Similarly for components, the definition of large-scale stationary industrial tools (Article 3(3)) draws a distinction between equipment and components. Therefore we interpret this that components are not considered equipment and do not need to be CE marked or need a Declaration of Conformity.
63. Furthermore products benefiting from exemptions (in scope but exceptionally allowed to contain the restricted substances) should be CE marked provided they meet the other obligations of the Directive with the exception of that specific use of a specific substance for which they have the exemption. It is expected further clarification will be provided in the Commission’s FAQ document for the new Directive.

⁷ <http://rohs.biois.com/consultations>

Clarifications

64. The Directive text contains a couple of clerical errors made in the production of the final text. The English text is thought to be correct with the exception of one small error in Article 9(b) where the last line makes reference to (f) and (g) in Article 7, which should read (g) and (h). It is understood that the Commission will be publishing a correction (Corrigendum), so the Regulations anticipate this change.
65. Article 15 allows the CE mark to be placed on packaging where due to the nature of the EEE it is “not possible or not warranted” to put it on the EEE itself. However it is unclear in what situation it would not be warranted to mark EEE. At the moment BIS proposes to transpose this wording, and in the case of an offence, require the manufacturer to establish that it was either not possible or not warranted to affix the CE mark to the EEE. Comments are also invited on where manufacturers might see a need for this provision.

Enforcement

66. As the recast Directive will be transposed into new Regulations, the regime of the old Regulations will be revoked and a new one put in place. The new Directive also requires the UK to enforce new provisions and obligations. It is now government policy that all new or amended powers of entry must now be submitted to the Home Office for ministerial approval. A new 'gateway' has been created with the aim of preventing the creation of needless powers and reduce unnecessary intrusion into people's homes. As such BIS has applied for new powers of entry from the Home Office via the Gateway process⁸ which will be needed to enforce the obligations of the Directive and wider EU obligations on market surveillance.
67. New obligations also mean that new criminal offences are created. The Government is committed to preventing a proliferation of unnecessary new criminal offences⁹ and this will inform our thinking on the development of any offences.
68. Regulation 765/2008/EC is a directly applicable EU Regulation, that sets out the requirements for accreditation and market surveillance (RAMS) relating to the marketing of products. This provides for a number of powers which are directly applicable in the UK. This proposed transposition does not seek to repeat those powers in full for the RoHS Regulations. It is important to note that certain specific powers are cross-referred in the Regulations to powers in RAMS. For example, Regulation 38 of the draft Regulations is supplemented by the detailed provisions of Article 19 in RAMS.

⁸ <http://www.homeoffice.gov.uk/crime/powers-entry/>

⁹ <http://www.justice.gov.uk/guidance/making-and-reviewing-the-law/criminal-offences-gateway.htm>

Questions about the Regulations	
1	Do you agree with the interpretation of Article 2.2?
2	Do you agree the Regulations contain only what is necessary to meet the requirements of the Directive?
3	Requirements will come into place on the Directive implementation date (2 January 2013) as no transition period is provided for. How should the transition to conformity and marking requirements be managed?
4	Do you have any comments on the draft Regulations' interpretation of the obligations for the supply chain for CE marking or alternative proposals?
5	Do you agree with the proposed enforcement regime's powers of entry and offences for non-compliance? Do you agree with the reversal of the burden of proof of establishing when it is "not possible" or "not warranted" to affix the CE mark at Regulation 37(5)?"

Impact Assessment

69. The associated consultation impact assessment¹⁰ is intended to measure the impact of the RoHS Directive on the UK. In doing so certain assumptions have been made about the current state of the market, existing RoHS requirements and the likely cost on new products and sectors which will have to comply with the new obligations.
70. The recast RoHS Directive affects a wide range of EEE manufacturers, professional importers, component suppliers, product assemblers, and distributors/retailers of EEE. It also has an impact on the 'downstream' industry treating, recycling and disposing of WEEE.
71. Costs will result mainly from the wider scope so that manufacturers of equipment brought into scope incur transition costs to modify their products. In addition reoccurring costs are assumed to be incurred due to the new CE marking requirements and increased costs for enforcement of the wider scope. Direct costs to business are estimated at £23.17m. This includes the cost of introducing lead free solders, transition cost, exemption cost and compliance costs. Direct benefits to business are estimated at £0.24m. This is from reduced cost including savings from compliance for business no longer in scope and savings in cost of disposal from WEEE avoided.
72. Whilst BIS has undertaken in depth research to identify costs, the nature of the new Directive's scope makes it hard to be sure all products have been identified. The recast

¹⁰ <http://www.bis.gov.uk/assets/biscore/business-sectors/docs/c/12-586-consultation-stage-impact-assessment-recast-rohs-directive.pdf>

clarifies several definitions which will harmonise interpretation of requirements across EU Member States. However it was not possible to monetise all benefits due to lack of evidence. For example the new category 11 is open ended and the exclusions list does not always provide certainty due to different possible interpretations of the meaning of certain terms such as “large scale”. Whilst these are likely to be further clarified in Commission guidance, for the purposes of the impact assessment certain assumptions had to be made.

73. The impact assessment does not consider the interpretation of Article 2.2 detailed above (paragraphs 57-58) and arising ambiguities on its application to second hand goods. We understand the Commission will provide clarity their FAQ document later in the year. Responses to this consultation will therefore be considered before any costs are attributed to it.

Questions on the impact assessment	
6	Do you agree with the assumptions made in the Impact Assessment?
7	Do you agree with the costs and benefits in the Impact Assessment? If not, please provide evidence of different figures.
8	Are there any examples of products you think may be ambiguous in meeting the exemptions?
9	Some products which were included in the original scope will now fall out of scope. Can you provide examples of products you believe might be affected?
10	Are there significant new products coming into category 11 you think we may not have captured in the impact assessment? This can be new items not in the other categories, or items falling in the scope of EEE from the new definitions.

74. A summary of all the questions in the consultation can be found at Annex 1.

Government Guidance Notes

75. Draft guidance notes have been developed and are attached in Annex 2. These are designed to help UK business on the practical application of the Regulations on their business and are provided in meeting better regulation obligations for guidance on UK Regulations¹¹. **They will supplement any European level guidance which may be published and BIS may decide to remove parts that might otherwise duplicate EU guidance.**

¹¹ <http://www.bis.gov.uk/files/file53268.pdf>

76. The guidance addresses the main areas of application and highlights changes to existing guidance on the original Directive. In particular it provides UK specific information on the Regulations, the penalties for non compliance and key sources of further advice and contacts.

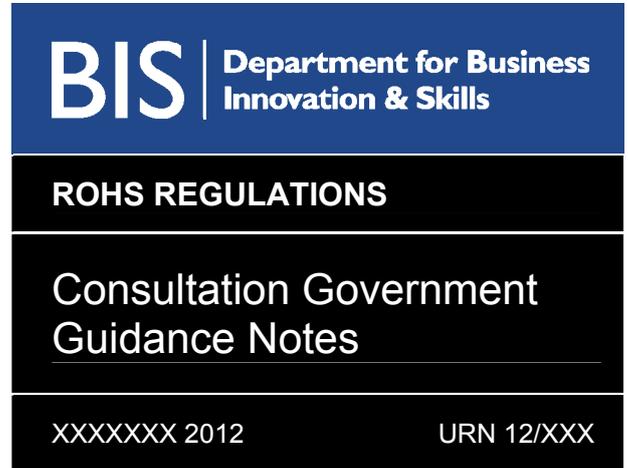
Questions about the Guidance Notes	
11	Does the guidance provide sufficient information on the intention and application of the Directive and its proposed implementation?
12	Are there specific additions or questions you have which might need to be added to the guidance?
13	If you do not agree with the answers provided in the draft guidance, do you have evidence to suggest where a different approach might be justified?
14	Are there any other comments that might help make the guidance clearer?

77. A summary of all the questions in the consultation can be found at Annex 1.

Annex 1 – Summary of consultation questions

Number	Question
1	Do you agree with the interpretation of Article 2.2?
2	Do you agree the Regulations contain only what is necessary to meet the requirements of the Directive?
3	Requirements will come into place on the Directive implementation date (2 January 2013) as no transition period is provided for. How should the transition to conformity and marking requirements be managed?
4	Do you have any comments on the draft Regulations interpretation of the obligations for the supply chain for CE marking or alternative proposals?
5	Do you agree with the proposed enforcement regime's powers of entry and offences for non-compliance?
6	Do you agree with the assumptions made in the Impact Assessment?
7	Do you agree with the costs and benefits in the Impact Assessment? If not, please provide evidence of different figures.
8	Are there any examples of products you think may be ambiguous in meeting the exemptions?
9	Some products which were included in the original scope will now fall out of scope. Can you provide examples of products you believe might be affected?
10	Are there significant new products coming into category 11 you think we may not have captured in the impact assessment? This can be new items not in the other categories, or items falling in the scope of EEE from the new definitions.
11	Does the guidance provide sufficient information on the intention and application of the Directive and its proposed implementation?
12	Are there specific additions or questions you have which might need to be added to the guidance?
13	If you do not agree with the answers provided in the draft guidance, do you have evidence to suggest where a different approach might be justified?
14	Are there any other comments that might help make the guidance clearer?

Annex 2: Draft government guidance notes



About this guidance

CONSULTATION GUIDANCE – This guidance is provisional. You should not rely on it as an interpretation of the obligations in the Directive and Regulations but should wait for the final published version.

This guide is addressed to all businesses and individuals placing electrical and electronic equipment on the UK market.

It clearly explains the requirements of the legislation, including a decision tree.

This guidance cannot cover every situation and, of course, it may be necessary to carefully consider the relevant legislation to see how it applies in your circumstances. However, if you do follow the guidance it will help you to understand how to comply with the law.

This guidance is aimed at the UK market to provide specific advice over and above EU level guidance, which will need to be read in conjunction with this document.

This guidance has been designed to comply with the “Code of Practice on Guidance on Regulation 2009”. This was published in October 2009 and a copy can be downloaded from the BIS website at www.bis.gov.uk.

This is the [MONTH] 2012 edition and replaces all earlier editions. The guidance is updated on a regular basis as necessary.

RoHS – the law in brief

Summary

1. The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012¹², (“the RoHS Regulations”) implemented the provisions of the European Parliament and Council Directive on the Restrictions of the use of certain Hazardous Substances in electrical and electronic equipment¹³ (“the RoHS Directive”).
2. The original RoHS Regulations¹⁴ have restricted the placing on the UK market of new Electrical and Electronic Equipment (EEE) containing more than the permitted levels of lead, cadmium, mercury, hexavalent chromium and both polybrominated biphenyl (PBB) and polybrominated diphenyl ether (PBDE) flame retardants since 1 July 2006 in certain products. There are a number of exempted applications for these substances and a number of products which will have limits imposed in the future.
3. Since 1 July 2006, manufacturers have needed to ensure that their products - and the components and subassemblies of such products - comply with the requirements of the original RoHS Regulations in order to be put on the single market. The Regulations have also had an impact on those who import EEE into the European Union on a professional basis, those who export to other Member States and those who rebrand other manufacturers’ EEE as their own.
4. The new RoHS Regulations do not affect the application of existing legal requirements for EEE, including those regarding safety, the protection of health, existing transport requirements or provisions on hazardous waste. In other words, existing legislation on EEE and hazardous substances must also be complied with.

Entry into force

5. The RoHS Regulations come into force on **2 January 2013**, and replace the existing Regulations that came into force on 1 February 2008.

Requirements

6. The RoHS Regulations impose obligations on economic operators (as defined in the Regulations) in relation to the placing and making available of EEE on the market.
7. The key restriction is that economic operators may not place, or make available, EEE containing lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE), in amounts exceeding the established

¹² Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 (SI 2012 No. xxxx).

¹³ Directive 2011/65/EU of 1 July 2011, (OJ No. L174/88).

¹⁴ The RoHS Regulations 2006, (SI 2006 No. 1463); revoked and replaced by the RoHS Regulations 2008 (SI 2008 No. 37), as amended by the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations 2009 (SI 2009 No. 581).

maximum concentration values, on the market. There are also requirements for EEE to be CE marked.

8. Regulation 5 and Schedule 1 of the Regulations outline what EEE are covered by the new Regulations and what EEE are exempt. Some EEE categories have special dates of application, and EEE that was outside the scope of the 2008 Regulations does not need to comply with the new Regulations until 22 July 2019.
9. Economic operators must be able to demonstrate compliance by submitting an EU Declaration of Conformity and technical documentation or other information to the market surveillance authority on request and must retain such documentation for a period of **ten** years after the EEE is placed on the market.

Enforcement

10. Responsibility for the enforcement of the RoHS Regulations lies with the Secretary of State for Business, Innovation & Skills, who has appointed the National Measurement Office (NMO), an executive agency of the Department, to act on his behalf.

RoHS Regulations

Scope

11. The RoHS Regulations apply to all EEE containing hazardous substances put on the market in the UK which falls into the categories broad categories listed. The RoHS Regulations define “EEE” and although this point is covered later in this guidance it should be noted that the definition has changed. In addition, the RoHS Regulations apply both to electric light bulbs and to household luminaires.
12. The broad categories bring products into scope of the RoHS Regulations at different times over a 6.5 year period starting from 2 January 2013. Details are provided below.
 - Existing categories 1-7 and 10 remain in scope, but are subject to new exclusions listed separately.
 - Categories 8+9 Medical devices, monitoring and control instruments enter into scope on the following timetable:
 - o From 22 July 2014: Medical devices and monitoring and control instruments
 - o From 22 July 2016: In vitro diagnostic medical devices
 - o From 22 July 2017: Industrial monitoring and control instruments.
 - A new category 11, other electrical and electronic equipment not covered by any of the categories above, comes into scope from 23 July 2019, as do two wheeled electric vehicles which are not type approved and any products in categories 1-7 or 10 not covered by the 2002 RoHS Directive, which was most recently transposed into UK law by the 2008 Regulations.

Assessing products to see if they are included in the scope

13. For many products, the decision on whether they are included within the scope of these Regulations should be reasonably straightforward. However there are a number of products (particularly in specialised or industrial sectors), where there may be significant areas of doubt and uncertainty.
14. An example of a 'decision tree' that could be used by economic operators to help determine whether their products might come within the scope of the RoHS Regulations can be found at Annex B.
15. The FAQ developed by the Commission for the previous Directive does **not** apply to the new RoHS Directive as they are considered to have different policy intentions. However, new guidance and FAQ are being developed by the Commission and is expected to be published in mid-2012.

Exclusions

16. The RoHS Regulations do not apply to:

- Equipment which is necessary for the protection of the essential interest of the security of member states, including arms, munitions and war material intended for specifically military purposes.
- Equipment designed to be sent into space;
- Equipment which is specifically designed to be installed as part of another type of equipment to which the RoHS Regulations do not apply, which can fulfil its function only if it is part of that equipment, and which can be replaced only by the same specifically designed equipment;
- Large-scale stationary industrial tools;
- Large-scale fixed installations;
- means of transport for persons or goods, excluding electric two-wheeled vehicles which are not type-approved;
- Non-road mobile machinery made available exclusively for professional use;
- Active implantable medical devices;
- Photovoltaic panels intended to be used in a system that is designed, assembled and installed by professionals for permanent use at a defined location to produce energy from solar light for public, commercial, industrial and residential applications;
- Equipment specifically designed solely for the purposes of research and development only made available on a business-to-business basis.

Exemptions

17. A list of specific exemptions that have been agreed for items in categories 1-7, 10 and 11 are provided in Annex III of the RoHS Directive. For categories 8 and 9 there is a separate list of exemptions contained in Annex IV of the RoHS Directive.

18. Furthermore:

- Until 1 July 2016, Reuse of recovered EEE spare parts in a closed loop are exempt.
- Please note there is no exemption for spare parts for products in category 11 which were placed on the market before 23 July 2019.

Possible future exemptions

19. The European Commission expects to receive many requests from industry for exemptions of additional specific applications of the hazardous substances. These requests will extend the list in the Annex to the RoHS Directive, once they have been agreed and adopted as Commission Decisions. Details on applying for exemptions are contained within the RoHS Directive in Article 5 and Annex V.

20. The RoHS Regulations incorporate both those exemptions which have already been adopted and any further exemptions which may be agreed¹⁵ while they remain in force, as the Regulations use provisions so as to refer to the exempt applications listed in the RoHS Directive Annex “as amended from time to time”. This has removed the need for further amendments to the RoHS Regulations every time that new exemptions are agreed.

Definitions

21. The definitions of “**electrical and electronic equipment**”, “**hazardous substances**”, “**place on the market**” and “**make available on the market**” can be found within the RoHS Regulations. It is worth noting these Regulations contain many more definitions than the previous ones, covering in addition e.g. “**homogeneous material**”, “**conformity assessment**”.

Maximum concentration values

22. For the purposes of the RoHS Regulations, a maximum concentration value of up to 0.1% by weight in homogeneous materials for lead, mercury, hexavalent chromium, PBB and PBDE and of up to 0.01% by weight in homogenous materials for cadmium will be permitted in EEE.

Compliance

23. The RoHS Regulations use self-declaration as the basis of the compliance regime. The UK market surveillance authority also undertakes market surveillance activities to detect non-compliant products and conducts tests for this purpose. The new RoHS Regulations also have important procedural obligations which must be complied with.

24. The RoHS Regulations now impose obligations on economic operators at different stages in the supply chain (manufacturers, importers, distributors) in relation to the placing and making available on the market of EEE. They also contain common definitions. This reflects the

¹⁵ Adopted and published as Commission Decisions in the EC Official Journal.

changes that were made at EU level to align the new RoHS Directive with Decision No 768/2008/EC on a common framework for the marketing of products, which was adopted in July 2008 as part of (what has become known as) the “Goods Package” with a view to introducing greater legislative consistency among EC harmonising measures, and in particular among the increasing number of members of the “New Approach” family of legislation setting harmonised requirements for a range of products.

Manufacturers’ obligations

25. The RoHS Regulations require manufacturers to self-certify the conformity of their products with the requirements of the RoHS Regulations. Manufacturers are required to complete an internal production control procedure in accordance with Module A of Annex II to Decision 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products and repealing Council Decision 93/465/EEC¹⁶. Manufacturers must also draw up technical documentation.
26. Once the conformity assessment is complete, manufacturers must prepare an “EU Declaration of Conformity” and affix the “CE marking”. The RoHS Directive’s Annex VI sets out the requirements for the declaration of conformity. In the absence of evidence to the contrary, it is assumed that EEE bearing the CE mark is compliant with the RoHS Regulations. The term “not possible” in Regulations (18(2)(b) and 24(2)) regarding affixing the CE marking has been copied out from the Directive. An informed judgement should be made on what is not possible in justifying the use of this provision to the enforcement authority.
27. The technical documentation, and the EU Declaration of Conformity, must be kept for a period of ten years after placing the product on the market.
28. Manufacturers also have other new obligations under the RoHS Regulations. These include:
 - i. marking EEE with information identifying the EEE and the manufacturer;
 - ii. putting procedures in place to ensure EEE manufactured by means of series production will remain compliant;
 - iii. keeping a register, and advising distributors, of non-compliant EEE which has been placed on the market, and any EEE which has been recalled;
 - iv. taking appropriate corrective measures if the manufacturer becomes aware that EEE placed on the market is non-compliant, and advising market surveillance authorities of that non-compliance, and the corrective measures taken;
 - v. co-operating with the market surveillance authority, including providing it with the information necessary (in English) to demonstrate compliance.

¹⁶ OJ L218, 13.8.2008 p.82

Importers' obligations

29. Importers have an obligation to ensure that EEE they place on the market comply with the content restrictions. They must ensure that the manufacturer has carried out a conformity assessment procedure, drawn up technical documentation, affixed the CE mark, and marked the EEE with the required information. Importers should also check that any documentation required is present, and mark the EEE with the importer's name, tradename or trademark, and a contact address. If EEE which they intended to place on the market is non-compliant, importers should inform the manufacturer, and the market surveillance authority, of the non-compliance.
30. Importers have the following additional obligations under the RoHS Regulations:
- i. keeping a register, and advising distributors, of non-compliant EEE which has been placed on the market, and any EEE which has been recalled;
 - ii. taking appropriate corrective measures if the importer becomes aware that EEE placed on the market is non-compliant, and advising market surveillance authorities of that non-compliance, and the corrective measures taken;
 - iii. co-operating with the market surveillance authority, including providing it with the information necessary (in English) to demonstrate compliance.
31. If an importer places EEE on the market under its own name or trademark, it is required to comply with the duties imposed on manufacturers, instead of the duties imposed on importers.

Distributors' obligations

32. Distributors' obligations arise when they make EEE available on the market. Distributors must not make EEE available if they have reason to believe it does not comply with the substance restrictions contained in regulation 3 of the RoHS Regulations. They should also inform the importer (or manufacturer if no importer exists), and the market surveillance authority.
33. *[subject to Commission FAQ, further guidance to be inserted regarding 'requirements applicable']*
34. Additional obligations for distributors under the ROHS Regulations include:
- i. taking appropriate corrective measures if the distributor becomes aware that EEE placed on the market is non-compliant, and advising market surveillance authorities of that non-compliance, and the corrective measures taken;
 - ii. co-operating with the market surveillance authority, including providing it with the information necessary to demonstrate compliance.

Enforcement

35. It is the duty of the National Measurement Office, acting on behalf of the Secretary of State for Business, Innovation & Skills, to enforce these Regulations.

36. Various powers of enforcement are available, including:

- Making test purchases.
- Exercising powers of entry to business premises (this excludes premises that are used wholly or mainly as a private dwelling).
- Obtaining warrants.
- Requiring the production of compliance documentation and other information which may provide evidence as to whether or not the Regulations have been complied with in a particular case or class of cases.
- Inspecting processes, documents, goods, EEE etc.
- Seizing and detaining EEE, documents, information etc and performing analytical tests, or retaining it for use as evidence in proceedings.
- Issuing a compliance or enforcement notice requiring certain action to be taken, or requiring non-compliant goods to be withdrawn from the market or prohibiting or restricting the placing of non-compliant goods on the market.
- Issuing a recall notice requiring the economic operator to use reasonable endeavours to organise the return of the EEE.
- The market surveillance authority can take an action that could have been required under a compliance, enforcement or recall notice in certain circumstances.

Offences and penalties

37. The RoHS Regulations carry the following offences:

- i. Contravening or failing to comply with the prohibition on placing non-compliant EEE on the market found in regulations 10, 23 and 29, or with an enforcement or recall notice, could result in those held responsible facing a fine up to the statutory maximum (currently £5,000) on summary conviction or an unlimited fine on conviction on indictment.
- ii. The following offences could lead to a fine up to level five on the standard scale (currently £5,000) on summary conviction:
 - a. failing to take corrective measures and notify the authorities in cases of non-compliant EEE, in accordance with regulations 20, 26 and 30;
 - b. failing to keep technical documentation or an EU declaration of conformity in breach of regulations 15 and 27;
 - c. failing to keep a register of non-compliant and recalled EEE in breach of regulations 19 and 25;
 - d. failing to co-operate with the authorities in breach of regulations 21, 27(5) or 31;

e. contravening or failing to comply with the requirements of regulation 34 regarding protection of CE marking.

iii. Procedural offences (obstruction of an enforcement officer, providing false or misleading information to the enforcement authority) are also punishable on summary conviction by a fine up to level five on the standard scale.

38. As an alternative, or in addition, to any of the above penalties, the court may, in certain circumstances, make an order requiring a person convicted of the offences referred to in paragraph 36 (i) and (ii) above to remedy the matters which have given rise to the commission of the offence. In addition, the court may order a person convicted of the offences referred to in paragraph 36 (i) above to reimburse the enforcement authority's costs of investigating the offence.

39. The defence of 'due diligence' is available where a person can show he took all reasonable steps and exercised all due diligence to avoid committing an offence. This may include reference to an act or default of, or reliance on information given by, a third party, in which case it must be accompanied by such information identifying the third party as is in the possession of the defendant.

40. The RoHS Regulations also provide for the 'liability of persons other than the principle offender', including a provision that where a company or other body corporate commits an offence, those concerned in its management and responsible (consciously or by negligence) for the commission of the offence, may also be prosecuted.

Contact points for further information

Department for Business, Innovation & Skills

Environmental Regulation Unit

Green Economy Team

1 Victoria Street

London SW1H 0ET

Tel: +44 (0) 20 7215 5000

Email: env.regs@bis.gsi.gov.uk

Website: <http://www.bis.gov.uk/policies/business-sectors/environmental-and-product-regulations/environmental-regulations/restriction-of-hazardous-substances-in-electrical-and-electronic-equipment-directive>

The National Measurement Office - RoHS Enforcement Team

RoHS Enforcement Team

NMO

Stanton Avenue

Teddington

TW11 0JZ

Tel: +44 (0) 20 8943 7227

Email: rohs@nmo.gov.uk

Website: www.rohs.gov.uk

Business Link

The Business Link website provides advice on obligations of RoHS and other legislation affecting business.

Website:

<http://www.businesslink.gov.uk/bdotg/action/detail?itemId=1082900812&type=RESOURCES>

Annex A – EEE categories for RoHS

Categories of electrical and electronic equipment covered by the RoHS Regulations.

Existing categories continuing to be within scope:

1. Large household appliances
2. Small household appliances
3. IT and telecommunications equipment
4. Consumer equipment
5. Lighting equipment, (including electric light bulbs and household luminaires)
6. Electrical and electronic tools (with the exception of large-scale stationary industrial tools)
7. Toys, leisure and sports equipment
10. Automatic dispensers

New categories being added to the scope:

8+9 Medical devices, monitoring and control instruments

From 22 July 2014: Medical devices and monitoring and control instruments

From 22 July 2016: In vitro medical devices

From 22 July 2017: Industrial monitoring and control instruments.

11. Any other EEE

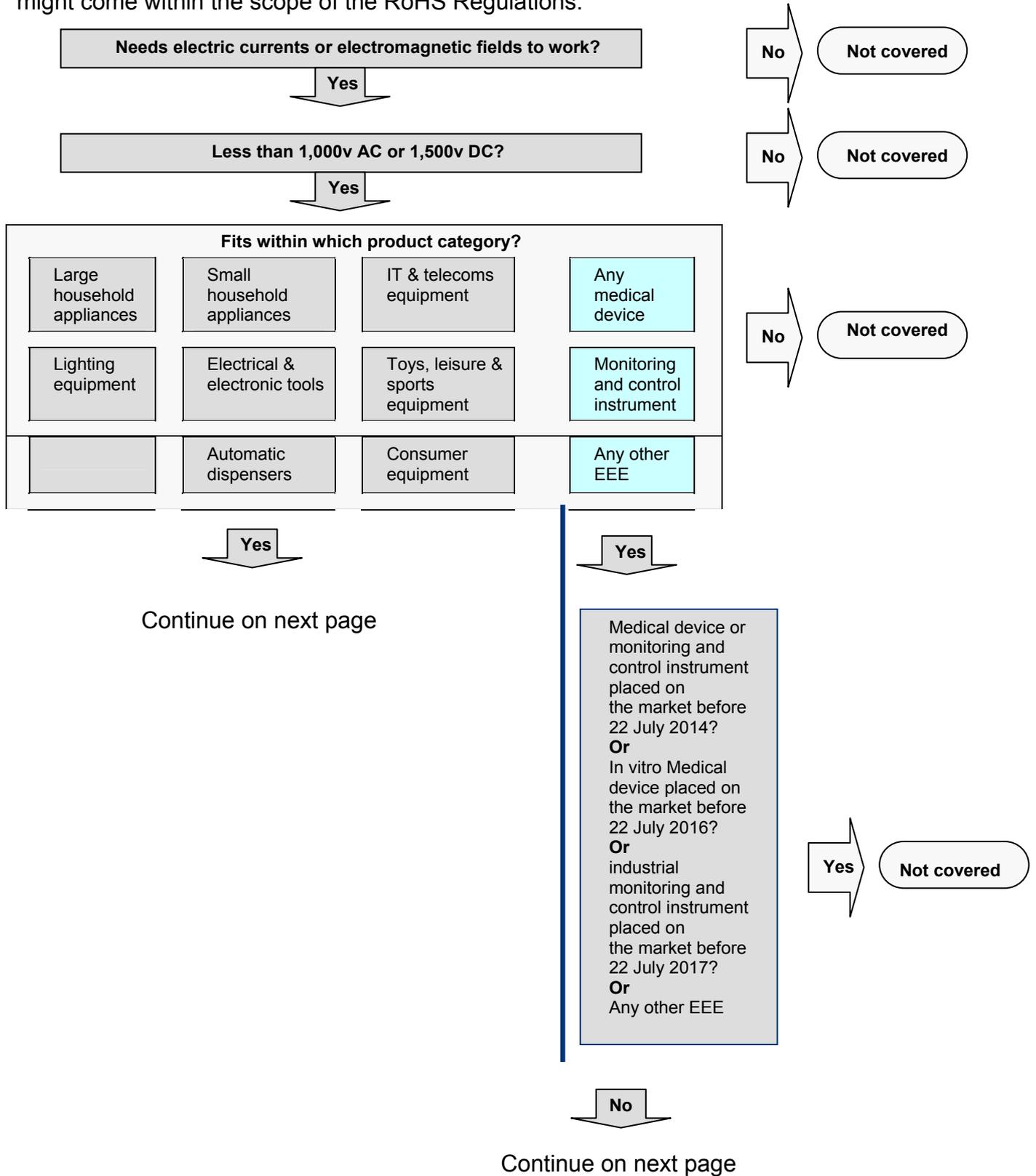
From 23 July 2019: other electrical and electronic equipment not covered by any of the categories above,

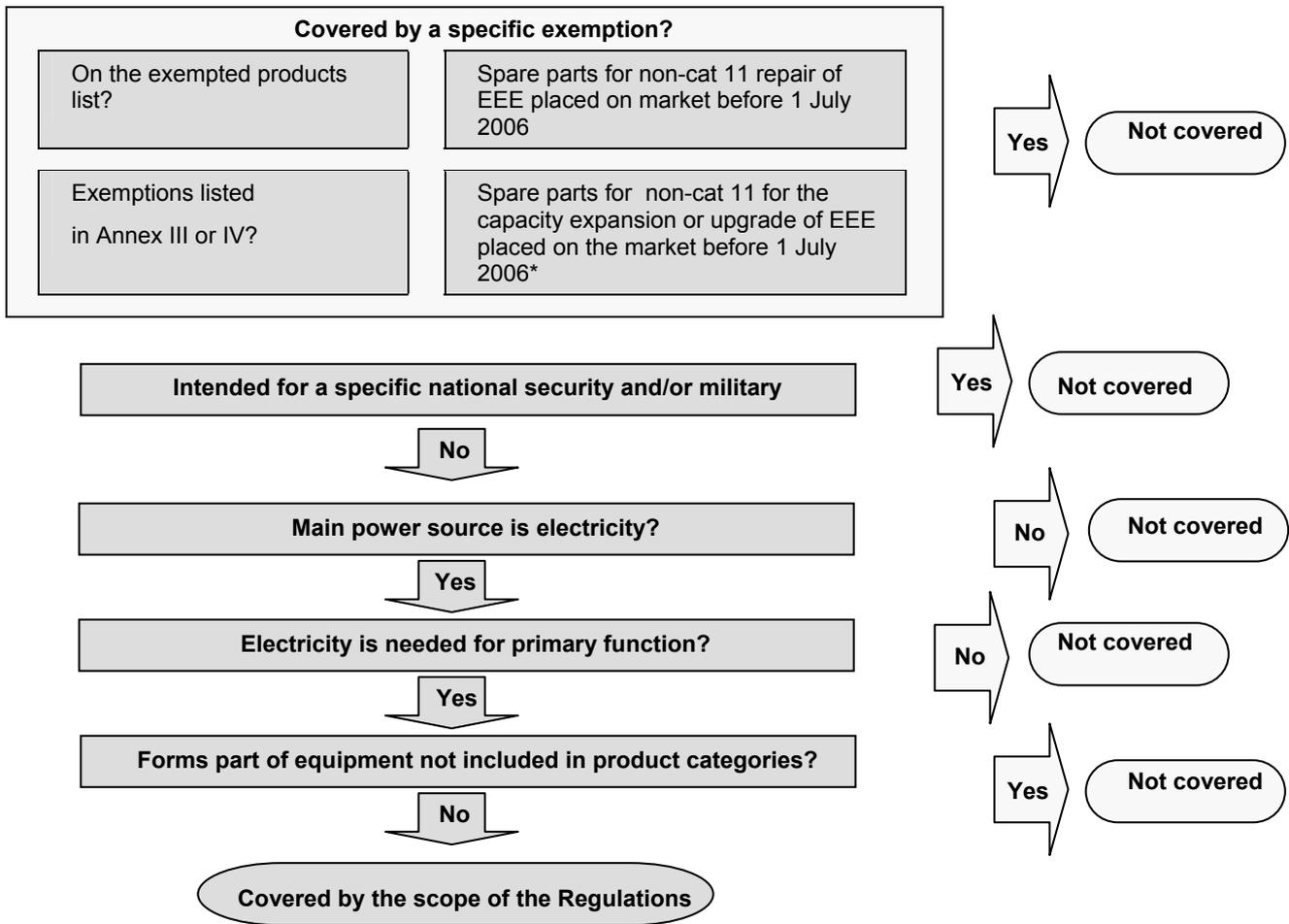
Other additions:

Two wheeled electric vehicles which are not type approved and any products in categories 1-7 or 10 not covered by the original Directive come into scope from 23 July 2019.

Annex B – Decision Tree

A 'decision tree' that could be used by economic operators to decide whether or not a product might come within the scope of the RoHS Regulations.





*While these exclusions are not expressly provided for in the Directive, it is the view of BIS that they apply. It should be noted, however, that a definitive legal interpretation is only available from the court. Economic operators should rely on independent legal advice on compliance.

---END OF DRAFT GUIDANCE---

Annex 3: Explanation of transposition and copy out

Overview of approach taken

In transposing the Directive, it has been “copied out” where possible. Additional material, which is necessary to provide the required enforcement mechanisms, has been added. We have departed from the principle of copy out by pulling together disparate provisions about the Directive’s scope of application in order to provide a coherent transposition. This document outlines the main departures from copy out.

Scope of Regulations – Articles 2 and 4

Article 2 of the Directive sets out its scope, with an exemption for certain EEE applying until 22 July 2019. However Article 4 also contains provisions stating when Article 4(1) (preventing EEE from containing substances listed in Annex II) applies to certain EEE products. This structure creates some uncertainty as to whether the obligations, such as applying CE marking, apply to EEE which are not subject to Article 4(1) of the Directive.

The Regulations therefore clearly set out the EEE to which the Regulations apply in regulation 5 and Schedule 1. The exemption found in Article 2(2) has been transposed to regulation 6. The Regulations have been drafted to reflect our analysis that EEE which are exempt from Article 4(1) of the Directive are exempt from all of the obligations in the Directive.

Manufacturers’ Obligations – Article 7

Article 7 of the Directive is split across regulations 10 to 21. This makes it easier to identify the obligations on the manufacturer. In transposing the various obligations under Article 7, provisions relating to the same obligation have now been grouped together. We have added regulation 10(2) in order to give structure to the requirements of Article 7 as transposed, and clarify the point at which the obligations apply. Particular attention is drawn to the following:

- Article 7(d) has been transposed by regulation 15. Regulation 15 has additional text clarifying that the documents must be available for inspection;
- Article 7(e) regarding compliance procedures for series production has been transposed by regulation 17, with some additions to clarify the meaning of ‘in conformity’;
- Article 7(f) has been transposed by regulation 19. Regulation 19 has been expanded to clarify what non-conforming means;
- Article 7(g) and (h) relate to information identifying EEE and the manufacturer. These have been transposed by regulation 18;
- Article 7(j), regarding cooperation with the authorities, has been transposed by regulation 21. However the time period during which a request can be made has been limited to the 10 year period during which the technical documentation has to be retained.

Authorised Representatives – Article 8

Article 8 has been transposed by regulation 22. The obligations have been formatted differently for clarity. An additional provision (regulation 22(4)) has been added deeming the authorised representative to be the manufacturer in relation to obligations in his mandate. This ensures actions can be taken in the EU where products are placed on the market by third country manufacturers. We think this is the purpose behind the Article 8 of the Directive.

Importers' Obligations – Article 9

Article 9 has been transposed by regulations 23 to 27. We have made the following departures from copy out:

- the Regulations anticipate a corrigendum by the Commission to Article 9(b), which will change the current reference to Article 7(f) and (g) to a reference to Article 7(g) and (h);
- Article 9(f) has been transposed by regulation 26(2). In doing so it has been presumed that the EEA will adopt the Directive;
- Articles 9(g) and (h) have been combined into regulation 27. Regulation 27 also specifies that documents must be translated into English, and the time period during which a request for information and documentation can be made has been limited to the 10 year period during which the technical documentation has to be retained.

Distributors' Obligations – Article 10

Article 10 has been transposed by regulations 29 to 31. We have made the following departures from copy out:

- slight changes to the wording of Article 10(a), in reformatting the provision into separate subparagraphs;
- Article 10(b) has been split between regulation 29(2) and regulation 30(1), in order to make notification obligations clearer;
- Article 10(d) is transposed by regulation 31. However the requirement to provide authorities with information has been limited to a requirement to provide the authorities with such information as they have in their knowledge or possession. The period during which the request can be made has been limited to the 10 year period during which the technical documentation has to be retained by other economic operators.

Application of obligations of manufacturers – Article 11

Article 11 has been separated into regulation 28 and regulation 32. This is to provide separate provisions for importers and distributors within the Regulations.

EU declaration of conformity - Article 13

Article 13 has been transposed by regulation 14 and regulation 12(2). It has been split up into separate paragraphs for clarity, and references to United Kingdom legislation have been added. Regulation 14 also specifies that the language required for EEE on the market in the United Kingdom is English. Regulation 12(2) transposes Article 13(2) subparagraph 2. In doing so it extends the reference to 'Union legislation' to 'EU legislation or legislation giving effect to EU legislation'. Slight changes have also been made to wording to make clear it is referring to a conformity assessment in relation to the EEE.

Rules and conditions for affixing the CE Marking – Article 15

Article 15 is largely transposed by regulation 16. The following points should be noted:

- a related provision has been added to regulation 37(5) setting out the burden of proof of establishing when it is 'not possible' or 'not warranted' to affix the CE mark;
- the requirement in Article 15(2) that CE marking be affixed prior to placing EEE on the market is captured by regulations 10 and 23;
- In line with Article 15(3), we have added regulation 34 relating to the Protection of CE Marking. This is based on Article 30 of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 (RAMS).

Presumption of conformity – Article 16

Article 16 is transposed by regulation 9. In doing so, the words 'in the absence of evidence to the contrary' have been replaced with 'rebuttable', and the formatting and wording has been streamlined.

Enforcement, Offences and Penalties

The Regulations contain enforcement provisions, offences and penalties, designed to meet the obligations placed on the United Kingdom by Articles 18 and 23 of the Directive and RAMS.

Annexes

Annex I has been transposed by Schedule 1, Part 1 of the Regulations. The other Annexes (as amended from time to time) are incorporated in the Regulations by reference.

Annex 4: Draft Regulations

STATUTORY INSTRUMENTS

2012 No. [DRAFT V9.1]

ENVIRONMENTAL PROTECTION

The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012

<i>Made</i>	- - - -	***
<i>Laid before Parliament</i>		***
<i>Coming into force</i>	- -	2nd January 2013

The Secretary of State is a Minister designated⁽¹⁷⁾ for the purposes of section 2(2) of the European Communities Act 1972⁽¹⁸⁾ in respect of measures relating to the restriction of the use of hazardous substances in electrical and electronic equipment.

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Secretary of State that it is expedient for certain references to provisions of an EU instrument to be construed as a references to those provisions as amended from time to time.

The Secretary of State, in exercise of the powers conferred by section 2(2) of, and paragraph 1A of Schedule 2 to, the European Communities Act 1972 makes the following Regulations.

PART 1

Preliminary

Citation and commencement

1. These Regulations may be cited as the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 and come into force on 2nd January 2013.

⁽¹⁷⁾ S.I. 2004/706.

⁽¹⁸⁾ 1972 c.68, as amended by numerous subsequent Acts; however, the only amendments relevant for the purposes of these Regulations are those introduced by Part 3 of the Legislative and Regulatory Reform Act 2006 (c.51).

Interpretation

2. In these Regulations—

“authorised person” means a person authorised by the market surveillance authority in accordance with regulation 35(2);

“authorised representative” means a person appointed in accordance with regulation 22(1);

“cables” means all cables with a rated voltage of less than 250 volts that serve as a connection or an extension to connect EEE to the electrical outlet or to connect two or more items of EEE to each other;

“CE marking” means a marking by which a manufacturer indicates that a product complies with the applicable requirements set out in EU legislation harmonising the conditions for the marketing of the product and which takes the form set out in Annex II of RAMS;

“conformity assessment” means the process demonstrating whether the requirements of these Regulations are met in relation to EEE;

“the Directive” means Directive 2011/65/EU of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment⁽¹⁹⁾;

“distributor” means a person in the supply chain, other than the manufacturer or the importer, who makes EEE available on the market;

“economic operator” means a manufacturer, authorised representative, importer or distributor;

“EEA” means the European Economic Area comprised of the territories of the EEA States;

“EEE” means electrical and electronic equipment as defined in regulation 4;

“enforcement notice” means a notice given under paragraph 2 of Schedule 3;

“harmonised standard” means a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services⁽²⁰⁾ on the basis of a request made by the European Commission in accordance with Article 6 of that Directive, the reference of which standard has been published in the Official Journal of the European Union;

“importer” means a person established within the EEA who places EEE from a third country on the EEA market;

“industrial monitoring and control instruments” means monitoring and control instruments designed for exclusively industrial or professional use;

“infringing EEE” means EEE that does not comply with the requirements of these Regulations;

“make available on the market” means supply in the course of a commercial activity (whether in return for payment or free of charge) for distribution, consumption or use on the EEA market, and related expressions are to be construed accordingly;

“manufacturer” means a person who manufactures EEE or who has EEE designed or manufactured and markets it under that person’s name or trademark;

“market surveillance authority” has the meaning given in regulation 35(1);

“medical device”, “active implantable medical device”, and “in vitro diagnostic medical device” have the meanings given in regulation 2(1) of the Medical Devices Regulations 2002⁽²¹⁾;

“notice” means a notice in writing;

“place on the market” means make EEE available on the EEA market for the first time, and related expressions are to be construed accordingly;

“previous Directive” means Directive 2002/95/EC of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment⁽²²⁾;

⁽¹⁹⁾ OJ No L 174, 1.7.2011, p. 88.

⁽²⁰⁾ OJ No L 204, 21.7.1998, p..37.

⁽²¹⁾ S.I. 2002/618, amended by 2008/2936; there are other amending instruments but none are relevant

“RAMS” means Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93⁽²³⁾;

“recall” means take any measure aimed at achieving the return of EEE that has already been made available to the end user;

“recall notice” means a notice given under paragraph 4 of Schedule 3;

“spare part” means a separate part of an item of EEE that can replace a part of an item of EEE and—

- (a) the item of EEE cannot function as intended without that part; and
- (b) the functionality of the EEE is restored or upgraded when the part is replaced by the spare part;

“technical specification” means a document that prescribes technical requirements to be fulfilled by a product, process or service;

“withdraw” means take any measure aimed at preventing an item of EEE in the supply chain from being made available on the market.

Prohibition on the use of certain hazardous substances in EEE

3.—(1) EEE placed on the market must not contain the substances listed in Annex II to the Directive, as amended from time to time.

(2) However, the presence of those substances in quantities no greater than the maximum concentration value by weight in homogeneous materials as specified in that Annex, as so amended, is allowed.

(3) “homogeneous material” means one material of uniform composition throughout or a material, consisting of a combination of materials, that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes.

(4) Regulation 4 defines “EEE” and regulation 5 and 6 define the categories of EEE and applications to which these Regulations apply either immediately or at a later date.

Definition of EEE

4.—(1) “EEE” means electrical and electronic equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields and designed for use with a voltage rating not exceeding 1000 volts for alternating current and 1500 volts for direct current;

(2) “dependent” means needing electric currents or electromagnetic fields to fulfil at least one intended function.

(3) References to EEE include references to cables and spare parts for its repair, its reuse, updating of its functionalities or upgrading of its capacity.

EEE to which these Regulations apply

5.—(1) These Regulations apply to EEE which—

- (a) falls within the categories set out in Part 1 of Schedule 1 and is placed on the market on or after 2nd January 2013;
- (b) was placed on the market before 2nd January 2013 as set out in regulation 7(2).

(2) These Regulations do not apply to EEE which falls within the categories set out in Part 2 of Schedule 1.

(3) These Regulations apply to EEE which falls within the categories set out in Part 3 of Schedule 1 from the dates set out in that Schedule.

(4) These Regulations do not apply in respect of the applications listed in Annexes III and IV to the Directive, as those Annexes are amended from time to time.

⁽²²⁾ OJ No L 37, 13.2.2003, p. 19.

⁽²³⁾ OJ No L218, 13.8.2008 p30.

Exclusion until 22nd July 2019 for EEE outside the scope of Directive 2002/95/EC

6.—(1) Any EEE to which these Regulations apply but which was outside the scope of the previous Regulations may be made available on the market until 22nd July 2019 even if the EEE does not comply with the provisions of these Regulations.

(2) Paragraph (1) is without prejudice to the provisions of Schedule 1, Part 3, paragraphs 1 and 2.

Revocation and transitional arrangements

7.—(1) The following are revoked—

- (a) the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2008⁽²⁴⁾ (“the 2008 Regulations”); and
- (b) the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations 2009⁽²⁵⁾.

(2) Where the 2008 Regulations, as amended, applied to any electrical and electronic equipment which was placed on the market before 2nd January 2013—

- (a) obligations that arose under the 2008 Regulations may be enforced under Schedules 2 and 3 of these Regulations;
- (b) Obligations under these Regulations which arise after the placing on the market of the electrical and electronic equipment apply.

(3) This does not affect liability under the 2008 Regulations for any offences committed before 2 January 2013.

Existing legislation

8.— Nothing in these Regulations affects the application of existing EU legislation and national legislation as regards requirements in relation to—

- (a) safety and health;
- (b) chemicals, in particular, as set out in the REACH Regulation; and
- (c) waste management.

Presumption of conformity for EEE goods

9.—(1) Any EEE which bears the CE marking is presumed to comply with the provisions of these Regulations.

(2) Materials, components and EEE—

- (a) on which tests and measurements demonstrating compliance with the requirements of regulation 3 have been performed; or
- (b) which have been assessed for compliance with the requirements of regulation 3 in accordance with harmonised standards,

are presumed to comply with the requirements of regulation 3.

(3) The presumptions of conformity in paragraphs (1) and (2) are rebuttable.

⁽²⁴⁾ S.I. 2008/37, amended by S.I. 2009/581.

⁽²⁵⁾ S.I. 2009/581.

PART 2

Prohibitions and Obligations on Economic Operators

Manufacturers and their authorised representatives

Prohibitions on placing EEE on the market

10.—(1) Manufacturers must not place EEE on the market unless the EEE complies with the requirements of regulation 3 (restriction on the use of certain hazardous substances in EEE).

(2) Manufacturers must not place EEE on the market without having complied with—

- (a) regulation 11 (design and manufacture of EEE to comply with requirements of regulation 3);
- (b) regulation 12 (conformity assessment procedure and drawing up of technical documentation);
- (c) regulation 13 (EU declaration of conformity and CE marking);
- (d) regulation 17 (compliance procedures for series production); and
- (e) regulation 18 (information identifying EEE and manufacturer).

Design and manufacture of EEE

11. Manufacturers must ensure that the EEE has been designed and manufactured to comply with the requirements of regulation 3.

Conformity assessment procedure and drawing up of technical documentation

12.—(1) Manufacturers must—

- (a) draw up technical documentation; and
- (b) carry out, and comply with their obligations under, the internal production control procedure,

in relation to the EEE in accordance with Module A of Annex II to Decision 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products and repealing Council Decision 93/465/EEC⁽²⁶⁾.

(2) Where other applicable EU legislation or legislation giving effect to EU legislation requires the EEE to be subject to a conformity assessment procedure which is at least as stringent as that required under paragraph (1), compliance with the requirements of regulation 3 may be demonstrated within the context of that procedure and a single set of technical documentation may be drawn up.

EU declaration of conformity and CE marking

13. Where the compliance of the EEE with the requirements of regulation 3 has been demonstrated by the procedure referred to in regulation 12, manufacturers must—

- (a) draw up an EU declaration of conformity in accordance with regulation 14; and
- (b) affix the CE marking in relation to the EEE in accordance with regulation 16.

14.—(1) The EU declaration of conformity must state that it has been demonstrated that the requirements specified in Article 4 of the Directive have been met in relation to the EEE.

(2) The EU declaration of conformity must also follow the structure, and include the information, specified in Annex VI to the Directive.

(3) Manufacturers must keep up to date the EU declaration of conformity drawn up in relation to EEE.

(4) Manufacturers must translate the EU declaration of conformity into the language required by each EEA State on the market of which they make the EEE available.

⁽²⁶⁾ OJ L218, 13.8.2008, p.82.

(5) An EU declaration of conformity in relation to EEE which is made available on the market in the United Kingdom must be drawn up in or translated into English.

(6) By drawing up the EU declaration of conformity, the manufacturer assumes responsibility for the compliance of the EEE.

Duty to keep technical documentation and EU declaration of conformity

15. Manufacturers must keep the technical documentation and the EU declaration of conformity for EEE available for inspection by the market surveillance authority for a period of ten years from the day on which the EEE was placed on the market.

EEE to bear CE marking

16.—

(1) The CE marking which manufacturers must affix under regulation 13 must be affixed visibly, legibly and indelibly.

(2) The CE marking must be affixed to—

- (a) the EEE; or
- (b) a data plate affixed to the EEE.

(3) Where due to the nature of the EEE it is not possible or not warranted for the CE marking to be affixed in accordance with paragraph (2), the manufacturer must instead affix the CE marking to—

- (a) the packaging of the EEE; and
- (b) any documents that accompany the EEE.

Compliance procedures for series production

17.—(1) Manufacturers of EEE which is manufactured by means of series production must ensure that procedures are in place to ensure that any EEE so manufactured complies with the requirements of regulation 3.

(2) In doing so, they must take adequate account of—

- (a) any changes in the design or characteristics of the EEE; and
- (b) any changes to any harmonised standards or technical specifications referred to in the EU declaration of conformity drawn up in relation to the EEE.

Information identifying EEE and manufacturer

18.—(1) Manufacturers must ensure that a type, batch or serial number or other element allowing the EEE to be identified is marked—

- (a) on their EEE; or
- (b) where the size or nature of the EEE does not allow this, on the packaging of the EEE or in a document accompanying the EEE.

(2) Manufacturers must indicate their name, registered trade name or registered trade mark and a single address at which they can be contacted—

- (a) on the EEE; or
- (b) where that is not possible, on the packaging of the EEE or in a document accompanying the EEE.

(3) Where other applicable EU legislation or legislation giving effect to EU legislation contains provisions for the affixing of the manufacturer's name and address to the EEE which are at least as stringent as those set out in this regulation, the provisions of this regulation may be met by satisfying the provisions of that other legislation.

Register of EEE

19. Manufacturers must keep a register of—

- (a) any EEE placed on the market in relation to which any provision of these Regulations has not been complied with; and
- (b) any EEE which has been recalled,

and keep distributors informed of these matters.

Non-compliant EEE

20.—(1) Where manufacturers have placed EEE on the market and have reason to believe that any provision of these Regulations has not been complied with by them in relation to the EEE, they must immediately—

- (a) take the corrective measures which are necessary to ensure that the provision is complied with in relation to the EEE, withdraw the EEE or recall it, if appropriate; and
- (b) provide the market surveillance authority and the competent national authorities of any other EEA States in which they made the EEE available with information about the non-compliance and any such corrective measures taken..

Co-operation with the authorities

21.—(1) The market surveillance authority may, during the period of 10 years from the day on which EEE was placed on the market, request the manufacturer who placed EEE on the market to—

- (a) provide it within such period as the authority may specify with all the information and documentation necessary to demonstrate that the provisions of these Regulations have been complied with in relation to the EEE; and
 - (b) co-operate with that authority on any action taken or to be taken to ensure that the provisions of these Regulations are complied with in relation to the EEE.
- (2) The information and documentation referred to in paragraph (1)(a) must be drawn up in or translated into English.
- (3) A request under paragraph (1)(a) must be accompanied by the reasons for making the request.
- (4) The manufacturer must comply with a request made under paragraph (1).

Manufacturers' authorised representatives

22.—(1) Manufacturers may, by written mandate, appoint a person established within the EEA as their authorised representative to act on the manufacturer's behalf in relation to specified tasks in relation to EEE.

(2) The mandate must allow the authorised representative to do at least the following in relation to EEE covered by the mandate—

- (a) perform the manufacturer's obligations under regulation 15 (duty to keep technical documentation and EU declaration of conformity available for inspection); and
- (b) perform the manufacturer's obligations under regulation 21(4) (duty to provide the market surveillance authority with information and documentation necessary to demonstrate the conformity of EEE and to co-operate with that authority to ensure these Regulations are complied with).

(3) An authorised representative may not be appointed to perform the manufacturer's obligations under regulation 11 (duty to design and manufacture EEE in accordance with regulation 3) or regulation 12(1)(a) (duty to draw up technical documentation).

(4) An authorised representative must comply with all the duties imposed on the manufacturer in relation to each obligation under these Regulations that the representative is appointed by the mandate to perform and, accordingly—

- (a) as far as those duties are concerned, references in these Regulations to the manufacturer are to be taken as including a reference to the authorised representative; and
- (b) if the authorised representative contravenes or fails to comply with any of those duties, the authorised representative may be proceeded against as though the authorised representative were the manufacturer.

(5) A manufacturer who has appointed an authorised representative to perform on the manufacturer's behalf an obligation under these Regulations remains responsible for the proper performance of that obligation.

Importers

Prohibition on placing EEE on the market

23.—Importers must not place EEE on the market unless

- (a) the EEE complies with the requirements of regulation 3;
- (b) they have ensured that the manufacturer has done all of the following in relation to the EEE—

- (i) carried out the conformity assessment procedure and drawn up the technical documentation in accordance with regulation 12(1);
- (ii) affixed the CE marking in accordance with regulation 16; and
- (iii) complied with regulation 18 (information identifying EEE and manufacturer); and
- (c) the EEE is accompanied by any documents by which it is required to be accompanied under these Regulations; and
- (d) the importer has complied with regulation 24 (information identifying importers).

Information identifying importers

24.—(1) Importers must ensure that the following information is marked on the EEE—

- (a) the importer's name, registered trade name or registered trade mark; and
- (b) an address at which the importer can be contacted.

(2) Where it is not possible to mark the information on the EEE the information may instead be marked on the packaging of the EEE or in a document accompanying the EEE.

(3) Where the importer complies with other applicable EU legislation, or legislation giving effect to EU legislation, containing provisions for the affixing of the importer's name and address which are at least as stringent as those set out in this regulation, it is sufficient to satisfy this regulation.

Monitoring of EEE

25. Importers must keep a register of—

- (a) any EEE placed on the market in relation to which any provision of these Regulations has not been complied with; and
- (b) any EEE which has been recalled,

and keep distributors informed of these matters.

Non-compliant EEE

26.—(1) If importers have reason to believe that EEE which they were intending to place on the market does not comply with the requirements of regulation 3, they must inform the manufacturer and the market surveillance authority of the non-compliance.

(2) Importers who have placed EEE on the market and have reason to believe that any provision of these Regulations has not been complied with in relation to the EEE must immediately—

- (a) take the corrective measures which are necessary to ensure that the provision is complied with in relation to the EEE, withdraw the EEE or recall it, if appropriate; and
- (b) provide the market surveillance authority and the competent national authorities of any other EEA States in which they made the EEE available with information about the non-compliance and any corrective measures taken in accordance with subparagraph (a).

Retention of documentation and co-operation with the authorities

27.—(1) Importers must for a period of ten years from the day on which they placed an item of EEE on the market—

- (a) keep a copy of the EU declaration of conformity for the EEE; and
- (b) ensure that the technical documentation is available for inspection by the market surveillance authority on request by the authority.

(2) The market surveillance authority may during the 10 year period request an importer who has placed EEE on the market to—

- (a) provide it within such period as the authority may specify with all the information and documentation necessary to demonstrate that the provisions of these Regulations have been complied with in relation to the EEE; and
- (b) co-operate with that authority on any action taken or to be taken to ensure that the provisions of these Regulations are complied with in relation to the EEE.

- (3) The information and documentation referred to in paragraph (2)(a) must be drawn up in or translated into English.
- (4) A request under paragraph (2)(a) must be accompanied by the reasons for making the request.
- (5) The importer must comply with a request under paragraph (2).

Duty in certain circumstances to comply with manufacturers' duties in place of importers' duties

28.—(1) An importer who places EEE on the market under the importer's name or trademark must comply with all of the duties imposed by these Regulations on manufacturers, and in such a case, a reference to the manufacturer in these Regulations is to be taken as being a reference to the importer.

- (2) Such an importer is not required to comply with the duties imposed by these Regulations on importers.

Distributors

Duty to act with due care and prohibition on making EEE available on the market

29.—(1) When making EEE available on the market, distributors must act with due care in relation to the requirements applicable, in particular by verifying that—

- (a) the EEE bears the CE marking;
- (b) the EEE is accompanied by the required documents in a language which can be easily understood by consumers and other end-users in the Member State in which the EEE is to be made available on the market;
- (c) the manufacturer has complied with regulation 18 (information identifying EEE and manufacturer);
- (d) the importer has complied with regulation 24 (information identifying importers).

(2) Distributors must not make EEE available on the market if they have reason to believe that the EEE does not comply with requirements of regulation 3.

Non-compliant EEE

30.—(1) If distributors have reason to believe that EEE which they were intending to make available on the market does not comply with the requirements of regulation 3, they must inform the following to that effect —

- (a) the importer (if there is one);
- (b) the manufacturer (if there is no importer); and
- (c) the market surveillance authority.

(2) Distributors who have reason to believe that EEE which they have made available on the market is not in conformity with these Regulations must—

- (a) take the corrective measures which are necessary to ensure that the provision is complied with in relation to the EEE, withdraw the EEE or recall it, if appropriate; and
- (b) immediately provide the market surveillance authority and the competent national authorities of any other EEA States in which they made the EEE available with information about the non-compliance and any corrective measures taken under subparagraph (a).

Co-operation with the authorities

31.—(1) The market surveillance authority may request a distributor who has made EEE available on the market to—

- (a) provide it within such period as the authority may specify with all the information and documentation within the distributor's knowledge or possession which demonstrate that the provisions of these Regulations have been complied with in relation to the EEE; and
- (b) co-operate with that authority on any action taken or to be taken to ensure that the provisions of these Regulations are complied with in relation to the EEE.

(2) A request under paragraph (1)(a) must be accompanied by the reasons for making the request.

(3) The distributor must comply with a request under paragraph (1).

(4) A request for information or documents may not be made more than 10 years after the day on which the EEE is placed on the market.

Duty in certain circumstances to comply with manufacturers' duties in place of distributors' duties

32.—(1) A distributor who modifies EEE already placed on the market in such a way that compliance with the requirements of regulation 3 may be affected must comply with all of the duties imposed by these Regulations on manufacturers, and in such a case, a reference to the manufacturer in these Regulations is to be taken as being a reference to the distributor.

(2) Such a distributor is not required to comply with the duties imposed by these Regulations on distributors.

All economic operators

Identification of economic operators to the market surveillance authority

33.—(1) The market surveillance authority may, for ten years following the placing on the market of the EEE, request an economic operator to identify to the authority, within such period as the authority may specify—

- (a) any economic operator who has supplied it with EEE; and
- (b) any economic operator to whom it has supplied EEE.

(2) The economic operator must comply with the request.

Protection of CE marking

34.—(1) A person must not affix a CE marking in relation to EEE unless—

- (a) the person is—
 - (i) the manufacturer; or
 - (ii) an authorised representative of the manufacturer who has been appointed by the manufacturer in accordance with regulation 22(1) to affix the CE marking on the manufacturer's behalf; and
- (b) it has been demonstrated by performance of the conformity assessment procedure referred to in regulation 12 (conformity assessment procedure and drawing up of technical documentation) that the EEE complies with the requirements of regulation 3.

(2) A person must not affix any marking in relation to EEE which—

- (a) is not a CE marking; but
- (b) purports to attest that the EEE satisfies the requirements of regulation 3.

(3) A person must not affix in relation to EEE any marking, sign or inscription which is likely to mislead any other person as to the meaning or form of the CE marking affixed in relation to the EEE.

(4) Any other marking may be affixed in relation to EEE provided that the visibility, legibility and meaning of the CE marking is not thereby impaired.

PART 3

Enforcement

Market surveillance authority

35.—(1) It is the duty of the Secretary of State to enforce these Regulations and the Secretary of State is the market surveillance authority for the purposes of these Regulations and RAMS in its application to EEE.

(2) The market surveillance authority may authorise in writing any person who appears suitable to act on its behalf to carry out any of its functions and to exercise any of the powers and duties conferred on it by these Regulations or RAMS.

(3) The market surveillance authority must not commence proceedings for an offence in Scotland.

Market surveillance powers

36. Where the market surveillance authority considers that there may be a breach of these Regulations it may—

- (a) exercise the powers set out in Schedule 2 (test purchases, powers of entry etc and warrants); and
- (b) take the actions set out in Schedule 3 (compliance, enforcement and recall notices).

Offences

- 37.**—(1) It is an offence for a manufacturer to contravene or fail to comply with any of the requirements of—
- (a) regulation 10 (prohibitions on placing EEE on the market);
 - (b) regulation 15 (duty to keep technical documentation and EU declaration of conformity);
 - (c) regulation 19 (monitoring EEE);
 - (d) regulation 20 (non-compliant EEE - corrective measures and notification of authorities); or
 - (e) regulation 21 (co-operation with the authorities).
- (2) It is an offence for an importer to contravene or fail to comply with any of the requirements of—
- (a) regulation 23 (prohibition on placing EEE on the market);
 - (b) regulation 25 (monitoring of EEE);
 - (c) regulation 26 (non-compliant EEE - corrective measures and notification of authorities); or
 - (d) regulation 27 (retention of documents and co-operation with authorities).
- (3) It is an offence for a distributor to contravene or fail to comply with any of the requirements of—
- (a) regulation 29 (duty to act with due care and prohibition on making EEE available on the market)
 - (b) regulation 30 (non-compliant EEE - corrective measures and notification of authorities); or
 - (c) regulation 31 (co-operation with authorities).
- (4) It is an offence for any person to contravene or fail to comply with any of the requirements of regulation 34 (protection of CE marking).
- (5) In any proceedings for an offence under paragraph 1(a) in respect of a failure to affix the CE marking in accordance with regulation 16, where the accused seeks to rely on regulation 16(3), it is for the accused to show that it was not possible, or (as the case may be) not warranted, for the CE marking to be affixed in accordance with regulation 16(2).

Obstruction, etc.

- 38.** It is an offence for any person—
- (a) intentionally to obstruct an authorised person acting in pursuance of their powers and duties under these Regulations or Article 19 of RAMS; or
 - (b) knowingly or recklessly to—
 - (i) make a statement; or
 - (ii) provide any information, document or record,
 which is false or misleading in a material respect, in purported compliance with any requirement imposed under these Regulations or Article 19 of RAMS.

Penalties

- 39.**—(1) A person who is guilty of an offence under—
- (a) regulation 37(1)(a);
 - (b) regulation 37(2)(a); or
 - (c) regulation 37(3)(a),
- is liable on summary conviction, to a fine not exceeding the statutory maximum and on conviction on indictment, to a fine.
- (2) A person who is guilty of—
- (a) any other offence under regulation 37; or
 - (b) an offence under regulation 38,
- is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

Remediation orders

40.—(1) This regulation applies where a person commits an offence under these Regulations in respect of a matter which appears to the court to be a matter which it is in the person's power to remedy.

(2) The court may specify in an order (“a remediation order”)—

- (a) the steps that the person must take to remedy any of the matters for which that person has been convicted; and
- (b) the period within which those steps must be taken.

(3) A period specified in a remediation order may be extended if an application is made to the court within that period.

(4) If a person is ordered to remedy a matter, that person is not liable under regulation 37 (offences) in respect of that matter during the period or the extended period.

(5) A remediation order may be made in addition to, or instead of, any other punishment.

Recovery of expenses of enforcement

41.—(1) This regulation applies where a person commits an offence under regulation 37(1)(a), (2)(a) or (3)(a) or paragraph 9 of Schedule 3.

(2) The court may (in addition to any other order it may make as to costs or expenses) order the person to reimburse the market surveillance authority for any expenditure which the authority has reasonably incurred in investigating the offence, including in purchasing or in testing or examining any EEE, or any part of it, in respect of which the offence was committed.

Time limit for prosecution of offences

42.—(1) In England and Wales an information relating to an offence that is triable by a magistrates' court may be so tried if it is laid within twelve months after the date on which evidence sufficient in the opinion of the prosecutor to justify the proceedings comes to the knowledge of the prosecutor.

(2) In Scotland

(a) summary proceedings for an offence may be commenced before the end of twelve months from the date on which evidence sufficient in the Lord Advocate's opinion to justify the proceedings came to the Lord Advocate's knowledge, and

(b) section 136(3) of the Criminal Procedure (Scotland) Act 1995 (time limit for certain offences)⁽²⁷⁾ applies for the purpose of this paragraph as it applies for the purpose of that section.

(3) In Northern Ireland summary proceedings for an offence may be instituted within twelve months after the date on which evidence sufficient in the opinion of the prosecutor to justify proceedings comes to the knowledge of the prosecutor.

(4) No proceedings are to be brought more than three years after the commission of the offence.

(5) For the purposes of this regulation a certificate of the prosecutor (or in Scotland, the Lord Advocate) as to the date on which such evidence as is referred to above came to their notice is conclusive evidence.

Defence of due diligence

43.—(1) In proceedings for an offence under these Regulations, it is a defence for a person to show that they took all reasonable steps and exercised all due diligence to avoid committing the offence.

(2) A person is not, without the leave of the court, entitled to rely on the defence if it involves an allegation that the commission of the offence was due—

- (a) to the act or default of another; or
- (b) to reliance on information supplied by another;

unless, not less than seven clear days before the hearing of the proceedings (in England, Wales and Northern Ireland), or the trial diet (in Scotland), the person has served a notice on the person bringing the proceedings.

⁽²⁷⁾ 1995 c. 46.

(3) The notice must give the information in the possession of the person (“A”) serving the notice which identifies or assists in identifying the person (“B”) who—

- (a) committed the act or default; or
- (b) supplied the information which was relied on.

(4) A may not rely on the defence by reason of reliance on information supplied by B, unless A shows that it was reasonable in all the circumstances to have relied on the information, having regard in particular—

- (a) to the steps that A took and those which might reasonably have been taken for the purpose of verifying the information; and
- (b) to whether A had any reason to disbelieve the information.

Liability of persons other than the principal offender

44.—(1) Where the commission by a person of an offence under these Regulations is due to anything which another person did or failed to do in the course of a business, that other person is guilty of the offence and may be proceeded against and punished, whether or not proceedings are taken against the first person.

(2) Where a body corporate commits an offence and it is proved that the offence was committed—

- (a) with the consent or connivance of a relevant person; or
- (b) as a result of the negligence of a relevant person,

that person, as well as the body corporate, is guilty of the offence.

(3) A “relevant person” means—

- (a) a director, manager, secretary or other similar officer of the body corporate;
- (b) in relation to a body corporate managed by its members, a member of that body performing managerial functions;
- (c) in relation to a Scottish partnership, a partner;
- (d) a person purporting to act as a person described in (a), (b) or (c).

Service of documents

45.—(1) Any document required or authorised by these Regulations to be served on a person may be served by—

- (a) delivering it to that person in person;
- (b) leaving it at that person's proper address; or
- (c) sending it by post or electronic means to that person's proper address.

(2) In the case of a body corporate, a document may be served on a director of that body.

(3) In the case of a partnership, a document may be served on a partner or a person having control or management of the partnership business.

(4) For the purposes of this regulation, “proper address” means—

- (a) in the case of a body corporate or its director—
 - (i) the registered or principal office of that body; or
 - (ii) the email address of the secretary or clerk of that body;
- (b) in the case of a partnership, a partner or person having control or management of the partnership business—
 - (i) the principal office of the partnership; or
 - (ii) the email address of a partner or a person having that control or management;
- (c) in any other case, a person's last known address, which includes an email address.

(5) If a person to be served with a document has specified an address in the United Kingdom (other than that person's proper address) at which that person or someone on that person's behalf will accept service, that address must also be treated as that person's proper address.

(6) In this regulation “partnership” includes a Scottish partnership.

PART 4

Miscellaneous

Review

- 46.**—(1) The Secretary of State must from time to time—
- (a) carry out a review of these Regulations;
 - (b) set out the conclusions of the review in a report; and
 - (c) publish the report.
- (2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how the Directive is implemented in other EEA States.
- (3) The report must in particular—
- (a) set out the objectives intended to be achieved by the regulatory system established by these Regulations;
 - (b) assess the extent to which those objectives are achieved; and
 - (c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.
- (4) The first report under this regulation must be published before the end of the period of five years beginning with the day on which these Regulations come into force.
- (5) Reports under this regulation are afterwards to be published at intervals not exceeding five years.

Consequential amendments

- 47.**—(1) The Enterprise Act 2002 (Part 9 Restrictions on Disclosure of Information) (Specification) Order 2004⁽²⁸⁾ is amended as follows:
- (a) In Schedule 1, for “The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2008” substitute “The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012”.
- (2) The Legislative and Regulatory Reform (Regulatory Functions) Order 2007⁽²⁹⁾ is amended as follows:
- (a) In Part 2 of the Schedule, under the heading “Weights and measures” omit the entry “Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2008” and after the last entry insert “The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012”.

Mark Prisk
Minister of State for Business and Enterprise
Department for Business, Innovation and Skills

⁽²⁸⁾ S.I. 2004/693, to which there are amendments not relevant to these Regulations.

⁽²⁹⁾ S.I. 2007/3544, to which there are amendments not relevant to these Regulations.

SCHEDULE 1

Regulation 5(1), (2) and (3)

PART 1

Categories of EEE to which these Regulations apply

1. Large household appliances.
2. Small household appliances.
3. IT and telecommunications equipment.
4. Consumer equipment.
5. Lighting equipment.
6. Electrical and electronic tools.
7. Toys, leisure and sports equipment.
8. Medical devices.
9. Monitoring and control instruments including industrial monitoring and control instruments.
10. Automatic dispensers.
11. Other EEE not covered by any of the categories above.

PART 2

EEE to which these Regulations do not apply

1. Equipment which is necessary for the protection of the essential interests of the security of EEA States, including arms, munitions and war material intended for specifically military purposes;
2. Equipment designed to be sent into space;
3. Equipment which is specifically designed, and is to be installed, as part of another type of equipment to which these Regulations do not apply, which can fulfil its function only if it is part of that equipment, and which can be replaced only by the same specifically designed equipment;
4. Large-scale stationary industrial tools being a large-scale assembly of machines, equipment, and/or components—
 - (a) functioning together for a specific application;
 - (b) permanently installed and de-installed by professionals at a given place; and
 - (c) used and maintained by professionals in an industrial manufacturing facility or research and development facility.
5. Large-scale fixed installations being a large-scale combination of several types of apparatus and, where applicable, other devices, which are—
 - (a) assembled and installed by professionals;
 - (b) intended to be used permanently in a pre-defined and dedicated location; and
 - (c) de-installed by professionals;
6. Means of transport for persons or goods, excluding electric two-wheel vehicles which are not type-approved;
7. Non-road mobile machinery made available exclusively for professional being machinery, with an on-board power source, the operation of which requires either mobility or continuous or semi-continuous movement between a succession of fixed working locations while working, and which is made available exclusively for professional use.
8. Active implantable medical devices;

9. Photovoltaic panels intended to be used in a system that is designed, assembled and installed by professionals for permanent use at a defined location to produce energy from solar light for public, commercial, industrial and residential applications;

10. Equipment specifically designed solely for the purposes of research and development only made available on a business-to-business basis.

PART 3

Categories of EEE with special rules of application

1. These Regulations apply

- (a) to medical devices and monitoring and control instruments placed on the market on or after 22nd July 2014;
- (b) to in vitro diagnostic medical devices placed on the market on or after 22nd July 2016; and
- (c) to industrial monitoring and control instruments placed on the market on or after 22nd July 2017.

2. These Regulations do not apply to cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of the following—

- (a) EEE placed on the market before 1st July 2006;
- (b) medical devices placed on the market before 22nd July 2014;
- (c) in vitro diagnostic medical devices placed on the market before 22nd July 2016;
- (d) monitoring and control instruments placed on the market before 22nd July 2014;
- (e) industrial monitoring and control instruments placed on the market before 22nd July 2017;
- (f) EEE which benefited from an exemption listed in an Annex to the Directive or the previous Directive and which was placed on the market before that exemption expired, provided that the specific exemption concerned those cables or spare parts.

3. These Regulations do not apply to reused spare parts—

- (a) recovered from EEE placed on the market before 1st July 2006; and
- (b) used in equipment placed on the market before 1st July 2016,

provided that reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts is notified to the consumer.

SCHEDULE 2

Regulation 36(a)

Test purchases, powers of entry etc and warrants

Test purchases

1.—(1) The market surveillance authority may purchase EEE for the purpose of ascertaining whether the requirements of these Regulations have been complied with in respect of it.

(2) If—

- (a) EEE which has been purchased under subparagraph 1 or seized under paragraph 3(1)(c) of Schedule 2 is submitted to a test;
- (b) the test leads to the bringing of proceedings for an offence under regulation 37 or the serving of a [compliance], enforcement or recall notice; and
- (c) a person—
 - (i) from whom the EEE was purchased;

- (ii) who is a party to the proceedings; or
- (iii) who has an interest in EEE which is identified as an infringing EEE in a [compliance] enforcement or recall notice,

requests the market surveillance authority to allow that person to have the EEE tested, the authority must, if it is practicable for such a test to be carried out, allow that person to have the EEE tested.

Power to enter premises

2.—(1) An authorised person may enter premises, except any premises used wholly or mainly as a private dwelling, at any reasonable hour, for the purpose of enforcing these Regulations.

(2) Before entering the premises an authorised person must give reasonable notice, unless the authorised person has a reasonable suspicion of a failure to comply with these Regulations.

(3) An authorised person must, if requested to do so, produce a written authorisation document.

(4) An authorised person may—

- (a) be accompanied by—
 - (i) such other persons as the authorised person considers necessary,
 - (ii) any representative of the European Commission; and
- (b) bring on to the premises such equipment as the authorised person considers necessary.

Power to inspect, seize and detain EEE etc

3.—(1) An authorised person may—

- (a) in order to ascertain if any provision of these Regulations has not been complied with—
 - (i) inspect any EEE, products, goods, substances, records, documents or information;
 - (ii) on entering any premises whether under a power of entry under paragraph 2 or under a warrant under paragraph 4, make such examination or investigation as is necessary;
- (b) in order to ascertain if any provision of these Regulations has not been complied with, require any person carrying on or employed in connection with a business to produce any EEE, products, goods, substances, records, documents or information and take copies of—
 - (i) any document or record; or
 - (ii) any entry in any document or record;
- (c) in order to ascertain by testing or otherwise if any provision of these Regulations has not been complied with, and reasonably suspecting such non-compliance, seize and detain any EEE, products, goods, substances, records, documents or information;
- (d) seize and detain any EEE, products, goods, substances, records, documents or information which may be required as evidence in any proceedings under these Regulations;
- (e) for the purposes of exercising any powers or duties under these Regulations or RAMS, but only if and to the extent reasonably necessary in order to secure that the provisions of these Regulations are complied with, require any person having authority to do so to break open any container and, if that person does not comply or if there is no person present having authority to open it, break it open using reasonable force.

(2) An authorised person may require information stored electronically to be made available in printed form.

(3) An authorised person entering any premises whether under a power of entry under paragraph 2 or under a warrant under paragraph 4 must, if the occupier is present, give to the occupier or, if the occupier is absent, leave in a prominent place a notice—

- (a) summarising the authorised person's powers of seizure and detention of EEE, products, goods, substances, records, documents and information;
- (b) disclosing at which office of the market surveillance authority and within which hours a copy of these Regulations is available to be consulted.

(4) An authorised person entering any premises which are unoccupied or from which the occupier is temporarily absent must leave them as effectively secured against unauthorised entry as they were before entry.

- (5) An authorised person exercising any power of seizure and detention must—
- (a) give to the person against whom the power has been exercised a written notice stating what has been seized and detained;
 - (b) detain those things only for as long as is necessary for the market surveillance authority to ascertain whether any provision of these Regulations has not been complied with and if required to present the evidence at court.
- (6) Nothing in this regulation compels the production by any person of a document which that person would be entitled to withhold production of in any proceedings in any court on the grounds that it is the subject of legal professional privilege or, in Scotland, that it contains a confidential communication made by or to an advocate or solicitor in that capacity.

Warrants

- 4.—(1) A justice of the peace may by signed warrant permit an authorised person or any other person to enter any premises in the exercise of the powers and duties under these Regulations or Article 19 of RAMS, if necessary by reasonable force, if the justice in England and Wales on sworn information in writing, in Northern Ireland on a complaint on oath, or in Scotland by evidence on oath is satisfied—
- (a) that there are reasonable grounds to enter those premises for the purposes of enforcing these Regulations; and
 - (b) that any of the conditions in sub-paragraph (3) is met.
- (2) Reference to a justice of the peace—
- (a) in Scotland includes a sheriff;
 - (b) in Northern Ireland is a reference to a lay magistrate.
- (3) The conditions are—
- (a) entry to the premises has been, or is likely to be, refused and notice of the intention to apply for a warrant has been given to the occupier;
 - (b) asking for admission to the premises, or giving such a notice, would defeat the object of the entry;
 - (c) entry is required urgently;
 - (d) the premises are unoccupied or the occupier is temporarily absent.
- (4) A warrant under sub-paragraph (1) is valid for one month.

SCHEDULE 3

Regulation 36(b)

Compliance, enforcement and recall notices

Compliance notice

- 1.—(1) The market surveillance authority may serve a notice under this paragraph (“a compliance notice”) on an economic operator who makes EEE available on the market if the authority has reasonable grounds for believing—
- (a) the EEE is an infringing product; or
 - (b) the economic operator has failed to comply with its obligations under regulation 15, 19, 25 or 27(1).
- (2) A compliance notice must—
- (a) describe the alleged infringing EEE (the “specified EEE”) or alleged failure to comply with the obligations set out in subparagraph 1(b) (the “alleged breach”) in a manner sufficient to identify it; and
 - (b) state the exact grounds on which the notice is based.
- (3) A compliance notice may—
- (a) require the economic operator in an appropriate case, and having regard to the economic operator’s ability to take the measures in light of that person’s position in the supply chain, to remedy the situation or matters which gave rise to the authority’s belief that the specified EEE was an infringing EEE or an alleged breach had occurred; or

- (b) where it is not possible for the specified EEE to cease to be an infringing EEE, require the economic operator to secure that the specified EEE is withdrawn or that its being made available on the market is prohibited or restricted.
- (4) A compliance notice must tell the economic operator—
 - (a) what compliance is required and the period within which it must be completed;
 - (b) to give the authority evidence that the economic operator has complied with the notice;
 - (c) the consequences of failing to comply with the notice; and
 - (d) the rights of appeal against the notice under these Regulations and any time limits for their exercise.
- (5) Proceedings must not be commenced against a person under regulation 37 in respect of an alleged contravention of a requirement of these Regulations where—
 - (a) a compliance notice has been served on that person in respect of the alleged contravention; and
 - (b) the specified compliance period in that notice has not come to an end.

Enforcement notice

2.—(1) Where the market surveillance authority serves a compliance notice on an economic operator and, at the end of the compliance period specified in the notice—

- (a) it appears to the authority that that person has failed to comply with the notice; and
- (b) the authority has reasonable grounds for considering that the specified EEE is an infringing EEE or that an alleged breach has occurred,

the authority may serve an enforcement notice on that person.

- (2) An enforcement notice must—
 - (a) describe the specified EEE or alleged breach in a manner sufficient to identify it; and
 - (b) state the exact grounds on which the notice is based.
- (3) An enforcement notice may—
 - (a) require the economic operator in an appropriate case, and having regard to the economic operator's ability to take the measures in light of that person's position in the supply chain, to remedy the situation or matters which gave rise to the authority's belief that the specified EEE was an infringing EEE or that an alleged breach has occurred; or
 - (b) require the economic operator to secure that the specified EEE is withdrawn or that its being made available on the market is prohibited or restricted.
- (4) An enforcement notice must tell the economic operator—
 - (a) what compliance is required and the period within which it must be completed;
 - (b) to give the authority evidence that the economic operator has complied with the notice;
 - (c) the consequences of failing to comply with the notice; and
 - (d) the rights of appeal against the notice under these Regulations and any time limits for their exercise.
- (5) Proceedings must not be commenced against a person under regulation 37(1) in connection with any specified EEE which it is alleged is an infringing EEE where—
 - (a) an enforcement notice has been served on that person in respect of the specified EEE; and
 - (b) the compliance period specified in that notice has not come to an end.
- (6) In this paragraph "specified EEE" means the alleged infringing EEE that has been identified in a compliance notice in accordance with paragraph 1(2)(a).

Supplementary provisions in relation to compliance and enforcement notices

3.—(1) The market surveillance authority must comply with the provisions of Article 21 of RAMS in relation to the serving of a compliance or enforcement notice which imposes any requirements to secure that EEE is withdrawn from the market or that its being made available on the market is prohibited or restricted.

(2) Where the market surveillance authority has served a compliance notice or enforcement notice under this Part, the authority—

- (a) must keep the notice under review and may withdraw or revoke it at any time;
- (b) may vary the notice, provided it is not made more restrictive for the economic operator or more onerous for that person to comply with.

Recall notices

4.—(1) The market surveillance authority may serve a recall notice on an economic operator if the authority has reasonable grounds for believing that EEE is—

- (a) an infringing EEE presenting a serious risk by reason of that infringement; and
- (b) that it has already been supplied or made available to end users.

(2) A recall notice is a notice which requires the economic operator to use reasonable endeavours to organise the return of the EEE from end users to the economic operator or another person specified in the notice.

(3) The provisions of—

- (a) regulation 15 of the General Product Safety Regulations 2005⁽³⁰⁾ (“GPSR”); and
- (b) Article 21 of RAMS,

apply in relation to the serving of a recall notice under these Regulations.

(4) For the purposes of serving a recall notice under this paragraph, regulation 15 of the GPSR applies as if—

- (a) references to the provisions of the GPSR were references to those provisions as modified by this paragraph and to these Regulations;
- (b) references to an “enforcement authority” were references to the market surveillance authority;
- (c) references to the product being “a dangerous product” were references to the EEE being an infringing EEE presenting a serious risk by reason of that infringement;
- (d) references to risks to the health and safety of persons were references to the serious risk presented by the EEE;
- (e) the reference in paragraph (4)(c) to a period of seven days were a reference to a period of ten days;
- (f) paragraphs (9) and (10) were omitted.

(5) In this paragraph, “serious risk” means a serious risk to health, safety, the environment, consumers, or security, requiring rapid intervention, including a serious risk the effects of which are not immediate. The decision whether or not an EEE presents a serious risk shall be based on an appropriate risk assessment which takes account of the nature of the hazard and the likelihood of an occurrence. The feasibility of obtaining higher levels of safety or the availability of other EEEs presenting a lesser degree of risk shall not constitute grounds for considering that an EEE presents a serious risk.

Action by the market surveillance authority

5.—(1) The market surveillance authority may itself take action which an economic operator could have been required to take by a compliance, an enforcement or recall notice where the conditions for serving such a notice are met and either—

- (a) the authority has been unable to identify any economic operator on whom to serve such a notice; or
- (b) the person on whom such a notice has been served has failed to comply with it.

(2) If the market surveillance authority has taken action under paragraph (1) following the failure of an economic operator to comply with a compliance, enforcement or recall notice, the authority may recover from that person as a civil debt any costs or expenses reasonably incurred by the authority in taking the action.

(3) A civil debt recoverable under the preceding paragraph may be recovered summarily—

- (a) in England and Wales by way of complaint pursuant to section 58 of the Magistrates’ Courts Act 1980⁽³¹⁾;
- (b) in Northern Ireland in proceedings under Article 62 of the Magistrates’ Court (Northern Ireland) Order 1981⁽³²⁾.

⁽³⁰⁾ S.I. 2005/1803.

⁽³¹⁾ 1980 c.43.

⁽³²⁾ S.I. 1675/1981 (N.I. 26).

Compensation provisions relating to compliance, enforcement and recall notices

6. Where the market surveillance authority serves a compliance, enforcement or recall notice, the authority is liable to pay compensation to a person in respect of any loss or damage suffered by that person by reason of the notice if—

- (a) the EEE is not an infringing EEE; and
- (b) the exercise by the authority of the power to serve the notice was not attributable to neglect or default by the person.

Appeals against compliance, enforcement and recall notices

7.—(1) An application for an order to vary or set aside the terms of a compliance, enforcement or recall notice may be made—

- (a) in the case of a compliance, enforcement or recall notice, by the economic operator on whom the notice has been served; and
- (b) in the case of a compliance or enforcement notice, by a person having an interest in the product in respect of which that notice has been served.

(2) An application must be made before the end of the period of 21 days beginning with the day on which the notice was served.

(3) The appropriate court (as determined in accordance with paragraph 8) may only make an order setting aside a compliance, enforcement or recall notice if satisfied—

- (a) that the EEE is not an infringing EEE; or
- (b) that the serving of the notice was not proportionate.

(4) On an application to vary the terms of a compliance, enforcement or recall notice, the appropriate court may vary the terms of the notice as it considers appropriate.

Appropriate court for appeals against notices etc and further appeals

8.—(1) In England and Wales or Northern Ireland the appropriate court for the purposes of paragraph 7 is—

- (a) the court in which proceedings have been brought for an offence under regulation 37(1)(a), (2)(a) or (3)(a) or paragraph 9 of this Schedule; or
- (b) in any other case a magistrates' court in England and Wales or Northern Ireland.

(2) In Scotland the appropriate court for the purposes of paragraph 7 is the sheriff for a sheriff court district in which a compliance, enforcement or recall notice has been served on an economic operator.

(3) A person aggrieved by an order made by a magistrates' court in England, Wales or Northern Ireland⁽³³⁾ pursuant to an application under paragraph 7(1), or by a decision of such a court not to make such an order, may appeal against that order or decision—

- (a) in England and Wales, to the Crown Court;
- (b) in Northern Ireland, to the county court.

Offences and penalties

9.—(1) It is an offence for any person to contravene or fail to comply with any of the requirements of—

- (a) an enforcement notice; or
- (b) a recall notice.

(2) A person convicted of an offence under sub-paragraph (1) is liable—

- (a) on summary conviction, to a fine not exceeding the statutory maximum;
- (b) on conviction on indictment, to a fine.

⁽³³⁾ In Scotland the making of, or refusal to make, an order by a sheriff is subject to appeal in accordance with sections 27 and 28 of the Sheriff Courts (Scotland) Act 1907 (c.51).

EXPLANATORY NOTE

(This note is not part of the Regulations)

© Crown copyright 2012

You may re-use this information (not including logos) free of charge in any format or medium, under the terms of the Open Government Licence. To view this licence, visit <http://www.nationalarchives.gov.uk/doc/open-government-licence/> or write to the Information Policy Team, The National Archives, Kew, London TW9 4DU, or e-mail: psi@nationalarchives.gsi.gov.uk.

This publication is also available on our website at <http://www.bis.gov.uk>

Any enquiries regarding this publication should be sent to:

Department for Business, Innovation and Skills
1 Victoria Street
London SW1H 0ET
Tel: 020 7215 5000

If you require this publication in an alternative format, email enquiries@bis.gsi.gov.uk, or call 020 7215 5000.

URN 12/582