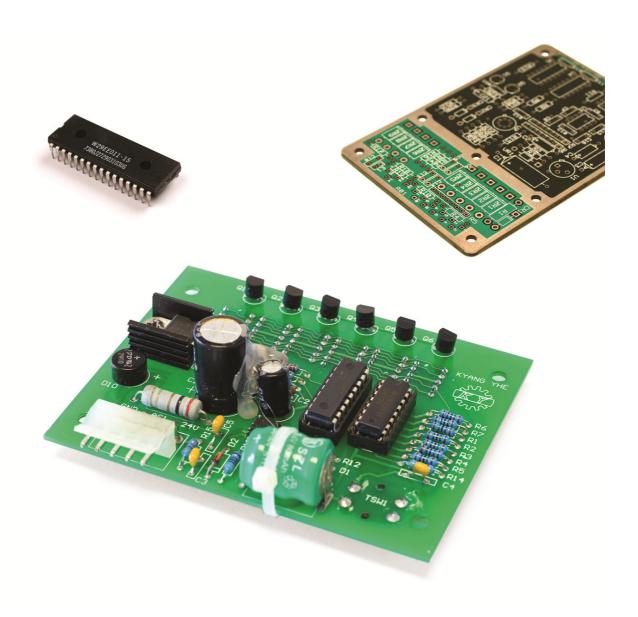
Step-by-step Guide to Using BOMcheck to Generate Technical Documentation for RoHS2 Conformity Assessment



November 2011

BOMcheck.net



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Disclaimer

This Guide comprises ENVIRON's opinion concerning how Manufacturers can meet their legal obligations to generate the technical documentation which is required by Directive 2011/65/EU on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (known as RoHS2). This opinion is based on the published legislation and guidance, and extensive research and consultation but is not legally binding. A binding interpretation of Community legislation is the exclusive competence of the European Court of Justice.



Executive Summary

Directive 2011/65/EU on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (known as RoHS2) became European Law on 21 July 2011 and will take effect in EU Member States from 2 January 2013. RoHS2 brings a much wider range of equipment into scope but does not introduce any new substance restrictions. Another very important difference is that RoHS2 is a CE Marking Directive.

RoHS2 requires Manufacturers to follow the procedures in Module A of Decision 768/2008/EC which prescribe the conformity assessment procedures that Manufacturers must carry out and the technical documentation they must draw up to demonstrate that their products are RoHS compliant. This is a significant difference compared to the RoHS1 Directive which does not prescribe any requirements for compliance documentation that Manufacturers need to maintain.

RoHS2 also includes obligations for all EU Member States to perform systematic market surveillance including "appropriate checks on product compliance on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks on the basis of adequate samples". RoHS1 does not prescribe any requirements for enforcement procedures that Member States need to undertake. In contrast, RoHS2 requires each Member State to carry out systematic market surveillance based on checking technical documentation provided by Manufacturers.

There are many different approaches that companies can use to draw up the required technical documentation to demonstrate that their products are RoHS compliant. Many companies already have established compliance processes and quality management systems for RoHS1 compliance and for other product regulatory requirements. Each company has to decide the best approach for drawing up the RoHS2 technical documentation which makes best use of their existing compliance processes and quality management systems.

CENELEC has produced a draft standard for "Evaluation of electrical and electronic products with respect to the restriction of hazardous substances" which concludes that most Manufacturers of complex products choose to interact with their supply chain to obtain and compile documentation which the Manufacturer then evaluates to demonstrate that the finished product complies with the RoHS substance restrictions. The draft CENELEC standard provides a list of the different types of documentation that the Manufacturer may choose to gather from their suppliers, but does not provide guidance on the choice and the application of evaluation methods.

Many companies have implemented their own information systems to gather declarations data individually from their own suppliers. The European Chemicals Agency (ECHA) REACH Draft Guidance on Substances in Articles highlights three information systems that industry sectors have developed to obtain and communicate information on substances in articles within the supply chain in an efficient manner: IMDS, JAMP and BOMcheck. This Guide focusses on the BOMcheck system.

This Guide provides a step-by-step practical approach that Manufacturers can choose to adapt and implement in their supply chains to generate the required RoHS2 technical documentation for a product model and provide a EU Declaration of Conformity. The table below provides a list RoHS2 processes and procedures that the Manufacturer can adapt and implement as required. This practical approach also explains how Manufacturers can choose to use BOMcheck to manage and maintain the supplier materials declarations which are needed for the RoHS2 technical documentation, and any analytical test reports which may also be required. Processes and procedures which the Manufacturer can choose to carry out in BOMcheck are highlighted in **blue bold font** in the table.

Step-by-step approach for generating RoHS2 technical documentation. Processes and procedures which the Manufacturer can choose to carry out in BOMcheck are highlighted in blue bold font.

RoHS2 Process/procedure

Assess the product to identify whether it is included within scope of RoHS2, and which category it falls into, and establish timelines for compliance program, (see section 3).





Generate the Bill of Materials for the product model to produce a list part codes for all of the materials, parts and sub-assemblies which are contained in a product model (see section 3.1.1). Identify and assign the supplier(s) for each of these part codes.

Screen the parts list to identify if there are any materials, parts or sub-assemblies in the product which do not have any risk of containing RoHS substances above the maximum concentration values (see section 3.1.2)

Carry out a conformity risk assessment by describing or referring to the processes and procedures for

- design control and design verification (see section 3.2.1)
- series production (see section 3.2.1)

Carry out a materials risk assessment to identify if any parts contain high risk materials (see section 3.3.1). For example, a Manufacturer may decide to define a material, part or sub-assembly as containing high risk materials if Table B.1 indicates that there is a high probability of it containing two or more RoHS substances.

Extend the supplier qualification process to include a supplier risk assessment for RoHS and categorise suppliers according to their performance (see section 3.3.2)

Apply the flow chart procedure to evaluate supplier materials declarations based on supplier risk assessment. Identify if any parts may require analytical test reports (see section 3.3.3)

Send the list of supplier part numbers that the Manufacturer buys with a letter to the supplier asking them to publish declarations for these supplier part numbers in BOMcheck (section 4.3)

Send e-mails to suppliers inviting them to attend free monthly BOMcheck introduction webinars (section 4.3)

If the Manufacturer has already established a different supplier coding system, then the Manufacturer should establish and maintain a table (for example in the IT / PLM system) to link their supplier codes to the BOMcheck Supplier Codes (section 4.3.1)

If the Manufacturer has their own part coding system and the Manufacturer wants to list their own part codes in the RoHS2 technical documentation, then the Manufacturer should upgrade to a Super User Account and map their part codes to the Supplier Part Numbers / Supplier Codes in BOMcheck (section 4.3.3)

Download supplier materials declarations from BOMcheck for the list of parts codes for the materials, parts and sub-assemblies which are contained in a product model (see section 4.4.1). The Manufacturer may choose to run reports in their PLM system or to include the BOMcheck declaration report PDF in their RoHS2 technical documentation.

The Manufacturer may choose to use the BOMcheck tools to assess any analytical test reports which may be required (see section 4.4.2). The Manufacturer may choose to include the BOMcheck assessment report PDF in their RoHS2 technical documentation.

Draw together and maintain all necessary information to write the technical documentation (see section 3 and in particular section 3.4) and write the EU Declaration of Conformity for a product model (section 3.5)



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1 Main differences between RoHS1 compliance requirements and RoHS2 Conformity Assessment Obligations

Directive 2011/65/EU¹ on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (known as RoHS2) became European Law on 21 July 2011 and replaced the previous Directive 2002/95/EC² (known as RoHS1). Member States are required to implement new Regulations to implement the new requirements in RoHS2, which will take effect from 2 January 2013.

RoHS2 brings a much wider range of equipment into scope but does not introduce any new substance restrictions. For example, it includes timelines by which Category 8: Medical Devices and Category 9: Monitoring and Control Instruments must comply with the RoHS substance restrictions – these equipment categories were previously exempt under RoHS1. RoHS2 also introduces a new Category 11: All EEE not covered by any other category.

Another very important difference is that RoHS2 is a CE Marking Directive. Article 7 of the RoHS2 Directive places new obligations on Manufacturers to draw up technical documentation, carry out internal production controls, provide a EU Declaration of Conformity and fix the CE Marking to compliant products. These new obligations are based on the "New Legislative Framework" (NLF) which consists of Decision 768/2008/EC and Regulation 765/2008/EC.

Under RoHS2, Manufacturers must follow the procedures in Module A of Decision 768/2008/EC which prescribe the conformity assessment procedures that Manufacturers must implement and the technical documentation they must draw up to demonstrate that their products are RoHS compliant. This is a significant difference compared to RoHS1 which does not prescribe any requirements in respect of compliance documentation that Manufacturers need to maintain.

Regulation 765/2008/EC includes obligations for all EU Member States to perform systematic market surveillance including "appropriate checks on product compliance on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks on the basis of adequate samples". RoHS1 does not prescribe any requirements in respect of enforcement procedures that Member States need to undertake. In contrast, RoHS2 requires each Member State to carry out systematic market surveillance based on checking technical documentation provided by Manufacturers.

1.1 New technical documentation requirements for Manufacturers

RoHS1 became European Law on 13 February 2003. The substance restriction requirements contained in Article 4.1 of RoHS1 (subject to further clarification under Article 5.1(a)) were quite brief:

- 4.1 Member States shall ensure that, from 1 July 2006, new electrical and electronic equipment put on the market does not contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE). National measures restricting or prohibiting the use of these substances in electrical and electronic equipment which were adopted in line with Community legislation before the adoption of this Directive may be maintained until 1 July 2006."
- 5.1(a) establishing, as necessary, maximum concentration values up to which the presence of the substances referred to in Article 4(1) in specific materials and components of electrical and electronic equipment shall be tolerated

On 18 August 2005 the European Commission clarified the RoHS1 substance restrictions by publishing Commission Decision 2005/618/EC.

1 'For the purposes of Article 5.1(a), a maximum concentration value of 0.1 % by weight in homogeneous materials for lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) and of 0.01 % by weight in homogeneous materials for cadmium shall be tolerated.'



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

² Available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:037:0019:0023:en:PDF

The EU Member State Enforcement Authorities created an informal network to share information and experience on RoHS1 enforcement and in May 2006 the network published a "RoHS Enforcement Guidance Document³". This Guidance starts by confirming that RoHS1 "does not prescribe any requirements in respect of compliance documentation that producers need to maintain or enforcement procedures that Member States need to undertake". The document goes on to provide **non-binding guidance** to assist Member States with national enforcement of RoHS1 and to provide clarity to industry on how producers may demonstrate compliance with the RoHS substance restrictions.

The RoHS1 Regulations in most Member States do not place any legal requirements on Manufacturers to provide technical documentation to RoHS Enforcement Agencies to demonstrate that their products are compliant to the RoHS substance restrictions. As a result, enforcement actions in most Member States are based on carrying out targeted X-ray fluorescence (XRF) analysis of higher risk products to detect infringements and then undertaking more detailed chemical analysis.

The RoHS1 Regulations in the UK⁴ took a different approach and include the following legal requirements on UK Manufacturers:

8. Producers shall-

- (a) prepare technical documentation or other information showing that any electrical and electronic equipment which they have put on the market complies with the requirements of regulation 7;
- (b) retain that technical documentation or other information for a period of four years from the date on which they put the equipment on the market; and
- (c) if the Secretary of State so requests by notice in writing, submit that technical documentation or other information (or copies of it) to the Secretary of State within 28 days of the date of the notice.

The UK Government Guidance Notes on the RoHS1 Regulations⁵ highlight that RoHS1 does not provide any prescribed methods that Manufacturers must follow to prepare technical documentation or other information to demonstrate that their products are RoHS compliant. However, the UK Government Guidance Notes do provide a helpful flow chart procedure in Annex D which a Manufacturer may choose to use as part of their RoHS1 compliance procedures. This RoHS1 compliance flow chart procedure was originally developed by Agfa and the Fraunhofer Institute and is used by many leading Manufacturers across Europe.

In contrast to the RoHS1 Directive, Article 7 of the RoHS2 Directive places new legal obligations on Manufacturers to draw up technical documentation, carry out internal production controls, provide a EU Declaration of Conformity and fix the CE Marking to compliant products. RoHS2 also prescribes the conformity assessment procedures that Manufacturers must implement and the technical documentation they must draw up to demonstrate that their products are RoHS compliant. These new regulatory requirements are discussed in detail in section 2.

Manufacturers who have already prepared technical documentation to comply with the UK RoHS1 Regulations will have already addressed many of the new regulatory requirements for RoHS2. In particular, many leading Manufacturers across Europe have already implemented the compliance flow chart procedure which is contained in Annex D of the UK Government RoHS1 Guidance Notes. This flowchart also provides a robust foundation for developing suitable compliance assurance procedures for RoHS2. It is used as the basis for the flow chart procedure in section 2.3.3 of this Guide for how Manufacturers can evaluate suppliers' materials declarations based on supplier risk assessment carried out during supplier qualification, and to decide if any analytical test reports are required for any high risk materials.

Directives which require CE Marking are called "New Approach" Directives. RoHS1 is not a CE Marking Directive and is not based on the based on the principles in the New Approach Directives. However, many leading Manufacturers decided voluntarily to base their RoHS1 compliance

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³ Available at http://www.bis.gov.uk/files/file30049.pdf

⁴ SI 2008/37 which is available at http://www.legislation.gov.uk/uksi/2008/37/pdfs/uksi 20080037 en.pdf and replaced SI 2005/2748 which is available at http://www.legislation.gov.uk/uksi/2005/2748/pdfs/uksi 20050748 en.pdf

⁵ Available at http://www.bis.gov.uk/assets/biscore/business-sectors/docs/r/11-526-rohs-regulations-government-guidance-notes

programs on the conformity assessment requirements for New Approach Directives, and in particular to follow the guidance provided in the European Commission's "Guide to the Implementation of Directives based on the New Approach and the Global Approach, 2000", (also known as the 'Blue Book'). Section 5.3 of the Blue Book explains that New Approach Directives require the Manufacturer to draw up technical documentation which should cover the design, manufacture and operation of the product and provide necessary information to demonstrate conformity of the product to the essential requirements of the relevant New Approach Directive.

A large number of the products which are included in the scope of RoHS1 are already required to have CE Marking to comply with other EU New Approach Directives such as the Low Voltage Directive, EMC Directive, Machinery Directive, etc. Many Manufacturers, who were already required to produce technical documentation for other CE Marking Directives, decided to apply the same conformity assessment procedures to manage RoHS1 compliance. As a result, there are a number of leading Manufacturers who already have considerable experience in developing suitable technical documentation to meet the regulatory requirements in RoHS2. We would like to thank these Manufacturers for sharing their experiences and providing valuable feedback during the writing of this Guide.

1.2 New market surveillance requirements for Member States

The EU Member State Enforcement Authorities' RoHS Enforcement Guidance Document, May 2006, starts by confirming that RoHS1 "does not prescribe any requirements in respect of compliance documentation that producers need to maintain or enforcement procedures that Member States need to undertake". As a result, most Member States chose to carry out their RoHS1 enforcement activities by carrying out targeted X-ray fluorescence (XRF) analysis of higher risk products to detect infringements and then undertaking more detailed chemical analysis.

For example, a recent RoHS1 enforcement action in Sweden⁶ in 2011 started with the purchase of products in toy stores and consumer electronic stores and was followed by selective analysis of components by XRF. If the screening analysis indicated that components contained banned substances then the components were sent to a laboratory for confirmation of the results. RoHS1 enforcement actions in the Netherlands⁷ also started with initial screening of products using XRF and then, for components that fail the screening, more detailed analysis by using chemical testing.

The UK took a different enforcement approach for RoHS1. The UK Government Guidance Notes on the RoHS Regulations⁸ highlight that

41. ii. Those failing to submit compliance documentation at the request of the enforcement authority may be liable on summary conviction to a fine up to a level five on the standard scale (currently £5,000).

The UK RoHS Enforcement Agency starts by sending a letter to the Manufacturer requiring them to provide technical documentation to demonstrate RoHS compliance for their products. The Agency provides a standard RoHS1 response template that the Manufacturer can use to complete their submission. Use of the RoHS1 response template is optional provided that the Manufacturer's submission covers the following areas:

- Company details, supply arrangements and any certifications or registrations to RoHS compliance schemes
- Overview of regulated product ranges and any RoHS exclusions or materials exemptions claims
- Internal control processes including policies and procedures, supplier assessment methods, testing, other systems or records used to control compliance
- Overview of compliance records which are maintained as required under Section 8 of the UK RoHS Regulations 2008
- Self-declaration statement of level and effectiveness of the Manufacturer's compliance with the RoHS Regulations, signed by authorized individual.



⁶ Published at http://www.kemi.se/templates/News 6548.aspx

⁷ Details are published in Dutch at http://www.vrominspectie.nl/

⁸ Available at http://www.bis.gov.uk/assets/biscore/business-sectors/docs/r/11-526-rohs-regulations-government-guidance-notes

⁹ Available at https://www.rohs.bis.gov.uk/onlineresponse/

In contrast to the RoHS1 Directive, the RoHS2 Directive includes obligations for all EU Member States to perform systematic market surveillance. Article 18 of the RoHS2 Directive states:

18. Member States shall carry out market surveillance in accordance with Articles 15 to 29 of Regulation 765/2008.

Articles 15 to 18 of Regulation 765/2008 require each Member State to:

- appoint a market surveillance authority with necessary powers, resources and responsibilities
- inform the European Commission and the public about the roles and responsibilities of their market surveillance authority
- establish communication and coordination mechanisms with other Member States market surveillance authorities
- review and assess their market surveillance activities at least every four years and communicate the results to all other Member States, the European Commission and the public

Article 19 and Article 21 of Regulation 765/2008 require each Member State to instruct their market surveillance authority to carry out specific market surveillance and enforcement measures including:

- 19.1 Market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks on the basis of adequate samples. When doing so they shall take account of established principles of risk assessment, complaints and other information.
- 19.3 Where the market surveillance authorities of one Member State decide to withdraw a product manufactured in another Member State, they shall inform the economic operator concerned at the address indicated on the product in question or in the documentation accompanying that product.
- 21.1 Member States shall ensure that any measure taken to prohibit or restrict the product's being made available on the market, to withdraw it from the market or to recall it, is proportionate and states the exact grounds on which it is based.
- 21.2 Such measures shall be communicated without delay to the relevant economic operator, which shall at the same time be informed of the remedies available under the law of the Member State concerned and of the time limits to which such remedies are subject.
- 21.3 Prior to the adoption of a measure referred to in 21.1, the economic operator concerned shall be given the opportunity to be heard within an appropriate period of not less than 10 days.
- 21.4 Any measure referred to in 21.1 shall be promptly withdrawn or amended upon the economic operator's demonstrating that he has taken effective action.

Article 27 and Article 28 of Regulation 765/2008 also place obligations on border control authorities to carry out specific market surveillance measures including:

- 27.1 The authorities of the Member States in charge of the control of products entering the Community market shall have the powers and resources necessary for the proper performance of their tasks.

 They shall carry out appropriate checks on the characteristics of products on an adequate scale, in accordance with the principles set out in Article 19(1), before those products are released for free circulation.
- 27.2 Where in a Member State more than one authority is responsible for market surveillance or external border controls, those authorities shall cooperate with each other, by sharing information relevant to their functions and otherwise as appropriate.
- 27.3 The authorities in charge of external border controls shall suspend release of a product for free circulation on the Community market when any of the following findings are made in the course of the checks referred to in paragraph 1:
 - (b) the product is not accompanied by the written or electronic documentation required by RoHS2 Directive or is not CE marked in accordance with the RoHS2 Directive
 - (c) the CE marking has been affixed to the product in a false or misleading manner. The authorities in charge of external border controls shall immediately notify the market surveillance authorities of any such suspension.
- 28.1 A product the release of which has been suspended by the authorities in charge of external border controls pursuant to Article 27 shall be released if, within three working days of the suspension of release, those authorities have not been notified of any action taken by the market surveillance authorities, and provided that all the other requirements and formalities pertaining to such release have been fulfilled.



2 RoHS2 Conformity Assessment Obligations for Manufacturers

Article 7(b) of the RoHS2 Directive states that the Manufacturer shall draw up the required technical documentation and carry out the internal production control procedure in line with Module A of Annex II of Decision 768/2008/EC or have the internal production control procedure carried out on their behalf. A Manufacturer is defined in Article 3(6) as any natural or legal person who manufactures EEE, or who has an EEE designed or manufactured, and markets it under his name or trademark. Module A of Annex II of Decision 768/2008/EC states that internal production control is the conformity assessment procedure whereby the Manufacturer fulfils the obligations for technical documentation, manufacturing, conformity marking and EU Declaration of Conformity, and ensures and declares on his sole responsibility that the EEE complies with the RoHS substance restrictions.

There are many different approaches that companies can use to draw up the required technical documentation to demonstrate that their products are RoHS compliant. Many companies already have established compliance processes and quality management systems for RoHS1 compliance and for other product regulatory requirements. Each company has to decide the best approach for drawing up the RoHS2 technical documentation which makes best use of their existing compliance processes and quality management systems.

CENELEC has produced a draft standard for "Evaluation of electrical and electronic products with respect to the restriction of hazardous substances" which concludes that most Manufacturers of complex products choose to interact with their supply chain to obtain and compile documentation which the Manufacturer then evaluates to demonstrate that the finished product complies with the RoHS substance restrictions. The draft CENELEC standard provides a list of the different types of documentation that the Manufacturer may choose to gather from their suppliers, but does not provide guidance on the choice and the application of evaluation methods.

Many companies have implemented their own information systems to gather declarations data individually from their own suppliers. The European Chemicals Agency (ECHA) REACH Draft Guidance on Substances in Articles¹⁰ highlights three information systems that industry sectors have developed to obtain and communicate information on substances in articles within the supply chain in an efficient manner: IMDS, JAMP and BOMcheck. This Guide focusses on the BOMcheck system.

This Guide provides a step-by-step practical approach that Manufacturers can adapt and implement in their supply chains to generate the required RoHS2 technical documentation for a product model and provide the EU Declaration of Conformity. This practical approach also explains how Manufacturers can choose to use BOMcheck to manage and maintain the supplier materials declarations which are needed for the RoHS2 technical documentation, and any analytical test reports which may also be required.

2.1 Technical Documentation

Module A of Annex II of Decision 768/2008/EC requires the Manufacturer to establish technical documentation which shall make it possible to assess the product's conformity to the RoHS substance restrictions, and shall include an adequate analysis and assessment of the risks. The technical documentation shall specify the RoHS substance restrictions and cover the design and manufacture of the product. Module A specifies that the technical documentation shall contain, wherever applicable,

- A general description of the product
- Conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits etc
- Descriptions and explanations necessary for the understanding of those drawings and schemes

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¹⁰ European Chemicals Agency (ECHA) Guidance on Requirements for Substances in Articles, Draft Version: 2, December 2010 available at http://guidance.echa.europa.eu/docs/draft_documents/Consolidated%20draft%20Guidance%20on%20requirements%20for%20SIA_MB.pdf

- A list of the harmonised standards and/or other relevant technical specifications the references of
 which have been published in the Official Journal of the European Union, applied in full or in part,
 and descriptions of the solutions adopted to comply with aspects of the RoHS substance
 restrictions which are not covered by these standards or where the standards have only been
 implemented in part.
- Results of design calculations made, examinations carried out, etc. and
- Test reports

2.2 Manufacturing

Article 7(e) of the RoHS2 Directive 2011/65/EU requires the Manufacturer to ensure that procedures are in place for series production to remain in conformity. The Manufacturer shall take into account changes in product design and changes in the harmonised standards or in technical specifications which the Manufacture has applied in full or in part.

In addition, Module A of Annex II of Decision 768/2008/EC states that the Manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured products with the technical documentation and with the requirements of the RoHS2 Directive.

2.3 Conformity Marking and EU Declaration of Conformity

Module A of Annex II of Decision 768/2008/EC states that the Manufacturer shall draw up a written EU Declaration of Conformity for each product model and keep this together with the technical documentation for 10 years after the product has been placed on the market. The EU Declaration of Conformity shall identify the product for which it has been drawn up. Article 13 (2) states that it shall be translated into the language or languages required by the Member State on the market of which the product is placed or made available.

Article 13(2) of the RoHS2 Directive states that the EU Declaration of Conformity shall contain the following elements and shall be updated

- 1. Model number or other means of uniquely identifying the product
- 2. Name and address of the manufacturer or his authorised representative
- 3. Statement that the EU Declaration of Conformity is issued under the sole responsibility of the manufacturer
- 4. Object of the declaration (identification of the product allowing traceability. It may include a photograph, where appropriate)
- 5. Statement that the object of the declaration described above is in conformity with the RoHS substance restrictions
- 6. Where applicable, references to the relevant harmonised standards used or references to the technical specifications in relation to which conformity is declared
- 7. Signature on behalf of the producer (name, function) and date of issue

Article 7(g) of the RoHS2 Directive requires the Manufacturer to ensure that the product bears a type, batch or serial number or other element allowing its identification, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document accompanying the product.

Article 7(c) of the RoHS2 Directive 2011/65/EU states that where the Manufacturer can demonstrate that the required technical documentation has been drawn up and the internal production controls in line with Module A of Annex II of Decision 768/2008/EC have been implemented, then the Manufacturer can affix the CE marking to the finished product. If the Manufacturer has already affixed the CE marking to the product to claim conformity to another Directive (for example the Medical Devices Directive) and the Manufacturer continues to supply the product after the date that the product is required to comply with the RoHS2 requirements, under Article 16 (1) of RoHS2 this CE marking now means that the Manufacturer is also claiming that their product conforms to the RoHS substance restrictions. If a single EU Declaration of Conformity is developed to cover several Directives, then the EU Declaration of Conformity should state that compliance to the RoHS2 Directive requirements is the sole responsibility of the Manufacturer.





3 RoHS2 Technical Documentation

As detailed in section 2.1, the Manufacturer is required to establish technical documentation which shall make it possible to assess the product's conformity to the RoHS substance restrictions, and shall include an adequate analysis and assessment of the risks. Module A of Annex II of Decision 768/2008/EC requires the Manufacturer to keep the technical documentation together with the EU Declaration of Conformity for 10 years after the product has been placed on the market.

This Guide recommends that the Manufacturer's technical documentation should contain the following chapters:

- Product description
- Product conformity risk assessment
- Procedure for evaluating materials declarations
- Evaluation results
- EU Declaration of Conformity

The technical documentation should include an assessment of the product to determine whether it falls within the scope of the RoHS2 Directive (see Article 2 of the RoHS2 Directive), and an assessment of the product against the 11 product categories contained in Annex I of the RoHS2 Directive to determine the deadlines for legal compliance. The Manufacturer may decide to take action ahead of these legal deadlines, for example to demonstrate early product compliance to their customers.

A company may decide to apply the conformity assessment procedures in this Guide to items which are not in scope of the RoHS2 Directive. For example, the RoHS2 Directive places legal obligations on Manufacturers who supply finished equipment – it does not place any legal obligations on companies which supply component parts. However, a component manufacturer may decide to apply the conformity assessment procedures in this Guide to their components to meet their customers' contractual requirements to supply RoHS compliant components.

3.1 Chapter 1: Product description

This chapter should start by identifying the product model so that the technical documentation can be linked to the EU Declaration of Conformity for the product. Article 7(g) of the RoHS2 Directive 2011/65/EU requires the Manufacturer to ensure that the product bears a type, batch or serial number or other element allowing its identification, and Article 13(2) of the RoHS2 Directive states that the EU Declaration of Conformity shall contain the following elements

- Model number or other means of uniquely identifying the product
- Object of the declaration (identification of the product allowing traceability. It may include a photograph, where appropriate)

Manufacturers who carry out series production of the same product model will most likely choose to prepare the technical documentation and EU Declaration of Conformity at the product model number level. Including photographs of the product would be good practice.

3.1.1 List of part codes and suppliers for all of the materials, parts and sub-assemblies which are contained in the finished product

Module A of Annex II of Decision 768/2008/EC states that the technical documentation shall contain, wherever applicable,

- Conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits etc
- Descriptions and explanations necessary for the understanding of those drawings and schemes

The technical documentation shall make it possible to assess the product's conformity to the RoHS substance restrictions, which apply to every homogenous material in the finished product. There are different approaches that companies can use to achieve this objective, depending on the complexity of the product design and supply chain. For less complex products the Manufacturer



may choose to carry out their own testing of homogenous materials in the finished product (for example, by using their own in-house laboratory or contracting a third-party to carry out the testing).

More complex electronic products may be made up of hundreds or thousands of homogenous materials. CENELEC's draft standard¹¹ for "Evaluation of electrical and electronic products with respect to the restriction of hazardous substances" highlights that it is impractical (and in many cases impossible) for the Manufacturer to determine the RoHS compliance of a complex product by carrying out their own testing of all homogenous materials in the finished product. Instead, the preferred industry approach is to prevent the RoHS substances from entering the supply chain, rather than allowing them to enter and then detecting them afterwards by testing. Hence, the CENELEC draft standard concludes that most Manufacturers choose to interact with their supply chain to obtain and compile documentation which the Manufacturer then evaluates to demonstrate that the finished product complies with the RoHS substance restrictions.

The draft CENELEC standard provides a list of the different types of documentation that the Manufacturer may choose to gather from their suppliers, but does not provide guidance on the choice and the application of evaluation methods. This Guide provides a step-by-step practical approach that Manufacturers can choose to adapt and implement in their supply chains to generate the required technical documentation for a product model and provide the EU Declaration of Conformity. This practical approach also explains how Manufacturers can choose to use BOMcheck to manage and maintain the supplier materials declarations which are needed for the RoHS2 technical documentation, and any analytical test reports which may also be required.

For Manufacturers who choose to adopt this approach, the technical documentation must enable traceability of all materials, parts and sub-assemblies which are contained in the Manufacturer's product model, by unique identification of:

- the supplier who is supplying the part, and
- the part number that the supplier uses to identify the part to the Manufacturer.

The Manufacturer should generate the Bill of Materials (BOM) for the product model to produce a list of part codes for all of the materials, parts and sub-assemblies which are contained in the finished product. The Manufacturer should then identify and assign the supplier(s) for each of these part codes.

This parts list may use the supplier's part codes, or it may use the Manufacturers own part coding system, provided that the relationship between the supplier's part code and the Manufacturer's part code is known. For example, if the Manufacturer has identified several alternative suppliers whose parts meet the specification for a Manufacturer part code, then these alternate suppliers and their supplier part codes should be identified in the technical documentation.

3.1.2 Initial screening to identify if there are any materials, parts or sub-assemblies which do not have any risk of containing RoHS substances

The Manufacturer should carry out an initial screening of the parts list to identify if there are any materials, parts or sub-assemblies in the product which do not have any risk of containing RoHS substances above the maximum concentration values. The Manufacturer should apply their own technical judgement of whether RoHS substances are not found in certain materials, parts and sub-assemblies. For example, an un-coated stainless steel screw does not contain any RoHS substances above the maximum concentration values. Similarly, a wooden case (e.g. for a hi-fi speaker) or a fabric filter (e.g. for a vacuum cleaner) will also not contain any RoHS substances above the maximum concentration values. The Manufacturer may decide to include their technical assessment of these parts in the product technical documentation and to not ask suppliers to provide materials declarations for such parts.

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¹¹ TC111X/Sec0216/DC, 2011-05-18

3.1.3 Identification of any materials exemptions claims

The technical documentation should identify whether any of the exemptions contained in Annex III and Annex IV of the RoHS2 Directive 2011/65/EU are being claimed for any parts or materials in the product, and the timescales for the expiry of these exemptions.

3.2 Chapter 2: Product conformity risk assessment

Module A of Annex II of Decision 768/2008/EC requires the Manufacturer to establish technical documentation which shall make it possible to assess the product's conformity to the RoHS substance restrictions, and shall include an adequate analysis and assessment of the risks. The technical documentation shall specify the RoHS substance restrictions and cover the design and manufacture of the product.

This means that the Manufacturer should assess the probability that non-compliant levels of RoHS substances may be present in their product either as a result of the materials, parts or sub-assemblies coming from the supply chain (after the initial screening of the parts list described in 3.1.2 has been carried out) or as a result of internal production operations. To carry out this product conformity risk assessment, the Manufacturer's technical documentation should describe the processes and procedures for:

- Design control and design verification
- Series production

The Manufacturer's technical documentation should identify any aspects of their design control and verification processes and series production processes which could present a conformity risk. For example, a product which is manufactured at one facility where all of the other products manufactured and/or repaired at this facility are also required to be RoHS compliant. In this case, the conformity risk will reside in materials, parts or sub-assemblies coming from the supply chain. On the other hand, if the product is manufactured at a facility which also manufactures and/or repairs non-RoHS compliant products then the Manufacturer will need to address conformity risks arising from possible cross-contamination between RoHS compliant and non-RoHS compliant process lines.

3.2.1 Design control and design verification

The Manufacturer's technical documentation should describe any processes and procedures for design control and design verification that were applied to the product.

For all new product designs, the design control process should include effective procedures for the selection and evaluation of parts and materials which comply with the RoHS substance restrictions. This should include specification of RoHS compliant parts and materials in all relevant sub-contract and procurement processes. The design verification process should include procedures for generation and maintenance of the RoHS technical documentation.

For old product designs (for example, legacy products which were not designed with RoHS compliance in mind), the Manufacturer should describe how compliance information for all materials, parts or sub-assemblies contained in the product was gathered and evaluated to demonstrate compliance with the RoHS substance restrictions.

3.2.2 Series production

The Manufacturer's technical documentation should describe the quality control processes and procedures that are applied to ensure that series production remains in conformity. The Manufacturer should also describe any additional inspections or examinations which may be carried out (e.g. XRF screening of incoming materials, parts and sub-assemblies, audits of suppliers, etc).

If RoHS compliant and non-RoHS compliant products are manufactured and/or repaired at the same facility then the quality control system should include procedures for:

• Inventory management to ensure segregation RoHS compliant and non-RoHS compliant materials, parts and sub-assemblies



- In-process quality control where parts mixing and/or cross contamination are possible (for example, segregation of lead and lead-free soldering process lines)
- Final product checking prior to shipment to ensure no parts mixing has occurred during manufacture

The Manufacturer should also take account of the quality control systems which are applied at contractor and sub-contractor facilities (e.g. for painting and coating operations). A complex product design may involve a number of manufacturing processes which take place at several different facilities and locations. Ensuring that series production remains in conformity requires adequate quality control systems to be in place at all of these facilities.

3.3 Chapter 3: Procedure for evaluating materials declarations

Module A of Annex II of Decision 768/2008/EC requires the Manufacturer to establish technical documentation which shall make it possible to assess the product's conformity to the RoHS substance restrictions, and shall include an adequate analysis and assessment of the risks. Module A specifies that the technical documentation shall contain, wherever applicable,

- Results of design calculations made, examinations carried out, etc, and
- Test reports

As discussed in section 3.1, it is impractical (and in many cases impossible) for the Manufacturer to determine the RoHS compliance of a complex product by carrying out their own testing of all homogenous materials in the finished product. Instead, the preferred industry approach is to prevent the RoHS substances from entering the supply chain, rather than allowing them to enter and then detecting them afterwards by testing. After the initial screening of the parts list described in 3.1.2 has been carried out, most Manufacturers choose to interact with their supply chain to obtain and compile documentation which the Manufacturer then evaluates to demonstrate that the finished product complies with the RoHS substance restrictions.

For Manufacturers who choose to adopt this approach, the type of supplier documentation that the Manufacturer decides to rely on to demonstrate RoHS conformity should be based on the Manufacturer's assessment of the risk that non-compliant levels of RoHS substances may be present in the materials, parts or sub-assemblies. The risk assessment should include an assessment of supplier risk and materials risk, and should identify:

- Suppliers for which further interactions are necessary in order to increase the confidence in that supplier, thereby reducing supplier risk, and in certain cases allowing the Manufacturer to rely on the supplier's material declaration for the material, part or sub-assembly;
- Materials, parts or sub-assemblies which contain high risk materials for which analytical test reports may be required;
- Materials, parts or sub-assemblies which contain low risk materials where supplier's materials declarations may be considered sufficient.

3.3.1 Materials risk assessment

The International Electrotechnical Commission (www.iec.ch) is a leading global organisation that prepares and publishes International Standards for all electrical, electronic and related technologies. In 2009, the IEC published a Publicly Available Specification IEC/PAS 62596:2009 "Electrotechnical products – Determination of restricted substances – Sampling procedure – Guidelines" Table B1 in Annex 1 of IEC/PAS 62596:2009 provides an overview of the typical materials and components in electrotechnical products and an assessment the probability that they may contain any of the six RoHS restricted substances. IEC/PAS 62596:2009 notes that this table is to be used as guidance to assist in selecting components/materials for testing that have a high probability of containing a RoHS restricted substance. IEC/PAS 62596:2009 also notes that not every part listed in this table requires testing and not every "high" probability substance is intended to be tested.

IEC/PAS 62596:2009 notes that the table provides a first indication of the relevant areas for testing. However as the electrotechnical industry covers many materials and components, and new



¹² IEC/PAS 62596 ed.1.0. Copyright © 2009 IEC Geneva, Switzerland.www.iec.ch

innovations are made daily this matrix does not intend to be comprehensive. Also, the table may not be up-to-date with the current list of RoHS exemptions.

This Guide recommends that the Manufacturer should use Table B1 in Annex 1 of IEC/PAS 62596:2009 as guidance to identify components/materials that have a high probability of containing a RoHS restricted substance. For example, a Manufacturer may decide to regard a material, part or sub-assembly as containing high risk materials if the table indicates that there is a high probability of it containing two or more RoHS substances.

<u>IEC/PAS 62596:2009 Table B.1 - Probability of presence of restricted substances in materials and components used in electrotechnical products</u>

L = Low probability, M = Medium probability, H = High probability, N/A = Not applicable

Components/ materials		I	Remarks					
	Hg	Hg Cd Pb Cr (VI) PBBs PBDEs					1	
Mechanical parts				•	<u> </u>			
Framework – metal	L	M	Н	Н	N/A	N/A	Unpainted	
Housing – plastic	L	L	L	L	L	М		
Power cord/cable	L	Н	Н	L	L	М		
Thick film sensor	L	Н	М	L	L	М		
Heat sink	L	L	L	L	N/A	N/A		
Screw, washer, fastener – metal	L	M	М	Н	N/A	N/A	Some are coated e.g. black and yellow chromate	
Glass – CRT, lamp glass- to-metal seal	L	М	Н	L	N/A	N/A	Pb in glass could be exempted	
Phosphorescent coating (e.g. CRT)	L	Н	L	L	N/A	N/A		
LCD panel/screen	Н	L	Н	Н	L	L		
Plasma panel/screen	Н	L	Н	Н	L	L	Pb in glass could be exempted	
Lamps, back light	Н	L	Н	М	N/A	N/A	Hg used in backlights could be exempted	
Magnetic head	L	L	Н	М	N/A	N/A		
Printed wiring board (PWB	5)							
PWB substrate/laminate	L	L	L	L	L	N/A		
Connector	М	L	Н	L	L	Н		
Capacitor – electrolytic	L	М	Н	L	L	М		
Capacitor – chip-type	L	М	М	L	L	М		
Resistor – IMT-type	L	M	Н	L	L	L		
Resistor – chip-type	L	Н	М	L	L	┙		
Diode	L	M	М	L	L	L		
Fuse	L	М	Н	L	L	L		
Solder (process and hand soldering)	L	М	Н	L	N/A	N/A		
Glue (red and white)	L	L	М	L	М	М	Used to fix components	
Component termination coating	L	Н	Н	L	N/A	N/A		
Component mouldings	L	L	L	L	L	Н		
Integrated circuit (IC) and BGAs	L	L	Н	L	L	L		

Relay – mercury	Н	L	М	L	L	L	
Relay – electromagnetic	L	Н	М	L	L	L	
Switch – mercury	Н	L	М	L	L	L	
Switch – mechanical	М	Н	М	L	L	L	
Thermostats	Н	М	М	L	L	L	
Flame sensors	Н	М	М	L	L	L	
Thermal imaging semiconductors	Н	М	М	L	L	L	
Transformer (LOT)	L	M	Н	L	L	М	
Accessories							
Remote controls	L	Н	Н	L	L	L	
External cable (e.g. Scart, USB, cinch)	L	Н	Н	L	L	L	
External power supply	L	Н	Н	L	L	М	
Materials							
Paint, ink and similar coating	L	Н	Н	М	L	L	
Adhesive			М		М	М	
Polyurethane – high gloss	Н	M	М	L	L	М	
Polyvinyl chloride (PVC)	L	Н	Н	М	L	М	
Styrene, polystyrene (HI-PS), ABS, polyethylene (PE), polyester	L	M	М	L	L	Η	
Rubber	L	М	М	L	L	М	
Plastics – other	L	M	М	L	L	М	
Colorants (all plastics) red, orange, yellow, pink, green	М	Н	Н	Н	N/A	N/A	
Metal	L	М	Н	Н	N/A	N/A	
Steel – other	L	L	L	Н	N/A	N/A	
Steel – free-machining	L	L	Н	L	N/A	N/A	
Copper alloy	L	Н	Н	L	N/A	N/A	Pb in metal could be exempt
Aluminium alloy	L	L	Н	L	N/A	N/A	Pb in metal could be exempt
Metallic chromium plating	L	L	L	L	N/A	N/A	
Zinc coating	L	Н	Н	Н	N/A	N/A	
Other metallic coatings	L	Н	L	Н	N/A	N/A	
Glass – other	L	М	Н	М	N/A	N/A	Pb could be exempt
Ceramics	L	М	Н	L	N/A	N/A	Pb could be exempt

3.3.2 Supplier risk assessment

When a Manufacturer accepts a RoHS materials declaration from a supplier, the Manufacturer should consider their relationship with the supplier and take into account the supplier's reputation and the Manufacturer's level of confidence in the supplier. Manufacturers should look to establish a level of trust with their suppliers. Some suppliers will readily provide documentation showing RoHS compliance of the materials, parts and sub-assemblies that they supply, but others may have lesser levels of awareness and can not produce the necessary information. In extreme cases, forged documents stating compliance are given.

Most manufacturers will already have a defined process of supplier qualification as part of their quality management system. This system should be extended to capture supplier qualification information critical to RoHS. This information could be based on audit, past experience, etc. The aim should be to determine if a supplier understands the RoHS substance restrictions and has effective systems in place to ensure RoHS compliance. The supplier qualification process should also consider how the suppliers assess their own suppliers. After using a certain supplier over a sustained period of time, the Manufacturer's knowledge and trust in the supplier's compliance systems may increase.

Where there may be less confidence in a supplier then an in-person audit (by the Manufacturer or an independent auditor) can be a more cost-effective alternative to the Manufacturer carrying out independent testing. An inspection of the supplier's manufacturing processes and RoHS compliance systems can not only aid understanding from both Manufacturer and supplier, but can also build a level of trust. Alternatively, a supplier could provide evidence that they have effective RoHS compliance systems in place by gaining accredited certification to the IECQ Standard QC 080000: Electrical and Electronic Components and Products Hazardous Substance Process Management System Requirements.

As an output from the supplier qualification process, the Manufacturer should assess supplier risk and categorise suppliers according to their performance. The supplier risk assessment should be used to evaluate the materials declarations that are provided by the supplier, and to decide if any analytical test reports are required for any high risk materials.

3.3.3 Flow chart procedure for evaluating supplier materials declarations based on supplier risk assessment

As discussed in section 1.1, Annex D of the UK Government RoHS1 Guidance Notes¹³ contains a compliance flow chart procedure which was originally developed by Agfa and the Fraunhofer Institute. The compliance flow chart procedure is already used by many leading Manufacturers across Europe and provides a robust foundation for developing suitable compliance assurance procedures for RoHS2.

ENVIRON has built on this flowchart to develop an enhanced flow chart procedure in Figure 1 that Manufacturers can use to evaluate suppliers materials declarations for RoHS2 based on supplier risk assessment carried out during supplier qualification. The flow chart procedure includes several notes which should be implemented as part of the procedure and provides the following three types that Manufacturers should use to categorise suppliers according to their performance:

- **Type A**: Supplier has a very good understanding of RoHS, comprehensive and effective systems in place to ensure RoHS compliance, and requires selective analysis of high risk components /materials that it purchases from its suppliers
- **Type B:** Supplier has a good understanding of RoHS and has a system for ensuring RoHS compliance but may be lacking in some respect, e.g. does not require selective analysis of high risk components /materials that it purchases from its suppliers
- **Type C:** Supplier does not understand RoHS requirements or does not have systems to ensure compliance and does not check declarations from its suppliers for incoming components/materials



¹³ http://www.bis.gov.uk/assets/biscore/business-sectors/docs/r/11-526-rohs-regulations-government-guidance-notes

The main enhancements in ENVIRON's RoHS2 flowchart in Figure 1 compared to the compliance flow chart procedure in Annex D of the UK Government RoHS1 Guidance Notes are:

- Figure 1 includes the initial screening step (which is discussed in section 3.1.2) to identify if there
 are any materials, parts or sub-assemblies which do not have any risk of containing RoHS
 substances
- Note 1 includes additional guidance on how to assess supplier materials declarations (and any analytical test reports that may be required) to ensure that they can be relied on by the Manufacturer to meet requirements for RoHS2 technical documentation
- Note 4 recommends that Table B1 in Annex 1 of IEC/PAS 62596:2009 should be used as guidance to identify components/materials that have a high probability of containing a RoHS restricted substance. For example, a Manufacturer may decide to regard a material, part or subassembly as containing high risk materials if the table indicates that there is a high probability of it containing two or more RoHS substances.

Note 1. Assessment of supplier's material declarations and / or analytical test reports

Supplier material declarations (and any analytical test reports that may be required) must be assessed to ensure that they can be relied on by the Manufacturer to meet requirements for RoHS2 technical documentation for the product model. The UK RoHS Enforcement Authority has published a RoHS Guidance Producer Support Booklet¹⁴ which provides valuable advice on how to assess supplier's material declarations and analytical test reports.

Supplier materials declarations

As discussed in Section 2.1, the Manufacturer's technical documentation for RoHS2 shall make it possible to assess the product's conformity to the RoHS substance restrictions and must enable traceability of all materials, parts and sub-assemblies which are contained in the Manufacturer's product model, by unique identification of:

- the supplier who is supplying the part, and
- the part number that the supplier uses to identify the part to the Manufacturer.

Wherever possible, the Manufacturer should insist that the supplier's material declaration:

- should contain an unambiguous statement that all six RoHS substances are not present above the maximum concentration values, or if an exemption is claimed the statement should specify the exemption(s)
- should enable identification of the supplier part codes for the list of supplier materials, parts or sub-assemblies which are contained in the Manufacturer's product
- must be signed by an executive officer at the supplier who has authority to sign on behalf of the company

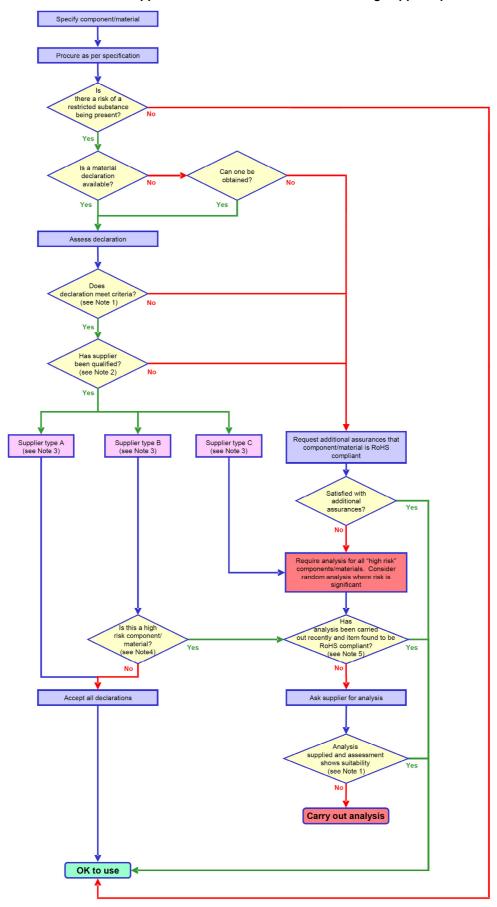
The Manufacturer should assess what the supplier is declaring and whether it is a generic declaration or specifically related to the materials, parts or sub-assemblies that are being supplied. The RoHS Guidance Producer Support booklet notes that the UK RoHS Enforcement Authority often sees declarations which are not relevant to RoHS compliance. The declaration may be stating that there was 'no intentional use' of the RoHS substances, that the parts used in the assembly were screened for RoHS compliance or that the declaration is limited to the non-use of lead in solder. The Authority also sees many declarations that contain caveats such as 'made best efforts' or 'to the best of senior management's knowledge'. These caveats reduce the level of reliance that the Manufacturer can place on the supplier's declaration.

Many suppliers provide declarations which are generic and use standard wording that could relate to any company or any product. This type of generic declaration may not provide the Manufacturer with sufficient assurance that the list of supplier materials, parts or sub-assemblies which are contained in the Manufacturer's product are RoHS compliant. Manufacturers should read the supplier's declaration carefully to ensure it is providing the protection expected.



¹⁴ http://www.bis.gov.uk/assets/bispartners/nmo/docs/rohs/support-literature/producer-support-booklet.pdf

Figure 1. Flow chart procedure that the Manufacturer can use to evaluate suppliers materials declarations for RoHS2 based on supplier risk assessment carried out during supplier qualification



Analytical test reports

If the Manufacturer's assessment concludes that they should require the supplier to provide analytical test reports for certain materials, parts or sub-assemblies, then the Manufacturer should inspect the test reports provided by the supplier to ensure that they can be relied on to meet requirements for RoHS2 technical documentation for the product model. In their RoHS Guidance Producer Support booklet, the UK RoHS Enforcement Authority notes that Manufacturers often do not examine analytical test reports closely enough and there is a lack of knowledge on their interpretation which can result in an over-reliance on the report provided. The Manufacturer should use the following criteria when they assess any test reports which are provided by their suppliers.

How old is the report? All test reports should be dated to indicate when the report was issued and when the test was conducted. The list of materials, parts and sub-assemblies used to manufacture the final product may change over time, so if the test report was written before these changes it may no longer be relevant to the final product. A Manufacturer with a frequently changing product design or production processes may need to update more regularly any test reports that they require for the final product.

Is the test laboratory accredited to the ISO/IEC 17025 standard? As part of their accreditation, a laboratory must apply the appropriate test methods specified in IEC 62321 and keep abreast of scientific and technological advances in relevant areas.

Does the test report cover all of the relevant homogenous materials in the part or sub-assembly that require testing? The test report(s) should identify which homogenous materials within the part of sub-assembly contain high risk materials that require testing, and which materials within the part or sub-assembly do not require testing (e.g. because they do not contain high risk materials). A homogenous material that contains high risk materials may not require testing for all six of the RoHS substances. For example, organic substances such as PBBs and PBDEs are not found in metal parts. For electronic components on an assembled printed circuit board, further analysis may be required because it can be difficult to assess compliance at the homogenous material level.

Do the test results confirm compliance? For each RoHS substance that was tested in each relevant homogenous material, the test results should show that the measured concentration of the RoHS substance does not exceed the maximum concentration values, or that the use of the RoHS substance in that homogenous material is covered by a valid exemption. The UK RoHS Enforcement Authority notes that they are often presented with RoHS test results that demonstrate that the product is non-compliant. This is a clear instance where no checking process is in place and a simple step can prevent the occurrence of larger problems.

Note 2 and Note 3. Supplier Qualification

The Manufacturer's supplier qualification process should be extended to capture supplier qualification information critical to RoHS and the Manufacturer should use the following three types to categorise suppliers according to their performance:

- **Type A**: Supplier has a very good understanding of RoHS, comprehensive and effective systems in place to ensure RoHS compliance, and requires selective analysis of high risk components /materials that it purchases from its suppliers
- **Type B:** Supplier has a good understanding of RoHS and has a system for ensuring RoHS compliance but may be lacking in some respect, e.g. does not require selective analysis of high risk components /materials that it purchases from its suppliers
- Type C: Supplier does not understand RoHS requirements or does not have systems to ensure compliance and does not check declarations from its suppliers for incoming components/materials

The flow chart procedure provides the following purchasing rules which the Manufacturer should follow when purchasing materials, parts and sub-assemblies from a supplier:

- Type A Supplier: Accept all supplier materials declarations without requiring any further analytical test reports.
- **Type B Supplier:** Require recent analytical test reports for all materials, parts and sub-assemblies that contain high risk materials



• **Type C Supplier:** Require recent analytical test reports for all materials, parts and sub-assemblies that contain high risk materials and also consider additional random testing for other materials, parts and sub-assemblies

Note 4. High Risk Components/Materials

The Manufacturer should apply their own technical judgement of whether RoHS substances are likely to be contained in certain materials. For example, an un-coated stainless steel screw does not contain any RoHS substances above the maximum concentration values. Similarly, organic substances such as PBBs and PBDEs are not found in metal parts.

This Guide recommends that the Manufacturer should use Table B1 in Annex 1 of IEC/PAS 62596:2009 as guidance to identify components/materials that have a high probability of containing a RoHS restricted substance. For example, a Manufacturer may decide to regard a material, part or sub-assembly as containing high risk materials if the table indicates that there is a high probability of it containing two or more RoHS substances.

Note 5. Analysis Requirements

The need for regular analysis depends on the risk of non-compliance as well as the risk to the environment. Where there is a risk of non-compliance, the frequency that analysis should be carried out may depend on the potential risk to the environment so that components/materials used in very large numbers would need to be analysed more regularly than components/materials used in small numbers.

3.4 Chapter 4: Evaluation results

In Chapter 1 of the technical documentation, the Manufacturer should include a list of the suppliers and the part codes for all of the materials, parts and sub-assemblies which are contained in the finished product. This table can be extended to include the results from applying the flow chart procedure for evaluating materials declarations to this list, Table 1. This evaluation table forms an essential element of the Manufacturer's technical documentation to demonstrate that the finished product complies with the RoHS substance restrictions. The table should be approved by the person who signs the EU Declaration of Conformity in Chapter 5, and should be reviewed regularly.

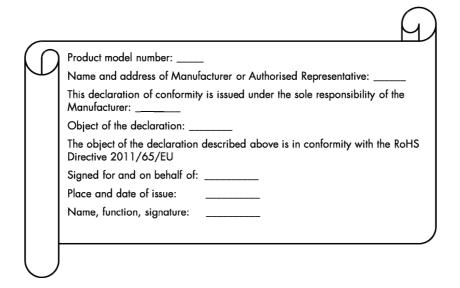
Table 1. Results from applying flow chart procedure for evaluating materials declarations to all of the materials, parts and sub-assemblies which are contained in the finished product

Materials risk		Supplier risk		Evaluation of declaration	materials	Evaluation of analytical test reports if required		
Part code	Does part code contain high risk materials?	Supplier name or supplier code	Supplier qualification type (A, B or C)	Materials declaration available?	Does materials declaration meet Manufacturer's acceptance criteria?	Analytical test report required?	Does analytical test report meet Manufacturer's acceptance criteria?	

3.5 Chapter 5: EU Declaration of Conformity

The person who is responsible for approving the technical documentation should ensure that the information contained in all Chapters is adequate, and in particular that the evaluation results from applying the flow chart procedure demonstrate that the finished product is RoHS compliant. They should also establish a review date for the technical documentation. This responsible person should then sign the EU Declaration of Conformity for the product model, Figure 2, and ensure that it is kept together with the technical documentation for 10 years after the product has been placed on the market.

Figure 2: EU Declaration of Conformity for a product model



If the Manufacturer has already affixed the CE marking to the product to claim conformity to another Directive (for example the Medical Devices Directive) and the Manufacturer continues to supply the product after the date that the product is required to comply with the RoHS2 requirements, under Article 16 (1) of RoHS2 this CE marking now means that the Manufacturer is also claiming that their product conforms to the RoHS substance restrictions. If a single EU Declaration of Conformity is developed to cover several Directives, then the EU Declaration of Conformity should state that compliance to the RoHS2 Directive requirements is the sole responsibility of the Manufacturer.

3.6 Maintenance of technical documentation and EU Declaration of Conformity

Article 7(e) of the RoHS2 Directive 2011/65/EU requires the Manufacturer to keep the technical documentation up-to-date with any changes to the product design and manufacturing process. Therefore, the Manufacturer needs to have a process for identifying product design changes (e.g. by changing the revision number for the product model number) and producing updated technical documentation which includes an updated list of part codes and suppliers for all of the materials, parts and sub-assemblies which are contained in the finished product.

If the Manufacturer chooses to use BOMcheck, then the Manufacturer should download supplier materials declarations from BOMcheck for the updated list of parts codes (see section 4.4.1). The Manufacturer may choose to run reports in their PLM system and/or to include the updated BOMcheck declaration report PDF (see section 4.4.1) in their RoHS2 technical documentation. The Manufacturer may also choose to use the BOMcheck tools to assess any analytical test reports which may be required (see section 4.4.2) and include the updated BOMcheck assessment report PDF in their RoHS2 technical documentation.

4 How to use BOMcheck to manage supplier materials declarations for RoHS2 Technical Documentation

4.1 Tools developed by industry sectors to communicate substance information in the supply chain

Many companies have implemented their own information systems to gather declarations data individually from their own suppliers. The European Chemicals Agency (ECHA) REACH Draft Guidance on Substances in Articles¹⁵ highlights three information systems that industry sectors have developed to obtain and communicate information on substances in articles within the supply chain in an efficient manner: IMDS, JAMP and BOMcheck.

4.1.1 IMDS

The automotive sector has developed a tool, known as International Material Data System (IMDS), to support the collection and communication of data about substances in the automotive supply chain. In the IMDS, information on all materials used in a car are archived and maintained in order to meet the substance related obligations placed on the car manufacturers, and thus on their suppliers, by national and international standards, laws and regulations. Further information is available at www.mdsystem.com.

In October 2011 a version of the IMDS tool called Compliance Data Exchange (CDX) was launched to support the Ship Building Industry in fulfilling future national and international legislative regulations concerning recycling and use of hazardous substances (see http://public.cdxsystem.com/web/cdx/ship). The Hong Kong International Convention for the Safe and Environmentally Sound Recycling of Ships, 2009¹⁶ will enter into force in the next 2 to 4 years and lead to hazardous substance management requirements and end-of-life recycling requirements for ships.

In addition, the CDX tool is also available for use in the electronics industry (see http://public.cdxsystem.com/web/cdx/electronics). MDS that have already been published in IMDS are not available in CDX. A supplier who has already published their data in IMDS and also wants to use CDX must enter their data separately into the CDX system.

4.1.2 JAMP

The Joint Article Management Promotion-consortium (JAMP) was established in September 2006 as an initiative to promote cross-industrial activities contributing to its mission; establishment and dissemination of effective and workable mechanisms to facilitate disclosure/transfer of information on chemicals contained in products across the supply chain. An objective of JAMP is to promote smooth transfer of information on substances in articles within supply chains and across sectors. In the trade of chemical substances and preparations, Material Safety Data Sheets (MSDS) or Material Safety Data Sheets plus (MSDSplus) have been established to provide users with chemical information. As for articles manufactured with chemical substances and preparations, the similar system to MSDS is desirable to disclose and convey chemical information of the ingredients for avoiding overload and confusion not only in the stage of investigation and procurement but also in complying with the regulations enforced in the future. For this purpose JAMP provides tools and operating rules for the disclosure and conveyance of such information, which are available at http://www.jamp-info.com/english.

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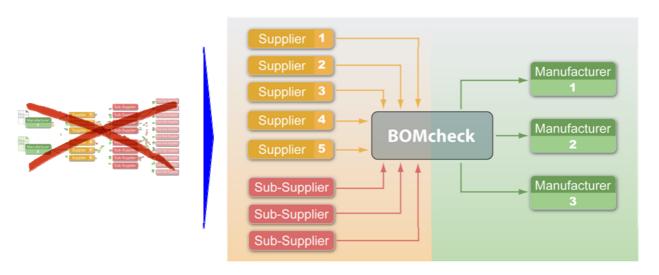
¹⁵ European Chemicals Agency (ECHA) Guidance on Requirements for Substances in Articles, Draft Version: 2, December 2010 available at http://quidance.echa.europa.eu/docs/draft_documents/Consolidated%20draft%20Guidance%20on%20requirements%20for%20SiA_MB.pdf

¹⁶ Further information is available at http://www.imo.org/ourwork/environment/shiprecycling

4.1.3 BOMcheck

BOMcheck is an industry led solution which was launched by the COCIR European Trade Association in June 2008 to benefit all sectors of the electronics industry. This Guide focusses on the BOMcheck tool and explains how Manufacturers can choose to use BOMcheck to manage and maintain the supplier declarations for the RoHS2 technical documentation for their product models, and any analytical test reports that may be required.

Figure 3. Shared industry-led web database for suppliers to publish materials declarations, and provide any analytical test reports that may be required



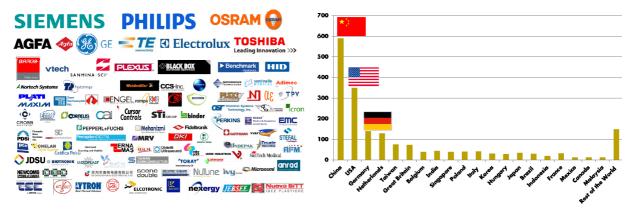
<u>www.BOMcheck.net</u> is a shared industry-led web database system which provides tools and guidance for suppliers to publish and maintain their materials declarations in international standard formats for their customers to access, Figure 3.

The BOMcheck Steering Group comprises Siemens, Philips, GE, Osram, Toshiba, Agfa, Texas Instruments, Tyco Electronics and Fujifilm and the Steering Group meets every two months by web meeting and conference call to direct the development of new functions and features on BOMcheck and to plan joint roll out to suppliers. BOMcheck is used by over 330 Manufacturers and over 2,000 Suppliers, Figure 4.

Figure 4. BOMcheck is used by over 330 Manufacturers and 2,000 Suppliers, October 2011

320 Manufacturers using BOMcheck to manage supplier regulatory compliance

Global distribution of 2,000 Suppliers using BOMcheck to make materials declarations



BOMcheck increases the quality and response rate for supplier materials declarations by providing benefits to suppliers:

 All manufacturers share one database system and one global list of restricted and declarable substances for materials declarations

- BOMcheck system provides expert guidance on all regulated substances worldwide, including North America, Asia Pacific and Europe
- Suppliers can choose to make a Regulatory Compliance Declaration (e.g. for REACH, ROHS, industry requirements) or to make a Full Material Declaration (FMD) in which case BOMcheck automatically calculates a Regulatory Compliance Declaration (RCD) from the FMD data. Suppliers can choose to make the FMD confidential to certain customers and allow other customers only to see the RCD which BOMcheck calculates from FMD data.
- The FMD tool includes built-in data validation. Suppliers declare each substance in each material by selecting from a searchable list of 524,000 substances down to the CAS-number level. BOMcheck calculates the percentages of substances in the part and maps substances against regulatory and other requirements.
- BOMcheck includes built-in electronic signature arrangements which comply with US FDA
 Regulations. When the Manufacturer downloads a supplier's declaration data from BOMcheck
 this is equivalent to the Manufacturer receiving a paper-based declaration with a handwritten
 signature from the supplier.
- Suppliers can attach evidence documents (e.g. analytical test reports) and can e-mail their declarations data to any manufacturer customers who are not on BOMcheck yet
- All suppliers data is updated centrally when the list of RoHS exemptions and regulated substances changes. Suppliers receive guidance and training on the regulatory changes and how to use the BOMcheck tools to re-certify their Regulatory Compliance Declarations
- All BOMcheck tools and User Guides are available in Chinese, Japanese, German and English
- Free webinar training for suppliers. The monthly introduction webinars provide an overview of
 the RoHS, REACH, Batteries and Packaging regulations and a detailed demonstration of how
 suppliers can publish materials declarations in BOMcheck. When a supplier joins BOMcheck
 they are required to complete a recording training program (available in Chinese and English)
 which includes a step-by-step demonstration of all of the tools on BOMcheck. A recorded
 introduction webinar is available at www.BOMcheck.net in Chinese, German and English.

Using BOMcheck to manage and maintain the supplier declarations for the RoHS2 technical documentation for product models involves the following steps:

- Setting up a RoHS2 project team and agreeing development plan and implementation plan
- Unique identification of suppliers and part codes
- Downloading RoHS PDF reports for the lists of part codes in the product models

4.2 Setting up a RoHS2 project team

There should be an officer appointed at the Manufacturer who manages RoHS compliance issues. This RoHS2 Program Manager must secure senior management commitment to set up a RoHS2 Project Team. At most companies the RoHS2 project team will require roles and responsibilities and support from:

- Product Design and Manufacturing
- Purchasing
- Quality / Regulatory
- IT / PLM

At the first meeting, the Project Team should review this Guide and decide how the Manufacturer will adapt and implement the guidance detailed in Section 3 to generate the required RoHS2 technical documentation for a product model and provide the EU Declaration of Conformity.

Table 2 and Table 3 provide a list of RoHS2 processes and procedures that the Manufacturer can adapt and implement. This step-by-step practical approach also explains how Manufacturers can choose to use BOMcheck to manage and maintain the supplier materials declarations which are needed for the RoHS2 technical documentation, and any analytical test reports which may also be required. If the Manufacturer chooses to use the BOMcheck system then they must sign a Manufacturer's Agreement¹⁷ with ENVIRON. Processes and procedures which the Manufacturer

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A sample Manufacturers Agreement is available at http://www.bomcheck.net/manufacturers/request-agreement

can choose to carry out in BOMcheck are highlighted in **blue bold font** in Table 2 and are also included in Table 3.

Table 2. Step-by-step approach for generating RoHS2 technical documentation. Processes and procedures which Manufacturer can choose to carry out in BOMcheck are highlighted in blue bold font. See Table 3 for processes and procedures which Manufacturer can choose to carry out in BOMcheck to identify suppliers and part codes.

RoHS2 Process/procedure

Assess the product to identify whether it is included within scope of RoHS2, and which category it falls into, and establish timelines for compliance program, (see section 3).

Generate the Bill of Materials for the product model to produce a list part codes for all of the materials, parts and sub-assemblies which are contained in a product model (see section 3.1.1). Identify and assign the supplier(s) for each of these part codes.

Screen the parts list to identify if there are any materials, parts or sub-assemblies in the product which do not have any risk of containing RoHS substances above the maximum concentration values (section 3.1.2)

Carry out a conformity risk assessment by describing or referring to the processes and procedures for

- design control and design verification (see section 3.2.1)
- series production (see section 3.2.1)

Carry out a materials risk assessment to identify if any parts contain high risk materials (see section 3.3.1). For example, a Manufacturer may decide to define a material, part or sub-assembly as containing high risk materials if Table B.1 indicates that there is a high probability of it containing two or more RoHS substances.

Extend the supplier qualification process to include a supplier risk assessment for RoHS and categorise suppliers according to their performance (see section 3.3.2)

Apply the flow chart procedure to evaluate supplier materials declarations based on supplier risk assessment. Identify if any parts may require analytical test reports (see section 3.3.3)

Download supplier materials declarations from BOMcheck for the list of parts codes for the materials, parts and sub-assemblies which are contained in a product model (see section 4.4.1). The Manufacturer may choose to run reports in their PLM system or to include the BOMcheck declaration report PDF in their RoHS2 technical documentation.

The Manufacturer may choose to use the BOMcheck tools to assess any analytical test reports which may be required (see section 4.4.2). The Manufacturer may choose to include the BOMcheck assessment report PDF in their RoHS2 technical documentation.

Draw together and maintain all necessary information to write the technical documentation (see section 3 and in particular section 3.4) and write the EU Declaration of Conformity for a product model (section 3.5)



4.3 Unique identification of suppliers and part codes

If the Manufacturer chooses to use the BOMcheck system then they must sign a Manufacturer's Agreement¹⁸. This requires the Manufacturer to send a letter to their suppliers asking them to set up a Supplier Account on BOMcheck and publish material declarations for the part codes that they supply to the Manufacturer. A standard letter is provided in Schedule 1 of the Manufacturer Agreement or the Manufacturer can develop an equivalent letter.

The Manufacturer should send the list of supplier part numbers that they buy from the supplier and ask the supplier to confirm that their part numbers are included correctly in the list. The supplier should use exactly the same part numbers when they publish their materials declaration(s) so that the Manufacturer can find the supplier part numbers easily on BOMcheck.

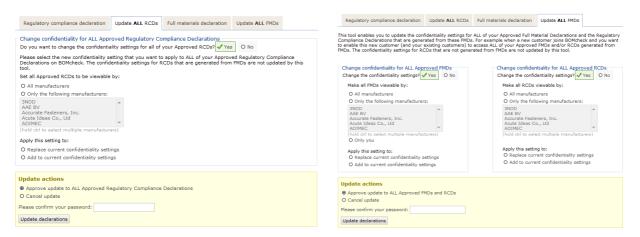
BOMcheck provides introduction webinars each month which suppliers can attend free-of-charge. BOMcheck will send the email invitation details for the Manufacturer to forward to their suppliers. BOMcheck runs two webinars each month – one for Asia Pacific/EU suppliers and one for US/EU suppliers. A supplier can attend the introduction webinar as many times as they like, and can also forward the invitation to their suppliers. Each webinar lasts about 1.5 hours, including questions and answers, and provides:

- an overview of the RoHS, REACH, Batteries and Packaging regulations, and
- a detailed demonstration of how suppliers can publish materials declarations in BOMcheck

When a supplier joins BOMcheck they are required to complete a recorded BOMcheck training program when they first login to the system. This recorded training webinar includes a step-by-step demonstration of all of the tools on BOMcheck.

A supplier who is already a member of BOMcheck and has made their declarations confidential to certain customers can add the Manufacturer to these confidentiality settings, for example by using the Update ALL RCDs tool or Update ALL FMDs tool, Figure 5.

Figure 5. How a supplier can use the Update ALL RCDs or Update ALL FMDs tool in a Supplier Account to add the Manufacturer to the confidentiality settings for their declarations data on BOMcheck



The Manufacturer Account on BOMcheck includes the 'View suppliers list' tool which the Manufacturer can use to identify their suppliers on BOMcheck, Figure 6. This enables the Manufacturer to download a list of all suppliers on BOMcheck, or to download a list of suppliers who have used the 'View manufacturers list' tool in their Supplier Account to inform the Manufacturer that they are on BOMcheck, Figure 7. The Manufacturer can also use the 'View supplies list' tool to instruct BOMcheck to send them a notification e-mail (immediately, daily, weekly or monthly) when a supplier joins BOMcheck and uses the 'View manufacturers list' to inform the Manufacturer that they are on BOMcheck.

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¹⁸ A sample Manufacturers Agreement is available at http://www.bomcheck.net/manufacturers/request-agreement

Figure 6. 'View suppliers list' tool in a Manufacturer Account enables the Manufacturer to identify their suppliers on BOMcheck

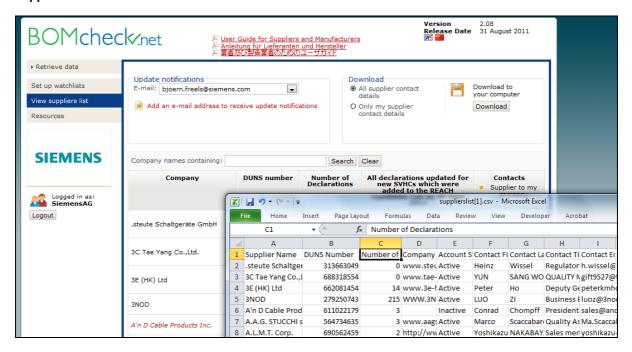
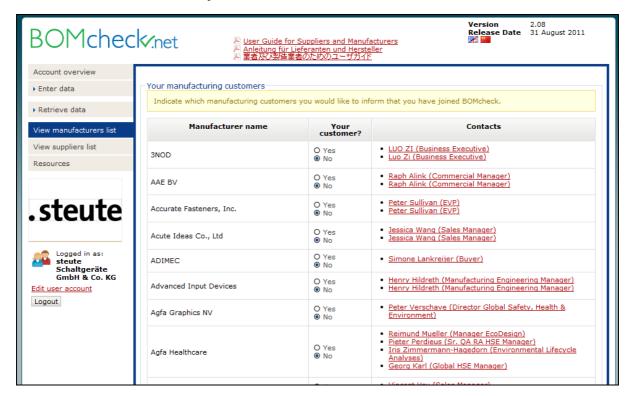


Figure 7. 'View manufacturer list' tool in a Supplier Account enables a supplier to inform their Manufacturer customers that they are on BOMcheck



4.3.1 Unique identification of suppliers

As discussed in Section 3.1.1, the Manufacturer's technical documentation for RoHS2 must enable traceability of all materials, parts and sub-assemblies which are contained in the Manufacturer's product model, by unique identification of:

- the supplier who is supplying the part, and
- the part number that the supplier uses to identify the part to the Manufacturer.

To enable unique identification of the supplier who is supplying the part, each distinct supplier on BOMcheck is allocated a unique Supplier Code. BOMcheck has chosen to use the DUNS number 19 as the unique Supplier Code because:

- the DUNS number is a globally recognised coding system
- a DUNS number is unique to an assigned business and is never re-used (even if the business goes bankrupt). This means it is impossible for two different suppliers to have the same **BOMcheck Supplier Code**
- the DUNS number enables BOMcheck to verify that the supplier is a legitimate business. This is necessary for the electronic signature arrangements on BOMcheck to comply with the US FDA Regulations (CFR Part 11 Electronic Signature Regulations)
- There is no other comparable global identification coding system available

When a supplier joins BOMcheck they are required to select only one DUNS number as their Supplier Code on BOMcheck (even though large companies may have a large number of DUNS numbers for different business addresses). BOMcheck recommends that suppliers choose their highest level corporate DUNS number to use as their Supplier Code on BOMcheck. There are two exceptions to this rule:

- If a supplier has several distinct brands and each brand has its own part coding system then each brand must have its own unique Supplier Code on BOMcheck:
- If a supplier has several distinct brands and each brand behaves as a separate company with its own set of customers then if may be appropriate for each brand to have its own unique Supplier Code on BOMcheck

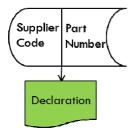
The Manufacturer Account on BOMcheck includes the 'View suppliers list' tool which the Manufacture can use to download a list containing the Supplier Code (DUNS Number) for every supplier on BOMcheck, Figure 6. The Manufacturer may have already established a different supplier coding system for its suppliers. In this case, the Manufacturer should establish and maintain a matrix table (for example in the IT / PLM system) to link the Manufacturer's Supplier Code to the BOMcheck Supplier Code.

4.3.2 Unique identification of supplier parts

Each supplier part on BOMcheck is identified by a unique pair of values, Figure 8:

- The unique Supplier Code (DUNS number) for that supplier in BOMcheck, and
- The supplier part number

Figure 8. Unique identification of a supplier part in BOMcheck



A part is uniquely identified by the combination of the supplier code (always unique on BOMcheck) and the supplier part number (may not be unique)

To download the materials declarations for a list of supplier parts in BOMcheck, the Manufacturer should load a parts list into BOMcheck which contains the supplier part number in column 1 and the Supplier Code (DUNS number) in column 2 (see section 4.4.1).

BOMcheck includes built-in electronic signature arrangements which comply with US FDA Regulations (CFR Part 11 Electronic Signature Regulations – further information is available at http://www.bomcheck.net/suppliers/electronic-signatures. When the Manufacturer downloads the



¹⁹ A DUNS number is a unique nine-digit identification number which is used to identify legitimate registered businesses, and is allocated by Dun & Bradstreet (www.dnb.com)

supplier's material declaration from BOMcheck this is equivalent to the Manufacturer receiving a paper-based material declaration with a handwritten signature from the supplier.

4.3.3 Using the mapping tool to map supplier parts to Manufacturer part codes

As discussed in Section 3.1.1, the Manufacturer's RoHS2 technical documentation should include a list of the suppliers and the part codes for all of the materials, parts and sub-assemblies which are contained in the finished product. In most cases the parts list in the RoHS2 technical documentation will comprise a list of supplier part numbers / supplier codes. However, larger Manufacturers often have their own part coding system and in some cases the RoHS2 technical documentation may use the list of Manufacturer part codes, provided that the relationship between the supplier part number / supplier code and the Manufacturer part code can be easily demonstrated.

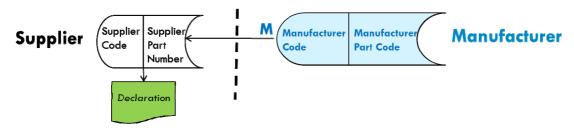
Many PLM systems store and maintain the relationship between the supplier part number / supplier code and the Manufacturer part code in the master data for a product. In this case, the Manufacturer can use the list of supplier part numbers / supplier codes to download the materials declarations (see section 4.4.1). The Manufacturer may choose to load these data into the PLM system (see section 4.4.3) and use the PLM system to run RoHS2 compliance reports and/or the Manufacturer may choose to include the BOMcheck declaration report PDF in their RoHS2 technical documentation (see section 4.4.1).

But some PLM systems only allow one part number to be stored in the master data for a product and some Manufacturers choose to store their own Manufacturer part code instead of the supplier part number / supplier code. In this case, the Manufacturer needs to be able to use the materials declarations from their suppliers to generate a report showing the RoHS compliance status for the list of Manufacturer part codes for all materials, parts and sub-assemblies in the product model. These Manufacturers also need to be able to easily demonstrate the relationship between the supplier code / supplier part number and the Manufacturer part code.

To assist these Manufacturers, BOMcheck provides a mapping tool which the Manufacturer can use to establish the relationship between the Manufacturer's part code and the supplier part number / supplier code in BOMcheck. The Manufacturer needs to upgrade their BOMcheck account to a Super User Account 20 to be able to use the mapping tool. The Super User Account requires the Manufacturer to select a DUNS number as their Manufacturer Code on BOMcheck. The Manufacturer Code is used to uniquely identify the Manufacturer Part Codes that Manufacturer creates on BOMcheck by using the mapping tool.

First of all, the supplier must publish a materials declaration for their supplier part number in BOMcheck. Then, the Super User can use the mapping tool²¹ to create the Manufacturer Part Code in BOMcheck as a Mapping Number which points to the supplier part number, Figure 9. The Mapping Number is a 'virtual' part number (i.e. an Alias) which points to a supplier part number that the supplier has already declared in BOMcheck.

Figure 9. Super User can create the Manufacturer Part Code as a Mapping Number which points to the supplier part number



²⁰ As explained at http://www.bomcheck.net/manufacturers/super-user-account, when a person has a Supplier Account and works for a company that has a Manufacturer Account, BOMcheck provides a free upgrade to convert the Supplier Account into a Super User account



²¹ See Section 5.5 of the BOMcheck User Guide for Suppliers and Manufacturers – release 2.06

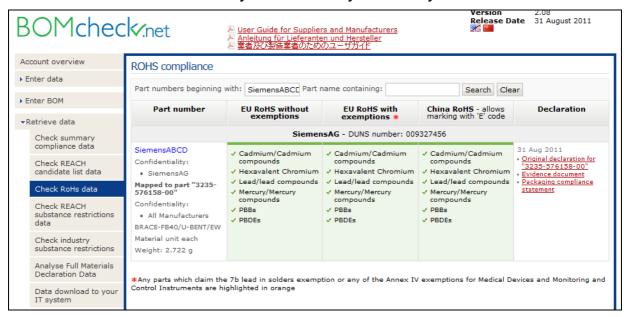
The Mapping Number (Manufacturer Part Code) has the same materials declaration status as the supplier part number. When the supplier updates the materials declaration for their supplier part number, BOMcheck automatically updates the materials declaration status for the Mapping Number (Manufacturer Part Code).

The mapping tool enables the Manufacturer to use their Manufacturer Code on BOMcheck and the list of Manufacturer Part Codes to download the materials declarations PDF reports from BOMcheck for inclusion in the RoHS2 technical documentation (see section 4.4.1). A Mapping Number is shown in **blue font** on BOMcheck to differentiate it from a supplier part number which is shown in **black font**, Figure 10. The Super User can set the confidentiality of the Mapping Number so that the Mapping Number can be viewed by:

- All Manufacturers in BOMcheck, or
- · Only selected Manufacturers, or
- Only the Super User

Figure 10 provides an example of a mapping that has been carried out by a Super User at SiemensAG. The Super User has mapped the Manufacturer Part Code SiemensABCD to supplier part number 3235-576158-00, and has set the mapping confidentiality so that Manufacturer Part Code SiemensABCD can only be viewed by other colleagues at SiemensAG who login to BOMcheck by using the SiemensAG Manufacturer Account. When another Manufacturer logs into BOMcheck they will be able view supplier part number 3235-576158-00 (because the supplier has allowed All Manufacturers to view this part number) but the Manufacturer will not be able to view Manufacturer Part Code SiemensABCD.

Figure 10. SiemensAG Super User has mapped part code SiemensABCD to supplier part number 3235-576158-00 and has set the confidentiality so that it can only be viewed by SiemensAG



4.3.4 RoHS2 processes and procedures for identification of suppliers and part codes

Table 3 summarises processes and procedures which Manufacturer can choose to carry out in BOMcheck to identify suppliers and part codes.

Table 3. RoHS2 processes and procedures which the Manufacturer can choose to carry out in BOMcheck to identify suppliers and part codes

RoHS2 Process/procedure

Send the list of supplier part numbers that the Manufacturer buys with a letter to the supplier asking them to publish declarations for these supplier part numbers in BOMcheck (section 4.3)



Send e-mails to suppliers inviting them to attend free monthly BOMcheck introduction webinars (section 4.3)

If the Manufacturer has already established a different supplier coding system, then the Manufacturer should establish and maintain a table (for example in the IT / PLM system) to link their supplier codes to the BOMcheck Supplier Codes (section 4.3.1)

If the Manufacturer has their own part coding system and the Manufacturer wants to list their own part codes in the RoHS2 technical documentation, then the Manufacturer should upgrade to a Super User Account and map their part codes to the Supplier Part Numbers / Supplier Codes in BOMcheck (section 4.3.3)

4.4 Downloading RoHS2 PDF reports for the list of part codes in the product

As discussed in section 3.4, the Manufacturer's RoHS technical documentation should include a table which summarises the results from applying the flow chart procedure for evaluating materials declarations to the list of suppliers and part codes for all of the materials, parts and sub-assemblies which are contained in the finished product. This evaluation table forms an essential element of the Manufacturer's technical documentation to demonstrate that the finished product complies with the RoHS substance restrictions.

This section explains how the Manufacturer can use the list of supplier part numbers / supplier codes to download the materials declarations. The Manufacturer may choose to load these data into the PLM system (see section 4.4.3) and use the PLM system to run RoHS2 compliance reports and/or the Manufacturer may choose to include the BOMcheck declaration report PDF in their RoHS2 technical documentation. The Manufacturer may also choose to use the BOMcheck tools to assess any analytical test reports which may be required and include the BOMcheck assessment report PDF in their RoHS2 technical documentation.

4.4.1 Downloading materials declarations for the list of part codes in the product

The Manufacturer Account on BOMcheck includes the 'Check RoHS data' tool which the Manufacturer can use to view the materials declarations for a list of supplier parts. The parts list file must contain the supplier part number in column 1 and the Supplier Code (DUNS number) in column 2 and must be saved as a Unicode Text File, Figure 11. If the Manufacturer has used the mapping tool to create Mapping Numbers for their Manufacturer Part Codes, then the Manufacturer can view the materials declarations by attaching a parts list file that contains their Manufacturer Part Code in column 1 and their Manufacturer Code (DUNS number) in column 2.

BOMcheck stores the supplier part numbers exactly as they are provided by supplier, including any dots, dashes, hyphens, slashes etc that the supplier includes in the supplier part number. The Manufacturer can search the BOMcheck database by looking for an exact match between their parts list file and the supplier part numbers stored on the database, or by looking for a similar match. If the Manufacturer selects a similar match, then BOMcheck searches the database by looking for a match when all dots, dashes, hyphens, slashes etc are removed from the part number in the Manufacturer's parts list and from the supplier part numbers stored on the database. BOMcheck always reports the supplier part numbers exactly as they are provided by the supplier.





Figure 11. Using the 'Check RoHS data' tool in a Manufacturers Account to view the materials declarations for a list of supplier parts

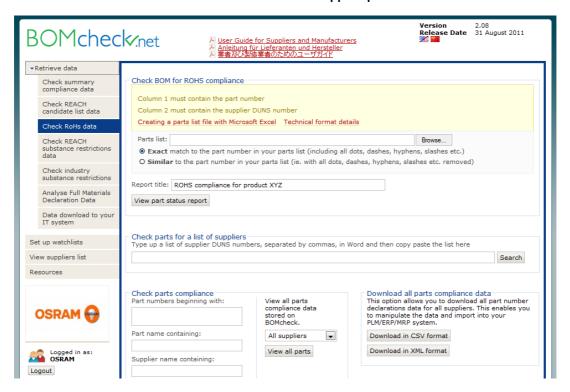
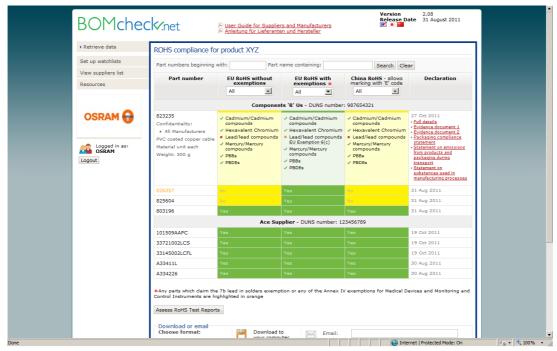


Figure 12 provides an example of RoHS materials declaration data for a list of supplier part numbers on BOMcheck. The Manufacturer can click on a part number to view further details about the compliance status and access any evidence documents that the supplier has attached to the declaration (e.g. analytical test reports).

Figure 12. Example RoHS materials declaration data for a list of supplier part numbers



The Manufacturer may choose to load these data into the PLM system (see section 4.4.3) and use the PLM system to run RoHS2 compliance reports and/or the Manufacturer may choose to include the BOMcheck declaration report PDF, Figure 13, in the RoHS2 technical documentation to provide evidence to support the results in the evaluation table for the product. BOMcheck includes built-in



electronic signature arrangements which comply with US FDA Regulations (CFR Part 11 Electronic Signature Regulations – see details at http://www.bomcheck.net/suppliers/electronic-signatures). When the Manufacturer downloads the supplier's material declaration from BOMcheck this is equivalent to the Manufacturer receiving a paper-based material declaration with a handwritten signature from the supplier. The PDF report shows the name of the Authorised Individual at the supplier and the date that they approved the materials declaration on BOMcheck, as well as the date that the declaration is effective from.

Most Manufacturers require their suppliers to sign a purchasing agreement which provides the contractual terms and conditions that the supplier is required to comply with for supply of materials, parts and sub-assemblies to the Manufacturer. This often includes a contractual requirement for the supplier to ensure that materials, parts and sub-assemblies comply with the Manufacturer's specifications and all applicable legislation. When a supplier publishes their materials declaration in BOMcheck, the materials declaration does not include any caveats that could interfere with such contractual terms and conditions.

Article 7(e) of the RoHS2 Directive 2011/65/EU requires the Manufacturer to keep the technical documentation up-to-date with any changes to the product design and manufacturing process. Therefore, the Manufacturer needs to have a process for identifying product design changes (e.g. by changing the revision number for the product model number) and producing updated technical documentation which includes an updated list of part codes and suppliers for all of the materials, parts and sub-assemblies which are contained in the finished product. The Manufacturer can download supplier materials declarations from BOMcheck for the updated list of parts codes and load these updated data into their PLM system and/or download a new PDF report containing the current materials declaration data on BOMcheck for the updated parts list file.

ROHS compliance for product XYZ BOMcheck.net ENVIRON logo.jpg ROHS compliance for product XYZ OSRAM Report generated: 27 October 2011, 16:13 GMT Components 'R' Us COMPONENTS 'R' US 10 Component Drive, Cardiff, South Glamorgan, CF1 4DD, United Kingdom Declarations authorised by: Joe Bloggs, Regulatory Director Declaration effective from: 25 March 2010 [Approved on 31 August 2011, 09:33 GMT] Do all single homogenous materials in the parts contain less than the Maximum concentration Substance maximum concentration? Cadmium/cadmium 0.01% compounds Chromium VI compounds Lead/lead compounds Mercury/mercury compounds 0.1% Polybrominated biphenyls 0.1% Polybrominated diphenylethers (PBDEs) 0.1% http://demo.bomcheck.net/assets/evidence/5710/5710/SGS RoHS test report.pdf http://demo.bomcheck.net/assets/evidence/5710/5710/Tin technology example test report.pdf Packaging compliance statement http://demo.bomcheck.net/packaging/downloadpackagingstatement/66 Attached parts list Part number Part name Part Mass Part Mass UoM 826357 Е Report generated: 27 October 2011, 16:13 GMT

Figure 13. Example materials declaration PDF report for a list of supplier part numbers

4.4.2 Downloading suppliers assessment of any analytical test reports that may be required for part codes in the product

As discussed in section 3.3.3, the analytical test reports which a supplier provides for their supplier part numbers must be assessed to ensure that they can be relied on by the Manufacturer to meet requirements for RoHS2 technical documentation for the product model. When the supplier attaches RoHS analytical test report(s) to a materials declaration for their supplier part(s), BOMcheck requires the supplier to assess the test reports to determine:

- Date of test report (dd/mm/yy)
- Is the test laboratory accredited to the ISO/IEC 17025 standard?
- Do the test report(s) cover all of the relevant homogenous materials in the part or sub-assembly that require testing? The test report(s) should identify which homogenous materials within the part of sub-assembly contain high risk materials that require testing, and which materials within the part or sub-assembly do not require testing (e.g. because they do not contain high risk materials). A homogenous material that contains high risk materials may not require testing for all six of the RoHS substances. For example, organic substances such as PBBs and PBDEs are not found in metal parts.
- **Do test results confirm compliance?** BOMcheck displays a guidance note to the supplier to explain that for each RoHS substance that was tested in each relevant homogenous material, the test results should show that the measured concentration of the RoHS substance does not exceed the maximum concentration values, or that the use of the RoHS substance in that homogenous material is covered by a valid exemption.

If the supplier finds that a test report does not meet some of these criteria, the supplier has the opportunity to obtain an improved test report which does meet the criteria. A test report that does not meet these criteria would be rejected by a Manufacturer anyway. So this process saves time by providing the supplier an early opportunity to attach an acceptable RoHS test report

Figure 12 highlights that when BOMcheck displays the RoHS materials declaration data for a list of supplier part numbers, the Manufacturer can choose to 'Assess RoHS Test Reports' for this parts list. BOMcheck then displays the suppliers' assessments of their RoHS test reports for this parts list, Figure 14.

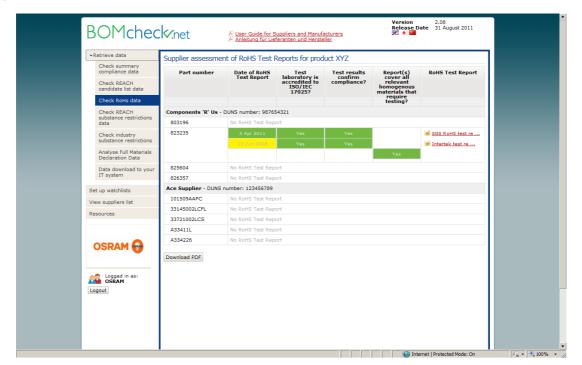


Figure 14. Suppliers' assessments of their RoHS test reports for a list of supplier parts

As well as checking that the suppliers' assessment indicates that the RoHS test reports meet all criteria, the Manufacturer can use the PDF links to view a sample of a supplier's test reports to check that the supplier has assessed their own test reports against the criteria correctly. This is another

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factor that the Manufacturer can include in their supplier qualification process to categorise suppliers (for example, for other supplier parts which only contain low risk materials and where the supplier is only required to provide a materials declaration).

Once the Manufacturer is happy with the suppliers' assessments, then the Manufacturer can download the suppliers assessments of their RoHS test reports as a PDF report, Figure 15. The Manufacturer can choose to include the PDF report in the RoHS2 technical documentation to provide evidence to support the results in the evaluation table for the product.

Assessment of RoHS Test Reports for product XYZ BOMcheck/net ENVIRON logo.jpg Report generated: 27 October 2011, 16:26 GMT OSRAM Components 'R' Us DUNS number: 987654321 COMPONENTS 'R' US 10 Component Drive, Cardiff, South Glamorgan, CF1 4DD, United Kingdom Date of RoHS Test laboratory Report(s) Test Report is accredited to cover all Report relevant compliance? homogenous materials that 17025? testing? 803196 No RoHS Test Report 3 Apr 2011 📑 SGS RoHS . 823235 Intertek ... 10 Jun 2008 825604 No RoHS Test Report 826357 No RoHS Test Report Ace Supplier **DUNS number:** 123456789 ACE SUPPLIER 24 Supplier Way, Bath, BANES, BA1 4QH, United Kingdom Date of RoHS Part number Test laboratory Test results Report(s) RoHS Test Test Report is accredited to cover all Report ISO/IEC compliance? relevant 17025? homogenous materials that require testing? 101509AAPC No RoHS Test Report 33145002LCFL No RoHS Test Report 33721002LCS No RoHS Test Report A33411L No RoHS Test Report A334226 No RoHS Test Report Report generated: 27 October 2011, 16:26 GMT Page 1

Figure 15. PDF summary report of supplier assessments of their RoHS Test Reports

Each RoHS Test Report that a supplier attaches to a declaration is stored as an Asset on BOMcheck and has its own unique URL weblink which is publicly available, regardless of whether the person viewing the PDF is logged into BOMcheck. This means that any person who receives the PDF report can use the URL weblinks in the PDF document to review the original RoHS test reports which the supplier attached to the materials declaration for their supplier part(s). The URL weblinks are maintained even if the supplier subsequently removes the test report when they next update a materials declaration for their supplier part(s).

The Manufacturer can choose to update the RoHS2 technical documentation regularly by downloading a new PDF report containing the current suppliers' assessments of their RoHS test reports on BOMcheck for the supplier part numbers / supplier codes in their parts list file.

Article 7(e) of the RoHS2 Directive 2011/65/EU requires the Manufacturer to keep the technical documentation up-to-date with any changes to the product design and manufacturing process. Therefore, the Manufacturer needs to have a process for identifying product design changes (e.g. by changing the revision number for the product model number) and producing updated technical documentation which includes an updated list of part codes and suppliers for all of the materials, parts and sub-assemblies which are contained in the finished product.

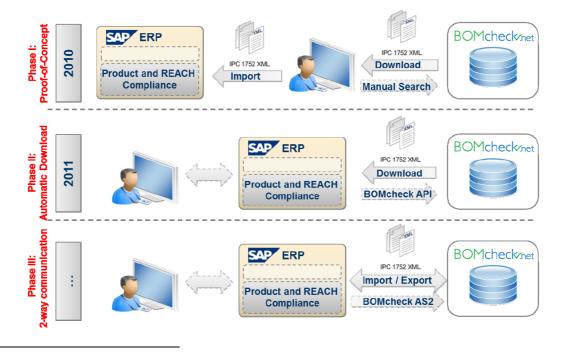
When the Manufacturer downloads the supplier materials declarations from BOMcheck for the updated list of parts codes the Manufacturer can choose to use the BOMcheck tools to assess any analytical test reports which may be required and can choose to include the updated BOMcheck assessment report PDF in their RoHS2 technical documentation.

4.4.3 Loading BOMcheck materials declaration data into the Manufacturer's PLM system

As highlighted in section 3.2.3, many PLM systems store and maintain the relationship between the supplier part number / supplier code and the Manufacturer part code in the master data for a product. In this case, the Manufacturer may choose to load the BOMcheck materials declarations data for the list of supplier part numbers / supplier codes into the PLM master data for the product.

The BOMcheck system provides a range of flexible options for downloading materials declarations data into the Manufacturer's PLM system. As highlighted in Figure 16, most companies start by manually logging into their Manufacturer Account and then manually downloading the materials declarations data in CVS format or in IPC 1752A XML format (both Class C XML and Class D XML formats are supported in BOMcheck). In general, most companies then progress to using the BOMcheck Application Programming Interface (API) which enables the Manufacturer's PLM system to send POST requests to BOMcheck. The API uses SSL encryption to ensure the security of the POST request to BOMcheck and the data transfer from BOMcheck to the Manufacturer's PLM system. More advanced companies can choose to implement the BOMcheck AS2 interface which provides two-way communication between the Manufacturer's PLM system and BOMcheck.

Figure 16. Phased development of interface at OSRAM to SAP Product and REACH Compliance²²



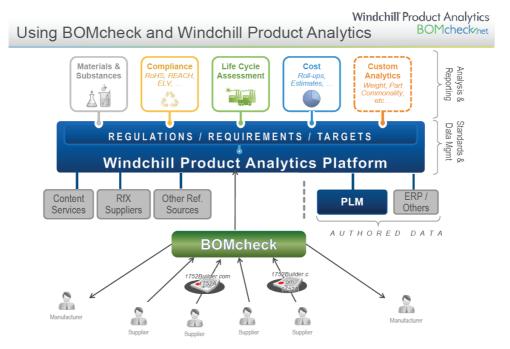
²² This slide was presented by OSRAM and TechniData GmbH (a SAP company) at "Going Green – CARE INNOVATION 2010", 9 November 2010, Vienna.

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Figure 17 highlights how the BOMcheck API can be used to load BOMcheck supplier declarations data into a PTC Windchill Product Analytics PLM system. Windchill Product Analytics (WPA) was formerly known as InSight and before that the system was known as EMARS.

Figure 17. Using the BOMcheck API to load supplier data into PTC Windchill Product Analytics²³



The IPC 1752A International Standard for Materials Declaration Management is widely supported by leading PLM solution providers including:

- PTC Windchill Product Analytics (<u>www.ptc.com/products/insight</u>)
- Dassault Systems Material Compliance Central (MCC) (www.enovia.com)
- SAP Product and REACH Compliance (<u>www.sap.com/best-run-now/product-and-reach-compliance.epx</u>)
- Oracle's Agile Product Governance and Compliance (www.oracle.com/ocom/groups/public/@ocompublic/documents/webcontent/018801.pdf)

BOMcheck and PTC are very active in leading the development of the IPC 1752A International Standard for Materials Declaration Management. Dr Aidan Turnbull of ENVIRON is the current co-Chair of the IPC 1752A International Standard (www.ipc.org/2-18b-committee).

4.5 BOMcheck Data Security Certifications and Security Assessments

BOMcheck is designed and implemented to achieve the highest commercial data security standards in the world. All sensitive data on BOMcheck is stored securely by encrypting the data to PCI DSS standards. The Payment Card Industry Data Security Standard (PCI DSS) is an information security standard for organizations that handle cardholder information for the major debit, credit, prepaid, epurse, ATM, and POS cards. Administrator access to the BOMcheck system is restricted to only 3 security-approved ENVIRON staff and ENVIRON's contract with each Member includes strict obligations on ENVIRON to ensure security and confidentiality of the Members' data. The security of the data on BOMcheck is tested every day by McAfee who use thousands of different hacking techniques to attack the www.BOMcheck.net web database system. The BOMcheck web database system is hosted using the same internet server arrangements as www.amazon.com.

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²³ This slide was presented by PTC and BOMcheck at a joint PTC/BOMcheck webinar "RoHS2 Compliance: Is your company ready?", 14 July 2011

4.5.1 Contractual obligations and Administrator access restrictions at ENVIRON

Administrator access to the BOMcheck system is restricted to only 3 security-approved ENVIRON staff. These named individuals have received appropriate security training. BOMcheck Steering Group companies do not have any special access to the BOMcheck system.

ENVIRON's contract²⁴ with each Supplier Member includes strict obligations on ENVIRON to ensure security and confidentiality of the Supplier Members' data, including the following clauses:

- 5.7 ENVIRON will not use any other means to distribute the Member's Data except via the Database. ENVIRON will not provide the Member's Data to any party who has not signed a Manufacturer's Agreement to use the Database. ENVIRON will not in any way sell, transfer, (sub-) license or otherwise commercially exploit the Data provided into the Database.
- 5.8 ENVIRON will treat any Data in the Database as strictly confidential and will not access the Member's account unless instructed to do so by the Member. Exception to this is system statistics calculation such as e.g. number of Regulatory Compliance Declarations, number of Full Materials Declarations etc. Furthermore ENVIRON's internal access to Data is restricted to specially selected persons that may need access under supervision of security personnel for system maintenance purposes

4.5.2 TLS 1.2 (SSL 1.3) security encryption of all communication between BOMcheck and the company's internet server

BOMcheck uses the TLS 1.2 (SSL 1.3) encryption protocol to prevent any eavesdropping or tampering of data which a company transmits to www.BOMcheck.net, Figure 18.

User Hello

Key Exchange

Cipher Suite Negotiation

Data Upload

User

Figure 18. TLS 1.2 (SSL 1.3) security encryption of all data to/from https://www.bomcheck.net

As part of the TLS 1.2 (SSL 1.3) encryption protocol, BOMcheck encrypts the segments of network connections above the Transport Layer, using asymmetric cryptography for privacy and a keyed message authentication code for message reliability. When a user logs into BOMcheck, the BOMcheck system communicates with the user's internet server to establish the parameters that will be used to ensure the highest level of security for the connection. BOMcheck chooses the strongest cipher and hash function that the user's server is able to support and then uses this for all communications. BOMcheck then sends our digital certificate to the user's server which includes the trusted certificate authority (CA) and BOMcheck's public encryption key. The user's internet server may contact the trusted certificate authority (CA) server and confirm the validity of the BOMcheck public encryption key before continuing.

Data Download



²⁴ The BOMcheck Supplier Member Rules are published at https://www.bomcheck.net/suppliers/member-rules

In order to generate the session keys used for the secure connection, the user's server then encrypts a random number with the BOMcheck public encryption key and sends the result to www.BOMcheck.net. Only www.BOMcheck.net can decrypt this message using BOMcheck's private key. This concludes the security handshake between BOMcheck and the user's server and begins the secured connection. This random number is then used to encrypt and decrypt all data that a user transmits to www.BOMcheck.net and all data which a user receives from www.BOMcheck.net. If any one of the above steps fails, the TLS handshake fails and the connection is not created.

4.5.3 McAfee SECURE (Hacker Safe) Website Certification

The BOMcheck web database system is certified to the McAfee SECURE (Hacker Safe) Website Certification Seal. As part of this certification, McAfee carries out intensive security tests of www.BOMcheck.net web database system by using thousands of different hacking techniques. McAfee then publishes the results of these intensive security tests as a certificate on www.BOMcheck.net with today's date, Figure 19.



Figure 19. McAfee SECURE (Hacker Safe) Website Certification

Further details about the McAfee SECURE (Hacker Safe) Website Certification Seal are available at http://www.mcafeesecure.com/us/products/mcafeesecure.jsp?tab=1.

4.5.4 BOMcheck uses the same internet server arrangements as www.amazon.com

BOMcheck is hosted on servers which are provided by Amazon Web Services (AWS). AWS customers include Amazon, Ericsson, Hitachi, Virgin Atlantic, European Space Agency, US Department of State.

AWS is compliant to several security certifications and third-party audit programs including:

- **SAS70 Type II.** The report covers the detailed controls that AWS operates along with an independent auditor opinion about the effective operation of those controls.
- **PCI DSS Level 1.** AWS has been independently validated to comply with the PCI Data Security Standard as a shared host service provider.
- **ISO 27001.** AWS has achieved ISO 27001 certification of the Information Security Management System (ISMS) covering infrastructure, data centers, and services.
- FISMA. AWS enables government agency customers to achieve and sustain compliance with the Federal Information Security Management Act (FISMA). AWS has been awarded an approval to operate at the FISMA-Low level. It has also completed the control implementation and successfully passed the independent security testing and evaluation required to operate at the FISMA-Moderate level. AWS is currently pursuing an approval to operate at the FISMA-Moderate level from government agencies.



AWS datacenters are housed in nondescript facilities. Physical access is strictly controlled both at the perimeter and at building ingress points by professional security staff utilizing video surveillance, intrusion detection systems, and other electronic means. Authorized staff must pass two-factor authentication a minimum of two times to access datacenter floors. All visitors and contractors are required to present identification and are signed in and continually escorted by authorized staff.

AWS only provides datacenter access and information to employees and contractors who have a legitimate business need for such privileges. When an employee no longer has a business need for these privileges, his or her access is immediately revoked, even if they continue to be an employee of Amazon or Amazon Web Services. All physical access to datacenters by AWS employees is logged and audited routinely.

Further details about AWS security systems are available at:

http://aws.amazon.com/security/

http://aws.amazon.com/about-aws/whats-new/2009/11/11/aws-completes-sas70-type-ii-audit/