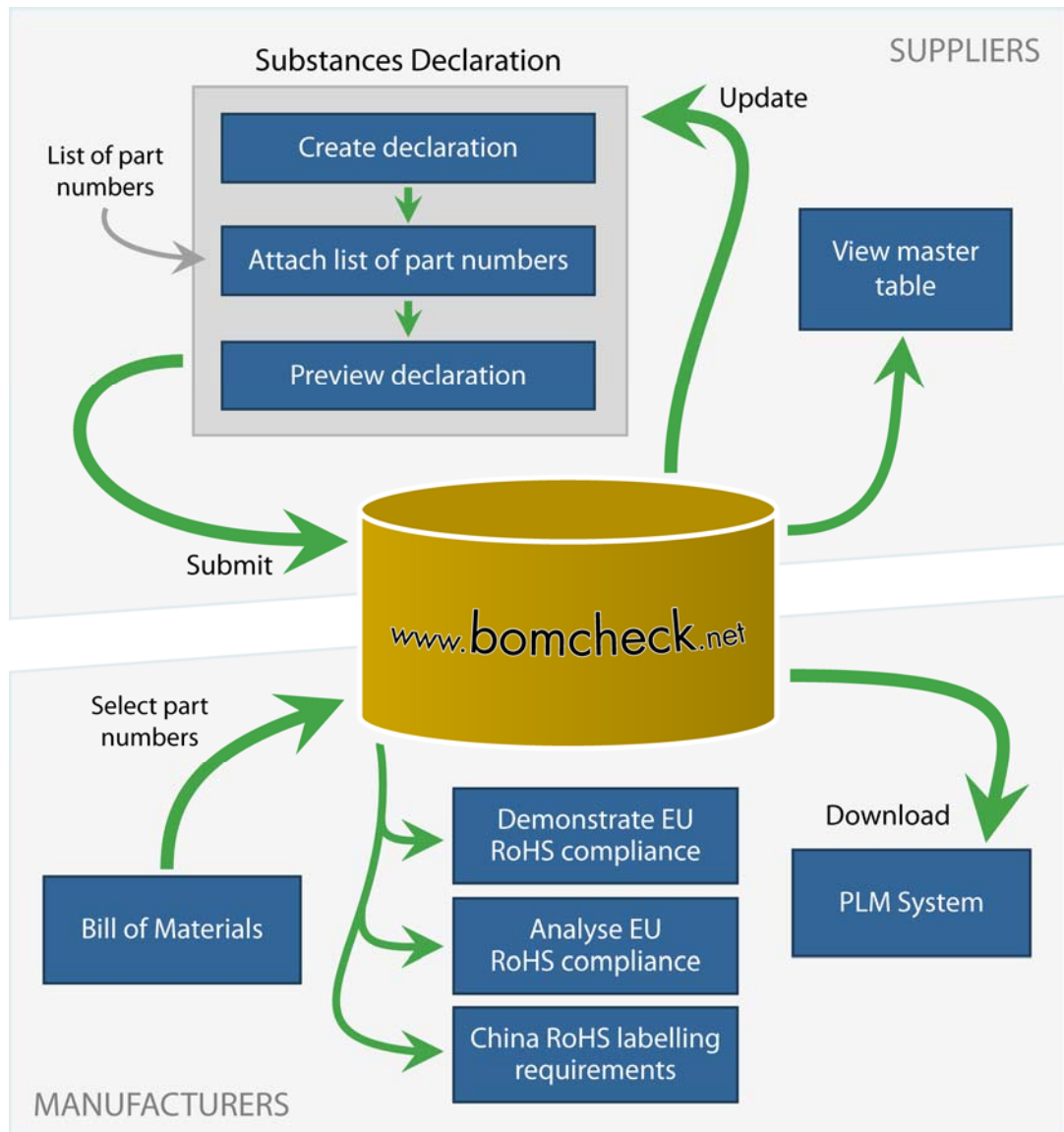


BOMcheck.net

Frequently asked questions and answers



June 2008

ENVIRON



Contents

1	Why does industry need a new approach to managing supplier data?	1
2	How is industry leading this initiative?	1
3	How do suppliers submit their data?	2
4	What reliance can manufacturers place on the supplier's electronic records in BOMcheck?	2
5	What are the data reporting options for manufacturers?.....	3
6	What are the new substances that may be added to RoHS?.....	3
7	How does BOMcheck manage changes in RoHS exemptions?.....	4
8	How does BOMcheck manage compliance with RoHS restrictions in China, Korea, Japan etc?	4
9	What are disclosure requirements in REACH Article 33?	5
10	How will BOMcheck address REACH Article 33?	6
11	What are the costs?	6
12	What are the benefits to manufacturers?.....	7
13	What are the benefits to suppliers?	7
14	About ENVIRON	7
15	Further information.....	8

1 Why does industry need a new approach to managing supplier data?

Gathering substances declarations from suppliers is a very time consuming process which often yields low response rates from suppliers for two main reasons:

- There is no standard questionnaire format which is widely used within the electronics industry. Completing different questionnaires for different manufacturers is a business cost to suppliers.
- Lack of understanding about restricted and hazardous substances. A supplier who does not understand a particular question may refuse to complete the questionnaire, or provide an incorrect response. This can cause the manufacturer to be non-compliant.

At the same time, the pressures on manufacturers to gather these data are increasing from

- Proposals to include additional substances under the RoHS Directive and possible removal of some exemptions. It is likely that the European Commission may add at least four new substances to RoHS. At the same time, when an exemption is removed (for example in the case of Deca BDE) the manufacturer needs to check which of its suppliers have relied on this exemption, and whether their components are still compliant with RoHS.
- Article 33 of the EU's incoming chemicals legislation REACH will require all manufacturers to provide customers with information on whether their products contain > 0.1% of any 'substances of very high concern' on the REACH 'Candidate List' of substances. The first Candidate List is likely to contain 12 substances and the requirement to disclose information on these substances may start as early as October 2008.

ENVIRON and COCIR believe the most cost-effective and efficient approach to these increasing pressures is for manufacturers to collaborate on a common process for gathering and sharing data from suppliers. As the number of substance declarations that manufacturers need to gather from their supply chains continues to increase, we believe it will become increasingly difficult for manufacturers to maintain their own independent systems for gathering this data from each of their suppliers. Suppliers will simply not be able to cope with supplying such massive amounts of new data to each manufacturer on an individual basis.

There are a number of existing web declarations systems that manufacturers can choose to purchase (e.g. Synapsis EMARS, GEMS, Technidata CfP etc). However, when ENVIRON and COCIR reviewed these systems we found that none of them allow data sharing between manufacturers. Even if several manufacturers buy the same system, each manufacturer is required to gather data separately from its own supply chain.

So we decided to build BOMcheck.

We also found that these existing web systems are very expensive for manufacturers. The most basic system costs \$60,000 in the first year and \$30,000 per year thereafter. Some web systems cost up to \$300,000 in the first year! (Of course, the manufacturer then has to convince its suppliers to use its system ...)

We have developed a highly cost-effective approach for sharing costs across the supply chain, which will considerably reduce the overall costs to industry.

2 How is industry leading this initiative?

The BOMcheck initiative is led by COCIR (www.cocir.org), the leading non-profit trade association for the radiological, electromedical and healthcare IT industry in Europe. COCIR membership comprises 14 of the largest manufacturers of electronic equipment in the world, including GE, Siemens, Philips, Toshiba, Hitachi, Agfa and Intel. These companies cover all sectors of the electronics industry.

The BOMcheck initiative was launched by COCIR at their offices in Brussels on 4 June 2008. The launch was attended by the European Commission and several other trade associations. COCIR has also formed a Steering Group to guide the development of BOMcheck , including

- The list of substances for supplier declarations. The first list comprises the 33 substances which are already restricted under existing legislation (e.g. the RoHS Directive, the Marketing and Use Directive) plus 14 substances which are particularly relevant to the product's environmental impacts across the life cycle.
- Extension to address REACH Article 33 later this summer
- Expansion to full materials declaration in line with the draft International Standard IEC 62474

3 How do suppliers submit their data?

BOMcheck enables suppliers to create a declaration by selecting from a list of restricted and hazardous substances and attaching a list of part numbers to the declaration. The list of part numbers must be in the universally recognised CSV format. This is a standard format option in Excel and is compatible with all major ERP/MRP/PLM systems including SAP, Oracle, JBA, Agile, MatrixOne, JD Edwards and BPCS.

Suppliers can view a master table which shows the current substances declarations for all of their part numbers.

Suppliers can update their declarations, submit additional declarations or delete part numbers at any time. As more substances become restricted (e.g. under the proposed RoHS amendments) or require declaration (e.g. under REACH Article 33), the supplier can easily update their data by submitting new declarations.

The web database helps suppliers to complete their substances declarations by:

- explaining the particular laws and regulations that apply to each substance and any exemptions that apply
- highlighting where the substances are commonly found in electrical and electronic equipment
- providing information on alternative substances, where available.

4 What reliance can manufacturers place on the supplier's electronic records in BOMcheck?

Title 21 CFR Part 11 of the US Code of Federal Regulations became effective on 20 August 1997 and defines criteria under which the FDA accept

“electronic records and electronic signatures as trustworthy, reliable and equivalent to paper records and handwritten signatures executed on paper.”

Electronic records and signatures that comply with this Regulation can replace paper records for

- FDA submission
- FDA inspection
- Archiving purposes

To ensure that a supplier's electronic records stored on BOMcheck comply with Title 21 CFR Part 11 requirements, there need to be two types of controls in place:



- Administrative and procedural controls which must be implemented and maintained by the supplier. These administrative and procedural controls are contained in the BOMcheck Member Rules for Suppliers. Failure to comply with these Member Rules can result in termination of the Membership by ENVIRON.
- Technical controls which are provided by the BOMcheck database.

A detailed document is published on BOMcheck.net which explains these two types of control in detail, and how compliance with the Supplier Member Rules will ensure that a Supplier's electronic records comply with Title 21 CFR Part 11 requirements, and are equivalent to paper records with handwritten signatures executed on paper.

5 What are the data reporting options for manufacturers?

A manufacturer can generate a

- Summary report of compliance status for a manufacturer BOM. (The BOM is not stored on the web database and there is no possibility for one manufacturer to see a BOM from another manufacturer)
- Parts compliance PDF report with suppliers electronic signatures
- Parts compliance CSV file or XML file with supplier electronic signatures

These options are explained in more detail on the BOMcheck.net website.

BOMcheck also provides a web-service for automatic download of data into the manufacturer's PLM system (e.g. SAP, Agile etc). This allows the manufacturer to develop a solution to periodically update the declaration data held on their PLM systems without the need for user interaction.

At a high level this involves your PLM system sending a HTTP request to BOMcheck.net including login details, and information regarding the parts data (and format) required and the last download date. The BOMcheck.net system will then authenticate the request and provide the required data via a HTTP response to your PLM system. BOMcheck provides low-level technical details regarding the format of both the request and possible responses. To improve the speed of the download, BOMcheck provides the option for you to request to download only the data that has changed or been added to BOMcheck since the last download date.

6 What are the new substances that may be added to RoHS?

ENVIRON represented the Medical Device Industry at the Commission stakeholder workshop on 6 May 2006 to discuss possible new substances to be added to the RoHS Directive. The Commission's consultants, Öko-Institut, presented proposals for including the following new substances:

- TBBP-A (tetrabromobisphenol-A) as an additive flame retardant. Use of TBBP-A as a reactive flame retardant in epoxy and polycarbonate resins would be exempted. TBBP-A is widely used as a reactive flame retardant in printed circuit boards. The main use of TBBP-A as an additive flame retardant is in ABS (acrylonitrile-butadiene-styrene) resins.
- HBCDD (hexabromocyclododecane). HBCDD is used as a flame retardant in HIPS (high impact polystyrenes)
- Three types of phthalates: DEHP (bis[2-ethylhexyl] phthalate), BPP (butyl benzyl phthalate) and DBP (dibutylphthalate). These are mainly used as plasticizers in polymer products, particularly PVC. A number of exemptions would be required for particular materials applications, for example in medical devices.



- MCCP (medium-chained chlorinated paraffins). These are mainly used as secondary plasticizers / softeners and as flame retardants in PVC.
- SCCP (short-chained chlorinated paraffins). The Commission is seeking clarification on whether these substances are still used in electrical and electronic equipment.
- Nonylphenol and nonylphenol ethoxylates. The Commission is seeking clarification on whether these substances are still used in electrical and electronic equipment.
- All organochlorine and organobromine compounds. The draft report from the Öko-Institut included a proposal to restrict all halogenated organic compounds. However, at the 6 May stakeholder workshop Öko-Institut clarified that in fact their proposal was only to restrict all organochlorine and organobromine compounds. But even this latter proposal would be an extremely wide-ranging restriction. It is likely that this restriction may not survive further scrutiny under the Commission impact assessment process.

Once the list of new substances to be added to the RoHS Directive is finalized, we will include these substances in the BOMcheck database and BOMcheck will notify all supplier members that they must now provide declarations for these substances for their part numbers.

The web database will help suppliers to complete their substances declarations by:

- explaining the restrictions that apply to each substance and any exemptions that apply
- highlighting where the substances are commonly found in electrical and electronic equipment
- providing information on alternative substances, where available.

7 How does BOMcheck manage changes in RoHS exemptions?

If a supplier claims that the use of certain substances in their parts is exempted under the RoHS Directive, then BOMcheck requires the supplier to select which particular exemption the supplier is claiming. If a particular exemption is removed from the RoHS Directive, BOMcheck will require all supplier members that relied on the exemption to update their substance declarations to indicate whether their parts still comply.

The recent removal of the Deca BDE exemption is a good example. Many manufacturers had not gathered sufficient information from their suppliers and so had to re-contact their suppliers to confirm whether they had relied on this exemption.

8 How does BOMcheck manage compliance with RoHS restrictions in China, Korea, Japan etc?

Other RoHS legislation around the world focuses on the same list of RoHS substances, but has different requirements. BOMcheck analyses the substance declarations provided by suppliers to identify any restrictions on using these parts in other parts of the world.

China RoHS

The Management Methods of Controlling Pollution by Electronic Information Products, known as China RoHS, is being implemented in two phases. It addresses the same substances as the EC RoHS Directive, but includes a much larger scope of products. Similar to the EC RoHS Directive, additional substances may also be covered under China RoHS in the future.

The first phase took effect from 1 March 2007 and comprises a series of marking requirements. In addition to a label on the product, if the product contains RoHS materials then the user manual must also include a Hazardous Substance Table (in Chinese) which lists where these substances are found in the product. Another marking requirement, described in Article 14, requires the manufacturer to label the packaging and to use non-toxic, harmless, readily degradable and recyclable materials.

The second phase is when the actual substance restrictions will take effect. In 2008 the Chinese government will publish a 'catalog' which will list the dates by which particular products must comply with the substance restrictions. This may include exemptions from materials restrictions for certain types of equipment and in certain applications. The catalog will also identify some products where pre-market testing and certification will be required before the product can be sold in China.

Korea RoHS

The *Act for Resource Recycling of Electrical/Electric Products and Automobiles* was published on 2 April 2007 and came into force on 1 January 2008. The Act applies the same EC RoHS materials restrictions and maximum concentration values to 10 categories of electrical and electronic equipment which are listed in Article 6, Enforcement Ordinance of the Act.

Japan RoHS

Under an amendment to the Law for the Promotion of the Effective Utilisation of Resources, Japan introduced a mandatory labelling standard for certain types of household electrical equipment and IT equipment from 1 July 2006. If any single homogenous material in these types of equipment contains > 0.01% by weight of cadmium or > 0.1% by weight of lead, mercury, hexavalent chromium, PBB or PBDE, the J-MOSS labeling standard requires that the equipment is marked with an orange "R" mark. If the equipment does not contain these materials it should be marked with a green "G" mark.

9 What are disclosure requirements in REACH Article 33?

REACH Article 33 requires electronics manufacturers to provide any customer with information on whether an article contains > 0.1% by weight of any substance in the 'Candidate List':

- Free-of-charge within 45 days of request from a consumer, and proactively to a business customer
- Regardless of whether there is any likelihood of release of the substance from the product

The first Candidate List is likely to contain up to 12 substances and is scheduled to be published in October 2008. Under the REACH Regulation, companies come under a duty to provide information as soon as the list is available. Three leading NGOs (the European Environmental Bureau, Friends of the Earth and Greenpeace) have banded together to form the Chemical Reaction project (www.chemicalreaction.org). They have been raising consumer awareness of their right to enquire about the presence of Candidate List substances in products and have been urging companies to prepare now, as there will be little time once the list has been published (see Chemical Watch 21 May 2008).

Member States have until 8 June to submit dossiers to the European Chemicals Agency (ECHA) on what substances should be included in the first Candidate List. A total of 12 dossiers have so far been received. These include the following dossiers from UK, France and Sweden:

- UK: MCCP (medium-chained chlorinated paraffins)
- France: Cyclododecane, nickel dioxide, arsenic pentoxide, arsenic trioxide, sodium dichromate and possibly dichloride cobalt
- Sweden: HBCDD (hexabromocyclododecane)

The proposals will then be conformity checked before being made available via ECHA's website for comment to other Member States, the Agency and interested parties. They will then be considered by ECHA's Member States committee in early October with a view to finalizing the list. ECHA has acknowledged that the first Candidate List would have a "high profile" and that the timeframe to consider it is very short.

10 How will BOMcheck address REACH Article 33?

As soon as the Candidate Lists is finalized, we will include these substances in the BOMcheck database and BOMcheck will notify all supplier members that they must now provide declarations for these substances for their part numbers.

The web database will help suppliers to complete their substances declarations by:

- highlighting where the substances are commonly found in electrical and electronic equipment. For example, sodium dichromate comprises hexavalent chromium which is already restricted under RoHS. Nickel dioxide is found in Lithium Ion batteries.
- providing information on alternative substances, where available

BOMcheck will ask supplier members to provide the weight of the part and declare whether the part contains less than 0.1% of the substance by weight. To assist in calculating the overall percentage composition of the product, supplier member will also be asked to declare if the part contains less than 0.01% by weight.

If the part contains more than 0.1% by weight, then the supplier is required to provide the actual percentage composition.

We are also planning for further expansion of BOMcheck to provide options for full materials declaration in line with the draft International Standard IEC 62474. This will be developed later in 2008 and will be available from early 2009.

11 What are the costs?

The web database is free for manufacturers to use provided that the manufacturer procures that its suppliers take out an annual subscription to the web database. Each supplier pays a low-cost subscription of 300 Euros per year to use the web database. The supplier pays their subscription by credit card on BOMcheck.net at the same time as it confirms the electronic signature arrangements.

Suppliers who have their own supply chain can also choose to use the web database to manage their own suppliers. For example, a supplier of power supply units (PSU) can use the web database to manage supplier declarations for the circuit boards, components etc that they purchase to go into the PSU.

Manufacturers can request a free annual subscription to the web database provided that manufacturer agrees to use reasonable endeavours to procure that those of its suppliers (including suppliers on the manufacturer's Approved Supplier Lists or equivalent) with whom the manufacturer spends (either directly or through third parties e.g. contract manufacturers) more than fifty thousand euros (€50,000) annually join the BOMcheck database within six (6) months of execution of the Agreement. Such endeavours will include sending a letter to these suppliers within three (3) months of execution the Agreement.

For suppliers (including suppliers on the manufacturer's Approved Supplier Lists or equivalent) where the manufacturer vouches that it spends (either directly or through third parties e.g. contract manufacturers) less than fifty thousand euros (€50,000) annually and where the manufacturer provides suitable evidence that the supplier has a total annual turnover of less than three million Euros (€3,000,000), the manufacturer is entitled to apply to ENVIRON for these suppliers to be granted free membership of the BOMcheck database. Environ will grant free membership to these suppliers for a period of one year provided that the manufacturer provides:

- a signed statement that the manufacturer spent (either directly or through third parties e.g. contract manufacturers) less than fifty thousand euros (€50,000) with the supplier in the previous year; and,



- a signed statement from the supplier that the supplier's total annual turnover in the previous year was less than three million euros (€3,000,000).

The manufacturer can apply to renew the free membership for these Suppliers each year, provided the above conditions are met.

To request a manufacturer agreement please contact Dr Aidan Turnbull Head of WEEE, RoHS & EcoDesign.

Email: aturnbull@uk.vironcorp.com

Telephone: +44 (0)1225 748420

12 What are the benefits to manufacturers?

- Time cost savings and better response rate from suppliers
- Confidentiality – no manufacturer product data is stored on the database
- CSV file, XML and PDF report download options, all of which contain suppliers electronic signatures which comply with CFR Part 11 so that the US FDA considers 'the electronic records are equivalent to paper records with handwritten signatures'
- Easy to manage compliance with new substance restrictions (e.g. under RoHS or REACH)
- Maintain up-to-date information. Suppliers are required to refresh all data at least once per year
- Free annual subscription to the web database provided that the manufacturer procures that its suppliers take out an annual subscription to the web database. Each supplier pays a low-cost subscription of 300 Euros per year to use the web database. This requirement must be implemented within six months of joining BOMcheck,

13 What are the benefits to suppliers?

- Continued sales access to some of the world's largest electronics manufacturers who purchase over 100 billion Euros per year through their supply chains. Participating manufacturers will be listed on BOMcheck.net
- Time cost savings from using only one system to provide data to multiple large electronics manufacturers
- Electronic signature system complies with CFR Part 11 so that the US FDA considers '*the electronic records are equivalent to paper records with handwritten signatures*'.
- Regulatory compliance tool enables suppliers to keep up-to-date on restricted substances legislation
- Easy to use and to update when new substances become restricted (e.g. under RoHS or REACH)
- Guidance to assist suppliers to make their declarations (e.g. where restricted substances are typically used in electronic equipment, available alternatives etc)
- Low-cost annual subscription of 300 Euros per year.

14 About ENVIRON

A leading international consultancy, ENVIRON partners with clients to assess and manage the potential environmental, energy, and health issues associated with their activities and products. Decision makers rely on us as they strive to reduce or eliminate health and environmental impacts throughout their business life cycles - from acquisition to ongoing operations to restructuring or divestiture. Whether responding to existing challenges or seeking strategies to prevent future



liabilities, clients around the world benefit from our blend of universally high technical skills and knowledge of local requirements and practices.

15 Further information

To request a free web demonstration or to receive a manufacturer agreement for your company, please contact:

Dr Aidan Turnbull Head of WEEE, RoHS & EcoDesign.

Email: aturnbull@uk.vironcorp.com

Telephone: +44 (0)1225 748420