EU ROHS 2 – Chemicals restrictions in Electrical and Electronic Equipment

March 2019

Summary

U.S. companies exporting Electrical and Electronic equipment ("EEE products") to the European Union need to be mindful of the requirements imposed by the Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment ("RoHS II" Directive - Directive 2011/65/EU).

From 22 July 2019, ROHS will apply to all electrical and electronic equipment (unless specifically excluded) and will restrict the use of certain substances in these equipment (unless an exemption is granted by the EU).

EEE products that fail to comply with the Directive's requirements may not be sold in the European Union.

1. Scope

a. Products covered

The Directive defines EEE as "equipment which is dependent on electric current or electromagnetic fields in order to work properly, and equipment for the generation, transfer and measurement of such currents and fields, and designed for use with a voltage rating not exceeding 1000V for AC and 1500V DC." The European Commission interprets this to mean that RoHS II applies to any product that requires an electric spark to begin operating.

The Directive applies to 11 product categories (set out in Annex I):

- Large household appliances.
- Small household appliances.
- IT and telecommunications equipment.
- Consumer equipment and photovoltaic panels.
- Lighting equipment.
- Electrical and electronic tools.
- Toys, leisure and sports equipment.
- Medical devices
- Monitoring and control instruments including industrial monitoring and control instruments
- Automatic dispensers
- Other EEE not covered by any of the categories above (from 22 July 2019)

Consequently, as of **22 July 2019**, all EEE will be covered by ROHS ("**Open scope**"), unless specifically excluded.

ROHS 2 exclusions: Military equipment, equipment designed to be sent into space, large-scale stationary industrial tools, large-scale fixed installations, active implantable medical devices, means of transport, and photovoltaic panels are excluded from ROHS 2, R&D equipment, equipment parts (Article 2).

U.S. exporters may want to review the RoHS II Frequently Asked Questions (FAQ) document. Though published by the European Commission in 2012, it is particularly helpful in identifying whether a product is covered or not by ROHS.

b. List of restricted substances (Annex II)

RoHS II restricts the use of the following substances ("restriction list" – Annex II):

- **Lead (Pb)**
- **Mercury (Hg)**
- **Cadmium (Cd)**
- **Hexavalent chromium (Cr6+)**
- **Polybrominated biphenyls (PBB)**
- **Polybrominated diphenyl ether (PBDE)**

Maximum concentration values by weight in homogeneous materials are specified (0.1%).

DEHP, DEHP, DBO and DIBP will be restricted from 22 July 2019 for all EEE except from category 8 (medical devices) and category 9 (monitoring and control equipment) that will have 2 additional years to comply by 22 July 2021. These restrictions on phthalates do not apply to toys who are covered by the stricter restrictions on phthalates in toys under the REACH chemicals regulation (Annex VII – entry 51).

Review of substances - restrictions:

Article 6 of the Directive specifies that the list of restricted substances in Annex II is to be reviewed and amended periodically. The European Commission is currently (December 2018) updating the existing **methodology** to identify and assess substances for possible restriction under the ROHS Directive (Annex II – list of restricted substances).

Seven substances are also currently (Dec. 2018) under review for possible restriction: **Diantimony trioxide, Indium phosphide, Beryllium and compounds, TBBPA, Cobalt compounds, Nickel compounds, MCCP.**

2. Exemptions (ANNEX III and IV)

Annex III contains the list of exemptions from the restriction of hazardous substances. For particular applications of lead, mercury, cadmium and hexavalent chromium, exemptions from the restrictions are laid down, indicating acceptable maximum concentration values or total content.

Annex III and IV regularly amended for **renewing existing exemptions** or for **new exemptions**. The usual duration of exemptions is 5 to 7 years. For renewals, applications have to be made no later than 18 months before the exemption expires. For new exemptions, you should apply no later than 18 months before your application comes under

the scope of ROHS 2. However, the legislation does not have time limits for the granting of new exemptions making the process unpredictable for industry.

Process for applying for exemptions: see the guidance and application form on the European Commission website:
http://ec.europa.eu/environment/waste/rohs_eee/pdf/Guidance_Document.pdf

U.S. exporters should check the European Commission ROHS II website to verify they have the latest update. And they can check the EU register of delegated acts for the status of exemptions: https://webgate.ec.europa.eu/regdel/#/delegatedActs

Latest exemptions: On 10 February 2019, 10 exemptions were published in the Official Journal. They include an exemption for lead in bearings and bushes applied in certain non-road professional use equipment.
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2019:033:TOC

Upcoming exemptions: (Feb. 2019): A new RoHS project (Pack 17) for the assessment of three exemption requests relating to Annex IV to Directive 2011/65/EU has started (see below table). For more information: http://rohs.exemptions.oeko.info/index.php?id=4

Table 3-1: Exemption requests that will be evaluated during this project as specified in the terms of reference

No.	Wording according to the terms of reference	Applicant
Requested renewal / amendment of existing exemption		
Annex IV, 31a	Bis(ethylhexyl) phthalate, Dibutyl phthalate, Di-isobutyl phthalate and Benzyl butyl phthalate in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer	COCIR
Request of new exemptions		
2019-1	Bis-(ethylhexyl) phthalate (DEHP) in ion selective electrodes for point of care analysis of ionic substances in human body fluids	COCIR
2019-2	Bis-(ethylhexyl) phthalate (DEHP) in plastic strain relief devices used to prevent damage to cable connections to MRI imaging coils	GE Healthcare

Source: OKO Institute

3. ROHS compliance

a. Manufacturer obligations

Manufacturers of EEE must, among other things:

- Ensure that all EEE products placed on the EU market have been designed and manufactured in accordance with the requirements of RoHS II;
- Draw up the required technical documentation and carry out the internal production control procedure or have it carried out;
- Draw up an EU declaration of conformity and affix the CE marking; and,
- Keep the technical documentation and the EU declaration of conformity for 10 years after the EEE has been placed on the market.

b. EU declaration of conformity

By drawing up the declaration of conformity, the manufacturer assumes responsibility for the compliance of his product with the Directive. The declaration of conformity must contain the following elements:

- EEE's identification number;
- Name and address of the manufacturer or his authorized representative;
- A description and picture of the object; and,
- Where applicable, references to the relevant harmonized standards used or references to the technical specifications in relation to which conformity is declared.

4. Labeling requirements

The RoHS II Directive requires that manufacturers conduct conformity assessment, prepare declarations of conformity and affix the CE mark to EEE sold in Europe (depicted below). Equipment bearing the CE mark is presumed to be in compliance with ROHS 2.

CE

5. ROHS 3

A legislative proposal for ROHS 3 must be submitted by the European Commission to the Council and European Parliament by 22 July 2021. The Commission will first prepare an impact assessment and negotiations will take up to 2 years.

6. Additional Information

The following links provide additional WEEE information and resources for U.S. companies.

- U.S. Commercial Service: http://export.gov/europeanunion/weeerohs/rohsinformation/
- EU RoHS II Directive (Original): http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:174:0088:0110:en:pdf
- EU RoHS II Consolidated Version (contains all amendments): https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02011L0065-20171211&from=EN
- EU RoHS II FAQ Document: http://ec.europa.eu/environment/waste/rohs_eee/pdf/faq.pdf
- European Commission RoHS II Website: http://ec.europa.eu/environment/waste/rohs_eee/index_en.htm

For More Information

The U.S. Commercial Service at the U.S. Mission to the European Union can be contacted via email at: Office.BrusselsEC@trade.gov; Phone: +32 2-811-5684; Fax: +32 2-811-5151; or visit our website: http://www.export.gov/europeanunion.

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