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TLG CLIENT BULLETIN

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Manufacturing or distribution of medical devices within the European Union

THE LION GROUP *Regulatory Consultants* has specifically prepared this bulletin for TLG clients, and associates, whose business interests include the manufacturing or distribution of medical devices within the European Union (EU).

Secondarily, clients should investigate the implications of the Directives on manufacturing processes such as equipment purchases and use as well as other process related functions.

Subject: Proposal for a Directive of the European Parliament of the Council on waste electrical and electronic equipment (WEEE).

Proposal for a Directive of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

Portions taken from the actual COUNCIL OF THE EUROPEAN UNION, Directive documents related to WEEE and RoHS, is part of this bulletin.

At this particular time, TLG clients are encouraged to fully familiarize themselves with this subject. Although the final timelines, scope, and content of the regulation is not fully defined, the implications are significant and affect every facet of particular operations. **The implications for products may include a compliance certification for product registrations, approvals, and trans-boundary transport compliance certifications within the various European markets. There may be other markets, such as Latin America, as well as other emerging markets, which will follow the EU's lead.**

Contact TLG

for further information

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It's a regulatory jungle out there, and you need THE LION.

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**COUNCIL OF
THE EUROPEAN UNION**

Brussels, 13 June 2001

**Interinstitutional File:
2000/0158 (COD)
2000/0159 (COD)**

9767/01

LIMITE

**ENV 315
CODEC 567**

INFORMATION NOTE

from : General Secretariat

to : Delegations

No. prev. doc. : 9075/1/01 ENV 247 ENV 456 REV 1

No. Cion prop. : 10802/00 ENV 268 CODEC 602 COM(2000) 347 final

Subject : – Proposal for a Directive of the European Parliament and of the Council on waste electrical and electronic equipment (WEEE)
– Proposal for a Directive of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

Delegations will find attached the text of the above proposals as agreed by the Environment Council at its meeting on 7 June 2001.

ANNEX IA to ANNEX A

**CATEGORIES OF ELECTRICAL AND ELECTRONIC EQUIPMENT
COVERED BY THIS DIRECTIVE**

1. Large household appliances
 2. Small household appliances
 3. IT & Telecommunication equipment
 4. Consumer equipment
 5. Lighting equipment
 6. Electrical and electronic tools (with the exception of large-scale stationary industrial tools)
 7. Toys, leisure and sports equipment
 - 8. Medical devices (with the exception of all implanted and infected products)**
 - 9. Monitoring and control instruments**
 10. Automatic dispensers
-

8. Medical devices (with the exception of all implanted and infected products)

Radiotherapy equipment

Cardiology

Dialysis

Pulmonary ventilators

Nuclear medicine

Laboratory equipment for in-vitro diagnosis

Analysers

Freezers

Fertilization tests

Other appliances for detecting, preventing, monitoring, treating, alleviating illness, injury or disability

9. Monitoring and control instruments

Smoke detector

Heating regulators

Thermostats

Measuring, weighing or adjusting appliances for household or as laboratory equipment

Other monitoring and control instruments used in industrial installations (e.g. in control panels)

10. Automatic dispensers

Automatic dispensers for hot drinks

Automatic dispensers for hot or cold bottles or cans

Automatic dispensers for solid products

Automatic dispensers for money

All appliances which deliver automatically all kind of products

ANNEX II to ANNEX A**Selective Treatment for Materials and Components of Waste Electrical and Electronic Equipment in accordance with Article 5.1**

1. As a minimum the following substances, preparations and components have to be removed from any separately collected WEEE:
 - Polychlorinated biphenyls (PCB) containing capacitors in accordance with Directive 96/59/EC on the disposal of PCBs and PCTs
 - Mercury containing components, such as switches or backlighting lamps
 - Batteries
 - Printed circuit boards of mobile phones generally, and of other devices if the surface of the printed circuit board is greater than 10 square centimetres
 - Toner cartridges, liquid and pasty, as well as colour toner
 - Plastic containing brominated flame retardants
 - Asbestos waste
 - Cathode ray tubes
 - Chlorofluorocarbons (CFC), hydrochlorofluorocarbons (HCFC) or hydrofluorocarbons (HFC), hydrocarbons (HC)
 - Gas discharge lamps
 - Liquid crystal displays (together with their casing where appropriate) of a surface greater than 100 square centimetres and all those back-lighted with gas discharge lamps
 - External electric cables
 - Components containing refractory ceramic fibres as described in Directive 97/69
 - Components containing radioactive substances with the exception of components that are below the exemption thresholds set in the BSS Directive (Euratom 96/29, Article 3 and Annex I)
 - Electrolyte capacitors containing substances of concern (height: > 25 mm, diameter > 25 mm or proportionately similar volume)

These substances, preparations and components shall be disposed of or recovered in compliance with Article 4 of Council Directive 75/442/EEC.

2. The following components of WEEE that is separately collected has to be treated as indicated:
 - Cathode ray tubes: The fluorescent coating has to be removed
 - Equipment containing CFC, HCFC, HFC or HC: The CFC, HCFC present in the foam and the refrigerating circuit must be properly dealt with according to Regulation (EC) N°2037/2000 on substances that deplete the ozone layer. The HFC and HC present in the foam and the refrigerating circuit must be extracted and properly treated.
 - Gas discharge lamps: The mercury shall be removed.
3. Taking into account environmental considerations and the desirability of re-use and recycling, paragraphs 1 and 2 shall be applied in such a way that environmentally-sound re-use and recycling of components or whole appliances is not hindered.
4. Within the procedure referred to in Article 14(2), the Commission shall evaluate as a matter of priority whether the entries regarding:
 - printed circuit boards for mobile phones, and
 - liquid crystal displaysare to be amended accordingly.