Amendment 355
Michèle Rivasi
on behalf of the Verts/ALE Group

Report
Dagmar Roth-Behrendt
COM(2012)0542 – C7-0318/2012 – 2012/0266(COD)

Proposal for a regulation
Annex I – part II – point 7.4

Text proposed by the Commission

7.4. The devices shall be designed and manufactured in such a way as to reduce as far as possible and appropriate the risks posed by substances that may leach or leak from the device. **Special attention shall be given to** substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, and to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Amendment

7.4. The devices shall be designed and manufactured in such a way as to reduce as far as possible and appropriate the risks posed by substances that may leach or leak from the device. **Medical devices or parts thereof that are invasive or come into contact with the body of patients, or (re)administer medicines, body liquids or other substances, including gases, to/from the body, or transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body, shall not contain, in concentrations above 0,1% by weight in homogeneous materials, substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, or substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health or which are identified in accordance with the procedure set out in Article 59 of**

The Commission shall be empowered to adopt delegated acts in accordance with Article 89 to allow the use of such substances for a period not exceeding four years where any of the following conditions is fulfilled:

- their elimination or substitution via design changes or materials and components which do not require any of these substances is technically impracticable,

- the reliability of substitutes is not ensured,

- the combined negative health or patient safety impact caused by substitution is likely to outweigh the combined health or patient safety benefits thereof.

The Commission shall be empowered to adopt delegated acts in accordance with Article 89 to renew the derogation if the criteria of the second subparagraph continue to be fulfilled.

Manufacturers wishing to apply for a derogation, a renewal of a derogation or the revoking of a derogation shall submit the following information to the Commission:

(a) the name, address and contact details of the applicant;

(b) information on the medical device and the specific uses of the substance in the material and components of the medical device for which an exemption, or its revocation, is requested and its particular characteristics;
If devices, or parts thereof, that are intended

– to be invasive devices and to come into contact with the body of the patient for short- or long-term, or

– to (re)administer medicines, body liquids or other substances, including gases, to/from the body, or

– to transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body

contain, in a concentration of 0.1% by mass of the plasticised material or above, phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008, these devices shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as devices containing phthalates. If the intended use of such devices includes treatment of children or

(c) verifiable and referenced justification for an exemption, or its revocation, in line with the conditions established in the second subparagraph;

(d) an analysis of possible alternative substances, materials or designs, including, when available, information about independent research, peer-review studies and development activities by the applicant and an analysis of the availability of such alternatives;

(e) other relevant information;

(f) the proposed actions to develop, request the development and/or to apply possible alternatives including a timetable for such actions by the applicant;

(g) where appropriate, an indication of the information which should be regarded as proprietary accompanied by verifiable justification.

If devices or parts thereof, as referred to in the first subparagraph, contain, in a concentration of 0.1% by mass or above, in a homogeneous material, substances which are classified as carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008, or substances identified as endocrine disrupters pursuant to the first subparagraph, and were granted a derogation pursuant to the second or third subparagraph, the devices shall be labelled on the device itself and/or on the
treatment of pregnant or nursing women, the manufacturer shall provide a specific justification for the use of these substances with regard to compliance with the general safety and performance requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.

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58 OJ L 136, 29.5.2007, p.3.

Packaging for each unit or, where appropriate, on the sales packaging as devices containing such substances. The manufacturer shall provide a specific justification for the use of these substances with regard to compliance with the general safety and performance requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.

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Or. en

(If this amendment is adopted, the references in Article 89 and Recital 84 concerning delegated acts need to be amended accordingly.)

**Justification**

CMR substances are banned in cosmetic products, and CMR phthalates are banned in toys. Similar restrictions should apply for medical devices where exposure is inevitable, unless there are no safer alternatives. The same should apply for endocrine disrupters. A proper procedure is necessary to assess the non-availability of alternatives. Where no alternatives exist, manufacturers should label the devices and provide specific justification as to the compliance with the safety provisions.
5. In the case of implantable devices and devices falling within class III, clinical investigations shall be performed unless it is duly justified to rely on existing clinical data alone. Demonstration of equivalence in accordance with Section 4 shall generally not be considered as sufficient justification within the meaning of the first sentence of this paragraph.

5. In the case of implantable devices and devices falling within Article 43a(1), with the exception of those used for a short term, clinical investigations shall be performed unless the medical device is identical in its material composition, function and indication to an existing authorised medical device, in which case it is duly justified to rely on existing clinical data alone.

Justification

The clinical investigation of high-risk medical devices before they are placed on the market is essential. Only if the new device is identical to an authorised medical device in its material composition, function and indication, the clinical investigation may be waived, in which case manufacturers may refer to existing clinical data alone.
Text proposed by the Commission

(8a) ‘reusable device’ means a device that is suitable for reprocessing and that is intended to be used on multiple patients or during multiple procedures;

Amendment

Or. en
16.10.2013 A7-0324/358

Amendment 358
Holger Krahmer
on behalf of the ALDE Group

Report A7-0324/2013
Dagmar Roth-Behrendt
COM(2012)0542 – C7-0318/2012 – 2012/0266(COD)

Draft legislative resolution
Article 15 a (new)

Text proposed by the Commission

Amendment

Article 15a

General principles on safe reprocessing

1. Any natural or legal person, including health institutions as specified in Article 4(4), who wishes to reprocess a single-use device to make it suitable for further use within the Union, and who can provide scientific evidence that such a device could be safely reprocessed shall be considered to be the manufacturer of its reprocessed device and shall be held liable for its reprocessing activities. The natural or legal person shall ensure the traceability of the reprocessed device and shall assume the obligations incumbent on manufacturers laid down in this Regulation, with the exception of obligations linked to the conformity assessment procedure.

2. Only reusable devices that have been placed on the Union market in accordance with this Regulation, or prior to [date of application of this Regulation] in accordance with Directive 90/385/EEC or Directive 93/42/EEC may be reprocessed.

3. Unless they are placed on the list of
single-use devices referred to in Article 15b, medical devices shall be considered as suitable for reprocessing and reusable devices in accordance with the provisions laid down in Art 15e, and providing the highest level of patient safety is guaranteed.

4. A Member State may maintain or introduce national provisions prohibiting, within its territory, on grounds of protection of public health specific to that Member State the following:

(a) the reprocessing of single-use devices and the transfer of single-use devices to another Member State or to a third country with a view to their reprocessing;

(b) the making available of reprocessed single-use devices.

Member States shall notify the Commission and the other Member States of the national provisions and the grounds for introducing them. The Commission shall keep the information publicly available.

Or. en
### Amendment 359

**Holger Krahmer**
on behalf of the ALDE Group

### Report

**Dagmar Roth-Behrendt**


COM(2012)0542 – C7-0318/2012 – 2012/0266(COD)

### Draft legislative resolution

**Article 15 b (new)**

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<td><strong>List of single-use devices unsuitable for reprocessing</strong></td>
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1. **In accordance with Article 15a(3), the Commission, after the mandatory consultation of the MDAC shall establish, by means of delegated acts, a list of medical devices or types of medical device which are unsuitable for reprocessing. The Commission shall regularly update that list, including by adding or removing items. A first list shall be established no later than six months before the date of entry into force of this Regulation.**

2. **The decision to include or remove any device or type of device from the list shall be made in particular by taking into account:**

   - their intended use in or on the human body and the body parts they will be in contact with;
   - the conditions of their use;
   - their intended purpose;
   - the material which of which they are composed;
- the severity of the disease that is being treated;
- a genuine safety risk; and
- the latest scientific and technological advancements in the relevant fields and disciplines.

3. The delegated acts referred to in paragraph 1 shall be adopted in accordance with Article 89.