



Joint Medical Device Industry Contribution on the ECHA consultation on “Draft recommendation of substances for inclusion in the list of substances subject to Authorisation”

Application for an exemption from authorisation for the use of DEHP in production /composition of medical devices

1. General comments on the justification

This reflects the view of European Trade Associations listed above. We support the objective of the REACH regulation to ensure a high level of human health and environmental protection in the approximation of legislation on substances, with the goal of achieving sustainable development.

The European Trade Associations are concerned, however, that the proposed inclusion of DEHP in the Annex XIV of the REACH Regulations, without appropriate exemptions, will produce counter-productive and adverse effects on medical devices. **We therefore require an exemption for the use of DEHP in medical devices as the specific use of DEHP in our industry is crucial for providing safe and efficient medical devices to the health care system.**

DEHP is the only plasticizer that is referenced in the European Pharmacopoeia. It has been used extensively and proven to be beneficial in many areas of medical device application for decades and is regulated by the Medical Device Directives (MDDs). This has been re-confirmed by the Scientific Committee of Emerging and Newly Identified Health Risks (SCENIHR) report (SCENIHR Opinion on: “The safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk” Adopted by the SCENIHR during the 22nd Plenary of 6 February 2008 (after public consultation)).

2. Comments on the uses proposed to be exempted

On the behalf of our members we are hereby applying for an exemption from authorisation in accordance with the provisions of Article 58.2 of Regulation (EC) 1907/2006 (the REACH Regulation) with regard to use DEHP (bis(2-ethylhexyl)phthalate) in the production/composition of medical devices in the scope of the Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices³, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices², and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

A. Existing Specific Community Legislation imposing Minimum Standards:

The draft recommendation of substances for inclusion into Annex XIV is based on Article 58.2 of the REACH Regulation, stating that “*categories of uses may be exempted from the authorisation requirement provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled.*”

To further explain this article, the Guidance on inclusion of substances in Annex XIV (at p. 39) provides that “*when considering the needs and possibilities to exempt uses or categories of uses from authorisation requirements, attention should be paid as to whether or not a specific existing Community legislation*

- *addresses the substance in question either by naming the substance specifically or by addressing the group the substance belongs to in an adequate manner (e.g. by referring to the classification criteria for CMR category 1 or 2);*

- covers the considered use or categories of use, taking into account exemptions;
- imposes minimum requirements for the control of risks;
- covers those properties that led to inclusion of the substance in Annex XIV.”

Bis (2-ethylhexyl) phthalate (DEHP) has been proposed for inclusion into Annex XIV because of Human Health concerns, specifically toxicity to reproduction, category 2. DEHP has not been proposed for inclusion on the grounds of environmental hazard or any other classification or hazard.

The use of DEHP in medical devices is subject to the EU medical device legislation, including Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices³, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices², and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices⁴. This legislation constitutes “*specific Community legislation imposing minimum requirements to protect human health*”. This legislation regulates the risks related to DEHP in a number of ways, and meets the Guidance criteria. Under the EU medical devices legislation, the risks associated with medical devices must be minimized and must be outweighed by the benefits to the patient (favorable risk/benefit ratio). Under Directive 93/42/EEC as amended by Directive 2007/47/EC,¹ certain devices (e.g. administration sets) that contain category 1 and 2 CMRs must be labelled as a device containing phthalates when there is a risk for the phthalate to leach into the human body. This new provision had to be implemented by 21 December 2008 and must be applied as and from 21 March 2010.

As noted above, the three directives making up the EU legislative framework governing medical devices ensure the safety of medical devices by requiring the risks be minimized and a favorable risk/benefit analysis to be carried out. They require that medical device manufacturers eliminate risks where feasible or reduce them as far as possible in line with the generally acknowledged state of the art. The acceptability of any residual risk is then determined by the level of benefits that the device brings. In this respect, the Medical Devices Directive, in pertinent part, provides as follows:

“Whereas the essential requirements and other requirements set out in the Annexes to this Directive, including any reference to ‘minimizing’ or ‘reducing’ risk must be interpreted and applied in such a way as to take account of technology and practice existing at the time of design and of technical and economical considerations compatible with a high level of protection of health and safety;” (Medical Devices Directive 93/42, preamble)

“The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.” (Medical Devices Directive 93/42, Annex I, section I.1)”

“The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.” .” (Medical Devices Directive 93/42, Annex I, section II, 7.5)

These provisions require specifically that the use of any dangerous substance, and the amount in which it is used, be assessed and justified. Of course, these provisions apply also to the use of DEHP in medical devices. In addition, there are further provisions dealing specifically with phthalates such as DEHP:

“If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category

¹Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market

²<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:EN:PDF>

³<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1990L0385:20071011:EN:PDF>

⁴<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1998L0079:20031120:EN:PDF>

1 or 2, in accordance with Annex I to Directive 67/548/EEC, these devices must be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates. If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential 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.” (Medical Devices Directive 93/42, Annex I, section II.7.5)

The Medical Device Directive provides for conformity assessment and CE marking to confirm compliance with all of these requirements.

The safety/effectiveness balance, or risk/benefit analysis, made pursuant to these directives results in product design that carefully balances benefits and performance against risks arising from medical devices. This balancing is best done by medical device experts in the context of the specific medical devices legislation. The authorisation process pursuant to the REACH legislation is not designed and equipped to deal with this specific balancing.

Further, if the design of a medical device is changed, or a chemical is substituted with another chemical, that medical device must be subjected to a new safety/effectiveness review and a new conformity assessment. In addition, any such changes may involve alternatives or substitutes that may, in fact, not provide the same benefits and performance, result in other safety risks, or command a higher price. For example, DEHP has beneficial properties regarding the storage of Red Blood Cells. The REACH authorisation process should not interfere with the rigorous process for regulated product design of medical devices.

The analysis of the medical device legislation presented above shows not only that this legislation imposes minimum requirements relating to the protection of human health for the use of DEHP, and properly controls the risks, but also that it would be problematic to apply the REACH authorisation process to the use of DEHP in medical devices. It is therefore justified to exempt the use of DEHP in medical devices subject to the EU medical devices legislation from the authorisation requirements. DEHP was placed, on the Candidate list only on grounds of human health concerns, and these concerns are addressed and controlled by the EU medical devices legislation.

B. Authorisation Process

The application of the REACH authorisation procedure to the use of DEHP in medical devices would be inappropriate. The REACH Regulation itself prevents the Commission from considering the human health risks associated with this substance use in medical devices. Article 60.2 states explicitly:

“The Commission shall not consider the risks to human health arising from the use of a substance in a medical device regulated by Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices or Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.”

DEHP has been placed on the candidate list only on grounds of its potential human health risk, not for other types of risk for which there is no substantial evidence for the Commission to consider.

Because (1) only a potential human health risk is assigned to DEHP, and (2) this risk may not be considered in respect of the use of DEHP in medical devices, there would be nothing to consider in an authorisation procedure concerning the use of DEHP in medical devices. This use in medical devices should therefore be exempt from REACH authorisation.

C. No Additional Risks

There is no environmental hazard classification associated with DEHP, and, thus, there is no justification for subjecting the use of DEHP in medical devices to authorisation on the grounds of an environmental risk or any other risk posed by DEHP when used in medical devices.

Considering the relatively low use of these substances in medical device applications; estimated at 0.5% of the total use of DEHP in the EU⁵, the prioritization criteria referred in Article 58(3) of REACH concerning wide dispersive use, high volume or PBT/vPvB properties are not applicable to the use of this substance in medical devices. Furthermore, the controlled and highly regulated environment of a hospital will prevent the disposal of devices containing these substances under substandard conditions.

In other words, the potential risks associated with the use of DEHP in medical devices are adequately controlled, thus the use of DEHP in medical devices should be exempted from authorisation.

Summary

In summary we request the exemption for the use of DEHP for manufacturing/composition of medical devices.

⁵ Final Report of EU-Contract No. ETD/FIF.20020892: Life Cycle Assessment of PVC and of principal competing Materials