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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

Report on the availability of mercury-free button cells for hearing aids, in accordance with Article 4.4 of Directive 2006/66/EC of the European Parliament and of the Council on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC

1. INTRODUCTION

Under Article 4.2 of Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators (the Batteries Directive), as amended in 2013[1], the prohibition to place on the market mercury-containing batteries or accumulators shall not apply to button cells with a mercury content of no more than 2 % by weight until 1 October 2015.

While in 2012 a report commissioned by the Commission concluded that alternatives to mercury-containing button cells for all applications were available[2], the Commission was requested in the amended Directive to conduct another, specific study to confirm this conclusion.

More specifically, Article 4.4 of the amended Batteries Directive stipulates that

"As regards button cells for hearing aids, the Commission shall maintain under review the exemption referred to in paragraph 2 and report to the European Parliament and the Council on the availability of button cells for hearing aids which are in compliance with paragraph 1(a) no later than 1 October 2014. Where justified due to the lack of availability of button cells for hearing aids which are in compliance with paragraph 1(a), the Commission shall accompany its report by an appropriate proposal with a view to extending the exemption referred to in paragraph 2 with regard to button cells for hearing aids".

The purpose of this report is to inform the European Parliament and the Council of the Commission's findings on the availability of button cells for hearing aid devices containing no more than 0,0005% of mercury by weight.

2. FINDINGS

2.1. Introduction

To prepare the present report, the Commission collected and assessed available information as regards mercury-free button cells used in hearing aids devices, focussing primarily on their technical and commercial availability and then, on the likely impact on users, as regards performance and financial aspects.

The Commission requested the services of independent consultants who reviewed relevant literature and knowledge, and held consultations with all major producers and manufacturers of batteries and hearing aid devices as well as with patients' and hearing aid associations.[3]

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[1] OJ L 266 26.9.2006, p.1-14; last amendment by Directive 2013/56/EU of the European Parliament and of the Council of 20 November 2013, OJ L 329, 10.12.2013, p. 5–9.

[2] BIO Intelligence (2012) "Study on the Potential for Reducing Mercury Pollution from Dental Amalgam and Batteries," Report for European Commission DG Environment, July 2012, in particular section 7.1, option 2 (page 123) in conjunction with the concluding section 9.2 (page 135).

[3] Eunomia & Öko Institut e.V. (2014) "Availability of Mercury-free Button Cells for Hearing Aids"Report for DG Environment, August 2014.

The reliability of the results of the consultation is ensured, in the opinion of the Commission, by the size of the market share of the producers and manufacturers of batteries and hearing aid devices that have been consulted. Their fair cooperation, even acknowledging usual limits applicable to sensitive business-related information, should be highlighted.

Particular attention was paid to the lessons learnt after the adoption of bans on mercury-containing button cells in the United States where 30 states have passed (or proposed) legislation in this respect.

In the opinion of the Commission, the use of different but complementary sources has allowed coming up with a wide-ranging and detailed appraisal of the situation, beyond the issues strictly related to the security of supply requested by the Directive.

The resulting conclusions obtained by the consultants have provided solid foundations upon which the Commission has completed its own evaluation and prepared the present report.

2.2. Key findings

On the basis of the mentioned study, which the Commission considers being a solid study with sound findings and conclusions and based on robust data and evidence, and own evaluation work carried out, the Commission arrives at following conclusions:

(1) Viable mercury-free alternatives exist for button cells used in hearing aids. The most frequently used types make use of zinc air technology, which has been developed by several firms. Other technologies also exist (e.g. Nickel Metal Hydride), but its use is less spread and is limited to devices not needing high power delivery or that allow less stringent usage patterns.

(2) As confirmed during the consultation and taking into consideration current levels of production, the security of supply of button cells for hearing aid devices will not be put at risk after the exemption for mercury-containing button cells expires on 1 October 2015. Those product types for which mercury-free alternatives are unlikely to be available (i.e. the smallest size 5 cells) are being phased out by the industry, independently of the shift to mercury-free products.

(3) Experience gained in the United States after the introduction of similar bans of mercury-containing button cells shows that issues that initially appeared in relation to the performance and usability of mercury-free alternatives for hearing aids have been overcome as a result of new technological developments and the expansion of markets. The performance issues facing some of the first generation mercury-free button cells for hearing aids supplied in the United States in 2010 have now been solved. While, depending on brands and models, a reduction of the lifespan of batteries by around 2–10% has been identified, current technical developments are expected to further improve performance.

(4) Cost differences between mercury-free and mercury-containing button cells used in hearing aids might appear in the EU market, as it has been the case in the US. An earlier study prepared for the Commission estimated the costs of

mercury-free button cells to be some 10% higher.[4] While at present the differences in retailing prices appear to be higher[5], a ban on mercury-containing button cells for hearing aids in the EU is expected to reduce price differences. This is due to larger markets and economies of scale and the removal of inefficiencies in production systems for those manufacturers that reorganize their production capacity to one single product line.

(5) The expiry of the exemption for mercury-containing button cells is expected to promote innovation. This will shorten the time needed to improve the performance of mercury-free products and enable new products to meet the needs of more developed devices that require higher power delivery.

(6) As regards the security of supply of mercury-free button cells for hearing aid devices no particular concerns were raised by the patients' and hearing aid associations consulted as part of the study commissioned by the Commission.

3. CONCLUSION

Expiry of the exemption for mercury-containing button cells as of 1 October 2015 is not expected to entail problems as regards the availability of button cells used in hearing aid devices. Consequently, there is no need to extend the exemption enshrined in Article 4 of Directive 2006/66/EC.

[4] BIO Intelligence (2012) "Study on the Potential for Reducing Mercury Pollution from Dental Amalgam and Batteries," Report for European Commission DG Environment, July 2012, page 117.

[5] For instance, US internet sale prices for a pack of six size 10 cells range from $ 3.25 to $ 3.95 for conventional hearing aid button cells and from $3.95 to $ 4.95 for mercury-free cells, depending on brands and sellers.