



**COUNCIL OF
THE EUROPEAN UNION**

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NOTE

from: General Secretariat
to: Delegations

Subject: Danish ban on two parabens in cosmetic products for children under the age of 3 years
- Information from the Danish delegation

Delegations will find attached an information note from the Danish delegation on the above subject, which will be dealt with under "other business" at the meeting of the Council (Environment) on 14 March 2011.

Danish ban on two parabens in cosmetic products for children under the age of 3 years

In 2009 the Danish Environmental Protection Agency published a comprehensive study of 2 year old children and their exposure to endocrine disrupters.

One conclusion was that propyl- and butylparaben may pose a risk to the young children because of the use in lotions and sunscreens due to their potentially endocrine-disrupting effects.

This is an especially vulnerable group, and we still do not know the long-term consequences of exposing young children to endocrine disrupters. Taking a precautionary point of view, we must act on the indications that these two parabens are potentially harmful and prevent the exposure of young children.

Given this background, Denmark is banning propyl- and butylparaben in cosmetic products for babies and young children under the age of 3. The ban will enter into force on 15 March 2011, after which cosmetic products on the Danish market intended for children under 3 years may no longer contain propyl- and butylparaben.

The ban is made with reference to the “safety clause” in the Cosmetics Directive (Article 12 of Directive 76/768/EEC).

Denmark fully acknowledges that such regulation is best dealt with at the EU level. Therefore, Denmark strongly encourages the Commission to present draft EU legislation introducing a similar ban and Member States to support it.

Background

The use of parabens as preservatives in cosmetic products such as body lotions, shampoos, sunscreens etc, has been discussed for several years. The discussion has been about the safety of these substances, as there are several studies that points to an endocrine effect. On the other hand, data has in general not been of a sufficient quality for the Scientific Committee for Consumer Safety to draw a final conclusion on the question of the possible endocrine-disrupting activity of these substances.

Since 2005, the industry has repeatedly been asked to deliver specific studies to the Scientific Committee, but it has not yet been able to deliver the requested studies. Even in the last opinion from the Scientific Committee, dated 14 December 2010, a long list of uncertainties is given, which leaves the question as to the endocrine potential of the parabens still unanswered. Furthermore, the degree to which the parabens are absorbed through the skin when using cosmetic products has not been clearly demonstrated either.

Endocrine disrupters are suspected of causing premature puberty in girls and poor semen quality in boys and men. Also the occurrence of testicular cancer is suspected to be linked to exposure to endocrine-disrupting substances. So far we do not know enough about the long-term consequences of direct exposure on the skin to products containing endocrine-disrupting substances.

Propyl- and butylparaben and the isoforms are the most problematic parabens, and babies and young children are a very sensitive consumer group.

The national ban is made with reference to the safety clause in the Cosmetics Directive (Article 12 of the Directive), whereby a Member State can prohibit the marketing of cosmetic products if the Member State notes that the products represents a hazard to health.