Question for written answer E-011676/2012
to the Commission
Rule 117
Anja Weisgerber (PPE)

Subject: Distinction between cosmetic products and medical devices in the case of tooth-bleaching products

Tooth-bleaching products are used to cosmetically brighten discoloured teeth, and the discolouration of teeth is, for example, considered a disease under German law and corresponding German jurisprudence. Under current law, it is not clear for manufacturers, competent authorities and notified bodies whether tooth-bleaching products containing up to 6% hydrogen peroxide should be considered as medical devices under Directive 93/42/EC or as cosmetic products within the meaning of Regulation (EC) No 1223/2009.

In his answer to Written Question E-1348/05 on the same topic, Mr Verheugen, who was Commissioner for Industry at the time, replied that it was for the Member States to establish on the basis of Community legislation whether the Medical Devices Directive or the provisions of the Cosmetics Directive should apply. The legal position may, however, have changed with the subsequent adoption of Directive 2011/84/EU.

1. Has the legal position changed with the entry into force of Directive 2011/84/EU on 31 October 2012, as the directive makes explicit provision for restrictions and requirements concerning the use of tooth-bleaching products containing between 0.1 and 6% hydrogen peroxide?

2. Can tooth-bleaching products that contain between 0.1 and 6% hydrogen peroxide and are intended for medical use on the basis of Directive 93/42/EC be placed on the market?

3. If the Commission should consider that Directive 2011/84/EU provides no greater clarity about the classification of tooth-bleaching products, will the current review of the legislation on medical devices influence the classification of tooth-bleaching products?

4. Which Directive covers tooth-bleaching products containing over 6% hydrogen peroxide?