



CED GUIDELINES

TO INTERPRET AND IMPLEMENT COUNCIL DIRECTIVE 2011/84/EU ON TOOTH WHITENING PRODUCTS

I – INTRODUCTION

This document provides guidance for interpreting and implementing the Council Directive 2011/84/EU of 20 September 2011 amending Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annex III thereto to technical progress (hereinafter “the Directive”). It intends to support CED Members and CED Observers when they contact the Ministries responsible for transposing the Directive into national legislation and to advise individual dental practitioners. It is important to ensure that CED Members and CED Observers are heard by the relevant competent authorities in the beginning of the transposition procedure.

This document can also serve to support CED Members and CED Observers in providing complete information about the regulation of tooth whitening and bleaching products to the dentists and the general public in their countries.

The Directive has entered into force on 18 November 2011. **Member States will have to apply the Directive provisions from 31 October 2012.**

II – WHAT HAS CHANGED IN THE DIRECTIVE?

The Directive regulates the use of hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide in tooth whitening or bleaching products.

Until now, according to entry 12 of the first part of Annex III of the Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (hereinafter “Directive 76/768/EEC”), the use of hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide was limited to 0.1% of hydrogen peroxide present in oral hygiene products or released. Concentrations above this limit were prohibited. Indeed, under Article 4 paragraph 1 (b) of Directive 76/768/EEC, marketing of cosmetic products which contained the substances listed in the first part of Annex III, beyond the limits and outside the conditions laid down therein, was prohibited in all Member States. Hence, only concentrations of 0.1 % of hydrogen peroxide were considered safe and were allowed to be freely available to the consumers on the market.

The current Directive establishes a **new legal framework**: products between 0.1% and 6% of hydrogen peroxide present in tooth whitening or bleaching products or released can now be sold to dental practitioners and must have their first use within the dental office i.e., by dental practitioners (or under their direct supervision if an equivalent level of safety is ensured). The rest of cycle of use can be performed by consumers themselves as long as the access to the product is provided by dental practitioners, as explained under point III a) below. These concentrations cannot be used on a person under 18 years of age.

The Directive aims at implementing the opinion of the Scientific Committee on Consumer Products of 18 December 2007 on hydrogen peroxide, in its free form or when released, in oral hygiene products and



tooth whitening products (see attached for your information). It intends to adapt to technical progress Directive 76/768/EEC while ensuring the protection of public health. The Scientific Committee on Consumer Products was replaced by the new Scientific Committee on Consumer Safety (hereinafter “SCCS”).

III – GUIDELINES

a) The meaning of the term “dental practitioners” in the Directive

Recital 4 of the Directive establishes that: *“Those products [products containing more than 0.1% and up to 6% of hydrogen peroxide present or released] should therefore be regulated in a way that ensures that they are not directly available to the consumer. For each cycle of use of those products, the first use should be limited to **dental practitioners, as defined under Directive 2005/36/EC** of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications or under their direct supervision if an equivalent level of safety is ensured. **Dental practitioners** should then provide access to those products for the rest of the cycle of use.”*

The new Directive does not provide a definition of “dental practitioners”. It refers to the definition established under Directive 2005/36/EC on the recognition of professional qualifications (hereinafter PQD). The PQD however does not provide a definition *stricto sensu* of a dental practitioner. In fact, under Article 36, the PQD describes the professional activities of dental practitioners and the conditions under which a dental practitioner can pursue his/her activities.

In this sense, Article 36 of the PQD establishes the following:

“1. For the purposes of this Directive, the professional activities of dental practitioners are the activities defined in paragraph 3 and pursued under the professional qualifications listed in Annex V, point 5.3.2.

2. The profession of dental practitioner shall be based on dental training referred to in Article 34 and shall constitute a specific profession which is distinct from other general or specialised medical professions. Pursuit of the activities of a dental practitioner requires the possession of evidence of formal qualifications referred to in Annex V, point 5.3.2. Holders of such evidence of formal qualifications shall be treated in the same way as those to whom Articles 23 or 37 apply.

3. The Member States shall ensure that dental practitioners are generally able to gain access to and pursue the activities of prevention, diagnosis and treatment of anomalies and diseases affecting the teeth, mouth, jaws and adjoining tissue, having due regard to the regulatory provisions and rules of professional ethics on the reference dates referred to in Annex V, point 5.3.2.”

As a result, by limiting the first use within a cycle of use to “dental practitioners”, **the new Directive intends to ensure that only dental practitioners, and no other professionals, have direct access to tooth whitening and bleaching products containing more than 0.1% and up to 6% of hydrogen peroxide present or released.** Those products cannot be directly available to the consumer or other professionals.

Nevertheless, **other qualified dental professionals can perform** tooth whitening and bleaching under the supervision of dental practitioners where an equivalent level of safety is ensured. Who can perform tooth whitening and bleaching under the abovementioned circumstances and how the equivalent level of safety is ensured needs to be further developed by Member States when transposing Directive 2011/84/EC. Indeed, in order to ensure consistency of what one should understand by *“an equivalent level of safety”*, Member States should specify the minimum conditions under which the equivalent level of safety is ensured. For example, Member States should specify the minimum professional qualifications required (i.e., in the area of dentistry and by qualified dental care professionals) and/or, if

appropriate, the need to be registered in a professional organisation or to be authorised by a competent authority.

Furthermore, the purpose of the new Directive is to enhance patient safety and to ensure that patients can only access appropriate products via trained and qualified dental professionals. Recital 3 of the Directive explains the conditions under which these products can be safely used. It mentions that an **appropriate clinical examination** needs to be carried out in order to ensure that there are no risk factors or any other oral pathology of concern, and that the **exposure to these products is limited** so as to ensure that the products are used only as intended in terms of frequency and duration of application.

A clinical examination implies therefore an examination by a clinician (the dental practitioner) in a clinical setting. Moreover, the clinical examination must be carried out **before the first use** of tooth whitening products, and the **ongoing exposure** to these products (the rest of the cycle of use), which shall be limited in terms of frequency and duration of application, must be **monitored** by the dental practitioner.

b) The substances regulated

The Directive regulates the use of **hydrogen peroxide** and other compounds or mixtures that release hydrogen peroxide, **including carbamide peroxide and zinc peroxide**. Note that the active ingredient of carbamide peroxide is hydrogen peroxide where **16.62% of carbamide peroxide corresponds to 6% of hydrogen peroxide**.

Sodium perborate and perboric acid are also regulated as they are considered to be hydrogen peroxide releasing substances, pursuant to the opinion of the Scientific Committee on Consumer Safety (SCCS) on sodium perborate and perboric acid, published on 22 June 2010 (see attached).

The conclusion of the SCCS opinion (pages 22 and 23) states the following:

“4. CONCLUSION

(1) Based on the current knowledge on the chemistry, biology and toxicology of sodium perborate and perboric acid, does the SCCS consider that sodium perborate and perboric acid can be considered as "hydrogen peroxide" releasing substances in the sense as the already regulated substances in Annex III, entry 12 of the Cosmetics Directive 76/768/EEC?

*The SCCS is of the opinion that **sodium perborate and perboric acid can be considered as "hydrogen peroxide" releasing substances** and thus are covered by the entries 12 of Annex III, of the Cosmetics Directive 76/768/EEC,*

(2) If the answer to question 1 is yes, does the SCCS consider that the general restrictions applicable to hydrogen peroxide releasing substances should apply to sodium perborate and perboric acid?

*The SCCS considers that **the general restrictions applicable to hydrogen peroxide releasing substances should apply to sodium perborate and perboric acid**. As laid out in opinion SCCS/1249/09, the substances listed in the Annex I of this mandate are, in addition to entry 12 of Annex III, also covered by entry 1a of Annex III of the Cosmetics Directive 76/768/EEC. The more restrictive of the two entries should apply.”*

The European Commission is currently discussing with Member States the legal regime for sodium perborate and perboric acid. In the future, it is possible that these substances are banned from cosmetic products.

c) Is there a difference between in-office and at-home concentrations?

The Directive regulates the use of hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide **regardless the place where their use occurs – in the dental office or at home**:

- **Concentrations of ≤ 0.1 % of hydrogen peroxide** present or released in oral products, including mouth rinse, tooth paste and tooth whitening or bleaching products are safe and will continue to be freely available on the market.
- **Concentrations of $>0.1\%$ - $\leq 6\%$ of hydrogen peroxide** present or released in tooth whitening or bleaching products can only be sold to dental practitioners and, for each cycle of use, the first use can only be carried out by dental practitioners or under their direct supervision if an equivalent level of safety is ensured, as explained under point III a) above. Afterwards the product may be provided by the dental practitioner, to the consumer to complete the cycle of use.
- **Concentrations of >6 % of hydrogen peroxide** present or released in oral products, including tooth whitening or bleaching products, **will continue to be prohibited, as before**. However, in several Member States, concentrations higher than 6% of hydrogen peroxide are currently being used due to the fact that the relevant national legislations regulating the use of tooth whitening or bleaching products containing more than 0.1% of hydrogen peroxide are based on the Medical Devices Directive (Council Directive 93/42/EEC of 14 June 1993 concerning medical devices).

Indeed, in several Member States tooth whitening or bleaching products are considered medical devices and not cosmetic products. For this reason, these products bear the CE marking provided for in Article 17 of the Medical Devices Directive (which is a declaration by the manufacturer that the products comply with the essential requirements of the relevant EU legislation). **For the European Commission, however, tooth whitening or bleaching products have always been considered cosmetic products and therefore regulated under Directive 76/768/ECC concerning cosmetic products. Thus, the CE marking is unduly affixed; under EU legislation they remain to be treated as cosmetic products.**

The present *status quo* already habilitated the European Commission to launch infringement procedures against those Member States which have been failing to comply with Directive 76/768/EEC (also known as the “pre-litigation administrative phase”). The European Commission is planning to be stricter with regards the enforcement of the new Directive 2011/84/EU.

d) Labelling

Entry 12 of the first part of Annex III of the Directive specifies the conditions of use and warnings which must be printed on the label of tooth whitening and bleaching products containing more than 0.1% and up to 6% of hydrogen peroxide, present or released. It requires the following:

- i. The indication in percentage of the concentration of hydrogen peroxide present or released;
- ii. The warning that it cannot be used on a person under 18 years-old;
- iii. The warning that it can only be sold to dental practitioners, specifying that for each cycle of use the first use can only be done by dental practitioners or under their direct supervision if an equivalent level of safety is ensured, as explained under point III a) above. Afterwards the product may be provided to the consumer [by the dental practitioner] to complete the cycle of use.

e) How to deal with illegal practice of tooth whitening

In 2011, the CED carried out a survey among its Members and Observers to investigate if tooth whitening by non-dentists was a problem and, if so, what was the attitude of national competent authorities, and what kind of actions had they taken against non-dentists performing tooth whitening. The survey also included questions about the materials being used and if CED Members and Observers were aware of any complaints about damage done by non-dentists. 11 countries out of 27 reported having problems with tooth whitening being carried out by non-dentists; 2 countries reported not having problems, but expected they would appear in the future.

For those countries where tooth whitening by non-dentists is a problem or a developing problem, please find below some suggestions which might help you to deal with the illegal practice of tooth whitening in your country, considering the new legal framework of the Directive:

- Discuss the present guidelines with national competent authorities that enforce the Cosmetics Directive 76/768/EEC and regulate the dental profession;
- Specify in national legislation that tooth whitening is a medical act reserved to dental practitioners, as explained under point III a) above;
- Trace on the internet the entities which are currently offering training courses and/or qualifications on tooth whitening, and promote awareness campaigns aimed at informing students that only dental practitioners and individuals under their direct supervision if an equivalent level of safety is ensured are legally authorised to carry out tooth whitening or bleaching activities (Note: in some countries, teaching an illegal activity is by itself illegal, while in others it is not. This suggestion should be adapted taking into consideration national legislation);
- Trace on the internet companies franchising tooth whitening and promote awareness campaigns about their illegal activities and the risks of having tooth whitening or bleaching performed by unqualified persons;
- Trace companies selling or supplying any tooth whitening products and remind them of their legal obligations that these can only be supplied to a dental practitioner;
- Encourage national governments to reach informal agreements with tooth whitening or bleaching suppliers establishing that they will not sell/supply to beauticians or hairdressers.
