1. **BACKGROUND**

The Scientific Committee on Cosmetics and Non Food Products intended for Consumers (SCCNFP), replaced by the Scientific Committee on Consumer Products (SCCP), by Commission Decision 2004/210/CE\(^1\), has been consulted and expressed its view in several occasions on the safety of hydrogen peroxide, in its free form or when released, in oral hygiene products, and, in particular, in tooth whitening products.

Its latest opinion is from **15 March 2005** (SCCP/0844/04) in which it concluded that:

**“tooth whitening products containing up to 0.1% hydrogen peroxide”**

- The use of tooth whitening products up to 0.1% hydrogen peroxide is safe.

**“tooth whitening products containing > 0.1% to 6.0 % hydrogen peroxide”**

- The proper use of tooth whitening products containing > 0.1 to 6.0 % hydrogen peroxide (or equivalent for hydrogen peroxide releasing substances) is considered safe after consultation with and approval of the consumer’s dentist.
  - The use of tooth whitening products is not recommended prior to or immediately after dental restoration.
  - Particular care should be taken in using tooth whitening products by persons with gingivitis and other periodontal diseases or defective restorations. Conditions such as pre-existing oral tissue injury or concurrent use of tobacco and/or alcohol may exacerbate the toxic effects of hydrogen peroxide (see e.g. section 3.3.13.1).

- There is an absence of good clinical data and long-term epidemiological studies that assess the possible adverse effects within the oral cavity.

- The new additional data supplied does not provide the necessary reassurance in terms of risk assessment to support the safety of hydrogen peroxide up to 6 % in tooth whitening products freely and directly available to the consumer in various application forms (strips, trays, etc...). SCCP cannot quantify the risk of potential serious adverse effects in relation to the use of tooth whitening products”.

At the request of the Commission services, in order to ensure that industry would carry out relevant and good clinical data and long-term epidemiological studies that assess the possible adverse effects within the oral cavity, the SCCP delivered “a guidance document on

\(^1\) OJ L 66, 4.3.2004, p.45.
epidemiological and clinical studies on tooth whitening products” on 28.03.2006 (SCCP/0974/06).

Commission services were then informed by a Member of the European Parliament and by the Council of European Dentists, formerly EU Dental Liaison Committee, of the existence of scientific articles which have not been considered by the SCCP. All relevant stakeholders were at that time asked to provide to the Commission services all available scientific articles on the matter. Norway and COLIPA\(^2\) forwarded documents.

2. TERMS OF REFERENCE

2.1. Context of the question

The SCCP clarified in its opinion of March 2005, that for the purpose of its opinion, the terms “tooth whitening products” and “tooth bleaching products” define the same kind of products. In this request, neither do the Commission services draw a distinction.

In its opinion of 23.06.1999 (SCCNFP/0158/99), the SCCNFP has reviewed the use of hydrogen peroxide in tooth pastes and mouth rinses. It then concluded that “an increase of hydrogen peroxide (and equivalent) in toothpaste and mouth-rinses to 3.6% is not permissible [...]”. In parallel, in its opinion of 17.02.1999 (SCCNFP/0058/99), the SCCNFP considered the use of hydrogen peroxide (and equivalent) in tooth whitening products. It was this opinion which has been reviewed at several occasions.

Therefore, in order to ensure consistency, this request concerns the safe use of hydrogen peroxide, in its free form or when released, in oral hygiene products (tooth whitening products and tooth pastes and mouth-rinses).

Currently, Council directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (the Cosmetics Directive) provides in Annex III, part 1, n°12 a limit of 0.1% of hydrogen peroxide (or equivalent for substances that release hydrogen peroxide) in oral hygiene products.

The Cosmetics Directive provides several options in order to ensure the safety of consumer when using cosmetic products. Those management options include:

− the requirement for a specific labelling;
− the requirement for the first use of a product by a professional;
− the requirement for the exclusive use by the professional.

In order to determine which of these options is the appropriate one, the Commission services need to know from the SCCP, within its scientific assessment, possible concerns and how scientifically these concerns can be handled.

\(^2\) COLIPA - European Cosmetics Toiletry and Perfumery Association
2.2. Request

Considering all data, those already submitted in support of previous opinions and those identified since its last opinion (15 March 2005, SCCP/0844/04) and submitted to the SCCP, can the Committee assess the possible health risks associated with the use of hydrogen peroxide, in its free form or when released, in oral hygiene products?

In doing so, the Committee is asked, wherever it is scientifically justified, to make a distinction in the assessment of hydrogen peroxide and to identify any specific health risks regarding the use of hydrogen peroxide in oral hygiene products, or equivalent for substances that release hydrogen peroxide, taking account of:

- **Types** of oral hygiene products: mouth-rinses and tooth pastes on the one hand and tooth whitening products (strips, trays with gel…) on the other, as the SCCP has done in its previous opinions;
- **Concentration limits** (for example 0.1%, 6%, more than 6%);
- **Different usage conditions** which can create differences in the resulting exposure of consumers to hydrogen peroxide.

3. **DEADLINE**

As soon as possible

4. **SUPPORTING DOCUMENTS**


- Rothuijzen Y., Buijs MJ., Van Amerongen JP., van Loveren C. In vitro demineralisation after bleaching with two 10 % carbamide peroxide products, to be published.


5. ANNEX

Submission IV from Colipa including:

- some of the articles mentioned above;
- review of all papers published on Hydrogen Peroxide (2004-Date);
- Review “use of bovine samples as substitutes in studies evaluation the impact of bleaching agents on dental enamel microhardness” by Prof. Dr. Thomas Attin of December 2006.