The view of the Department of Health, having sought several independent clinical opinions, remains that tooth whitening products containing or releasing up to 6% hydrogen peroxide can be safely used by consumers at home provided that the products have clear usage instructions. These products could be purchased from reputable retailers or supplied by their dentists. The Department does not believe there is a need for dental supervision, nor any necessity for prior consultation with a dentist. Product labels should prompt individuals to consult their dentists if they have any questions, and that they should inform their dentists at their next routine visit that they have recently used a tooth whitening product.

Tooth whitening products containing hydrogen peroxide or carbamide peroxide have been used for many years, particularly in North America where they may be obtained from a variety of retail outlets in addition to dental practices. The trend for whiter teeth and the supply of the tooth whitening products has spread to Europe in recent years. These products have been made available through many dental practices in Eire and the UK. In many other EU countries, tooth whitening products are also available in pharmacies and supermarkets alike.

The safety profile of hydrogen peroxide at up to 6% in these products is well established. The incidence of adverse effects is very low. When they do occur, the adverse events typically involve gingival irritation and/or tooth sensitivity, regardless of mode of delivery. Moreover, these effects are mild in intensity and usually resolve spontaneously or within one to two days of the individual stopping use. Dental intervention is very rarely required. Even individuals who need to use tooth whitening products for an extended period of time (e.g. six months continuous use) to bleach teeth stained through disease or drug therapy do not exhibit a different pattern of adverse effects compared with the more usual treatment of two to four weeks, every one to two years. More extended usage is uncommon, largely because individuals achieve a plateau in the whiteness of the teeth.

The application of tooth whitening products by individuals suffering with gingivitis and periodontitis does not of itself cause concern. Hydrogen peroxide has a history of use as an oral antiseptic and so may even be of benefit to these individuals. The key to resolving their condition is effective oral hygiene and, in the case of periodontitis, intervention by their dentist. The fact that individuals are choosing to bleach their teeth suggests that they are becoming more aware of their own oral health and more likely than ever to visit their dentist to achieve or maintain good health. At this point, the dentist or hygienist can manage gingivitis or any periodontitis. As a reminder, the product label should advise individuals to visit their dentists regularly, especially if they have sore gums or teeth prone to sensitivity.

Tooth whitening products should not be used immediately prior to, or after, dental restoration as this may in certain circumstances weaken the bonding of some of the restorative materials used. Similarly, these products should not be used on teeth adjacent to crowns or veneers, as the natural teeth will bleach and subsequently no longer match the colour of the adjacent restorations. This is purely an aesthetic concern rather than a safety issue.

It has been well established through extensive clinical studies and considerable practical experience of the use of tooth whitening products, that hydrogen peroxide

does not damage hard tissue or tooth pulp, even at higher strengths than the 6% proposed for at-home use.

In conclusion, therefore, it is the view of the Department of Health that tooth whitening products containing or releasing up to 6% hydrogen peroxide can be safely used by consumers at home, without the need for dental supervision, provided that the products have clear usage instructions.

This paper represents the views of its author on the subject. These views have not been adopted or in any way approved by the Commission and should not be relied upon as a statement of the Commission's or Health & Consumer Protection DG's views. The European Commission does not guarantee the accuracy of the data included in this paper, nor does it accept responsibility for any use made thereof.