



TOOTHFRIENDLY GUIDELINES

# Toothfriendly Certification

General provisions for the  
Toothfriendly Certification of  
products and services



## General provisions for the Toothfriendly Certification of products and services

### 1. General aspects

Goods and services which are offered to consumers must be fit for purpose and safe under their intended conditions of use.

The criteria for Toothfriendly Certification are laid down in full recognition of these two basic requirements with a specific focus on dental and oral health.

Where necessary, specific circumstances may need to be taken into account which could result in slight differences of the certification criteria for specific goods and services for different regions or groups of consumers. For example, the addition of fluoride to table salt is typically an efficient and recommended caries preventive measure. However, in communities with fluoridated drinking water or water with a naturally high fluoride content, the addition of fluoride to table salt could lead to an excessive fluoride intake and is therefore contraindicated. Similarly, there may be differences between countries for recommended dental treatments depending upon existing treatment needs, supply of dental services and the patients' affluence. Hence, both safety and fitness for purpose of products and services must be examined in a wider context that may even change slightly over time.

### 2. Specific criteria for Toothfriendly Certification

#### 2.1 Foods and food ingredients

Current legislation aims at a high level of safety of the food supply. In addition, extensive labelling requirements should enable consumers to select and consume healthy food.

Yet, food and beverages that are loaded with sucrose and often also contain added food acids are widely consumed although it is well known that the frequent consumption of sucrose (and other fermentable carbohydrates) increases the incidence of caries, particularly in populations with insufficient oral hygiene practices. Furthermore, the frequent consumption of acidic foods and beverages may lead to the formation of erosive defects of the teeth. In this situation, the Toothfriendly Certification offers a valuable help to consumers by positively identifying products that neither promote tooth decay nor tooth erosion even on frequent consumption.

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Foods and food ingredients can be considered safe for teeth if they are neither cariogenic nor erosive. These “Toothfriendly“ properties are determined in a standardized in vivo plaque-pH telemetry test conducted by independent University Dental Institutes. Toothfriendly products may not lower plaque-pH below 5.7. The acid exposure of the teeth may not exceed 40  $\mu\text{mol H}^+$  min. The validity of the plaque pH test is generally recognized in the dental profession and is cited by reference in the US Code of Federal Regulations and in the EU Regulation on Nutrition and Health Claims.

The exact the test method that is applied for checking the compliance with the test criteria of food (solid foods and beverages) are described in the following document: [Guidelines to pH-telemetry testing](#)

The criteria that pertain to the dental safety of food are applicable generally, i.e. in all countries and for the entire population.

## 2.2 OTC Pharmaceutical products

Certain OTC pharmaceutical products, such as throat lozenges, cough syrups, chewable or effervescent vitamin tablets and teething gels for babies with erupting teeth, come in contact with teeth in the same way as food. Hence, the Toothfriendly Certification criteria and the applied test methods are the same as for food.

## 2.3 Fluoride fortified table salt

The fortification of table salt with added sodium fluoride is a well-established method for (passive) caries prevention at population level. The appropriate level of fluoride fortification depends on the intake of fluoride with an average diet and the current average use of table salt in households.

In most countries, the fortification of foods with minerals and vitamins is regulated and maximum use levels are defined. In addition, special labelling requirements apply which inform the consumer about the fortification of food. Under these conditions, the fortification of table salt with fluoride is a save means of caries prevention and fortified table salt therefore qualifies for Toothfriendly Certification.

At this time, Toothfriendly certified fluoridated table salt contains 310 ppm and 250 ppm fluoride in Germany and Switzerland, respectively.

## 2.4 Children’s toothpaste

Like food and beverages, also toothpaste comes in contact with teeth. Since children are a particularly vulnerable group of consumers, it is important to establish Toothfriendly criteria for children’s toothpaste.

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Toothpaste is typically considered to be a cosmetic product i.e. its composition must comply with the applicable legislation on cosmetic products. While this legislation is generally silent on the aspect of fitness for purpose, this aspect is decisive for the Toothfriendly Certification. In this context, the concentration of fluoride in a form that can be incorporated directly in the surface layer of the dental enamel is of primary importance. The other parameter that determines the caries preventive benefit of toothpaste is its correct application. The Toothfriendly Certification therefore, includes also criteria for the appropriate labeling and the provision of consumer information on the appropriate use of the product.

The exact criteria for Toothfriendly children's toothpaste are described in the following document: [Guidelines to Children's Toothpaste](#)

## 2.5 Pacifier

Pacifiers are devices which are regulated with regard to (a) the materials that may be used for their production and (b) certain mechanical characteristics that ensure their safe use by the target population.

However, no legal requirements exist as to the construction characteristics of the pacifier that might adversely affect the position of the erupting teeth, upon frequent and prolonged use of the pacifier. It is this orthodontic aspect which forms the basis for the Toothfriendly Certification of pacifiers. This aspect can be examined only by means of a controlled, single-blind (examiner) study of sufficient duration and statistical power in babies.

Considering the logistic difficulties in performing such a study and its duration that is required to obtain data also for long-term pacifier users, it appeared unrealistic to establish a priori certification criteria for pacifiers. Instead, the data of an existing study was used as basis for the Toothfriendly Certification of the tested pacifier. This study demonstrates the safety of use of the pacifier over a period of 27 months and it also shows the superiority of this pacifier over another such product. In this specific case, the Toothfriendly Certification pertains, therefore, to the superiority rather than the absolute safety under typical conditions of use.

Further information about orthodontic pacifiers is described in the following document: [Toothfriendly pacifiers](#)

## 2.6 Tooth saving box

In case of accidental tooth loss, the tooth saving box is a suitable means for storage of the tooth or tooth fragment under conditions which preserve the living adhering cells. The box contains a sealed vial filled with a sterile standard culture medium with optional protective antibiotics. That such a tooth saving box is better suited for the transport of an avulsed permanent tooth than any

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other means and that it is safe for this purpose is evident. Any loss of sterility of the transport medium that would make it unsuitable would become apparent from a changed color of the added pH indicator (from light red to yellow) and from turbidity.

## 2.7 Services of a dentist

Services of a dentist are a priori assumed to be safe and fit for the maintenance of dental health. However, there may be differences in the level of safety and the adequacy of the treatment depending upon the level of education, continued education and practice of the dentist.

In certain countries, the dental chambers supervise the education and continued education of dentists (or at least the dentists who are members of the chamber). However, where there exist large differences in the quality and adequacy of the execution of dental services (for example with regard to the applied hygiene practices, the application of minimum invasive dentistry principles, the professional use of a functioning recall system with professional teeth cleaning in regular intervals) it may be reasonable to enable patients to identify Toothfriendly certified dentists who live up to a predetermined set of quality criteria. As the average quality of dental services increases in a given society over time, these criteria may need to be modified so as to preserve their value as a means of differentiation.

## 3. Future applications of the Toothfriendly Certification

The Toothfriendly Certification of further products and services will be considered as and when the need arises and to the extent that pertinent criteria for such Certification can be established. In addition to the two basic criteria, i.e. „safe“ and „fit for purpose“, other considerations may come into play for certain oral hygiene articles, such as the average cost to the consumer per year of use. This may be a relevant parameter particularly in populations with low-income who at the same time are still prone to caries and periodontal disease.

For other potential applications of the Toothfriendly Certification appropriate testing methods may need to be developed before a recommendation for specific products or services may be expressed. In such future cases it also may not always be possible to make a black and white distinction (as it is presently the case for foods, see Section 2.1). However, it may be possible to distinguish the more desirable from the less desirable good or service (see Section 2.7 for an example).