

# Legal aspects of fluoride in salt, particularly within the EU

## Summary

*In seven European countries there are national legal regulations, or salt producers have obtained individual authorisations, for the production and marketing of fluoridated edible salt. On the basis of EU mutual recognition rules, there are other countries which import fluoridated edible salt.*

*All European countries practise salt fluoridation on a voluntary basis. In the near future, a European regulation is expected to supersede the national conditions.*

FRANZ GÖTZFRIED

Südsalz GmbH, Heilbronn

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## Introduction

Salt enjoys unique advantages as a vehicle for micronutrient fortification in most parts of the world in terms of universal access, uniformity of consumption and low cost of fortification. Encouraged by the progress made in several countries in implementing successful salt iodisation, efforts have been directed at

examining the feasibility of fortifying salt with iron and other nutrients such as fluorine along with iodine. Fluoridation of edible salt profits from the experience gained in production, quality control and monitoring in respect of the iodisation of edible salt.

After approval to produce and sell fluoridated salt was first given in Switzerland in 1955, the next to follow in Europe was Spain in 1983, then France in 1986, and later Germany (1991), Belgium (1992), Austria (1995), the Czech Republic (1997) and Slovakia (1999). Approvals and legal regulations on fluoridation of salt must take a range of different factors into account. Legislation should address the problem of enforcement (voluntary/mandatory), the areas where fluoridated salt may or may not be sold, the types of salt which may be fluoridated, the minimum levels and maximum limits of fluoride ion in salt, the permitted fluoride substances (potassium fluoride, sodium fluoride), purity criteria for the fluoride compounds, the labelling of packages and claims for fluoridated salt.

Corresponding Author:

Dr. Franz Götzfried

Südsalz GmbH, Salzgrund 67, D-74076 Heilbronn

Tel. +49 7131 6494 116, Fax +49 7131 6494 177

E-mail: franz.goetzfried@suedsalz.de

## Current European legislation

The addition of nutrients (vitamins and minerals) to foodstuffs is regulated exclusively on a national level in all European countries. This has so far also applied for all 25 member states of the European Union. Regarding the addition of fluorides to edible salt, one of two forms of national regulation model are in use:

- addition of fluoride to edible salt is generally permitted.
- addition of fluoride to edible salt requires an individual production and marketing approval.

Fluoridated edible salt is produced in the following European countries: Austria, the Czech Republic, France, Germany, Slovakia, Spain and Switzerland (Fig. 1). Fluoridation of salt in each case is always on a voluntary basis. The consumer has the option of also buying edible salt without fluoride. In the Netherlands, fluoridated edible salt is only produced for export. However, fluoridated salt can be found on the market in many European countries due to the European expansion strategies of major discounters such as Aldi and Lidl of selling fluoridated, iodised salt as well: Austria, the Czech Republic, France, Germany, Greece, Ireland, Italy, Lithuania, Portugal, Slovakia, Spain, Switzerland. The market shares vary widely. Some examples of European fluoridated salts are shown in Figure 2.

There are countries with marginal sales, but there are also countries such as Germany with 65% and Switzerland with 88% market share in household salt sales. In countries without their own production locations, before importing the fluoridated salt special authorisation is obtained or notification made to the responsible

national health authority. The notification procedure is based on the principle of mutual recognition. This procedure applies to products for which it can be proven that they comply with the national rules on food fortification of another EU/EEU Member State and for which thorough safety documentation is available (ARTICLE 28, 30 EUROPEAN COMMUNITY TREATY).

Existing current individual authorisations and legal regulations are summarised in Table I.

### Austria

In a letter from the Federal Ministry of Health and Consumer Protection dated April 10<sup>th</sup>, 1995 to the Austrian salt producer, the fluoridation of household salt with 200–250 mg/kg of fluoride was authorised. The additive is potassium fluoride. Imports must be individually authorised.

### Belgium

The Royal Decree on Nutrients and Foods with Added Nutrients dated March 3<sup>rd</sup>, 1992 originally regulated the fluoridation of edible salt. In the meantime fluoride has been eliminated from the minerals list.

The use of fluoride in food supplements and salt is currently not permitted due to safety concerns despite its inclusion in the Annex of the EU food supplement Directive. It would currently seem that the European Commission accepts the safety concerns presented by Belgium based on a scientific opinion of the Belgian

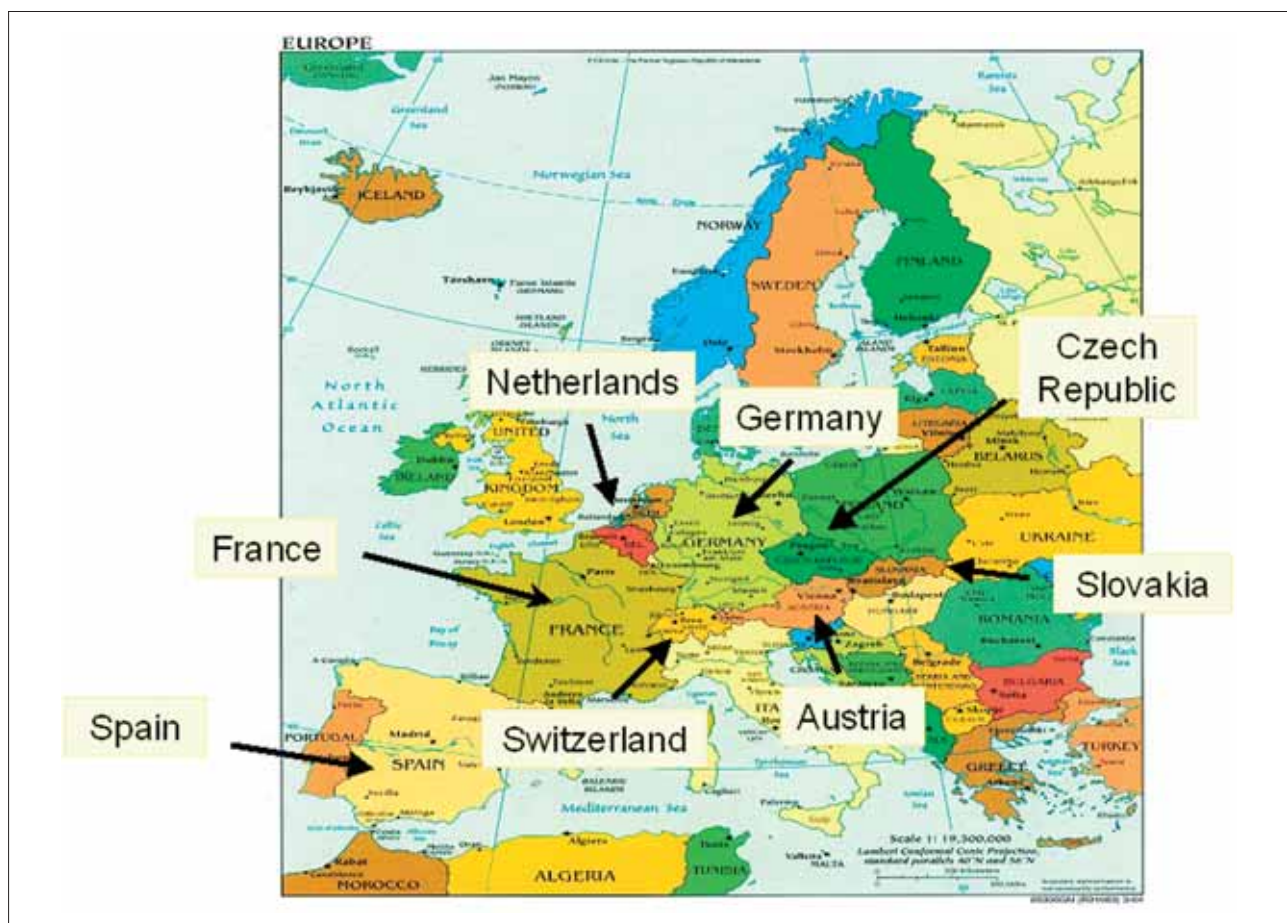


Fig. 1 European countries with production of fluoridated salt



Fig. 2 Examples of European fluoridated salts

Tab. 1 Overview on legislation for fluoridated salt in Europe

Country	Law/Authorisation	Fluoride	Concentration (ppm fluoride)	Availability (H=Household)	Market share (% Household salt)
Austria	Letter from Federal Ministry of Health and Consumer Protection dated April 10 <sup>th</sup> , 1995	KF	200–250	H	6
Czech Republic	Communiqué No. 331 of the Czech Ministry of Agriculture of 1997 on Law No. 110 of 1997	KF, NaF	250	H	15
France	Decree on Edible Salt and Additives for its Fortification dated May 28 <sup>th</sup> , 1997	KF	250 +/- 15%	H School canteens	27
Germany	Exceptional time-limited agreements (Section 37 Foodstuffs and Food Contact Materials Law)	KF, NaF	250 +/- 15%	H	65
Slovakia	Foodstuffs Code, part 3, chapter 23 on Edible Salt (Decree No. 1781/3/1999-100 dated June 2 <sup>nd</sup> , 1999)	KF	260	H	unknown
Spain	Royal Decree 1424/1983	KF, NaF	90–225	H	10
Switzerland	Nutrients Order SR 817.021.55 by the Swiss Department of the Interior, Article 10, dated June 26 <sup>th</sup> , 1995	KF, NaF	250	H Foodstuff processing Commercial caterers	88

Council for Hygiene in 2002, and that the ban on fluoridated salt in Belgium will therefore be maintained.

### Czech Republic

The basis for production and marketing fluoridated, iodised salt for households is to be found in Communiqué No. 331 of the Czech Ministry of Agriculture of 1997 on Law No. 110 of 1997. The prescribed contents are 250 mg/kg of fluoride (potassium fluoride, sodium fluoride) and 20–34 mg/kg of iodine.

### France

In the French Decree dated May 28<sup>th</sup>, 1997 on Edible Salt and Additives for its Fortification, the addition of potassium fluoride in a proportion of 250 mg fluoride per kg of edible salt was approved. This does not apply to salt for the industrial processing of foodstuffs, and not for commercial catering. There are purity standards laid down for the potassium fluoride and the wet dosage is prescribed. A tolerance of +/- 15% is accepted in the fluoride content. Packaging of the fluoridated salt must bear the endorsement: "Not permitted for use when the drinking water contains more than 0.5 mg/L of fluoride." Non-iodised edible salt may also be fluoridated. Since 1993, it has been permissible to use fluoridated edible salt in school canteens, provided the drinking water contains no more than 0.5 mg/L of fluoride.

Edible salt containing sodium fluoride and potassium iodate is not permitted. For this, it is necessary to make an application to the AFFSA (French Food Safety Agency), on the basis of whose statement, the DGCCRF (Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes) will decide. No import licence is required for products which comply with the French law on edible salt.

### Germany

Beginning in 1991, fluoridated, iodised salt imported from France on the basis of a notification procedure was offered on the German market. Today, German salt producers have individual exceptional time-limited agreements for the production and marketing of fluoridated, iodised salt. Legal basis for these exceptional agreements has until now been section 37 paragraphs 1 and 2, item 1 of the Foodstuffs and Food Contact Materials Law. As fluorine substances, potassium and sodium fluoride are permitted. Fluoride content should be 250 mg per kg of salt. The permitted tolerance of the fluoride content is +/- 15%. The licences are only valid for household salt in packages of up to 500 grams. The packaging must bear the wording "with the addition of fluoride" or a corresponding product labelling. The packaging must in addition state "If using this edible salt, medicines containing fluoride should only be taken on the advice of your doctor". In the future, such exceptional licences will be granted in accord-

ance with the conditions of section 68 in the new Foodstuffs and Feeding Stuffs Law.

The Federal Institute for Risk Assessment recommends that fluoride is not used in food supplements and to limit the addition of fluoride to edible salt (DOMKE et al. 2004). In 2002, approval was given for the production and sale of a new multiple fortified edible salt: 20 mg/kg iodine (as potassium iodate), 250 mg/kg fluoride (as sodium fluoride or potassium fluoride) and 100 mg/kg folic acid.

## Slovakia

In Slovakia, fluoridation is regulated by the Slovakian Foodstuffs Code, part 3, chapter 23 on edible salt (DECREE NO. 1781/3/1999-100 DATED JUNE 2<sup>nd</sup>, 1999). The maximum permitted amount of technically pure potassium fluoride is 800 mg per kg of salt. Any launch of a table salt in Slovakia has to be notified to the local or regional Sanitary Inspector at the time of marketing at the latest.

## Spain

In Royal Decree 1424/1983, there are regulations specifically for salt. The addition of potassium and sodium fluoride in proportions of 90–225 mg fluoride per kg of household salt is permitted. Simultaneous iodisation is also possible. For approval of production or of imports, the General Direction for Public Health must be notified of the origin and composition of the product.

## Switzerland

Legal basis for edible salt is the Swiss Foodstuffs Order, Chapter 35: Spices, edible salt, mustard, section 2: Edible salt, articles 361–363. This order defines the requirements for edible salt. Supplementing this, the Nutrients Order by the Swiss Department of the Interior dated June 26th, 1995 regulates the addition of fluoride, iodide and iodate to edible salt. Article 10 (ADDITIVES TO EDIBLE SALT AND DRINKING WATER) hereof lays down that edible salt must contain 20–30 mg per kg iodide or iodate, calculated as iodine, or 250 mg fluoride, calculated as fluorine. In the case of fluoridated edible salt, the following claim is permitted: "Fluoride helps fight caries." Since 1995, companies in the foodstuffs processing sector and commercial caterers have been permitted to use fluoridated edible salt in all cantons on a voluntary basis. Switzerland is the only European country which so far has authorised fluoridation of all edible salt. However, this general use is common in Latin America and the Caribbean.

Both of the producers in Switzerland – United Swiss Saltworks and Saline de Bex – are under an obligation to supply the Swiss population with salt. Due to the existing monopoly situation in salt, imports are not possible.

## The proposed EU Fortified Food Regulation

On November 10th, 2003, the European Commission presented a proposal for a "Regulation on the addition of vitamins and minerals and certain other substances to food", which was passed on to the European Parliament (EP) and the Council. According to this, only those vitamins and/or minerals listed in Annex I are permitted to be used as foodstuffs additives, in the forms listed in Annex II. Fluoride is listed in Annex I, and the substances potassium fluoride and sodium fluoride in Annex II.

In the meantime, the proposed Regulation has been exhaustively discussed both in the EP and in the Council's committees. The EP voted at the first reading on May 26<sup>th</sup>, 2005 to delete fluoride from Annex I, without, however, altering Annex II. Regarding fluoride, in its political agreement of June 3<sup>rd</sup>, 2005, the Council adopted the Regulation proposed by the Commission. According to this, fluoride remains in Annex I and the above substances in Annex II.

In accordance with the co-decision procedure provided for in the EC Treaty, it is now expected that the Council will lay down the common view on the basis of the political agreement and notify this to the European Parliament. The EP can then within three months of notification propose alteration to the common view. We must wait and see whether and how far the EP decides to uphold the decision to delete fluoride.

The Standing Committee on the Food Chain and Animal Health (SCFCAH) can decide to include foods or categories of foods to which vitamins and minerals may not be added. Such decisions will be based on scientific evidence.

The maximum limits and minimum levels for vitamins and minerals are not included in the Regulation as such, only the criteria for how they should be established. The EUROPEAN FOOD SAFETY AUTHORITY (EFSA, 2005) has already published an opinion related to the tolerable upper intake level of fluoride. Purity criteria for the substances listed in Annex II will be established by the SCFCAH at a later stage.

The proposed EU Fortified Food Regulation will supersede the existing national regulations. The Regulation, together with an EU Regulation on nutrition and health claims, is likely to come into force in late 2006 or early 2007.

The results of the new EU Regulations should in particular be as follows:

- a) The addition of fluoride to foodstuffs should be limited to the foodstuffs which have been fortified up to now such as salt, water and chewing gum.
- b) Fluoridation should be restricted to salt for domestic use and for commercial catering only.
- c) The optimum fluoride concentration in the salt should be 250 mg/kg (WHO 1994).
- d) Formulation of a health claim ("Fluoride helps fight caries").
- e) Warning statements ("If using fluoridated edible salt, intake of food supplements containing fluoride and of fluoride tablets should be avoided", "Fluoridated edible salt should not be used if the drinking water contains more than 0.5 mg fluoride per litre").
- f) Purity criteria for sodium fluoride and potassium fluoride.

## Situation in China

Outside Europe, there exists an example of a totally different situation in China. There, the national standard GB 14880-94 "Hygienic Standard for the Use of Nutritional Fortification Substances in Foods" contains no provision for the fortification of foodstuffs with fluoride.

On the other hand, in the two Chinese salt standards there are different values given for maximum permitted fluorine content. The China National Food Safety mandatory standard GB 2721-1996 "Table Salt Hygienic Standard" specifies that the content of fluorine shall not exceed 25 mg/kg, whereas the mandatory standard GB 5461-2000 "Table Salt" specifies that the content of fluorine shall not exceed 5.0 mg/kg. This is a consequence of the fluorosis which is widespread in China on account of the high natural incidence of fluoride in drinking water.

## Codex Alimentarius

General Principles for the Addition of Essential Nutrients to Foods were adopted by the Codex Alimentarius Commission (CAC) at its 17<sup>th</sup> session in 1987. Further amendments were adopted by the 18<sup>th</sup> and 19<sup>th</sup> CAC sessions in 1989 and 1991. According to the General Principles, essential nutrients may be added to foods for the purpose of restoration, nutritional equivalence of substitute foods, fortification/enrichment and ensuring an appropriate nutrient composition of a special purpose food. The General Principles point out that fortification/enrichment should be the responsibility of national authorities since the types and amounts of essential nutrients to be added and foods to be fortified will depend upon the particular nutritional problems to be corrected, the characteristics of the target populations, and the food consumption patterns of the area. No revision of this position is foreseen in the near future.

In the Codex Standard for Food Grade Salt CX STAN 150-1985 (REVISION 1-1997, AMENDMENT 1-1999, AMENDMENT 2-2001) the following is laid down in section 3.3 "Use as a carrier":

"Food grade salt shall be used when salt is used as a carrier for food additives or nutrients for technological or public health reasons. Examples of such preparations are mixtures of salt with nitrate and/or nitrite (curing salt) and salt mixed with small amounts of fluoride, iodide or iodate, iron, vitamins, etc., and additives used to carry or stabilize such additions".

## Zusammenfassung

In sieben europäischen Ländern gibt es für die Herstellung und das Inverkehrbringen von fluoridiertem Speisesalz nationale, gesetzliche Regelungen oder individuelle Genehmigungen für

Salzhersteller. Andere Mitgliedsstaaten der EU importieren auf Basis des Grundsatzes des freien Warenverkehrs fluoridiertes Speisesalz.

Die europäischen Länder fluoridieren das Salz auf freiwilliger Grundlage. Es wird erwartet, dass in naher Zukunft eine europäische Regelung die nationalen Bestimmungen ablöst.

## Résumé

Dans sept pays européens, il y a, pour la fabrication et la mise en circulation de sel de table fluoré, des règlements nationaux légaux ou des autorisations individuelles pour les fabricants de sel. D'autres états membres de l'UE importent du sel de table fluoré sur la base du principe de la libre circulation des marchandises. Les pays européens fluorent le sel sur une base facultative. On s'attend à ce que, dans un proche avenir, un règlement européen remplace les conditions nationales.

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