

LEGISLATION ON IODINE PROPHYLAXIS

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Introduction

Experience has shown that iodine deficiency is the essential etiological factor in endemic goitre and that iodine prophylaxis has been successful in remedying it. In Switzerland,^{13, 15} for example, where iodine prophylaxis was introduced more than 30 years ago, endemic goitre has largely disappeared, and the use of iodized salt has not had any pathological consequences. At first sight it is surprising, therefore, to find that only a few countries have introduced this preventive measure and enforced it by law—or to find that this step has only been taken quite recently.

It is true that insufficient iodine intake is not the sole cause of endemic goitre. A variety of other factors, whose nature and physio-pathological mechanisms are still imperfectly understood, may play a secondary role and, in some cases, may even be of major importance.¹⁴ Even so, the effects of these other etiological factors can usually be countered by increased iodine intake, and in most countries where goitre is endemic the reason why iodine prophylaxis has not been made compulsory by law are of quite a different nature. This emerges clearly from the study of the prevalence and geographical distribution of endemic goitre made by Kelly & Snedden, in which the measures that have been taken so far are also reviewed (see pp. 27-233).

In fact, health administrations in many countries find themselves confronted with technical obstacles or policy difficulties which make it impossible to take administrative or statutory measures. While in some countries or regions the technical problem is only of secondary importance, in others it may be a very difficult one to overcome. In certain countries, only unrefined, coarsely crystalline salt is used. Furthermore, climatic factors, such as temperature and humidity, may render suitably iodized salt unstable, and thus lead to further difficulties in the way of general

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See, for example, the chapter *Etiology of endemic goitre* by J. Roche & S. Lissitzky, page 351.

prophylaxis based on this method. Again, some peoples may regard the introduction of refined and iodized salt with suspicion.¹⁰

There are also questions of policy: it may be difficult for the health administration of a country where there are other health problems demanding priority to persuade the legislative authorities that there is real justification for introducing iodine prophylaxis.

In addition the introduction of iodized salt raises economic problems:¹³ special equipment is required, iodine compounds are expensive, and so is the labour required for homogeneous mixing and the proper packing to prevent loss of iodine. Iodine prophylaxis in two countries (Argentina, province of Mendoza,⁵ and Mexico,¹²) was attended by economic difficulties. If, in addition to all this, it is remembered that some circles—even medical ones—are opposed to the consumption of iodized salt, it is hardly surprising that very few countries have made iodine prophylaxis compulsory. However, the most simple explanation of all is that in many countries no sampling survey or systematic examination of the population has been made until quite recently. In fact, it is only as a result of such surveys that in the last few years several Latin American countries have introduced regulations making iodine prophylaxis compulsory.

The various surveys have shown that endemic goitre is present, to a greater or lesser extent, in some 100 countries and territories, but of these only about ten have adopted legal measures to combat the disease. In Austria, the USA⁵ and the United Kingdom,⁷ the recommendations of the scientific committees were in favour of the introduction of iodized salt but did not lead to the enactment of legislation.

In some countries iodine prophylaxis has been applied on a purely optional basis or left to the initiative and the propaganda efforts of the health authorities. This raises an important question: should iodine prophylaxis be enforced by law or should the method of persuasion and propaganda be adopted?

The experience of various countries which have adopted one or other of these approaches shows that legal compulsion is the only rapid way to bring about the consumption of an adequate amount of iodized salt. Some authors estimate that 90% of the salt consumed must be iodized if endemic goitre is to be eradicated. Sollgruber¹¹ states that in Austria, in spite of propaganda in favour of the consumption of iodized salt, the population makes practically no use of "Vollsalz", although they can obtain it without difficulty. In the State of Ohio in the USA, where experiments on prophylaxis with iodized salt were made even before those in Switzerland, a recent survey (1954) showed that it was still being insufficiently used.⁴ In the State of Michigan,¹ there is a sharp drop in the consumption of iodized salt as soon as there is any relaxation in the efforts made to educate the public on this question. When iodized salt was introduced officially into New Zealand in 1924, its use was not made compulsory.^a Initially, con-

sumption was only 5% of all salt consumed. This figure had risen to 30% in 1934 as a result of intensive propaganda. In 1940, the New Zealand Medical Research Council's Thyroid Research Committee recommended that non-iodized salt should be supplied only to people asking specifically for it and although this policy has not been rigidly followed, 80% of the population were using iodized salt by 1957. In the United Kingdom, the Goitre Subcommittee of the Medical Research Council noted that although individual medical men had recommended the use of iodized salt within the district that they served, there had been no public demand for it.³

In the Netherlands,² on the other hand, attention was drawn to the danger of the public taking the initiative in regard to iodine prophylaxis. This may lead to excessive consumption of iodine with all its attendant dangers. For this reason it is essential to establish official standards.

It was probably because of the above considerations that the WHO Study-Group on Endemic Goitre recommended that "...all food salts should be iodized compulsorily in any country or area in which goitre is endemic, local variations in incidence of the disease being disregarded."¹⁶

Legislation

Most of the regulations relating to the iodization of kitchen salt and other methods of iodine prophylaxis date from 1950 onwards. However, the use of iodized salt was first made compulsory in 1924⁸ (Switzerland, Cantons of Nidwalden and Vaud). Between 1924 and 1950, similar legislation was introduced in Canada (1949), Costa Rica (1941), Hungary (1948), Mexico (1942) and the Netherlands (1942).

Apart from these legal provisions, ministerial circulars were issued in some countries (Austria, 1923; Sweden, 1936, 1950) for the sole purpose of promoting iodine prophylaxis. In Switzerland also, cantonal health authorities issued circulars for the same purpose (for example, Canton of Zurich, 1923).

Nevertheless, most of the regulations of this nature have been introduced since 1950: Brazil (1953, 1956); Chile (1959); Colombia (1955) (under the terms of an earlier text of 1945 the Institute of Nutrition was created and the executive empowered to make the necessary arrangements in order to find economic ways and means of combating goitre); Bulgaria (1956, 1958); Guatemala (1954, 1955); Panama (1955); Paraguay (1954) (text establishing measures of a temporary character only); Union of South Africa (1954) and Yugoslavia (1953). It seems also that the use of iodized salt is compulsory in some parts of Northern Nigeria. In the USSR, the Ministry of Health issued instructions on the iodization of kitchen salt in the period 1950-1955.

¹⁶ See also the chapter *Prevalence and distribution of endemic goitre* by Kelly & Snedden, p. 27.

Of the legal texts mentioned above, the only ones making the use of iodized salt compulsory throughout the national territory are those of Canada, Colombia, Costa Rica, Guatemala, Panama, Paraguay and Yugoslavia. In Switzerland, where the authority in matters of health is decentralized, the measures are applicable throughout the cantons where they are promulgated.

In Brazil, Bulgaria, Hungary, Mexico and Peru, the legislation covers only the goitrous areas. In the Netherlands, the measures are applicable to certain communes. In Mexico, the law applies only to areas where more than 20% of the inhabitants are suffering from goitre, and in Brazil, only to those localities where the endemicity rate exceeds 15% in male and 25% in female children. It has been suggested that iodine prophylaxis be instituted when 10% or more of children between 7 and 15 years of age show visible enlargement of the thyroid gland.⁶

In Paraguay, the 1954 legislation was of a temporary character only: it provided for the administration of iodized chocolate to schoolchildren for 30 weeks pending the introduction of prophylactic measures to cover the whole population.

The Chilean legislation authorizes the introduction of iodized salt but does not indicate whether its use is obligatory.

Obviously, the existence of a legislative text does not necessarily mean that it is applied. Stacpoole¹² refers to the fact that in Mexico (where iodized salt was to be used in the goitrous regions, in which the endemicity rate was high) the technical and economic difficulties encountered were such that, several years after the promulgation of the regulations, only a few thousand people were consuming iodized salt. It is true that other techniques were used, but these were only for the benefit of schoolchildren.

Levels of Iodization

1. *Iodized salt*

The most commonly used method of remedying iodine deficiency is the iodization of kitchen salt. The WHO Study-Group on Endemic Goitre¹⁶ recommended that "food salt" be iodized in the proportion of 1:100 000 (10 mg per kg), on the basis of a daily salt consumption of 10 g. It was agreed, however, that this proportion might be varied in cases where daily salt consumption has been shown to differ from 10 g. The proportions of iodine or iodide required by the regulations of the various countries are as follows:

Brazil: 10 mg of iodine per kg of salt (1: 100 000).

Bulgaria: 20 g of potassium iodide stabilized with 10 kg of sodium thio-sulfate and 200 g of magnesium carbonate per ton of salt (1: 50 000).

Canada: 100 mg of potassium iodide per kg of salt (1: 10 000).

Chile: 100 mg of iodine per kg of salt (1: 10 000), in the form of potassium iodide (130 mg per kg), sodium iodide (120 mg per kg), potassium iodate (170 mg per kg), or sodium iodate (160 mg per kg). If iodide is used, it must be stabilized by addition of one of the following substances or mixtures, the quantities indicated being for 1 kg of salt:

- (a) basic magnesium carbonate (10 g);
- (b) basic magnesium carbonate (5-10 g) plus sodium thiosulfate (1 g);
- (c) sodium thiosulfate (1 g) plus basic carbonates of magnesium and calcium (7.5 g) plus calcium oxide (1 g);
- (d) tricalcium phosphate (10 g);
- (e) tricalcium phosphate (9 g) plus sodium bicarbonate (0.5 g) plus dextrose (9 g).

Colombia: one part of iodine in 10 000-20 000 parts of salt.

Costa Rica: one ounce of potassium iodide per ton of salt (1: 36 000).

Guatemala: addition of a mixture of potassium iodate and calcium carbonate in the proportion of 1:9, in such an amount that the final product contains not more than one part of iodine in 10 000 parts of salt nor less than one part of iodine in 15 000 parts of common salt.

Hungary: 10 mg of potassium iodide per kg of salt in endemic zones (1: 100 000); 5 mg of iodide per kg of salt, against medical prescription,¹⁴ in para-endemic zones (1: 200 000).

Mexico: 15 mg of potassium or sodium iodide per kg of salt (1: 66 000).

Panama: one part of iodine in 10 000-15 000 parts of salt.

Switzerland: in two cantons (Appenzell and St-Gallen), 10 mg of potassium iodide per kg of salt (1: 100 000); in the other cantons, 5 mg of potassium iodide per kg of salt (1: 200 000).

Union of South Africa: not less than 10 p.p.m. (1: 100 000) and not more than 20 p.p.m. (1: 50 000) expressed as potassium iodide (standard for "Iodine-fortified salt").

Yugoslavia: 10 mg of potassium iodide per kg of salt, or an amount of sodium iodide containing the same quantity of iodine (1: 100 000).

In the USSR also, ministerial instructions issued in 1950 provided for the iodization of kitchen salt in the proportion of 10 mg of potassium iodide per kg of salt.

In France,⁹ the Higher Health Council (Conseil supérieur d'Hygiène) recommended that the iodine content of common salt expressed as sodium iodide, should be not less than one part and not more than one-and-a-half parts in 100 000 parts. No stabilizing agents should be added to iodized salt.

2. *Other methods of iodine prophylaxis*

Netherlands. Formerly the quantity of potassium iodide to be incorporated in kitchen salt for use in bread-making in the communes mentioned in the relevant Ministerial Order was 31 mg per kg of salt; at the present time the quantity of iodide has been increased to 39 mg. In 1952, the use of iodized salt in bread-making was compulsory in 260 communes.

Paraguay (transitional measures). Each schoolchild receives one tablet of chocolate containing 10 mg of iodine once a week for 30 weeks.

Sweden (1936). The circular of 1936 states that two methods of prophylaxis are available: one consists of the addition of a very small amount of iodized salt to common salt, for example 1 g of iodized salt per 10 kg, the other is school prophylaxis. During the first trials, schoolchildren were given one pastille of iodized liquorice, containing 200 mg of sodium iodide, every day for ten days in spring and in autumn. No cases of Basedow's disease were observed. In 1950 the instructions were changed, and it is now recommended that iodized sweets should not be distributed to children except where it is certain that iodized salt is not being consumed. The iodized sweets contain one mg of iodine and are distributed once a week.

The regulations may provide for certain exceptions. Thus, in Switzerland, it was already possible in 1924 to obtain non-iodized salt in two cantons on presentation of a medical prescription and at the express wish of the person concerned. In Costa Rica, the salt co-operative supplies non-iodized salt to pharmacies and to persons presenting an appropriate medical certificate. This prevents consumption of iodized salt by persons in whose case there is some medical contra-indication. In Panama also, pharmacies may sell non-iodized salt on presentation of a medical prescription.

Control of Salt Iodization

In some cases, the regulations provide for supervision of iodization factories and installations, and for analysis of samples of iodized salt to check whether the product contains the stipulated amount of iodine.

In Brazil, for example, the rule is that the factories must be inspected at least every four months, and salt samples taken at each inspection. In Bulgaria, iodized salt must be analysed every two months and more often if there is any suspicion of its deterioration during storage; any stock of salt whose iodine content falls below 5 mg per kg must be immediately disposed of. Requirements in the USSR (1950) are the same; the instructions also provide that consignments of salt must be accompanied by a certificate indicating the iodine content and that, if difficulties arise during transport or if the packing is defective, the salt must also be analysed on arrival. Salt

samples are taken by representatives of the health and epidemiological services of the USSR Ministry of Health or by the authorities in charge of goitre control. In Colombia, the Ministry of Health is responsible for the inspection of iodized salt; it takes samples and supervises the preparation. In Guatemala, the General Association of Salt-Makers is authorized to inspect private factories preparing the salt, and is responsible for notifying the health authorities of any fault, deficiency or irregularity and for taking the measures necessary in each case to remedy such defects. The Public Health Administration may also order the inspection of factories by departmental delegates or health inspectors in order to ensure that the salt is being correctly iodized. For this purpose the Administration has samples taken both where the salt is prepared and where it is distributed. In Peru, supervision is entrusted to the medical officers in charge of the health units of the departments where the State salt enrichment factories are situated. Such factories are required to report each month to the Department of Endemic Goitre the quantity of salt that has been iodized and to supply samples taken at both the factory and the place of distribution.

Packing and Labelling of Iodized Salt

Some regulations include conditions governing the packing and labelling of iodized salt offered for sale. In Bulgaria, fine iodized salt for retail sale must be packed in containers made of parchment-paper and cardboard; salt for wholesale supply must be in a triple wrapping. The following details must appear on the packing: the name "Iodized kitchen salt", the iodine content (mg per kg) at the time of delivery by the supplier or manufacturer, the date of production, the name of the supplier or manufacturer, and the net weight. In Guatemala also, the packing must carry, in legible print, the name of the manufacturer, the manufacturer's trademark, the place of manufacture, and the countermark of the General Association of Salt-Makers. In the USSR the salt is sold retail in packages of 300-1000 g and the packets, consisting of multiple wrappers, must show the following details: "Iodized kitchen salt", quantity of iodide in mg per kg at the time of delivery by the manufacturer, the manufacturer's name, the quality of the salt, the size of the crystals, and the net weight. In Canada, the presence of iodide must be indicated on the label.

Provisions relating to Technical and Financial Assistance

The introduction of iodine prophylaxis raises technical and economic problems, but only a few of the regulations contain any provisions to facilitate the preparation and distribution of iodized salt.

In Brazil, the Ministry of Health facilitates the importation of sodium iodide or potassium iodide and supplies it at cost price to firms preparing iodized salt. The National Salt Institute, in collaboration with the Health

Departments of the States concerned, gives the salt merchants technical assistance in the installation of the equipment necessary for the preparation of iodized salt. Iodized salt, in packages marked accordingly, is carried at a reduced tariff on the railways.

In Guatemala, any firm producing more than 4000 quintals (400 000 kg) of salt per year must acquire and install the necessary equipment to enable it to supply iodized salt. The General Association of Salt-Makers transmits to the competent authorities the necessary applications for exemption from customs duties, etc., in order to facilitate the purchase of equipment for the preparation of iodized salt. Where the annual production of manufacturers is less than 4000 quintals of salt, the General Association of Salt-Makers must set up iodization factories for the benefit of these producers. The Association provides small producers with all the facilities and technical aid necessary for the correct iodization of their salt.

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Legislation

Brazil

- Law No. 1944 of 14 August 1953, prescribing the iodization of kitchen salt intended for human consumption in the goitrous regions of the country (see *Int. Dig. Hlth Leg.*, 1955, **6**, 666)
- Decree No. 39814 of 17 August 1956, to delimit the goitrous zones of Brazil and making provision for the use of iodized salt and other provisions connected therewith (see *ibid.*, 1958, **9**, 420)

Bulgaria

Sanitary Regulations of 10 October 1956 on iodized kitchen salt (see *Int. Dig. Hlth Leg.*, 1957, 8, 608)

Extract from Decree No. 18 of 3 February 1958 of the Council of Ministers, to introduce goitre control by means of iodine into areas in which goitre is endemic (see *ibid.*, 1959, 10, 599)

Order No. 367 of 24 April 1958 of the Minister of Public Health and Social Welfare, relating to the introduction of goitre control by means of iodine into areas in which goitre is endemic (see *ibid.*, 1959, 10, 599)

Canada

Office Consolidation of the Food and Drugs Act and of the Food and Drug Regulations (1954)

Chile

Decree No. 387 of 13 May 1959, authorizing the manufacture and sale of iodized, purified table salt and of iodized table salt

Colombia

Decree No. 0591 of 10 March 1955, instituting the preparation and use of iodized salt and fixing a period of two years within which such measures are to be carried out (see *Int. Dig. Hlth Leg.*, 1956, 7, 370)

Costa Rica

Decree No. 6 of 24 April 1941, concerning the iodization of salt

Guatemala

Decree No. 115 of 19 October 1954 (see *Int. Dig. Hlth Leg.*, 1956, 7, 651)

Regulations of 24 March 1955 for the application of Decree No. 115 of the President of the Republic, promulgated by the Ministry of Public Health and Social Welfare, relating to the iodization of common salt (see *ibid.*, 1956, 7, 651)

Mexico

Decree of 13 March 1942, declaring the prophylaxis of endemic goitre to be in the public interest

Netherlands

Order of 23 March 1942 concerning iodized salt (see *Bull. Off. int. Hyg. publ.*, 1942, 34, 112)

Order of the Minister of 4 February 1952, determining the quantity of alkali-metal iodide to be contained in iodized salt per kilogram of kitchen salt, etc. (see *Int. Dig. Hlth Leg.*, 1954, 5, 97)

Panama

Law No. 17 of 25 January 1955, requiring the addition of iodine to common salt for consumption on the territory of the Republic (see *Int. Dig. Hlth Leg.*, 1958, 9, 315)

Paraguay

Decree No. 8265 of 14 October 1954, to institute control of endemic goitre in school-children in Paraguay (see *Int. Dig. Hlth Leg.*, 1958, 8, 125)

Peru

Ministerial Decision of 9 November 1957 on the supervision of salt enrichment plants (see *Int. Dig. Hlth Leg.*, 1958, 9, 811)

Sweden

Royal Medical Board Circular of 27 April 1936 on measures for the prevention of endemic goitre (see *Bull. Off. int. Hyg. publ.*, 1937, **29**, 2286)

Royal Medical Board Circular of 18 February 1950 containing further particulars of the free supply of preventive medicines to certain women and children, and of medicines to women suffering from pregnancy diseases

Switzerland

Ordinance of 26 May 1936, to regulate trade in foodstuffs and various articles in everyday use

Switzerland (Canton of Zurich)

Circular of 16 April 1923 to local health authorities and medical practitioners in the Canton of Zurich concerning the distribution of iodized salt to the public and the control of endemic goitre in schools

Circular of 14 November 1931 of the Zurich Public Health Department to medical practitioners, medical officers, public health officers, and food inspectors concerning the control of endemic goitre

Union of South Africa

Government Notice No. 2519 of 10 December 1954. Amendment of regulations made under the Food, Drugs and Disinfectants Act, No. 13 of 1929 (see *Int. Dig. Hlth Leg.*, 1956, **7**, 693)

USSR

Instructions of the Minister of Health of 14 February 1950 concerning iodization of kitchen salt

Yugoslavia

Decree No. 371 of 26 October 1953 on the iodization of salt intended for human consumption and for consumption by domestic animals (see *Int. Dig. Hlth Leg.*, 1955, **6**, 368)