Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs

Arbeitskreis Jodmangel (AKJ), the German co-ordinating committee on preventing iodine deficiency disorders (IDD), welcomes the opportunity to comment on the above-mentioned discussion paper regarding the use of iodised salt in Germany and the European Union. Given that IDD problems persist in Europe, there is a need to harmonise the widely varying regulations on iodine within the European food and feed market, particularly to ensure universal salt iodisation (USI) as the preferred method for improving the iodine status of humans.

The main issues that the legislation needs to address can be summarised as follows:

- The addition of iodine to foodstuffs should be limited to foodstuffs which have already been fortified up to now such as table salt and food supplements.
- The extension of iodine addition to other foods should be rejected because of the risk of triggering a life-threatening thyrotoxic crisis in older people with undiagnosed thyroid autonomy.
- For the same reason, the maximum amounts in food supplements should be fixed at 100 µg per daily portion of consumption as recommended by the manufacturer.
- Minimum amounts for iodine in food supplements should be established and should be 15% of the recommended allowance specified in the Annex to Directive 90/496/EC, i.e. 22.5 µg per daily portion of consumption as recommended by the manufacturer.
- Europe-wide uniform minimum and maximum amounts (20 and 40 mg/kg salt) should be established for the iodisation of table salt. In either case, the Codex Alimentarius Standard for food-grade salt should be adopted as a minimum requirement in legislation by all EU Member States.

General aspects

Arbeitskreis Jodmangel (AKJ) was established in 1984 as national co-ordinating committee on preventing iodine deficiency disorders (IDD) in Germany. It consists of thyroidologists, endocrinologists, other physicians and scientists primarily specialising in human nutrition as well as animal nutrition. It is supported by the salt and pharmaceutical industry and by the government. The *AKJ* welcomes the initiative to harmonise the widely varying regulations on the addition of vitamins and minerals including iodine to foods within the European Union. There are special issues regarding iodine which were not covered by the discussion paper, and which should also be discussed as part of the consultation process:

- Iodine deficiency remains a problem for many European countries, despite their efforts to promote the use of iodised salt. The main cause of this situation is due to the lack of awareness and consequently the absence of appropriate action by national authorities, medical doctors and the public at large.
- There are various different national regulations on the addition of iodine to salt for human and animal consumption and for the food industry. As a result, the free trade of foodstuffs produced using iodised salt has taken place only at a very limited level.
- There are shortcomings in relying solely on numerical tolerable upper intake levels (ULs) for iodine to establish maximum amounts for foods. There is a need to consider how differences in iodine status influence susceptibility to excess iodine especially in the elderly and other vulnerable population groups. This should be taken into account when setting maximum levels for iodine in specific foods or categories of foods.

It should be mentioned that there are 4 important areas which must be considered in connection with the current European and national legislation/regulation in setting minimum and maximum amounts for iodine in foods:

- Iodisation of salt for human consumption (household, bakery and food industry)
- Addition of iodine to food supplements
- Addition of iodine to other foods
- Addition of iodine to feedingstuffs of farm animals, which can increase the iodine content in food of animal origin

Current iodine status and the regulatory problem with regard to universal salt iodisation in Europe

Recent studies have shown that the iodine intake of more than half of the population in western and central Europe is still inadequate (**Table 1**) and mild iodine deficiency is re-emerging as a widespread problem in the general population (Manz et al., 2000; WHO, 2000; ICCIDD, 2002; 2004).

A diet deficient in iodine is associated with a wide range of adverse health effects, with the foetus, neonate, young children and preadolescents being at greatest risk from IDD. The most damaging effect of iodine deficiency is on the developing brain, especially during the foetal and neonatal periods. Mild iodine deficiency can cause subtle deficits in visual motor skills, hearing and intelligence. For women of child-bearing age, iodine deficiency reduces fertility and increases the risk of miscarriage or stillbirth. Mild iodine deficiency over long periods of time can result in an autonomous or overactive thyroid that produces thyroid hormone in direct correlation with iodine intake regardless of circulating thyroid hormone levels. When an additional dietary intake of iodine increases more than 200 µg per day in a person with an autonomous thyroid, the result can be iodine-induced hyperthyroidism (IIH). However, the correction of mild iodine deficiency helps prevent the formation of autonomous thyroid and therefore minimises IIH, but only for those who haven't already developed autonomous thyroid areas (Hetzel and Clugston, 1998). Thus, IDD represent a significant threat to the health, wellbeing and productivity of the European community.

Reasons for low iodine intake may include:

- A reduction in the use of salt in cooking and table salt (particularly iodised salt).
- Consumption of processed foods, which do not contain iodine or iodised salt.
- Less iodine in milk because of changes in animal care and feeding.

In countries without own production of iodised salt, special authorisation needs to be obtained or notification to be made to the responsible national health authority before importing iodised salt. 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 and 30 of the European Community Treaty; European Community, 2002). Several German companies have reported problems exporting salt to Austria, the Netherlands, France and Belgium. These problems arose from differences in opinion: regulations regarding the composition and production methods, maximum and minimum allowed levels of fortification, labelling of the products and the name under which the products are sold (Deloitte & Touche, 2000).

Table 1: A comparison of iodine nutritional status in some European countries

Country	Ioduria median [µg/l]	Iodine intake	Iodine nutritional status
Belgium	80	Inadequate	Mild iodine deficiency
Denmark	38-110	Inadequate	Mild/moderate iodine deficiency
Germany	83-99	Inadequate	Mild iodine deficiency
France	83	Inadequate	Mild iodine deficiency
Greece	84-160	Partially inadequate	Mild iodine deficiency to optimum
Netherlands	155	Adequate	Optimum
Austria	98-120	Adequate	No iodine deficiency
Poland	>100	Possibly adequate	No sign of iodine deficiency apart from pregnant women
Spain	50-100	Inadequate	Mild iodine deficiency
Sweden	>100	Possibly adequate	No sign of iodine deficiency, lack of monitoring
Switzerland	115	Adequate	Optimum
Hungary	<100	Inadequate	Mild iodine deficiency
United Kingdom	141	Adequate	Optimum

(According to ICCIDD, 2004)

The differences in iodine status can be explained by the fact that the legal preconditions for universal iodised salt prophylaxis vary considerably in Europe.

Table 2 give an overview of regulations in 31 European countries, including 20 countries of the European Union (Cyprus, Estonia and Latvia are not included). When viewing this table it must be kept in mind that the existence of regulations does not guarantee that in a given country the iodised salt program is already operating successfully. Of the 25 EU Member States, 7 have compulsory enforcement of iodised salt use. Ten EU Member States permit iodide (KI or NaI) only, two permit iodate (KIO_3) only and nine both iodide and iodate. There are also differences in the existing maximum levels of iodine in salt (8-60 mg/kg). On average only 56% of all households in Europe use iodised table salt (WHO target >90%). It should be noted that restriction of iodisation to discretionary salt i.e. cooking/table salt only affects 15 to 30% of salt intake in countries where food products are the major source of dietary salt intake. From an average intake of 10 g salt/day, only 3 g/day are theoretically playing a role as iodine carrier in that case. Moreover, iodine loss should not be ignored when trying to quantify the iodine content of salt and the iodine intake depending on salt.

In most Member States and other European countries it would make sense to take into account the WHO recommendation aimed at universal salt iodisation (USI) and to permit the use of iodised salt for food processing (ICCIDD *et al.*, 2001). It must also be taken into account that the iodisation of feedstuffs makes an indirect but significant contribution to iodine supply. However, USI has not been adopted in several European countries – Denmark, France, Greece, Ireland, Italy, the Netherlands, Poland, Portugal and Spain – due to the fact that there are no legal provisions for the iodisation of feedstuffs in these countries (Delange et al., 2002; Delange and Hetzel, 2003; WHO, 2000).

On the other hand, in Finland, Norway and the United Kingdom, all salt is iodised and cattle are fed iodised fodder. Endemic goitre has disappeared and iodine intakes in the UK have risen progressively over the last half century. Almost all iodine intake comes from animal foods, and only 2.5% from iodised salt. An average daily intake of 255 µg/person/day has been calculated. Iodine is added to animal feeds, and consequently it appears in milk and milk products, and this may be increased by the use of iodine-based disinfectants. Currently, the UK does not appear to have iodine deficiency; this has been called "iodisation by default", and it is principally the result of the use of iodine in the dairy industry and the greater availability of dairy products (ICCIDD, 2004; Dahl et al., 2003).

This situation is totally different from the situation in other EU Member States that have improved the iodine status of the population by more supply of iodised salt (WHO, 2000; ICCIDD, 2004).

As not all of these countries have introduced regular monitoring, the relative impact of these initiatives is not clear although there has been a documented overall improvement in iodine status following the implementation of the various approaches to iodine fortification. Control measures should, however, ensure that the median of urinary iodine excretion of school pupils and adults is, if possible, in the optimum range of 100-199 µg/l. More particularly, there should be no sudden increase in iodine intake in order to avoid any rapid exceeding of the median of urinary iodine excretion of 200 µg/l. According to WHO/UNICEF/ICCIDD (2001), the risk of an iodine-induced hyperthyroidism in sensitive individuals increases with iodine excretion of 200-299 µg/l. In the case of an ioduria >300 µg/l, there is also a higher risk of the development of immunological thyroid disorders (Delange et al., 2002).

Table 2: Regulations governing universal salt iodisation (USI) in some European countries and market shares of iodised household salt

Country	Legal status	Permitted iodine source	Iodine content (mg/kg salt)	Appli-cations	Market share of house-hold salt (%)	Iodisation of feedstuffs
Albania		KI	25	R	56	N
Austria	C	KI, KIO_3	15-20	R, B, F	95	Neg.
Belgium	V	KI, NaI, KIO_3	6-45	R, B, F	10	Y
Bosnia	C	KI	5-15	R	37	Y
Bulgaria	C	KIO_3	22-58	R, B, F	90	N
Croatia	C	KI, KIO_3	25		90	Y
Czech Republic	C	KI, KIO_3	20-34		90	Y
Denmark	C	KI	8-13	R, B		
Finland	V	KI	20	R	>90	Y
France	V	NaI	15	R	55	Y
Germany	V	KIO_3	15-25	R, B, F	84	Y
Greece	V	KI	50	R	18	N
Hungary	C	KIO_3	15		10-50	Y
Ireland	V	KI	25	R		N
Italy	V	KI, KIO_3	30	R, B, F	3	N
Lithuania	V	KI, KIO_3	10-40		12	Y
Luxembourg	V	NaI, KIO_3	10-25			Y
Macedonia	C	KIO_3	20-30		100	Y
Netherlands	V	KI, NaI, KIO_3	20-50 househ. 45-85 bakers	R, B, F	60	
Norway	V	KI	5			Y
Poland	C	KI, KIO_3	20-40	R	90	N
Portugal	V	KI	11	R, F		N
Romania	C	KIO_3	15-25	R, F	25	Y
Slovakia	C	KI	15-35		85 (imports;	Neg.
Slovenia	C	KI	5-15			Y
Spain	V	KI, KIO_3	60	R	16	
Sweden	V	KI, NaI	50	R		Y
Switzerland	V	KI, KIO_3	20-30	R, B, F	94	Y
Turkey	C	KIO_3	20-40		64	N
United Kingdom	V	KI	10-22		2	Y
Yugoslavia (Serbian Rep.)	C	KI, KIO_3	12-18	R,F	73	N

V: voluntary. C: compulsory.
KI = Potassium iodide, NaI = Sodium iodide, KIO_3 = Potassium iodate.
R = retail, B = bread, F = processed food. processed food
Y = yes, N = no, Neg. = negligible.
Void cases: no information available.

Data adapted from ICCIDD (2004), J. de Jong (2004), F. Delange (2002) and WHO (2000)

Uncertainties in derivation of tolerable upper intake levels (ULs) for iodine
Various scientific bodies like FAO/WHO (2001), FNB (2000), SCF(2002) focus their risk assessment on the same effects, in particular the impact of iodine surplus on thyroid function, which in turn depends on current individual iodine status. The differences in the derived tolerable upper intake levels (ULs) mainly result from the application of divergent uncertainty factors. This testifies to a certain degree of uncertainty when it comes to assessing the same study results. However, in the final instance it is due to the ongoing, in some cases, very different iodine nutritional supply situation in individual countries which determines the "window of iodine intake" at which fewer thyroid diseases generally occur (Laurberg et al., 2001). In the opinion of the SCF it is stated that the derived UL does not apply to populations with iodine deficiency disorders, as these are more sensitive to iodine exposure (SCF, 2002).
An overview of the ULs for iodine derived for various age groups by three scientific bodies is given in **Table 3**.

Table 3: Comparison of the ULs of the FAO/WHO Expert Consultation, FNB and SCF

Age group	UL (FAO/WHO, 2001) µg/kg bw/day	UL (FNB; 2000) µg/day	UL (SCF, 2002) µg/day
Premature babies	100	–	–
Infants, 0-6 months	150	–	–
Infants, 7-12 months	140	–	–
Children, 1-3/4-6 years	50	200/300	200/250
School pupils, 7-10/11-14 years	50	600	300/450
Adolescents, 14-18 years	30	900	500
Adults (≥ 19 years)	30	1100 (900)[1]	600
Pregnant and lactating women	40	1100 (900)[1]	600

[1] 14-18 years

By contrast, the Expert Group on Vitamins and Minerals of the United Kingdom (EVM) was unable to derive a safe upper level of intake for iodine. Instead, it laid down a guidance level of 0.5 mg/day (corresponding to 0.003 mg/kg body weight for an adult weighing 60 kg) for supplements. At this level of iodine intake, which can be taken up additionally to dietary iodine (0.43 mg/day = 97.5 percentile), EVM does not expect any side effects of any kind for adults (corresponding to an intake of 0.94 mg and 0.015 mg/kg body weight and day in total). Unlike SCF, EVM is not of the opinion that an uncertainty factor (UF) should be taken into account (Food Standards Agency, 2003).

The German Society on Nutrition (DGE) has recommended, on precautionary grounds, that dietary iodine intake in adults should not exceed 500 µg/day in general to protect sensitive consumers as a consequence of the existing chronic iodine deficiency (D-A-CH, 2000).

While the current iodine supply has continued to improve in Germany and in numerous other European countries, the consequences of chronic iodine deficiency in the older generations have not been overcome. For that reason no UL can be accepted as the tolerable upper intake level for iodine which does not take this vulnerable group of people into account. People with a tendency towards so-called autoimmune thyroid diseases, such as Graves' disease or Hashimoto's thyroiditis, or who have previously been iodine deficient, may tolerate less. Pregnant women, premature babies, neonates, infants and older people who have grown up with an iodine deficiency or with a functional autonomy and patients with a genetic predisposition for auto-immune thyroiditis are the risk groups sensitive to iodine excess. In this context there is a degree of uncertainty when it comes to determining the "window of iodine intake" at which fewer thyroid diseases generally occur (Laurberg et al., 1998; 2001). According to WHO/UNICEF/ICCIDD (2001) there is no risk for sensitive groups with an undiagnosed functional autonomy in the range of optimum iodine supply, i.e. at an ioduria median of 100-199 µg/l. An increased health risk for sensitive individuals with functional autonomy or auto-immune disease of the thyroid gland is only to be expected at excessive iodine intake where the ioduria median is >300 µg/l which is corresponding to a dietary intake of 500 µg/day. The *AKJ* is, therefore, of the opinion like the Federal Institute of Risk Assessment (BfR) that the ULs derived by the SCF should not be applied in Germany (Domke et al., 2006).

Need for harmonisation of Regulations on the addition of iodine to foods

Setting maximum amounts for iodine in fortified foods

The proposed Regulation of the European Parliament and Council on the addition of vitamins and minerals and of certain other substances to foods is not intended at this stage to harmonise existing national rules on compulsory addition of nutrients to food (dictated by public health considerations at the national level). It permits voluntary iodine fortification of foods. In that case, iodine must be present at least in a significant amount as defined in the Annex to Directive 90/496/EEC in order to bear an indication on the label. Consequently, a minimum amount of 22.5 µg/ 100 g product would be necessary (e.g. around 225 µg/kg could be added to breakfast cereals, sweets, bread, beverages etc.). The addition of this minimum amount would for instance already lead to an additional intake of 243 µg iodine from 60 g of breakfast cereals, 20 g of sweets and one litre of a refreshment beverage. In purely arithmetic terms, taking into account the 95 percentile of iodine intake (209.6 µg) (Manz et al., 1998) and a daily portion of 100 µg from food supplements, the tolerable upper intake level of 500 µg of the DGE would already be exceeded (Domke et al., 2006). A hazard to health from uncontrolled iodine intake cannot be ruled out as, in the case of conventional foods, the amount of these foods consumed is not dictated by the levels of nutrients contained therein but by factors like hunger, thirst, appetite and availability.

For that reason the *AKJ* recommends that in the forthcoming regulation on the addition of vitamins and minerals to foods, the addition of iodine should be restricted to salt. At the international level, WHO, UNICEF and ICCIDD support the iodisation of table salt but not the addition of iodine to other foods (WHO/UNICEF/ICCIDD, 1996). Excessive use of iodine can be harmful for consumers. An extension of iodine fortification to other foods, with the exception of food supplements, should be rejected because of the risk of triggering a life-threatening thyrotoxic crisis in older people with undiagnosed thyroid autonomy.

The Codex Alimentarius does not support the addition of iodine to foods other than to some special purpose foods and iodine to salt in deficient areas. Section 3.4 – Iodisation of food grade salt of the Codex Standard for Food Grade Salt (CODEX STAN 150-2001) states: ‘in iodine deficient areas, food-grade salt shall be iodised to prevent iodine deficiency disorders for public health reasons. Levels of iodisation in the above-mentioned range should be established by national authorities in light of the local iodine deficiency problem". Nevertheless, Europe-wide uniform minimum and maximum levels (20 and 40 mg/kg salt) should be established for the iodisation of table salt by all EU Member states. Most countries already have regulations calling for 20-40 mg iodine/kg salt (20-40 ppm); thus if an individual consumes 5 g of salt iodised at 30 ppm, he/she gets 150 µg iodine from this source alone. The amount to be added varies for particular populations, depending on the amount of salt ingested, the purity of the salt (and therefore, the amount lost between production and consumption), and the amount of iodine ingested from other sources. The level of iodine in salt is calculated in such a way that there is no overdose even if all foods were to be manufactured with iodised table salt. The nutritional-physiologically desirable goal of increasing the iodine content of food makes technological sense. The target addition can only be achieved with any degree of reliability by means of standard use of table salt. On the one hand, this facilitates controlled intake of iodine and on the other it prevents excess supply which could not be ruled out if foods were directly fortified. In some countries, when daily salt intake decreases, the health authorities raise the amount of iodine in the salt so as to provide a constant adequate daily amount. Properly iodised salt will rarely add more than about 300 µg iodine daily to the diet. Therefore, concern about iodine excess is not a reason to stop or avoid consumption of iodised salt.

In order to dismantle trade obstacles, the iodine compounds mentioned in Annex 2 to this Regulation should also be approved for use in salt. This would remove the current trade obstacles for products manufactured with iodised salt. The definition which is available in the Codex Alimentarius Standard for food-grade salt should be the basic reference whereas low quality salt like cottage salt is not fit for sustainable fortification. Therefore, this Codex Standard should be adopted as a minimum requirement on legislation by all EU Member States.

Setting maximum amounts for iodine in food supplements

With regard to the most sensitive consumers with undiagnosed functional autonomy of the thyroid gland, the *AKJ* is also of the opinion that iodine carries, by way of definition, a high risk of adverse effects linked to its use in food supplements. The *AKJ*, therefore, supports the recommendation that a maximum level for food supplements (100 µg/day) should be set and that only iodised salt be used as a suitable carrier food as this can certainly guarantee that foreseeable amounts of iodine can be ingested by the general population and the tolerable upper intake level of 500 µg iodine is not exceeded (Domke et al., 2006).

Setting minimum amounts for iodine in food supplements

Minimum amounts for iodine in food supplements should be established and should be15% of the recommended allowance specified in the Annex to Directive 90/496/EC that means 22.5 µg per daily portion of consumption as recommended by the manufacturer.

Addition of iodine to feedingstuffs of farm animals

The iodine content of milk and eggs can be increased by adding iodine exceeding the animals' requirements to animal feed. Feeding maximum concentrations of 10 mg iodine per kg of feed, admissible until recently, may lead to concentrations of >1000 µg iodine per kg milk or eggs. Excessive iodine supply – mainly after longer iodine deficiency – may interfere with the thyroid metabolism in humans. Admissible maximum contents in mixed feed (containing 88 % T) for dairy cows and laying hens were reduced from 10 mg down to 5 mg/kg across the EU according to a study (EFSA). The maximum content of iodine in feed for these two types of production needs to be lowered in order to reduce the risk of any adverse effects on human health (EFSA, 2005; Commission, 2005). The *AKJ* supports the amended regulation on setting maximum levels (5 mg/kg) for the iodisation of feedstuffs for dairy cows and laying hens which ensures that only physiological amounts of iodine can be ingested from food of animal origin, in particular milk and eggs.

Conclusions

The *AKJ* hopes that these comments will be useful and will be taken into consideration when minimum and maximum amounts for iodine in salt and food supplements are set. A comprehensive harmonisation of these regulations will remove existing trade barriers and will therefore make a valuable contribution towards combating iodine deficiency disorders in Europe.

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