EuSalt Response to the Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs
GENERAL COMMENTS

The European Salt Producers’ Association EuSalt welcomes the DG SANCO initiative to consult on the setting of maximum and minimum amounts for vitamins and minerals in food, and offers the comments detailed below.

EuSalt and its members are committed to the elimination of IDD (Iodine Deficiency Disorders) and to the prevention of caries by producing and promoting respectively the use of iodized salt in all Member States and of fluoridated iodized salt in some Member States; EuSalt and its members are involved in many different activities on national, European and international levels since many years.

Related to iodine, EuSalt strongly advocates the implementation of the Universal Salt Iodization (USI) system in the European Union for the following reasons:

- In many European countries, you still find Iodine Deficiency Disorders caused by an inadequate intake of iodine. More than half of the people in Western and Central Europe live in ID countries. The highest prevalence of school children with inadequate iodine nutrition is found in Europe (59.9%). The proportion of households consuming iodized salt is the lowest in Europe (27%). That should be eliminated by the USI system.

- Since the World Summit for Children and the World Health Assembly held in 1990, the WHO as well as UNICEF and the ICCIDD implemented and promoted the USI system around the world (Assessment of Iodine Deficiency Disorders and Monitoring their Elimination, Second edition, WHO 2001). The USI system was also incorporated in the international Codex Standard for Food Grade Salt, CX 150-1985 (Amend.1-1999, Amend. 2-2001).

- The European legislator also agrees to USI as laid down in recital 15 of the proposed Regulation on the addition of vitamins and minerals and other substances to foods.

- USI is the safest option for increasing iodine status of the population. It restricts the addition of iodine to salt only. This guarantees a safe and controlled intake of iodine because salt is the only food, which is consumed around the world day by day in a consistent general range from 6 g/day to 12 g/day depending on the climate, age, sex, eating habits etc.

- USI means the iodization of all salt for human consumption, i.e. table salt, and also the use of iodized salt in the processing of foods. This is very important because the salt intake by table salt is only 25% compared to 75% by processed food.

- There is a need to harmonise the regulations on the addition of iodine to salt. The existing diverging regulations re iodized salt within the Member states are causing serious problems to the free circulation of the products. It concerns the free circulation of iodized salt itself and especially of foodstuffs produced with iodized salt.

Fluoride plays a vital role in the prevention of caries. EuSalt has made efforts to promote the use of fluoridated salt and would like to make the following comments:

- The successes in preventing caries by using fluoridated salt – fluoridated iodized salt to be more exact – show that this preventative method should also be retained in the future.
• The addition of fluoride to foodstuffs is currently limited to salt, water and chewing gum. The Regulation should not allow regular foods to be fluoridated in an uncontrolled way.

• There is an abundance of documented benefits of fluoridated iodized salt for the prevention of caries especially in Germany, as over 60% of table salt has added fluoride, as well in France with a proportion of 30% of fluoridated iodized salt. Also in Austria, the Czech Republic, Denmark, Finland, Greece, Italy, Croatia, the Netherlands, Portugal, Slovakia, Sweden, Spain and the UK iodized salt with fluoride is produced or imported.

• The example set by the Swiss which has been practised for 50 years is especially successful.

• The new European provisions for the addition of minerals to foodstuffs should protect the tried-and-tested methods as fluoridated iodized salt and not endanger their resultant successes which are linked to long-term consumer behaviour patterns.

• It may be necessary to introduce corresponding labelling and information obligations to prevent a possible excessive consumption of fluoride as a result of coincidence of parallel caries prevention measures.

Establishment of maximum amounts for food supplements and other foods

| 1. Where there is not yet a scientifically established numerical tolerable upper intake levels for several nutrients, what should be the upper safe levels for those nutrients that should be taken into account in setting their maximum levels? |

Sodium

EFSA has not derived ULs for sodium due to the lack of sufficient available data (The EFSA Journal (2005) 209, 1-26). There is no need to set ULs for sodium. Sodium is – in contrast to other sources - mostly added to food as salt (NaCl) and not as a “nutrient” like iodine or other nutrients.

The setting of maximum levels based on established UL is not an appropriate tool in the framework of the “Salt & Health” debate. The recommendation to reduce the sodium or salt intake for the population at large, which is still subject of scientific controversy, cannot be realized in the framework of the Regulation. NaCl is not included in annex 2 of the Regulation. It is clearly stated in recital 10 that “although sodium chloride (common salt) does not appear among the substances in this list, it may continue to be used as an ingredient in the preparation of food”.

Furthermore, the conditions for the addition of nutrients to foods as specified in Art. 3 of the Regulation do not apply to NaCl. This is logic and appropriate since NaCl is mainly used in foods because of its organoleptic and technological properties, not for its nutritional effects.

It is therefore clear that setting a maximum value for sodium in foodstuffs would fall outside the scope of the Regulation and should not be attempted based upon an UL approach, suitable for other vitamins and minerals.
In this context, EuSalt also wants to stress the – very often neglected – fact that there still is no scientific consensus related to salt and cardiovascular diseases. Three recent studies related to salt and hypertension, published in the Cochrane Library in 2004, clearly show that there is no need for healthy people to reduce the salt intake. The study of Jürgens & Graudal (1) and the study of Hooper et al (2) revealed that the salt reduction had almost zero effect in normotensives. Furthermore the study of He & McGregor (3) showed that for normotensives there was only a fall in blood pressure of 2 mmHg systolic and 1 mmHg diastolic after cutting down salt intake by 4.5 g/day for four weeks. The recent study of Cohen et al (4) even shows evidence, that there is a cardiovascular risk reducing the salt intake to 6g/day as recommended in the USA.

Related to physiology, recent science (5) shows that the human body has an additional system to manage too much salt. The salt is stored under the skin. This might explain why healthy people have no benefit in reducing salt intake.

Finally, there are also risk groups for which a salt reduction may be dangerous. As mentioned above Alderman shows that the reduction of salt can increase the risks of stroke up to 35 %. Jürgens & Graudal (1) find that by cutting down salt intake other risk factors increase, including cholesterol, LDL cholesterol, and adrenaline. Füsgen (6) and others (7; 8; 9) show that elderly people suffer from a lack of sodium and that dehydration is a real danger for the elderly. It is also vital that pregnant women do not cut down their salt intake even if they suffer from oedema. Sportsmen are also in at risk of a lack of salt by sweating during intense muscular effort.

**Chloride**

For chloride no UL exist. Chloride is added to foods mainly via salt (NaCl). The situation is the same as for sodium and so we refer to the above mentioned statement re sodium.

3. Where we set maximum levels, do we inevitably also have to set maximum amounts for vitamins and minerals separately for food supplements and fortified foods in order to safeguard both a high level of public health protection and the legitimate expectations of the various food business operators? Are there alternatives?

**Iodine**

The world wide recommended maximum level for iodine added to salt – and only to salt following the above mentioned Universal Salt Iodization (USI) system – is 40 mg iodine/1 kg salt.

With regard to the risk of adverse effects, a maximum level for food supplements should be set.

**Fluoride**

The first studies of the effect on dental caries of fluoride added to alimentary salt were carried out from around 1965 to 1985 in Switzerland, Hungary and Colombia and proved this to be as effective as water fluoridation; the number of teeth affected by caries was reduced by approximately 50%.
The maximum amount of fluoride added to table salt in Germany and Switzerland is 250 mg F⁻/1 kg Salt. Fluoride supplements is regarded as a public health measure and regulated as drugs available on prescription and not as a food supplement.

**Intake of vitamins and mineral from dietary sources**

4. **The Commission would appreciate receiving available information on intakes of vitamins and minerals or indications of the best sources providing such data at EU level.**

The salt intake figures are not only important for the intake of added iodine and fluoride but also for the current “Salt & Health” debate. The EFSA opinion on sodium shows clearly that there are no reliable data available. An efficient monitoring, data analysis and collection of dietary intake are urgently needed to assess the nutritional status of EU citizens.

EuSalt would urge the European Union to take as a priority to develop monitoring tools for assessing the nutritional status of the population.

**Minimum amounts**

8. **Should the minimum amount of a vitamin or a mineral in a food to which these nutrients are added be the same as the significant amount required to be present for a claim and/or declaration of the nutrient in nutrition labelling?**

For addition to salt, the world wide recognized minimum amount for iodine is 20 mg iodine/1 kg salt and for fluoride 200 mg F⁻/1 Kg salt.

The “significant amount” of iodine and fluoride and its labelling have to be regulated differently compared with other vitamins and minerals.

Almost all EU member states allow the addition of iodine only to salt and the use of iodized salt in the food processing in many cases. Iodine is thus present in the foodstuffs only via salt and is not added directly to foods. The "significant amount" of iodine depends on the individual consumption of iodized salt and of the foodstuffs processed with iodized salt. This criterion cannot be met with the "15% of the RDA per 100 g/100 ml" rule. The 15% rule is not consistent with and cannot be applied for the salt iodisation system.

In many EU members states (Germany, Austria, the Czech Republic, etc), the addition of fluoride to iodized salt is allowed. With the new regulation for the addition of minerals and vitamins to foods, it might be possible to add fluoride to iodized salt. As for the application of the "significant amount", it would be the same issue as for above mentioned iodine.

The "significant amount" of both iodine and fluoride cannot be guaranteed if the 15% rule is applied. In this respect, an exception should be made for both iodine and fluoride. The "significant amount" should be ensured by the application of above mentioned minimum amounts of both iodine and fluoride added to salt.
Sources

1. Effects of low sodium diet versus high sodium diet on blood pressure, rennin, aldosterone, catecholamines, cholesterols, and triglyceride (Cochrane Review) Jürgens G., Graudal N.A. – The Cochrane Library, Issue 1, 2004


