Response from Ireland:
Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs

Introduction

Ireland welcomes DG Sanco's paper and the opportunity it gives to Member States to express their views on this issue. At the request of the Department of Health and Children, the Food Safety Authority of Ireland (FSAI) undertook a public consultation exercise on the "Discussion Paper on the setting of maximum amounts for vitamins and minerals in foodstuffs". The comments received have assisted in developing the Irish response to the questions raised.

SETTING OF MAXIMUM AMOUNTS

1. Establishment of maximum amounts for food supplements and other foods

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

Although some stakeholders have expressed the view that where there is no demonstrable safety concern no maximum level should be set or, that upper levels should be set via a qualitative risk characterisation on the basis of the available risk assessment by EFSA/SCF, Ireland supports the establishment of maximum limits for as many vitamins and minerals as possible. Current intakes of most vitamins and minerals are not thought to be harmful. However, excessive intakes of some vitamins and minerals can have harmful effects, particularly if taken over long periods of time. Thus, foods to which vitamins and minerals are added may present a potential risk to health from the levels present in a single product or, more likely, from a range of products consumed. In such a case, the risk would be the probability of adverse effects occurring and the severity of those effects.

For nutrients where there is not yet a scientifically established numerical upper intake level, the maximum level should be the optimal intake based on RDA/RNI (Reference Nutrient Intake covering 97% of the population). The rules for appropriate use of RDA/RNI for certain vitamins and minerals in supplements and fortified foods should be established by EFSA on the basis of food consumption data and the history of safe/unsafe use of fortified foods and supplements currently available on the European Market. Consideration would need to be given to whether existing food consumption data from some Member States would be sufficient or whether an EU wide food consumption survey would be required.

1.2 For some vitamins and minerals the risk of adverse effects, even at high levels of intakes, appears to be extremely low or non-existent according to available data. Is there any reason to set maximum levels for these vitamins and minerals?

Some stakeholders hold the view that there is no reason to set maximum levels for these vitamins and minerals and that where there is no demonstrable safety concern, no maximum level should be set. Nevertheless, Ireland believes that as far as possible, a maximum limit should be set for vitamins and minerals allowed in fortified foods and supplements.

This will enable protection against unknown effects of excessive consumption of nutrients and allow clear enforcement. These limits can be set at relatively high values where evidence of safe use exists, although such evidence should be scientific in nature and preferably be elucidated from specifically designed studies. Anecdotal evidence should not be sufficient to ascertain a high maximum limit. The precautionary principle may be necessary in some cases where limited scientific data is available to support anecdotal evidence of safe use. Vulnerable sub-groups of the population (i.e. children, pregnant women) should be considered in the risk assessments supporting the setting of maximum limits as well as the robustness of any evidence of long term adverse effects.

1.3 Where maximum levels are set, does this inevitably require that maximum amounts are set 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?

Stakeholder opinion on this issue differs between the belief that separate maximum amounts for foods and food supplements are unnecessary and the view that maximum amounts for foods and supplements will need to be considered separately, since the intake and thus contribution to overall intakes, differ within population groups. Ireland considers this a complex issue which will need to be discussed further.

In the case of food supplements, it is easier for consumers to adhere to the recommended dose. However, there are an increasing number of fortified foodstuffs on the market making it difficult to ensure that over-consumption of vitamins and minerals does not occur for any population subgroup. While consideration may need to be given to separate limits for supplements and fortified foods, any system put in place needs to be as straightforward as possible to ensure protection of public health and to aid compliance and enforcement of the rules.

2. Intake of vitamins and minerals from dietary sources

The Commission has requested that any available information on intakes of vitamins and minerals or indications of the best sources providing such data at EU level be forwarded to them.

2.1 If such existing data refer only to the intake in some Member States, can they be used for the setting of legitimate and effective maximum levels of vitamins and minerals at European level?

Yes, but preferably data should come from Member States where there is a wide range of fortified foods available and where there are no restrictions on food choice (due to socio-economic factors, cultural choices etc). Such databases could be used to assess what level is safe when people freely choose fortified foods.

However, data quality is very important. Dietary assessments should be based on individual food choices – not household surveys where the intake of individuals is not apparent. Allowances for underreporting need to be built into the exercise of setting legitimate and effective maximum levels. Assessment of subgroups in the population who are more vulnerable to risk of over-consumption also needs to be addressed.

Some stakeholders disagree and argue that there are weaknesses in dietary survey data overall and that there is a huge variability of dietary intakes between Member States.

On the basis of what adjustments, if any?

The food supply in different regions and cultural habits need to be accounted for to ensure safe upper levels of intake are not exceeded by any particular population subgroup. Prevailing public health issues in different regions may also need to be considered.

2.2 Should the intake from different population groups be taken into account in the setting of maximum levels of vitamins and minerals?

Yes, but assessment of subgroups in the population who are more vulnerable to risk of over-consumption also needs to be addressed – these groups include those whose upper tolerable level of intakes of vitamins and minerals is lower (i.e. children, pregnant women) and those who are high consumers of food (adolescent boys).

3. Reference intakes of vitamins and minerals

3.1 Taking into account all the considerations mentioned in paragraphs 34 to 42 of the discussion paper, how far should PRIs (Population reference Intakes)/RDAs be taken into account when setting maximum levels for vitamins and minerals?

Food Supplements
In the case of food supplements Ireland believes maximum levels should be set at the optimal intake levels. There is no benefit in exceeding the optimal intake of nutrients (PRI/RDAs), however, as cited above there may be risk associated with long-term excessive intakes of some nutrients.

Fortified foods
Nutrients added to foods should not exceed a pre-determined proportion of the optimal intake (PRIs/RDAs) per daily average adult intake. This needs to be carefully established nutrient by nutrient and take account of supplement use and vulnerable subgroups (i.e.

children). The addition of nutrients to foods where there is little margin between optimal and safe upper intakes of that nutrient (e.g. vitamin A) should be highly controlled.
In the context of a mandatory fortification programme (e.g folic acid), the maximum level for voluntary fortification with a particular vitamin or mineral may need to be adjusted to protect public health.

Most stakeholders favour the setting of maximum levels based on risk assessment and express the view that the use of arbitrary multiples or fractions of RDAs/PRIs to set upper levels is no longer acceptable.

MINIMUM AMOUNTS

4. Minimum Amounts

4.1 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?

Yes. Ireland believes it is important that a consistent approach is adopted across the different legislative instruments affecting this issue, i.e. Directive 90/496/EC (nutrition labeling) and the recently adopted Regulations on the addition of vitamins and minerals and certain other substances to food and on nutrition and health claims made on foods. This would facilitate enforcement and compliance.

4.2 Should different minimum amounts be set for certain nutrients in specific foods or categories of foods? If yes, on what basis?

As stated in answer to 4.1 above, Ireland believes consistency across all the legislation in this area is necessary. If different minimum amounts are to be set for certain nutrients in specific food or categories of foods issues that may need to be considered are the number of servings recommended, the total number of servings consumed daily, and the amount of the nutrient that should be present in the final product.

The need for consistency needs to be borne in mind in the current review of Directive 90/496/EC.

4.3 Should minimum amounts for vitamins and minerals in food supplements also be linked to the significant amounts that should be present for labelling purposes or should they be set in a different way?

The significant amount for labeling purposes under Directive 90/496/EC is 15% and typically minimum amounts in food supplements are at higher levels than this. It is reasonable to expect that food supplements should provide a higher concentration of nutrients than fortified foods and that minimum amounts should be set in a different way.

Food Unit
Department of Health and Children
November 2006