

ROADMAP

Title of the initiative:

Establishment of maximum levels of vitamins and minerals that can be added to foods and to food supplements

Lead DG: SANCO

Expected date of adoption: 1st half 2009

Initial impact assessment screening & planning of further work

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

The establishment of maximum amounts of vitamins and minerals in foods and food supplements is a legal obligation under the Directive (2002/46/EC) on food supplements and the Regulation on the addition of vitamins and minerals to foods (EC 1925/2006).

What are the main problems identified?

At present, Member States have divergent attitudes towards this issue. Some have adopted very restrictive policies, which have resulted in obstacles to the free circulation of these products on the EU market. Challenges to such policies have resulted also in Court Cases. Others have taken a more liberal approach and have not established any maximum amounts, which has resulted in the introduction on their market of products containing quantities of vitamins and minerals which may potentially be a risk to human health.

Explain how EU action is justified on grounds of subsidiarity

Food supplements containing vitamins and minerals and the addition of vitamins and minerals to foods are harmonised by Directive 2002/46/EC and by Regulation (EC) 1925/2006. The establishment of maximum amounts is an implementing measure foreseen in both pieces of legislation.

B. Objectives of EU initiative

What are the main policy objectives?

- Secure the functioning of the internal market for concerned products
- Ensure the same high level of consumer protection in all EU countries
- Facilitate trade with non-EU partners.

Does the objective imply developing EU policy in new areas or in areas of strategic importance?

No

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

The setting of maximum amounts of vitamins and minerals, via the regulatory committee procedure with scrutiny, is foreseen by Regulation (EC) 1925/2006 and by Directive 2002/46/EC. It is one of the core principles of those legislations and therefore it is difficult to envisage any alternative to setting maximum amounts of vitamins and minerals via the Comitology procedure. It is considered that there would be legal implications if maximum amounts of vitamins and minerals were not set (the "do nothing" option), whilst it is clear that the complexity of the issue would make it difficult to consider "soft law" options (e.g. guidance).

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

No

Explain how the options respect the proportionality principle

An Impact assessment will be conducted in order to analyse the potential impacts of the measure.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

Industry

- The establishment of maximum amounts will facilitate the free circulation of the concerned categories of products on the internal market
- Some products containing high levels of vitamins and minerals (especially supplements) would need to be reformulated and/or to be relabelled
- Food industry could be obliged to limit the range of products that could be fortified with certain nutrients.

Consumers

- The range of available products would probably increase in many MS and consumers would have access to a wider range of safe products
- Those consumers who were used to buying specific products containing high levels of nutrients (valid particularly for food supplements), may be induced to buy them directly from third countries and/or via the internet. The control of the quality of these products would be more difficult to check.

Member States

- The harmonisation would create legal clarity and avoid further complaints by the industry to MS resulting from variable national levels of nutrients allowed in the concerned products.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

No.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

The maximum amounts would apply equally to community products and to products from third countries thereby guaranteeing fair competition on the EU market.

Who is affected?

Specific groups of consumers, food business operators, and competent authorities.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

Some information has been gathered through a public consultation carried out in 2006. A study to obtain an overview of the market shares of the concerned products has been outsourced to an external contractor. The study is expected to be completed by the end of 2008.

Which stakeholders & experts have been/will be consulted, how and at what stage?

A public consultation has been carried out in 2006 and the answers received are published on the Europa website (http://ec.europa.eu/food/food/labellingnutrition/supplements/index_en.htm)

Working groups with Member States experts are being organised.

The Advisory group on food chain will be consulted before the finalisation of the measure.