Chairman: Mr Basil Mathioudakis

All the Member States were present.


No discussion took place as draft document was not yet available.

2. **Exchange of views on the maximum limits for vitamins and minerals permitted in dietary foods for special medical purposes (FSMP) in the framework of Commission Directive 1999/21/EC on dietary foods for special medical purposes, requested by Denmark**

Denmark asked the Commission to propose a revision of the limits for vitamins and minerals set out in Directive 1999/21/EC. According to Denmark, several maximum levels specified in Annex 2 of the above mentioned Directive could result in the Upper Limits (UL) on vitamins and minerals established by the Scientific Committee on Food (SCF) being exceeded in some cases.

The Commission recalled briefly that the ULs derived by the SCF apply for all group of the general population (excluding those receiving the nutrient under medical supervision), and that FSMPs are designed for exclusive or partial feeding of patients with limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary foodstuffs.

The Commission also pointed out that the cases referred to by Denmark should be considered in relation to the products currently marketed and should be evaluated before considering any action toward the review of these maximum levels.

The Danish request was supported by some Member States.

Consequently, it was suggested that this complex and technical issue should be discussed during the next meeting of the working group on dietetic foods on 6 April 2009.

The Committee, on the request of Germany, held an exchange of views on the report from the Commission to the Council and the European Parliament on the use of substances other than vitamins and minerals in food supplements.

Germany was of the view that there is an urgent need for Community legislation on the use of substances with a nutritional or physiological effect other than vitamins and minerals in supplements. The German delegation expressed their disagreement with the Commission's conclusion that the Community legal instruments described in the report already constituted a sufficient legislative framework for regulating this area and that it is not opportune to lay down specific rules for the substances concerned.

A majority of Member States supported the German position and affirmed that they faced problems related to the free circulation of goods due to the lack of harmonisation of rules for these other substances. This situation was creating difficulties for both food business operators and for controlling authorities.

Some Member States did not intervene or express their position whereas two others expressed their agreement with the Commission's position.

The Commission took note of the opinions of the Member States but maintained the position expressed in the report.

4. Exchange of views concerning the possible authorisation of oil rich in DHA (docohexaenoic acid) from micro-algae (Schizochytrium spec. and possibly Ulkenia sp.) for additional uses under Regulation (EC) No 258/97

DHA-rich oil from micro-algae was not available as a food ingredient before the Novel Food Regulation (Regulation (EC) No 258/97) entered into force. Therefore its use as food ingredient required authorisation under the Regulation.

DHA is an omega-3 fatty acid for which concerns have been expressed that excessive intakes may have adverse effects. In 2003 in order to avoid high intakes, a first authorisation concerning DHA-rich oil from the micro-algae Shizochytrium sp. was limited to certain uses and use levels were fixed.

A new application concerning the DHA-rich oil for additional uses was assessed as safe. However some Member States raised objections, because of concerns about possible excessive intakes of DHA as such.

The main source of DHA is fish oil. Although not a novel food, the use of fish oil as food ingredient was limited in the past. Since 2003 fish oil is being used as ingredient in a large number of foods, and in particular in those for which request for allowing the use of DHA-rich oil from micro-algae was submitted.
Some Member States are monitoring the intake of DHA. The FDA (Food and Drug Administration of USA) as a measure of prudence has recommended in 2003 not to exceed 3g/day of the omega-3 fatty acids (EPA and DHA).

There was agreement that DHA from micro-algae is an alternative to DHA from fish oil and that its use was not likely to add to DHA intakes. However, because of concerns about overall intakes, it was concluded that the request for authorisation of additional uses of DHA from micro-algae should be considered carefully. In particular, the estimated intake of DHA from micro-algae as requested by the applicant should be less than 2g/day.

It should be noted that there is ongoing research in some Member States on the effects of high intakes of omega-3 fatty acids. Possible risk management measures, in the light of the results of new knowledge, should be considered for all sources of omega-3 fatty acids, and not be limited to oil from micro-algae.


The draft Regulation aims at drawing up of a list of feed and food of non-animal origin that is, on the basis of known or emerging risk, to be subject to an increased level of controls at the point of entry into the EU. This draft Commission Regulation is a measure for the implementation of Article 15(5) of Regulation (EC) Nº 882/2004.

Member States are asked to carry out on such listed products systematic documentary checks, and identity and physical checks on a given percentage of samples corresponding to a frequency appropriate to the risk.

The Regulation establishes minimum requirements to be fulfilled by the designated point of entry and the template of a Common Entry Document (CED) to be used by the feed and food business operator for prior notification of the arrival of the listed goods at the DPE, and by the competent authority to confirm completion of the required official controls.

Products subject to the increased level of controls shall remain under official control by the competent authorities in the sense that, while they can travel towards their final destination, they cannot be released for free circulation until the favorable results of all checks, including of physical checks and laboratory analysis if required, are obtained.

The draft Regulation was first discussed at the SCFCAH Toxicological Section meeting of 12 February 2009, which resulted in an amended version submitted for the vote.

The Committee delivered a favorable opinion by qualified majority (in favour: 307 votes; against: 26 votes; abstention: 12 votes)

The Draft Regulation aims at amending Directive 2007/68/EC\(^1\) which provides for a transitional period for products placed on the market or labelled before 31 May 2009 in order to smooth the transition towards new labelling requirements introduced by that Directive for allergenic ingredients.

That amendment was put forward in the context of the recent adoption of implementing rules for Council Regulation (EC) No 479/2008 of 29 April 2008 on the common organisation of the market in wine\(^2\), providing inter alia for specific labelling rules applicable to the wine sector, which will be applicable as from 1 August 2009. In order to ease the transition from the previous wine sector legislation, those rules also provide for a transitional periods for wines placed on the market or labelled before 31 December 2010 to be marketed until stocks are exhausted.

As a result, the wine operators would be subject to two sets of labelling requirements, those provided under Directive 2007/68/EC and those of the implementing rules of the wine CMO. In this context, in the interests of sound administration and to avoid unnecessary burdens on the authorities of the Member States as well as economic operators, a single date should be established for the mandatory application to the wine sector of Directive 2007/68/EC and of the implementing rules adopted in the framework of Regulation (EC) No 479/2008.

Therefore, it was proposed to extend the end of the transitional period foreseen in Directive 2007/68/EC to 31 December 2010 as regards wines covered by Regulation (EC) No 479/2008.

The SCFCAH delivered a favourable opinion by unanimity.

7. Miscellaneous

Following the scrutiny by the juristes-linguistes of the two draft Regulations on health claims, voted at the Standing Committee meeting of 20 February 2009, Member States were informed of some editorial changes brought to the English version. It was explained that these changes have no consequence on the substance of the two draft Regulations.

DE, AT and other Member States expressed their strong wish that this should in no way set a precedent. The Commission gave assurances to that effect.

---

\(^{1}\) OJ L 310, 28.11.2007, p. 11