STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH
SECTION ON GENERAL FOOD LAW

Summary Record of Meeting of 26 January 2010

Chairman: Mr Basil Mathioudakis

1. Exchange of view on a draft revised version of the guidelines on Articles 12, 14, 18 and 19 of Regulation (EC) No 178/2002.

The Guidelines on Articles 11, 12, 17, 18, 19 and 20 of Regulation (EC) No 178/2002 were elaborated through discussion with Member States and approved by the Standing Committee on 20 December 2004. The Committee also agreed in the same time that the guidelines should be reviewed and, if necessary, completed, in the light of the experience gained by the full application of the Regulation from 1 January 2005. Other interested parties were also consulted on the draft.

Though having no binding legal effect, the Guidelines aim at assisting all players in the food chain to better understanding the Regulation and to applying it correctly and in a uniform way.

The revised version submitted to the Committee was therefore elaborated in the context mentioned above, within the working group "General Food Law". New versions of the sections on Articles 12, 18 and 19 were prepared, as well as a new section on Article 14, and were discussed at the meeting of the Advisory Group on the Food Chain on 4 December 2009.

The Commission introduced the discussion explaining that a lot of textual amendments were proposed but did not result in as much modification on substance as the exercise was also intended to simplify and clarify the guidelines. The revised section on Article 12 specifies which food safety rules have to be applied for foodstuffs to be exported to third countries. For the one on Article 18, traceability, it simplifies the list of information that an operator has to keep and reviews the duration it had to be maintained. The substantial change to the section on Article 19, withdrawals and recalls, has to be seen in connection with the new section on Article 14, which elaborates on the criteria to be used in assessing whether a food should be considered safe.

During the exchange of views, most of the Delegations which took part to the discussion expressed their satisfaction for the improvements brought to the Guidelines.

In the section on Article 14, following a request from one delegation, it was agreed to modify the wording of the second paragraph of the part on Article 14(7).
Subject to the modification mentioned above, the Standing Committee approved the revised version of the Guidelines.

2. Exchange of views on a notification (Directive 2000/13/EC) by Italy of a draft Decree governing the use of substances other than vitamins and minerals.

On 27 November 2009, the Italian authorities notified under Article 19 of Directive 2000/13/CE a draft Regulation governing the use of substances other than vitamins and minerals in food supplements.

The Italian delegation explained that the notified measure provides for national provisions applicable to food supplements containing substances other than vitamins and minerals, in line with the guidelines on food supplements developed by the Ministry of Health. It was also emphasised that the draft Regulation aims to ensure a high level of health protection and to correctly orient consumers’ choices. Therefore, it lays down labelling requirements for mandatory indications and warnings with respect to food supplements containing specific herbal extracts with nutritional or physiological effects and to food supplements containing other substances with nutritional or physiological effect.

The Italian delegation also indicated that a clause of mutual recognition is inserted in Article 5 of the draft Regulation. Therefore, products lawfully manufactured or marketed in other Member States can be marketed in Italy without being labelled in accordance with the notified draft Regulation.

Some Member States took the opportunity to underline the need to harmonize the lists of substances other than vitamins and minerals which can be used in food supplements. The Commission took note of those opinions of the Member States but stated that the position expressed in the report to the Council and the European Parliament on the use of substances other than vitamins and minerals in food supplements (COM (20008) 824) has not changed so far.

The Commission asked whether the nutritional or physiological effects of the substances included in the Italian notified measure as mandatory indications have been substantiated, taking into account all available evidence, including in particular evidence based on traditional use. The Italian delegation confirmed this and explained that although the indications were included in Annexes 1 and 2 of the draft Regulation, any decision to place a product on the market will be taken on the basis of the results of an assessment carried out on a case-by-case basis following the notification of the product to the authorities.

During the exchange of views, some Member States also sought more clarifications about the interaction of the notified measure with Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. The Italian delegation said that the national measures would be kept under review taking into account decisions under the Regulation on claims.

The Commission informed the Committee that on 22 January, the Italian authorities have submitted complementary information in support of the notified measure. Under these
conditions and in accordance with the procedure laid down in Article 19 of Directive 2000/13/EC, the Commission will express an opinion regarding this notification by 23 April, taking into consideration this exchange of views.

3. Exchange of views on the consideration of fermented red yeast rice in food supplement as a novel food (requested by Belgium).

'Fermented red yeast rice' is produced by cultivating the yeast Monascus purpureus (syn. M. albidus, M. anka, M. araneosus, M. major, M. rubiginosus, and M. vini) on rice.

The request by Belgium was exclusively concerning whether fermented red yeast rice (Monascus purpureus), to be used in food supplements, was a novel food within the meaning of Regulation (EC No 258/97) concerning novel foods and novel food ingredients.

Italy confirmed that food products meeting the definition of food supplements (Directive 2002/46/EC) were on the market in Italy already before the entering into force of the Novel Food Regulation.

The Committee therefore concluded, that 'fermented red yeast rice' when used in or as food supplement, should not be considered as subject to the novel food Regulation.


The draft Regulation was submitted to the Standing Committee, in accordance with Article 17(1) of Regulation No (EC) 1924/2006; it concerns authorisation following two applications provided for in Article 14(1)(b) and rejection following three applications of health claims provided for in Article 14(1)(a) and (b) of that Regulation.

Regarding the health claims to be permitted, a discussion took place on the specific issue of ensuring that the upper levels set for iodine and expressed in the EFSA opinion Q-2008-324 are not exceeded. The Commission recalled that maximum levels for the addition of vitamins and minerals are to be set in the context of Regulation (EC) No 1925/2006, and that such maximum levels do not need to be included in the measures authorising the use of certain health claims as they would in any case be applicable. It was also recalled that in the absence of EU maximum levels Member States could set national ones taking into account the provisions of the Directive 2002/46/EC on food supplements and the provisions of the Treaty.

During the exchange of views, and in the context of the EFSA opinion on glucosamine and reduced cartilage degeneration (EFSA Q-2009-00412), the Commission brought to
the attention of Member States that in the above opinion EFSA could not draw any scientific conclusions from the submitted clinical data obtained from studies conducted with diseased people because they do not establish that patients with osteoarthritis are representative of the target population with regard to the status of joint tissues, or that results obtained in studies on subjects with osteoarthritis relating to the treatment of symptoms of this disease (e.g. erosion of articular cartilage, reduced mobility of joints) can be extrapolated to the target population. Member States were asked to express views on this issue. One Member State said that the extrapolation of the results from such studies to the general population should be evaluated on a case by case basis in the context of the claimed effect, taking into account the target group for the claim subject of the application, and considering whether health benefits would be provided for such target group. To the contrary, another considered that where an effect is shown only on diseased people, extrapolating the studies in order to authorise the claim for the healthy population would not be scientifically sound and could be misleading. The Commission invited the delegations to reflect further on that issue, as it has been raised by interested parties and would be pertinent both for individual applications but also for health claims referred to in Article 13(2)-(3).

The Committee took note of the submitted draft that will be subject to further discussions and put to the vote of the Committee in a future meeting.


The draft Commission Regulation was submitted to the Standing Committee, in accordance with Article 18(5) of Regulation (EC) No 1924/2006, refusing to authorise the use of one health claim provided for in Article 13(5) of that Regulation. The application was based on newly developed scientific evidence, as provided for in Article 13(5) of that Regulation.

The draft Regulation will be subject to further discussions and put to the vote of the Committee in a future meeting.