Expert Group on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control
Summary Report

Brussels, 7 February 2014

Chairman: Mr. Basil Mathioudakis

1. Exchange of views on certain elements of the future delegated act on food for special medical purposes

The Commission opened the meeting by describing the provisions (and relevant text) that could be included in the new delegated act on food for special medical purposes (hereinafter 'FSMPs'), with respect to the subject matter and scope of the delegated act, as well as to the categories of FSMPs, their composition and the name of the food in different languages. Delegations supported the Commission's proposals with regards to these provisions and suggested some minor redrafting.

Specific requirements that could be included in the delegated act as regards ***food information*** for FSMPs were then discussed. The Commission explained the importance to ensure as much consistency as possible with Regulation (EU) No 1169/2011 on the provision of food information to consumers (hereinafter 'FIC Regulation') (with derogations/additions where necessary). The Commission also specified that several future provisions of the delegated act will follow the existing provisions of Directive 1999/21/EC on dietary foods for special medical purposes. More specifically, the Commission described how the provisions of Articles 4(3), 4(4) and 4(5) of Directive 1999/21/EC would be transferred with some minor redrafting in order to improve legal clarity and therefore facilitate application of rules at national level. Experts supported the Commission's approach.

The Commission, then, introduced the provisions of the new delegated act that would ensure that rules on font size provided by the FIC Regulation would apply to all mandatory particulars required for FSMPs – and not only those foreseen by the FIC Regulation – and, furthermore, that no derogation on the provision of the nutrition declaration is granted to FSMPs in packaging or containers the largest surface of which has an area of less than 25 cm^2. Member States supported the Commission's approach.

The Commission described the provisions of the new delegated act that would ensure that the mandatory nutrition declaration of FSMPs will include the requirements currently laid down in Article 4(2)(b), (c), (d) and (e) of Directive 1999/21/EC, in addition to the particulars listed in Article 30(1) of the FIC Regulation. Member States supported the Commission's approach.

The Commission introduced the provision of the new delegated act to clarify that the requirements set out in the FIC Regulation on calculation, expression, and presentation of the nutrition declaration would apply to all nutrients of the nutrition declaration of FSMPs and not only to those which are covered by the FIC Regulation. Member States supported the Commission's approach.

The Commission described the provision of the new delegated act to clarify that the indication on vitamins and minerals in FSMPs is not subject to the requirements of the FIC Regulation on the presence of the vitamins/minerals in significant amounts and on the indication as a percentage of the reference intakes. Member States supported the Commission's approach and added that further consideration should be given to the possibility of explicitly prohibiting indication of the amount of vitamins and minerals in FSMPs as a percentage of the reference intakes in the delegated act.

Subsequently, the Commission focused on the provisions to ensure that the presentation of the nutrition declaration of FSMPs follows the format set out in the FIC Regulation (but taking into account the additional obligations required for FSMPs) and to specify how salt and sodium should be indicated for labelling purposes. Member States supported the Commission's approach and suggested one correction.

The Commission introduced the requirements on the ***notification procedure*** that should be included in the delegated act and should follow the currently applicable provisions set out by Article 5 of Directive 1999/21/EC. Delegations described their experiences with the notification procedure at national level. In this context, several delegations stated that competent authorities often face difficulties when demanding detailed information to the operators in order to verify compliance of products with the requirements applicable to FSMPs. The Commission took note of the views expressed by experts and will further reflect on it. The Commission however recalled that Member States have the right at any moment to ask operators to provide information they consider appropriate in order to monitor compliance of products with the legislation.

Discussion then took place regarding ***nutrition and health claims*** on FSMPs. The Commission introduced this issue by describing the applicable rules and the existing situation on the market. Member States' experts were asked to elaborate on what rules should apply to the use of claims on FSMPs. The discussion showed that most of the experts who intervened would support stricter rules on the use of nutrition and health claims for FSMPs, taking into account the specific nature of these products. Several delegations were in favour of a complete prohibition of the use of claims for these products. The comments expressed during the discussion will be taken into account by the Commission in finalising the delegated act.

2. Exchange of views on FSMPs for infants on the basis of the input provided by Member States upon request of the European Commission

The Commission presented the outcome of the data collection exercise carried out on products marketed as FSMPs for infants in the different national territories. After having reported on the data submitted by Member States, the Commission focused on four issues: (1) misclassification of FSMPs for infants, (2) technical adaptation of the legislation on infant formulae and follow-on formulae, (3) use of nutrition and health claims on FSMPs for infants, (4) statement on the importance of breastfeeding for FSMPs for infants. The Commission also covered other issues, such as the provision of samples of FSMPs for infants via the health care system and communication to health care professionals.

The Commission sought experts' views and a discussion followed on the different issues. Delegations showed openness on technical adaptations of the legislation on infant formulae and follow-on formulae in order to limit unnecessary recourse to classification of products as FSMPs. Delegations also expressed support for stricter rules on claims for FSMPs for infants.

Those delegations who intervened agreed that, if proper application of the rules is ensured, there would be no necessity for a mandatory statement on FSMPs for infants referring to the superiority of breastfeeding (taking into account the cases in which this statement would contradict medical advice).

While no opposition was raised by delegations on the possibility to distribute samples of FSMPs for infants to the health care system, there were no conclusions regarding the issue of advertising of FSMPs for infants. It was agreed that the Commission will get back to the experts on this issue after further reflection. The Commission will take into consideration the comments expressed during the discussion in finalising the delegated act.