

WORKING DOCUMENT

on young-child formulae

[Supporting Document for the Expert Group meeting of 18 February 2015]

Introduction

Article 12 of Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control¹ requires the Commission to present a report to the European Parliament and to the Council, after consulting the European Food Safety Authority (EFSA), on the necessity, if any, of special provisions for milk-based drinks and similar products intended for young children (hereinafter "young-child formulae").

In preparation for the drafting of the report required by Article 12 of Regulation (EU) No 609/2013, and in order to collect useful data and information, the services of DG Health and Food Safety (SANTE) consulted national competent authorities, relevant stakeholders and NGOs by the means of a questionnaire on young-child formulae in June-July 2014.

Consultation with national competent authorities continued in October 2014 with an Expert Group meeting on young-child formulae on the basis of a Working Document. That Working Document provided a summary of the contributions received to the questionnaire and described possible future options for action on young-child formulae. More specifically, the options described in the Working Document were:

- Option 1: No specific legislation for young-child formulae;
- Option 2: Adoption of specific rules for young-child formulae;
- Option 3: Extension of existing requirements to cover young-child formulae.

Member States' experts were asked to provide arguments in favour or against the different options (stakeholders and NGOs were also consulted on the different options).

Further consultation

Following discussions within the Commission services on the different policy options that could be explored in the report on young-child formulae, a new option has been identified that would deserve further consideration. This additional option is briefly described below.

Member States' experts are invited to provide their feedback on this option during the Expert Group meeting of 18 February (or in writing by 27 February 2015 at the latest). (NGOs and stakeholders will also be consulted on this option).

In providing arguments in favour or against the option, focus should be on the same aspects covered in the first consultation phase, namely the expected impact of the option on:

- Consumers' protection;
- Consumers' choice (variety of products being offered to consumers), information (e.g. level of information on the products) and behaviour (e.g. ability to understand information provided);

¹ OJ L 181, 29.6.2013, p. 35

- Free circulation of young-child formulae in the internal market;
- Access to the EU market from third countries operators;
- Competitiveness of enterprises, operating costs, especially SMEs;
- Development of innovative products;
- Price of young-child formulae;
- Legal clarity, administrative burden for operators (especially SMEs) and national authorities;
- Enforcement by national authorities.

New policy option (Option 4): Non-legislative measures

This option would exclude changes to the legal framework for young-child formulae. As a consequence, as in the case of option 1 (no specific legislation for young-child formulae), after 20 July 2016 (date of entry into application of Regulation (EU) No 609/2013), young-child formulae notified today as "dietetic foods" would be considered as foods for normal consumption targeting a specific sub-group of the population (i.e. young children) and would have to comply with the existing relevant rules of EU food law. The *status quo* would remain in those Member States that already consider young-child formulae as fortified foods.

In the context of this new option, the Commission would explore non-legislative measures at EU level in cooperation with the Member States, NGOs and stakeholders. Such non-legislative measures could include, by way of example:

- Engaging into a dialogue with food business operators to encourage development of self-regulatory commitments for young-child formulae placed on the market in the EU. These commitments could cover composition aspects as well as the modalities for appropriately marketing the products.
- Engaging into a dialogue with national competent authorities to encourage Member States to refrain from adopting legislation at national level on the matter provided that the manufacturers respect their self-regulatory commitments. This would reduce burdens related to the circulation of young-child formulae complying with self-regulation in the Internal Market and at the same time ensure consumer protection across Europe.
- The development of a Commission's guidance document explaining what marketing practices for young-child formulae should be considered as incompatible with the horizontal rules of food law (in particular the rules of Regulation (EU) No 1169/2011 on the provision of food information to consumers, and the rules of Regulation (EC) No 1924/2006 on nutrition and health claims). This, together with self-regulation, would also facilitate the enforcement activities of national competent authorities.
- The establishment of a platform for information exchanges between all parties on all upcoming issues with respect to young-child formulae. The platform would allow all interested parties to exchange views on difficult cases and/or shortcomings of this non-legislative approach and the situation could be further reviewed after a fixed period of time to evaluate whether self-regulation combined with appropriate guidance successfully addressed the issue, or whether problems still exist.