COMMISSION STAFF WORKING DOCUMENT

On the requirements for FSMPs for infants

[Supporting Document for the Expert Group meeting of 15 November 2013]

During the Expert Group meeting of 13 September 2013 a preliminary discussion was held with Member States' experts on the provision of Art. 11(1)(g) of the FSG Regulation which requires that specific rules are set in delegated acts for FSMPs for infants with respect not only to compositional requirements, but also on pesticides, labelling, presentation, advertising, and promotional and commercial practices, as appropriate.

During that discussion it appeared that experts agree that rules on pesticides applicable to infant formulae and follow-on formulae should also apply to FSMPs for infants. Discussions on what other requirements should apply to FSMPs for infants demonstrated that certain points need further consideration. In particular, it appeared that Member States' experts' consideration of what requirements should apply to FMSPs for infants is influenced by their experience at national level with different types of products that are marketed as FSMPs on the basis of a loose interpretation of the definition.

In the meantime, certain stakeholders have shared their comments on the topic with the Commission's services. According to one of them, stricter requirements should be set for FSMPs for infants and these products should comply with the requirements applicable to "normal" formula, in particular with respect to labelling and marketing. Another of them acknowledges that certain requirements applicable to "normal" formula should be extended, but underlines that adaptation is needed in certain cases in order to take into account the specific use of FSMPs. Some Member States' experts have also shared their views on the topic with the Commission's services.

Taking this into account, it is considered appropriate to further seek experts' views on certain specific aspects that demand further consideration. The content of this Working Document is without prejudice to further consideration of how the provisions of Directive 2006/141/EC and Directive 1999/21/EC should be transferred in the delegated acts for Infant Formulae and Follow-on Formulae and FSMPs. The content of this Working Document is also without prejudice to further consideration of other provisions that could be made applicable to FSMPs for infants.

1. Two Member States underlined in their comments that specific statements should be requested for FSMPs for infants in order to explain their relationship to breastfeeding.

- According to one Member State, this could take the form of an adaptation of the provision of Article 13(1)(a) of Directive 2006/141/EC[1] in a way that makes it clear that the product is suitable for infants from birth when breastfeeding is not adequate for the infant; or an adaptation of the provision of Article 13(4)(a)[2], in a way that

[1] "*The labelling shall bear (...) in the case of infant formulae, a statement to the effect that the product is suitable for particular nutritional use by infants from birth when they are not breast fed*;"
[2] "*The labelling of infant formulae shall, in addition, bear the following mandatory particulars, preceded by the words 'Important Notice' or their equivalent: (a) a statement concerning the superiority of breast feeding*;"

underlines the superiority of breastfeeding and makes it clear that the product must be used only under medical supervision when breastfeeding is not adequate for the infant due to its medical condition.

- According to another Member State the provision of Article 13(4)(a) should be applicable as such to FSMPs for infants, with the exception of those products given in cases in which breastfeeding is not adequate for the infant (e.g. metabolic disorders such as phenylketonuria).

2. One comment from a stakeholder underlined that the provision of Article 13(3) of Directive 2006/141/EC second paragraph[3] should not be retained as such for FSMPs for infants. According to the stakeholder's comments, while the word 'humanised' and 'maternalised' should not be allowed for FSMPs for infants, it is important to allow the use of the word 'adapted', which corresponds to the adapted nature of FSMPs for infants.

3. One Member State underlined in its comments that the provision of Article 13(6) of Directive 2006/141/EC[4] should be extended to FSMPs for infants. During the Expert Group meeting of 13 September, several Member States' experts flagged that a reflection on the use of claims for FSMPs for infants should be carried out but no clear suggestion was made.

4. One Member State underlined in its comments that all the provisions of Article 14 of Directive 2006/141/EC[5] should be made applicable to FSMPs for infants. One stakeholder has raised concerns with respect to the issue of distribution of samples (already discussed in previous meetings) as well as with the provision of Article 14(1)(a). Concerns have been raised in particular that extending this provision to FSMPs for infants would make it difficult for operators to communicate with caregivers / Health Care Professionals and would deprive them of useful information. Issues would, reportedly, arise because communication on FSMPs often mentions the brand name and is done in a number of ways (not only in scientific publications).

Experts are invited to provide comments on the different issues identified above.

Experts are of course also invited to provide comments on other provisions that they believe should be considered for the labelling, presentation, advertising and promotional and commercial practices of FSMPs for infants.

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[3] "*The use of the terms 'humanised', 'maternalised', 'adapted', or similar terms shall be prohibited*."

[4] "*The labelling of infant formulae may bear nutrition and health claims only in the cases listed in Annex IV and in accordance with the conditions set out therein.*"

[5] "*1. Advertising of infant formulae shall be restricted to publications specialising in baby care and scientific publications. Member States may further restrict or prohibit such advertising. Such advertisements for infant formulae shall be subject to the conditions laid down in Article 13(3) to (7) and Article 13(8)(b) and contain only information of a scientific and factual nature. Such information shall not imply or create a belief that bottle-feeding is equivalent or superior to breast feeding.*

2. There shall be no point-of-sale advertising, giving of samples or any other promotional device to induce sales of infant formula directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales.

3. Manufacturers and distributors of infant formulae shall not provide, to the general public or to pregnant women, mothers or members of their families, free or low-priced products, samples or any other promotional gifts, either directly or indirectly via the health care system or health workers."