



2015/0000(DEA)

16.12.2015

DRAFT MOTION FOR A RESOLUTION

pursuant to Rule 105(3) of the Rules of Procedure

on Commission delegated regulation (EU) No .../... of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding formula (DEA)

Committee on the Environment, Public Health and Food Safety

Rapporteur: Keith Taylor

European Parliament resolution on Commission Delegated Regulation (EU) .../... of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding formula (DEA)

- having regard to Commission delegated regulation (C(2015)06478),
 - having regard to Article 290 of the Treaty on the Functioning of the European Union,
 - having regard to Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009¹, and in particular Article 11(1) thereof,
 - having regard to the Scientific Opinion on the essential composition of infant and follow-on formulae of 5 August 2014, by the European Food Safety Authority²;
 - having regard to the UK Government's Scientific Advisory Committee on Nutrition (SACN) position statement of 24 September 2007³;
 - having regard to the United Nations Convention on the Rights of the Child;
 - having regard to the International Code of Marketing of Breast-Milk Substitutes adopted by the World Health Assembly in 1981 and the 16 subsequent relevant World Health Assembly Resolutions⁴;
 - having regard to the motion for a resolution by the Committee on the Environment, Public Health and Food Safety;
 - having regard to Rule 105(3) of its Rules of Procedure,
- A. whereas there is convincing evidence and consensus that exclusive breastfeeding followed by continued breastfeeding alongside appropriate complementary foods is the optimal way to feed infants and young children from a health, social and environmental point of view and that breastfeeding confers long-term health benefits for mothers including reduced risks for breast and ovarian cancers and birth spacing;
- B. whereas poor diet is now by far the biggest underlying cause of disease and death

¹ OJ L 181, 29.6.2013, p. 35.

² http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/3760.pdf

³ http://webarchive.nationalarchives.gov.uk/20140507013106/http://www.sacn.gov.uk/pdfs/position_statement_2007_09_24.pdf

⁴ http://www.who.int/nutrition/publications/code_english.pdf

globally - bigger than tobacco, alcohol and physical inactivity added together¹ and breastfeeding is related to lower risk of childhood obesity;

- C. whereas the World Health Organization (WHO) recommends that: *“infants should be breastfed exclusively during the first 6 months of life. From 6 months of age, breast milk should be complemented with a variety of adequate, safe and nutrient dense complementary foods. Salt and sugars should not be added to complementary foods”*²;
- D. whereas all Member States have consistently endorsed the International Code of Marketing of Breast-Milk Substitutes, adopted by the World Health Assembly (WHA) in 1981, and the 16 subsequent WHA resolutions that are designed to ensure that all parents and caregivers receive objective and truly independent information, to remove obstacles to breastfeeding and to ensure that breast milk substitutes are used safely if needed; they aim to protect everyone from misinformation and commercial promotion – protecting both breastfed and bottle-fed babies;
- E. Recent data on exclusive breastfeeding from 21 countries in the WHO European Region show that, on average, only 13 % of infants are exclusively breastfed during the first 6 months;
- F. whereas the delegated regulation fails to reference 16 WHA resolutions which strengthen and clarify the 1981 International Code;
- G. whereas according to the WHO, *“marketing of breast-milk substitutes, commercial “follow-on” and complementary foods are just some of the reasons for low breastfeeding rates and inequality in the WHO European Region”*;
- H. whereas the delegated regulation allows advertising of Infant Formula (IF) in 'publications specialising in baby care and scientific publications' but also states that *'Member States may further restrict or prohibit such advertising'* ;
- I. whereas the delegated regulation provides no legal certainty to Member States regarding the prohibition or restriction of advertising of Follow-on Formula (FOF);
- J. whereas in its 2014 Scientific Opinion, which was published only after the adoption of Regulation (EU) No 609/2013, EFSA notes that IF and FOF are compositionally the same (apart from a slight difference in target iron levels), demonstrating that the distinction between them is minimal and that there is no logic to permit such radically different marketing rules;
- K. Whereas the WHO position confirming that FOFs fall under the scope of the International Code³, was also published after Regulation (EU) No 609/2013.

¹ *Changes in health in England, with analysis by English regions and areas of deprivation, 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013 Lancet 2015; 386: 2257–74 Published Online September 15, 2015 [http://thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(15\)00195-6.pdf](http://thelancet.com/pdfs/journals/lancet/PIIS0140-6736(15)00195-6.pdf)*

² <http://www.who.int/mediacentre/factsheets/fs394/en/>

³ *Information concerning the use and marketing of follow-up formula WHO July 2013*

World Health Assembly Resolution (WHA 39.28) adopted in 1986 stated: (b) *the practice being introduced in some countries of providing infants with specially formulated milks (so-called “follow-up milks”) is not necessary.*

- L. whereas the delegated regulation allows pesticide residues in IF and FOF up to a limit of 0.01 mg/kg, whereas derogations are made to this limit for certain active substances listed in annex IV;
- M. whereas total exposure to harmful chemicals should not only take residues of pesticides into account but also residues of pharmaceuticals, both contained in mineral water necessary for the preparation of the formula and the migration into water and food of chemicals contained in food contact materials;
- N. whereas infants and young children are a particularly vulnerable population regarding endocrine disrupting chemicals, which are present in pesticides, and other contaminants;
- O. whereas in 2015 the International Agency for Research on Cancer - the specialized cancer agency of the World Health Organization - classified glyphosate as probably carcinogenic to humans¹;
- P. whereas, although Article 8 of the delegated regulation bans nutritional and health claims for IF, there is no such ban on these claims for FOF;
- Q. whereas any health and nutrition claim can be permitted for FOF provided it is authorised by the Commission under Commission Regulation (EC) No 1924/2006, even though FOF are not necessary, convey no health advantage to children and their marketing presents many risks;
- R. whereas nutritional and health claims on formulas for infants and young children threaten to undermine breastfeeding which is not on sale with clever packaging;
- 1. Objects to the Commission² delegated regulation;

International obligations

- 2. Considers that the delegated regulation does not contain sufficient provisions to prevent unfair competition with breastfeeding and therefore undermines the International Code of Marketing of Breast-Milk Substitutes and subsequent WHA Resolutions and MS efforts to implement them effectively;

Advertising

- 3. Considers that marketing of FOF should not be used as a Trojan horse that will mislead parents and caregivers and undermine breastfeeding both before and after six months;
- 4. Considers that advertising on IF should be prohibited;
- 5. Considers that advertising of FOF should be limited to 'publications specialising in baby care and scientific publications' and that Member States should be allowed to further restrict or prohibit advertising;

Contaminants

¹ <http://www.iarc.fr/en/media-centre/iarcnews/pdf/MonographVolume112.pdf>

²

6. Considers that, given the particular vulnerability of the endocrine system of infants and young children, zero tolerance for pesticides should apply as a general principle;
7. Considers that all derogations to the zero tolerance for pesticides principle should be explicitly listed in Annex IV which should regularly be updated towards constantly stricter maximum residue levels, in line with new scientific evidence. For instance, glyphosate should be added;

Health claims

8. Considers that health and nutrition claims on both FOF and IF should be prohibited;

Docosahexaenoic acid (DHA)

9. Considers that given the lack of available evidence on risks and benefits, the mandatory addition of DHA should be reconsidered. No additional transitional period for the statement referred to in Article 9(3) should be foreseen. The addition of warnings that some infants may not tolerate synthetic DHA should be considered.
10. Considers that, in line with the precautionary principle, the wording in Article 3(3) needs to be more specific and more stringent, and that the following should be added:
 - a) the systematic reviews should be carried out independently of the manufacturers and distributors of the products in question;
 - b) food ingredients that are not listed as essential should be kept to the bare minimum and all ingredients should only be pre-authorized following rigorous independent scrutiny. Particular care should be taken over new technologies, such as nanotechnologies;
 - c) the evidence base must be reviewed on a regular basis to ensure infants are not exposed to levels of nutrients that might put a burden on their metabolism, a concern already raised by EFSA;
 - d) the text must call for regular post market surveillance and assessment of the scientific data, indicating the frequency of such reviews.

Transparency

11. Considers that for the sake of building public trust in Union institutions and EU decision making, the list of "bilateral meetings" (including the date and participants) that the Commission held with interested parties in the process of drafting the delegated regulation should be made public;
12. Instructs its President to forward this resolution to the Commission and to notify it that the delegated regulation cannot enter into force;
13. Calls on the Commission to submit a new delegated act which takes account of Parliament's recommendations;
14. Instructs its President to forward this resolution to the Council and to the governments

and parliaments of the Member States.