European Parliament
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Committee on the Environment, Public Health and Food Safety

2015/0000(DEA)

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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 food for special medical purposes
(DEA)

Committee on the Environment, Public Health and Food Safety

Rapporteur: Keith Taylor

B8-0000/2015

European Parliament resolution 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 food for special medical purposes
(DEA)

The European Parliament,

– having regard to Commission delegated regulation (C(2015)06482);

– 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 953/2009[1], 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 Authority[2];

– having regard to the United Nations Convention on the Rights of the Child[3];

– having regard to the International Code of Marketing of Breast-Milk Substitutes adopted by the World Health Assembly in 1981[4] and the 16 subsequent relevant World Health Assembly Resolutions;

– 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 the existing lax rules on food for special medical purposes (FSMPs) have led to a growth in the market for unnecessary products containing thickeners and other ingredients labelled without the 'breastfeeding is best' statement;

B. whereas sick infants and children, at a vulnerable stage of growth and development, when the energy and nutrient intake per kilo bodyweight is greater, are in an even greater need of the protection of the International Code of Marketing of Breast-milk Substitutes (the 'International Code') and World Health Assembly (WHA) Resolutions than healthy babies;

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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://www.ohchr.org/en/professionalinterest/pages/crc.aspx
4 http://www.who.int/nutrition/publications/code_english.pdf

C. whereas while the ban on promotional claims for FSMP in the draft delegated regulation is welcome, it is however substantially weakened by the call in its recital 18 for 'restrictions' [on advertising, and promotional and commercial practices] to be 'similar to those applicable to infant formula and follow-on formula for healthy infants';

D. whereas the 'restrictions' [on advertising, and promotional and commercial practices] are mentioned in Article 10 of the draft delegated regulation on infant formula and follow-on formula, but whereas in the current wording of this Article, this draft Regulation makes a distinction that is not mirrored in recital 18 of the draft delegated Regulation on FSMP between infant formula and follow-on formula by allowing "*Member States*" to" *restrict or prohibit such advertising*" on infant formula but not on follow-on formula; whereas this lack of coherence between both draft delegated regulations might lead to legal uncertainty for Member States;

E. whereas many brand names used for FSMPs are de facto health claims leading to medicalization of common feeding occurrences;

F. whereas Article 8(4) of the draft delegated act contradicts the International Code and allows advertising of infant formula in 'publications specialising in baby care and scientific publications';

G. whereas publications 'specialising in baby care' are most likely to be read by pregnant women and new parents and will lead to misuse and self-diagnosis;

H. whereas scientific and factual information about FSMPs should be restricted to scientific publications;

I. whereas FSMP should only be used under medical supervision as they may require a risk assessment before use and therefore restrictions should be similar to those for infant formula with information about these products only permissible in scientific publications for health professionals;

J. whereas FSMP should carry all the warnings and notices required by the International Code regarding the superiority of breastfeeding and risks of artificial feeding, alongside the necessary precautions, known side-effects, contraindications, product-drug interactions, and alongside appropriate information about the correct use of the product; whereas only where this is necessary for specific conditions should a warning that breastfeeding is contraindicated be added;

K. whereas necessary measures must be taken to prevent misleading information to consumers;

L. whereas total exposure to harmful chemicals should also take into account the residues of pesticides and pharmaceuticals, both contained in mineral water and the migration into water and food of chemicals contained in food contact materials;

M. whereas the International Agency for Research on Cancer - the specialized cancer agency of the World Health Organization - classified glyphosate, a broadly used

herbicide, as probably carcinogenic to humans on 20 March 2015[1];

N. whereas the draft delegated regulation was prepared at a critical time when law-making processes are subject to intense lobbying, legal challenges from industry interests and diplomatic interventions from trading partners;

O. whereas in addition to transparent consultations with NGOs and other stakeholders in the context of the Advisory Group on the Food Chain and Animal and Plant Health, bilateral meetings were also held with "interested" parties without any public record of those;

1. Objects to the Commission delegated regulation;

Advertising, promotion and labelling

2. Considers that advertising of FSMPs should not be permitted and that information for health professionals must be restricted to scientific and factual matters;

3. Considers that points a to i in Article 5(1) and the statements required by the International Code, should all be preceded by the words 'IMPORTANT NOTICE';

4. Considers that the delegated regulation should specify that brand names that are de facto health claims should not be permitted;

Contaminants

5. Considers that given the particular vulnerability of the endocrine system of infants and young children as well as the de facto vulnerability of people with diagnosed disease, zero tolerance for pesticides should apply as a general principle;

6. Considers that all derogations to the zero tolerance for pesticides principle should be explicitly listed in Annex II which should regularly be updated towards constantly stricter maximum residue levels, following new scientific evidence on the health effects of active substances and their metabolites. For instance, glyphosate should be added;

Transparency

7. 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;

8. Instructs its President to forward this resolution to the Commission and to notify it that the delegated regulation cannot enter into force;

9. Calls on the Commission to submit a new delegated act which takes account of Parliament's recommendations;

[1] http://www.iarc.fr/en/media-centre/iarcnews/pdf/MonographVolume112.pdf

10. Instructs its President to forward this resolution to the Council and to the governments and parliaments of the Member States.