Annex 5

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Question 1. The Commission proposal restricts the scope of PARNUTS foods to three categories of foods, infant formula and follow-on formula, processed cereal-based foods and baby foods for infants and young children and medical foods. We would be grateful for your views on the proposed list.
The following comments are submitted on behalf of Baby Milk Action, IBFAN and the Baby Feeding Law Group, It is critically important that all foods for infants and young children (up to the age of three years) including milks for pre-term babies, foods for special medical purposes and young children are covered by a thorough process that ensures safety and efficacy. For this to be effective, the changes to the PARNUTs procedures recommended by the Baby Feeding Law Group must be made.
Question 2. The proposal plans to repeal Regulation (EC) 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten. It is proposed that the statements 'gluten-free' and 'very low gluten' and their associated requirements would be recast as nutrition claims as defined in Regulation (EC) No 1924/2006. We would welcome views on the impact of the proposed changes to the legislative requirements to these foodstuffs.
We have no opinion on this.
Question 3. The proposal aims to repeal Directive 96/8/EC, the slimming foods directive, what is the impact of this on this food sector?
We have no considered opinion – but in general agree that the list of foods covered should be reduced.
Question 4. What is the impact of the removal of the concept of dietetic foods from the Framework? How would you like the products marketed as dietetic foods to be handled?
We have no regarding the word 'dietetic' The important issue is whether all foods for infants and young children are to be considered as a special case and whether the rules governing them can be made much more specific and safer in

relation to the authorisation of ingredients, labelling and marketing.

Question 5. What is the impact of the proposed pre-authorisation of PARNUTS being centralised to the European Commission?

We strongly support Option 4 of a standard prior-authorisation procedure across the European Union. But understand that this NOT the option preferred by the Commission

Although the application of such a standard would ensure more harmonisation across the European Union than the general notification procedure currently in place. The argument is given that this would increase the burden on industry and would be disproportionate in terms of consumers' protection

This is unacceptable and totally false. Since infants and young children are a vulnerable group it is essential that all ingredients are thoroughly tested for safety and efficacy by an independent process The notification procedure outlined in the EU Directives are inadequate and contain numerous loopholes and exceptions. The definitions regarding the scientific justification for the inclusion of new ingredients are also inadequate and out of date.

Although the revised EU Directive (2006/141/EC) in many ways improved the *essential* composition of formulas, this improvement is undermined by the provision on *optional ingredients* which allows companies to add *other food ingredients, as the case may be.* There is no requirement that the ingredients are evaluated by an independent scientific body prior to introduction onto the market - even though the majority of EU member States and the EU's advisory body, the Scientific Committee for Food [1], called for this important safeguard. If manufacturers introduce a new infant formula they only have to submit a label to the authorities - and that is all. While some Member States may require a dossier to support safety or efficacy claims, there is no legal requirement. There is no notification procedure at all for follow-on milks. To make matters worse, follow-milks may be able to carry claims which are supported only by research on adults.

The relevant Directives should be revised to reflect these concerns by removing the provisions regarding optional ingredients and requiring a rigorous pre-authorisation system involving a thorough review of all evidence (which must include independently funded evidence) by an independent body.

Baby Milk Action and the Baby Feeding Law Group consider that if an ingredient is essential for health and has proven to be safe by

[1] Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae SCF/CS/NUT/IF/65 Final 18 May 2003

independently funded and independently reviewed research, then it should be a mandatory requirement for all formulas.

Question 6. The Commission expects the proposal will reduce administrative and financial burdens on industry and Member States' competent authorities. We would be grateful for your views on possible financial implications including costs and benefits, which will inform the UK impact assessment.

The impact assessment does not take into account the health impact of a failure to include a pre-authorisation, nor does it take into account the impact such an omission has on global health.

Breastmilk substitutes are the sole source of nutrition during a critical period of rapid growth and development. Minor modifications can have major effects on infant health. The Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae identified some of problems that have occurred with the introduction of modified infant formulae. Examples included reduced protein availability with impairment of growth; trace element deficiency with severe clinical disease; chloride deficiency with long-term neurological damage and thiamine deficiency with severe clinical disease, including neurological damage and several cases of infant death. The EU Directive's failure to include a rigorous pre-market authorisation has allowed companies to add any ingredient they choose - before its safety has been properly evaluated - simply to gain competitive advantage, and effectively using European babies in a mass uncontrolled trial.

ESPGHAN also made comments in the conclusion of the International Expert Group report on the composition of infant formulae and the issue of established history of apparently safe use, [2] pointing out that problems with infant formulas

[2] ESPGHAN Comments on the Circular Letter CL 2005/53-NFSDU and on the Synopsis of comments received until 30 April (prepared by Germany) *"The question arises whether the ranges of nutrient levels in infant formulae that are reported by ISDI, without documented occurrence of side effects, suffice to establish a "history of safe use", or even of adequacy of such nutrient levels for infant formulae. ISDI suggests that a history of apparently safe use of products might be based on the use of commercially produced infant formula and the monitoring of spontaneous consumer reports of observations that may indicate a problem with a specific batch of formula. In some areas, such as Europe, Israel and the USA, there are consumer phone line services have been established where parents may call in, usually free of charge, to place questions or complaints to the manufacturer or distributor of an infant formula. ISDI explains that such customer reports are monitored and should provide a tool for post-marketing surveillance of infant formula safety. Based on the evaluation of these consumer phone line services and the absence of detected serious side effects, ISDI implies that a history of safe use has been established for the nutrient levels reported in their compilation. ESPGHAN wishes to emphasize that there is no evidence available to show that the evaluation of consumer phone line services is sensitive enough to detect adverse effects of infant formulae."*

are not always disclosed, and one should certainly not rely - as ISDI had suggested in its position paper – that consumer phone lines (especially industry-sponsored ones) provide reliable evidence of safe use.

"ESPGHAN wishes to emphasize that there is no evidence available to show that the evaluation of consumer phone line services is sensitive enough to detect adverse effects of infant formulae. On the contrary, for example the very severe adverse effects recently induced by an infant formula with inadequate contents of vitamin B1 (thiamine), which resulted in failure to thrive, severe neurological damage, severe lactic acidosis and even infant deaths (2-4), were not detected by the distributor's consumer phone line services…."

Question 7. Would the changes proposed impact differently on any of the "protected characteristics" (age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex or sexual orientation) with regard to the Equality Act 2010 and Equality Duty?

We welcome your views on any other questions/issues that you may have with the proposal.

Further comments and recommendations:

3 **Transparency and accountability:**

The following 'whereas' must be amended or deleted: *"Whereas the drawing-up of specific Directives implementing the basic principles of Community rules and amendments thereto are implementing measures of a technical nature, whereas their adoption should be entrusted to the Commission in order to simplify and expedite the procedure."*

- Directives covered by PARNUTs such as the Infant Formula Directive (2006/141/EC) are not confined to 'technical' issues and have a substantial impact on public health policies. It should be mandatory that Parliamentarians and public interest NGOs are consulted and give approval for any changes to legislation relating to any foods for infants and young children – whether or not these products are covered by the PARNUTS Directive.
- It is not sufficient that the Commission consults only the *Standing Committee on the Food Chain and Animal Health (SCFCAH),* in closed sessions with inadequate and partial summary records. There should be publicly available records of these meetings, detailing the opinions of all Member States and the rationale for how decisions are made. Similar records of the working groups should also be made available.
- Observers should be permitted to attend the Expert Meetings and Working Group meetings and give the opportunity to participate in discussion as is the case in Codex

Alimentarius and World Health Assembly meetings.

4 **The words "in good health" must be removed from Article 1 (iii)** Despite many attempts to do so, the medical profession is unable to define the term "good health." The range of products includes those for infants with special medical conditions. The words are unnecessary and create loopholes.

5 **Policy coherence** A new paragraph should be inserted stating that the all articles of the PARNUTS Directive should be in conformity with the World Health Assembly Resolutions on Infant and Young Child Feeding and the Global Strategy on Infant and Young Child feeding and the Global Strategy on Diet, Physical Activity and Health, which all EU Member States have endorsed. The UK Government and all EU Member States have international obligations to implement the International Code and Resolutions which are ***minimum standards*** to be ***implemented in their entirety***.

- Regulatory Impact analysis should take into account the health, social and environmental costs of the proposed changes – not only in Europe but also globally.

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