Department of Health

Public Health Directorate
Department of Health
Wellington House
133-155 Waterloo Road
London
SE1 8UG

www.gov.uk/dh

(E-mail only)

Your Ref: BNSA/028/13

29 July 2014

Dear Colleagues,

Re: Request for information on infant and follow-on formula

The EU regulation No 609/2013 on Food for Specific Groups adopted on 12 June 2013 requires the European Commission to set specific compositional and information requirements for infant and follow-on formula by means of a delegated act. The Commission asked EFSA to provide a Scientific Opinion on the "essential composition of infant and follow-on formulae", which was published on the 24th July 2014 (http://www.efsa.europa.eu/en/press/news/140724.htm).

Discussions are now underway at EU level on the development of new delegated acts on infant and follow-on formulae. As part of these discussions, the Commission is seeking views on proposals regarding the compositional requirements of infant and follow-on formulae and use of nutrition and health claims on infant formulae.

Please provide any comments you may have in response to the following issues and respective questions:

1. Mandatory ingredients

Directive 2006/141/EC sets compositional requirements for infant and follow-on formulae. Based on updated scientific advice, in their recent scientific opinion, EFSA proposes values for energy and nutrients that have to be included in infant and follow-on formulae on a mandatory basis. The main difference compared to existing legislation is the presence of DHA (in the range 20-50mg/100kcal).

a) Do you agree that it is appropriate to follow EFSA's recommendations with regard to mandatory ingredients?

2. Optional ingredients and claims on these ingredients

Annexes to Directive 2006/141/EC list certain substances that may be added to formulae on a voluntary basis (long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids, taurine, nucleotides, fructo-oligosaccharides and galacto-oligosaccharides (FOS/GOS)

and phospholipids) and set out specific values if these are added. Other substances may be added provided they meet suitability requirements set out in Articles 5 and 6.

EFSA reviewed the scientific evidence for substances that could be voluntarily added and concluded that there is no necessity for such ingredients.

There are conflicting views on this subject, with some stakeholders arguing for the flexibility to allow manufacturers to develop innovative products, without which it would not have been possible to prove the necessity of some substances which are now regarded as essential e.g. choline, inositol and DHA. Others believe that unnecessary ingredients put an additional burden on the delicate metabolism of infants and only ingredients proven to have a beneficial effect should be included on a mandatory basis. Some Member States have called for a centralised prior authorisation procedure at EU level for the addition of optional ingredients, based on EFSA advice, ensuring harmonisation in the market and consumer protection.

With the aim of finding a balanced solution, the Commission proposes continuing to allow optional ingredients but to no longer allow nutrition claims to be made in relation to these ingredients given that the beneficial effects of these substances are not sufficiently scientifically substantiated yet.

1) Do you agree that optional ingredients should continue to be allowed to be added to formulae
   a) under the current provisions (i.e. Food business operators providing evidence on the suitability of ingredients for national control authorities to approve)? Or
   b) under a harmonised approach for all optional ingredients to be agreed through a centralised agreement process for use in all Member States?
2) Do you agree that nutrition claims should no longer be allowed on optional ingredients? Please provide evidence to support your position.

3. Protein hydrolysates as protein sources for infant and follow-on formulae

Protein hydrolysates are permitted as a protein source in infant and follow-on formulae. It is the manufacturer's responsibility to ensure such formulae comply with the requirements on safety and suitability set out in Directive 2006/141/EC.

The Commission believes that the use of protein hydrolysates may be widespread because of the possibility to use the health claim on the reduction of risk to allergy to milk proteins, although they may also be in products without a claim.

The Commission has made a request for information on infant and follow-on formulae manufactured from protein hydrolysates currently available on the market.

Please provide any information you have in response to the following questions:

a) Details of products available on the market that contain protein hydrolysates and the market share of these products.

b) The composition of the product, in particular the sources used to create the protein hydrolysates and the extent of protein hydrolysation?

c) The price of these products, i.e. are they more or less expensive than formulae from intact protein?

d) What claims are made for the product, particularly with regard to hypoallergenicity? Are there any infant formula products on the market which contain hydrolysed protein but do not use any claim in relation to the hypoallergenicity of the product?

In its Scientific Opinion, EFSA states that "the safety and suitability of each specific formula containing protein hydrolysates has to be established by clinical studies" and concludes that "those formulae are insufficiently characterised by the declared protein content…and that the safety and suitability of each specific IF or FOF containing protein hydrolysates has to be established by clinical evaluation."

The Commission sets out the following two options regarding the manufacture of formulae from protein hydrolysates.

- Maintaining the status quo to minimise market disruption given that no adverse effect has been reported in relation to protein hydrolysates.
- The suitability of the formulae manufactured from protein hydrolysates should be demonstrated on a case-by-case basis through clinical studies. This would be aimed at increasing infants' protection but would impact on products already on the market.

e) What is your preferred option?

f) Do you have any alternative suggestions?

4. Maximum amounts for micronutrients

In its Scientific Opinion, EFSA proposes minimum amounts of micronutrients for formulae and noted that these should be considered target values, sufficient for the needs of virtually all healthy infants. EFSA concluded there was no need to provide nutrients in higher amounts and proposed no maximum levels.

They noted that there is lack of evidence around adverse effects of currently permitted maximum amounts of micronutrients and therefore EFSA do not consider it appropriate to propose maximum values. However, an infant consuming formula containing currently permitted maximum micronutrient levels could exceed the tolerable upper levels (TUL) for zinc, iodine, vitamin A and folate.

A statement by the UK's Committee on Toxicity has identified that intakes of vitamin A could exceed TULs by 80% (http://cot.food.gov.uk/pdfs/cotstavita.pdf). However, there is scientific uncertainty related to the setting of tolerable upper levels of micronutrients for

infants, therefore as EFSA has given a target level for composition rather than a minimum and maximum, tolerance levels for nutrient declarations could be considered around this target level, rather than maximum tolerable upper levels.

The Commission recommends maximums should be set for safety reasons, to avoid indiscriminate addition of micronutrients and to ensure uniform judgement across Europe. They suggest a range approach allows manufacturers flexibility, taking into account variability in nutrient sources and shelf-life. The following options are proposed:

- Retaining the maximum amounts set in Directive 2006/141/EC, taking into account history of safe use. Theoretically, this could result in exceeding upper limits for some micronutrients.
- Retaining the maximum amounts but revising the maxima for zinc, iodine, vitamin A and folate to avoid risk of upper limits being exceeded.

Another option may be to apply a tolerance level to the target amount for micronutrients in the same way as those that have been agreed for nutrition declarations for other foods http://ec.europa.eu/food/food/labellingnutrition/nutritionlabel/guidance_tolerances_december_2012.pdf. Actual tolerance levels would need to be discussed and agreed.

a) Do you agree with maintaining maximum amounts as they currently stand?
b) Should the maximums for zinc, iodine, vitamin A and folate be revised?
c) Should 'minimum' levels be viewed as target levels for micronutrient content with appropriate tolerances for the nutrient declarations?

Please provide evidence to support your position.

5. Nutrition and health claims in infant formulae

Infant formula can only display the following nutrition and health claims (with their associated conditions of use) listed in Annex IV of Directive 2006/141/EC:
Nutrition claims: Lactose only, Lactose free, Added LCP, Addition of taurine, FOS/GOS, nucleotides
Health claim: "Reduction of risk to allergy to milk proteins"

Lactose – The Commission proposes that information regarding the presence of lactose should no longer be considered as nutrition claims but instead should be "statements related to the lactose content in formulae" with specific regulations set out in the delegated act.

Foods for special medical purposes with a lactose free claim could be affected by this change and could be repositioned as normal formulae.

The Commission also suggests 'lactose free' should be allowed on formulae containing less than 10mg/100kcal, which is compatible with requirements of infants suffering from galactosaemia. To obtain this, the current requirements for minimum lactose content would have to be adjusted in cases where the product bears the 'lactose free' statement.

a) Are you content with the proposed approach? Please provide evidence to support your position.

Omega 3 – EFSA recommends the mandatory addition of DHA to infant formulae and follow-on formulae. The Commission proposes that operators could continue to make a claim related to omega 3, as currently permitted, but should make it clear that this applies to the whole category of products, for example 'contains LCP (as required by legislation for all infant formulae)'.

b) Are you content with the proposed approach? Please provide evidence to support your position.

Health claim on hypoallergenic properties – In addition to EFSA's recommendation for individual assessment of the suitability of each hydrolysed protein formulae, EFSA recommends a case-by-case approach to assessing the proposed claim for reduced risk of developing allergy for each formulae containing hydrolysed protein.

c) Are you content with the proposed approach? Please provide evidence to support your position.

We appreciate any input you are able to provide and please contact me if you wish to discuss.

Yours faithfully,

Trudy Netherwood

Nutrition Legislation Team, Obesity & Food Policy Branch, Health & Wellbeing Division
D: 0207 972 3255
E: Trudy.Netherwood@dh.gsi.gov.uk