

To: Lead Food Officers

Cc: SFELC

22 March 2019

Ref: FSS/ENF/19/001

Dear Colleague

**Notification of changes in formulation of infant formula**

In July 2016, [Regulation \(EU\) No 609/2013](#), otherwise known as the Regulation on 'Foods for Specific Groups' (FSG), came into force, and replaced the 2009/39/EC European Framework Directive on Foods for Particular Nutritional Uses (the 'PARNUTs' Framework).

Under the FSG framework, the specific specialist [Directive 2006/141/EC](#) on infant formula and follow-on formula will be replaced by [Commission Delegated Regulation \(EU\) 2016/127](#). This European [Commission Delegated Regulation \(EU\) 2016/127](#) will apply from 22 February 2020, except in respect to infant formula and follow-on formula manufactured from protein hydrolysates, to which it shall apply from 21 February 2021. Under the new [Delegated Regulation \(EU\) 2016/128](#), from February 2020, infant food for special medical purposes (FSMPs) will be similarly affected by formulation changes.

The new legislation brings some significant compositional changes based on the latest scientific research to infant and follow-on milks. One particular significant change introduced by these new Regulations is the mandatory addition of Docosahexaenoic acid (DHA) to infant formula, follow-on formula and infant FSMPs, as recently recommended by the European Food Safety Authority in its opinion on the essential composition of infant and follow-on formulae. DHA was allowed on a voluntary basis under [Directive 2006/141/EC](#).

These compositional changes will have an impact on the organoleptic properties of the baby formulae. As such, care must be taken to communicate these compositional changes to health care professionals (HCPs) and parents in a timely manner to let them know that their bottle-fed babies will notice a difference in taste and smell. Settling issues may also be noticed by parents; however, this is normal and they should be

reassured that those changes are based on the latest science and are made for the benefit of their babies.

The British Specialist Nutrition Association (BSNA) (the trade association representing infant formula manufacturers) wish to provide information to parents/carers regarding changes to the composition of infant formula due to the new EU legislation and have developed shelf edge and website notices for that purpose (attached below).

To ensure compliancy by 22 February 2020, companies will need to start implementing these changes very soon. Therefore, while this regulation does not come into force until post-Brexit, these changes will be seen on the UK market pre-Brexit.

If you have any queries on this letter, please do not hesitate to contact me.

Yours sincerely

Amber Souter  
Projects Manager  
Food Standards Scotland

## Regulatory Compliance: Reformulation changes

### Point of sale: Notice on shelf

#### *Important information*

*The regulations on the ingredients of infant and follow-on formula have been updated.*

*As a result, all the recipes will be changing over the next 15 months and you may notice some small differences in the smell, appearance or taste of the products.*

*If you have any questions or concerns, please contact your health care professional and/or the manufacturer/careline. Look out for further information to tell you when your brand is changing.*

Notices at point of sale and on website from January 2019 to February 2020, or earlier, if all formulation changes have been made before February 2020.

### On stakeholder/microsite websites

#### *Important information*

*The regulations on the ingredients of infant and follow-on formula have been updated to reflect current scientific thinking.*

*As a result, all the recipes will be changing over the next 15 months and some nutrients will now be present in different amounts. For example, there are now higher minimum amounts for an omega-3 essential fatty acid. You may notice some small differences in the smell, appearance or taste of the products. Look out for further information to tell you when your brand is changing.*

*If you have any questions or concerns, please contact your health care professional and/or the manufacturer/careline.*