

NEW EU INFANT NUTRITION LEGISLATION

what you need to know and how it affects you as a health care professional

The European Commission has recently introduced new legislations that affect all FSMPs (EU Delegated Regulation 2016/128) as well as infant formulas and follow-on formulas (EU Delegated Regulation 2016/127), thus enhancing existing legislations. This means that all medical nutrition manufacturers distributing these product categories in the European Union need to adapt their formulations to specific nutritional requirements. All companies need their infant feeds to be compliant with the new EU regulations within the 22nd of February 2020*.



Composition changes

Changes in mandatory minimum and maximum amounts of nutrients

- All our complete formula products need to be reformulated
- Mandatory addition of the omega-3 fatty acid Docosahexaenoic Acid (DHA) in the range 20-50 mg/100 kcal
- Detailed compositional rules concerning the minimum/maximum content of vitamins, mineral substances and other nutrients

Other minor improvements to the product formulations may be made.



Nutrition labelling

Changes in the presentation of the nutrition table and ingredients list

- Unit changes for some nutrients
- Changes in the declaration of some nutrients, e.g. Folic Acid to be listed as Folate (µg-DFE)
- Changes to permitted statements on the pack information

WHAT ARE THE KEY CHANGES?



Communication

Updated rules for support materials and label descriptions

- Enhanced restrictions on permitted declarations and wording
- Only information on properties and characteristics related to the medical condition and the use of infant FSMP shall be provided
- No nutrition and health claims allowed for infant FSMPs

Compliance

From the 22nd of February 2020, all infant formulas, follow-on formulas (EU Delegated Regulation 2016/127) and infant food for special medical purposes (EU Delegated Regulation 2016/128) manufactured must comply with the changes. FSMPs intended for infants manufactured after the 22nd of February 2020 must be produced with the updated formulations.

*However, as per legislation, feeds produced before this specific date may continue to be sold until stocks are exhausted. Some of our products, especially those with low usage which may be produced infrequently, will be available with the updated formulation from mid 2020. Infant and follow-on formula manufactured from protein hydrolysates must be compliant by the 22nd of February 2021.