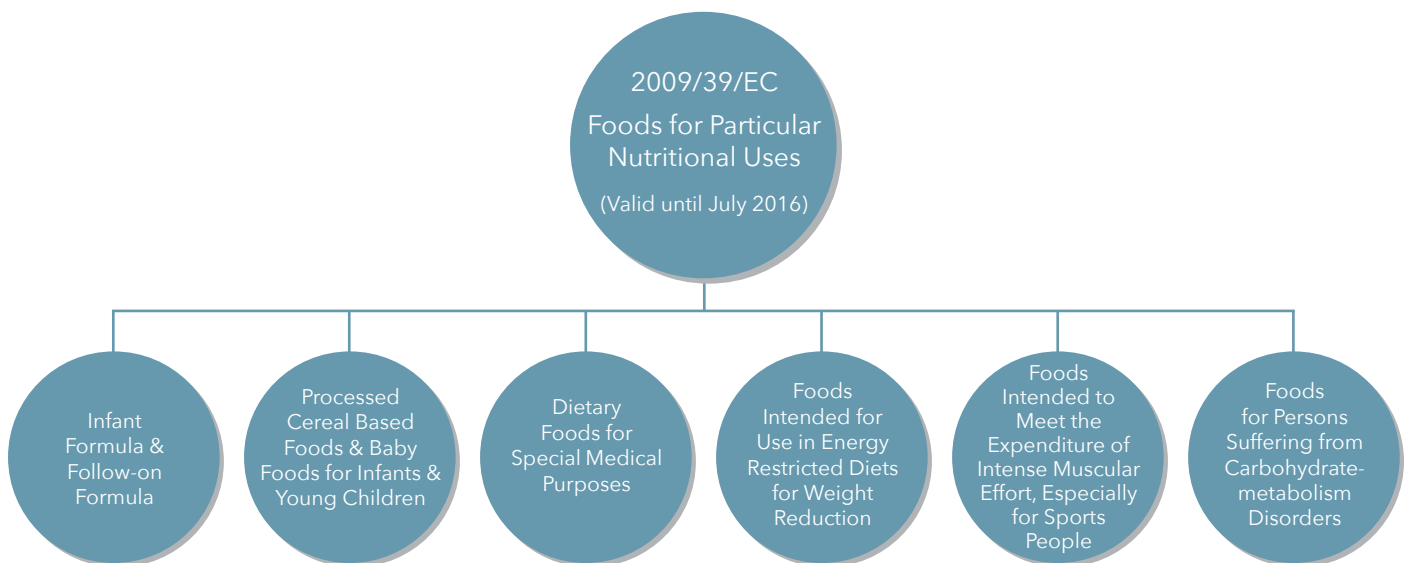


# Changing Eu Legislation On Foods For Particular Nutritional Uses

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The past few years have seen big changes in how nutritional or dietetic products are regulated in the European Union. Historically Foods for Particular Nutritional Uses (PARNUTs) were regulated via a framework Directive (2009/39/EC) and specific Directives were foreseen for certain categories of PARNUTs as shown below:



Under this framework, specific Directives were published for infant and follow on formula; cereal based and other baby foods; medical foods; and products for weight reduction. The specific Directives laid down rules for the relevant product category e.g. the essential requirements (nature or composition) of the

product; provisions regarding raw materials; rules for labelling, presentation and advertising etc. Specific rules for 'Food Intended to Meet the Expenditure of Intense Muscular Effort Especially for Sports People' and 'Foods for Persons Suffering from Carbohydrate-metabolism Disorders' (diabetes) were never established.

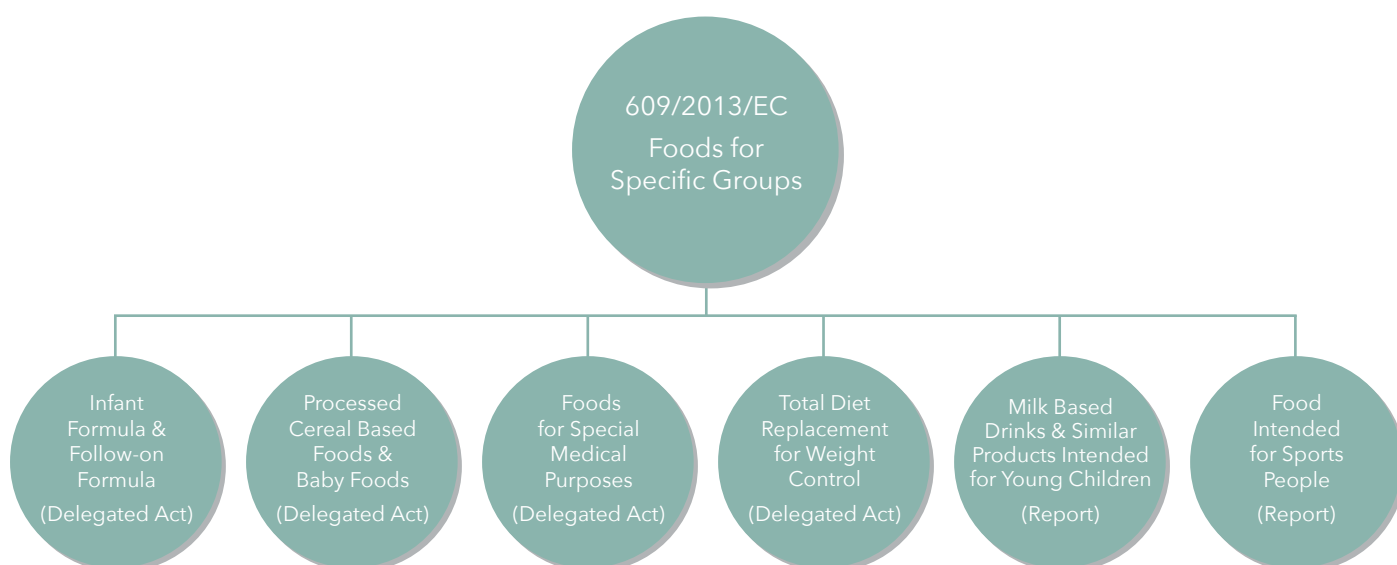


Regulation 609/2013/EC on Foods for Specific Groups has been in force since July 2013 and will apply from July 2016. This legislation foresees the establishment of delegated Acts, which would outline specific compositional and labelling rules for:

- **Infant and Follow-on Formula**
- **Processed Cereal Based Food and Baby Food**
- **Foods for Special Medical Purposes**
- **Total Diet Replacement for Weight Control**

In addition to removing the reference to Article 11 PARNUTs as described above, the FSG legislation acknowledges the need to consider the state of play for milk based drinks and similar products intended for young children and foods intended for sports people (as depicted below). This is because many products marketed in this way are available on the EU market but there is no specific legislation regulating such products. The idea of specific rules for 'Foods for Persons Suffering from Carbohydrate-metabolism Disorders' was dismissed by the Commission as current dietary advice for diabetics recommends following healthy eating guidelines in line with those for the general population. With no need for specific foods for diabetics, there is no requirement for specific rules for such foods.

The PARNUTs legislation also had the benefit of Article 11, which allowed the food industry flexibility to market other nutrition products, which had no specific rules. Such products had to be marketed to indicate their suitability for the nutritional use i.e. their special composition or manufacturing process, which distinguished them from foods for normal consumption. However, differences in implementation of this Article across Member States was a cause for concern for the EU Commission and the PARNUTs model was abolished in 2013 with the advent of the Regulation on Foods for Specific Groups (FSG).





## FSG Regulation

In February 2016, the first of the delegated acts linked to the FSG Regulation were published:

- Commission Delegated Regulation 2016/127/EC regarding the specific compositional and information requirements for infant formula and follow-on formula, and regarding requirements on information relating to infant and young child feeding
- Commission Delegated Regulation 2016/128/EC regarding the specific compositional and information requirements for food for special medical purposes

### The main changes to these pieces of legislation were:

- Modifications to the maximum and minimum levels of nutrients
- Updates to labelling rules in line with legislation on food information to consumers (1169/2011/EC)
- Changes to rules on nutrition and health claims for such products
- Provision for an update to rules on pesticides
- Introduction of an EFSA (European Food Safety Authority) approval for infant and follow on formula made from protein hydrolysates

### The legislation for different product categories will come into force on the following dates:

Product	Infant Formula & Follow-on Formula	Infant Formula & Follow-on Formula from Protein Hydrolysates	Foods for Special Medical Purposes	Foods for Special Medical Purposes for Infants
Date	22 February 2020	22 February 2021	22 February 2019	22 February 2020



It was expected that the Delegated Act on Baby Foods would also be published in February 2016, however this draft legislation was rejected by the European Parliament due to concerns regarding the sugar content of such products. MEPs felt that maximum sugar levels should be reduced to be more in line with levels recommended by the World Health Organisation (WHO). The European Commission must now redraft the legislation on baby foods, which is expected to take another two years. The current Directive (125/2006/EC) will remain in force for the foreseeable future.

The draft Delegated Act on Total Diet Replacements for Weight Control was not brought to vote at the European Parliament as it is still in discussion at the Commission level. A significant difference to this draft legislation is the change in scope: the existing legislation is for all foods intended for weight reduction, however it is proposed that new legislation will be for total diet replacements to be used in weight control. Changes to labelling rules as well as changes to maximum and minimum nutrient levels are also expected for this product group.

The FSG Regulation had foreseen European Commission reports on the necessity of specific legislation on Young Child Formulae and Sports Foods by July 2015. At the time of writing (April 2016) the report on Sports Foods is still in preparation and the final version has yet to be published. The Commission report on Young Child Formulae was published in March 2016 and concludes that 'the correct and complete application of the general framework of EU food law seems sufficient to adequately regulate the composition of young-child formulae'. This means there will be no specific legislation covering this particular food group.



Once the FSG regulation comes into force in July 2016, the PARNUTs legislation will be repealed. This means the so called Article 11 PARNUTs (as discussed above and including young child formulae) will no longer be able to market themselves to indicate their suitability for a particular nutritional use and may have to adapt their composition.

These foods will no longer be considered PARNUTs, but rather general foods. This means they will have to comply with all legislation specific to general foods, most notably legislation on:

- Nutrition and health claims
- Food fortification
- Food supplements

The change in how these products are regulated will bring new challenges to the industry. This will be most noticeable in the need to comply with nutrition and health claims as a means to indicate suitability given that the nutrition and health claims process has been problematic for the food industry to date.

