

Consultation for Ireland on proposed changes to legislation regulating Foods for Particular Nutritional uses (PARNUTs)

The FSAI are seeking your views on the proposed changes to legislation regulating PARNUTs. The European Commission has reviewed the PARNUTs Directive (2009/39/EC) and related specific legislation and has developed a proposal to simplify the rules for PARNUTs. This document endeavours to explain the options available and outlines the advantages and disadvantages that were recognised by the EU working group for each option.

Topic: Proposed revision of European legislation on Foodstuffs intended for Particular Nutritional Uses (also known as 'PARNUTs') covered by Directive 2009/39/EC and related legislation

Start date of consultation: 15/11/2011

Closing date of consultation: 15/12/2011

Consultation details

Background:

Current Situation

Foodstuffs regulated by Directive 2009/39/EC and related legislation are referred to as PARNUTs. They include the wide number of foods on the market which have a particular nutritional use, see **Figure 1**.

Current legislation regulating foods for Particular Nutritional uses (PARNUTs) which includes PARNUTS Framework Directive 2009/39/EC and related specific legislation

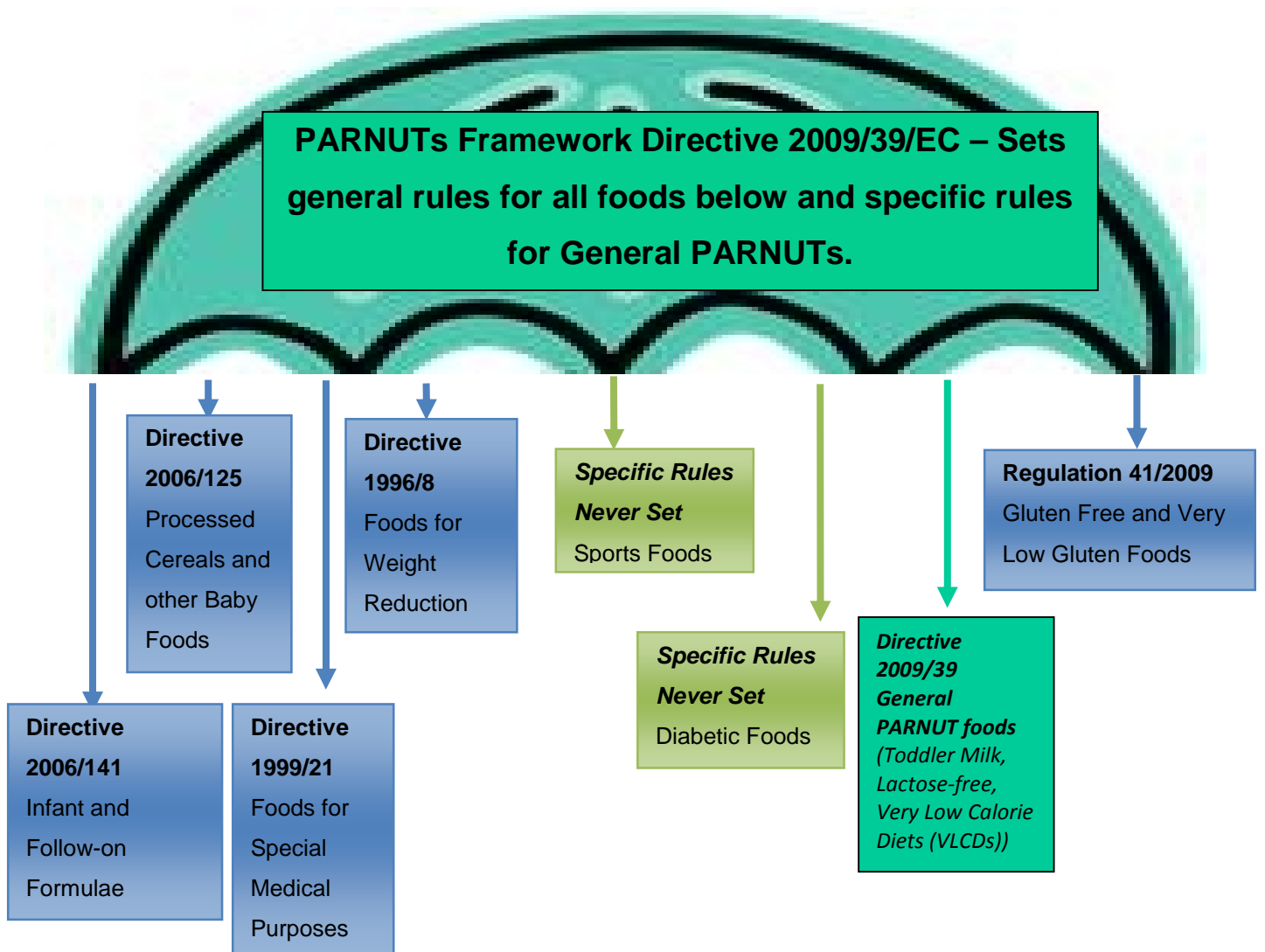


Figure 1: PARNUTs Framework Directive 2009/39/EC and related specific legislation

As outlined in **Figure 1** PARNUTs Framework Directive 2009/39/EC regulates general PARNUTs which are not covered by related specific legislation. This Directive (2009/39/EC) sets out labelling, composition and other rules for General PARNUTs.

Examples of General PARNUTs include;

- Toddler Milks (that do not meet the criteria to be covered by Infant and Follow on Formula Directive 2006/141)
- Very Low Calorie Diets (VLCDs) (do not meet the criteria to be covered by Foods for Weight Reduction Directive 1996/8)

- Other General PARNUTs which are not covered by any specific legislation such as lactose-free foods, etc.

Also outlined in **Figure 1** is the related legislation (four Directives and one Regulation) which sets out specific rules for certain categories of PARNUTs:

- Directive 2006/141 Infant and Follow-on Formulas
- Directive 2006/125 Processed Cereals and other Baby Foods
- Directive 1999/21 Foods for Special Medical Purposes
- Directive 1996/8 Foods for Weight Reduction
- Regulation 41/2009 Gluten-free and Very Low Gluten foods

While it was planned to develop specific rules to cover Sports Foods and Diabetic Foods, these have never been established.

Why change the current situation?

The current PARNUTs Framework Directive and related specific legislation is very complicated. It presents practical difficulties for both food industry and enforcement.

In addition some aspects of the more recent Nutrition and Health Claims Legislation are not compatible with the PARNUTs Framework Directive and related specific legislation. For example, in the future food products bearing weight loss health claims approved under 1924/2006 may have conditions of use that are not consistent with compositional criteria in Directive 1996/8.

Proposal:

The European Commission has reviewed the PARNUTs Directive (2009/39/EC) and related specific legislation and has developed a proposal to simplify the rules for PARNUTs.

The draft proposal merges the specific rules of 3 Directives, into a new regulation- *Food Intended for Infants and Young Children and Foods for Special Medical Purposes*. The 3 Directives are:

- Infant formula and follow on formula (Directive 2006/141)
- Food Intended for Infants and Young Children (Directive 2006/125) and

- Foods for Special Medical Purposes (FSMP) (Directive 1999/21/EC)

It is intended to discard the following legislation:

- PARNUTs Framework (Directive 2009/39/EC),
- Foods for Weight Reduction (Directive 1996/8),
- Gluten Free and Very Low Gluten Foods (Regulation 41/2009).

Furthermore under the draft proposal specific rules will not be developed for the following PARNUTs:

- Sports Foods
- Diabetic Foods

PARNUTs covered by legislation which is to be discarded will be regulated under existing related nutrition law:

- Nutrition and Health Claim (Regulation 1924/2006)
- New Food Information Regulation (*The proposed new Food Information Regulation will replace the current rules for General Food Labelling of pre-packaged foodstuffs. It is due to be published on 22nd November 2011 and will apply 3 years after this date.*)

The options are illustrated in **Figure 2**.

It is currently unclear which legislation may be used to regulate *General PARNUTs* categories. For example, Lactose-free foods currently covered under General PARNUTs (Directive 2009/39/EC) may be regulated under Nutrition and Health Claims or the New Food Information Regulation.

VLCDs are another example of a General PARNUT that may be regulated under Nutrition and Health Claim (Regulation 1924/2006) or alternatively VLCDs may be categorised as a FSMP and covered under the new proposal.

Toddler Milks are another category where it is unclear whether they can be adequately regulated under Nutrition and Health Claims (Regulation 1924/2006). There are no other options for regulating Toddler Milks under discussion at present.

Specific related legislation related to the PARNUTs Framework Directive (2009/39/EC) for Foods for Weight Reduction (Directive1996/8) are proposed to be regulated under the Nutrition and Health Claim (Regulation 1924/2006). Similarly it is proposed that those PARNUTs where specific rules have never been developed Sports Foods and Diabetic Foods will also be regulated under Nutrition and Health Claims (Regulation 1924/2006).

It is unclear whether Gluten Free and Very Low Gluten Foods (Regulation 41/2009) will be regulated under New Food Information Regulation or under Nutrition and Health Claims (Regulation 1924/2006)

The FSAI seek your views on the implications of the proposed changes to PARNUT legislation (outlined above and illustrated in Figure 2).

The FSAI welcome any recommendations you may have for progressing the development of the new rules for PARNUTs.

To help guide your response we have included the possible advantages and disadvantages of the proposed legislative changes to the PARNUTs legislation that were raised by the EU working group. To make a submission please complete the attached questionnaire outlined in Appendix 1. Please note section 1 is compulsory. The remaining sections are optional and you may complete what is relevant to you.

Please complete **SECTION 1** of the questionnaire and any of the questions in **SECTION 2** that you wish to comment on.

~~PARNUTs Framework Directive 2009/39/EC –
Sets general rules for all foods below and
specific rules for General PARNUTs.~~

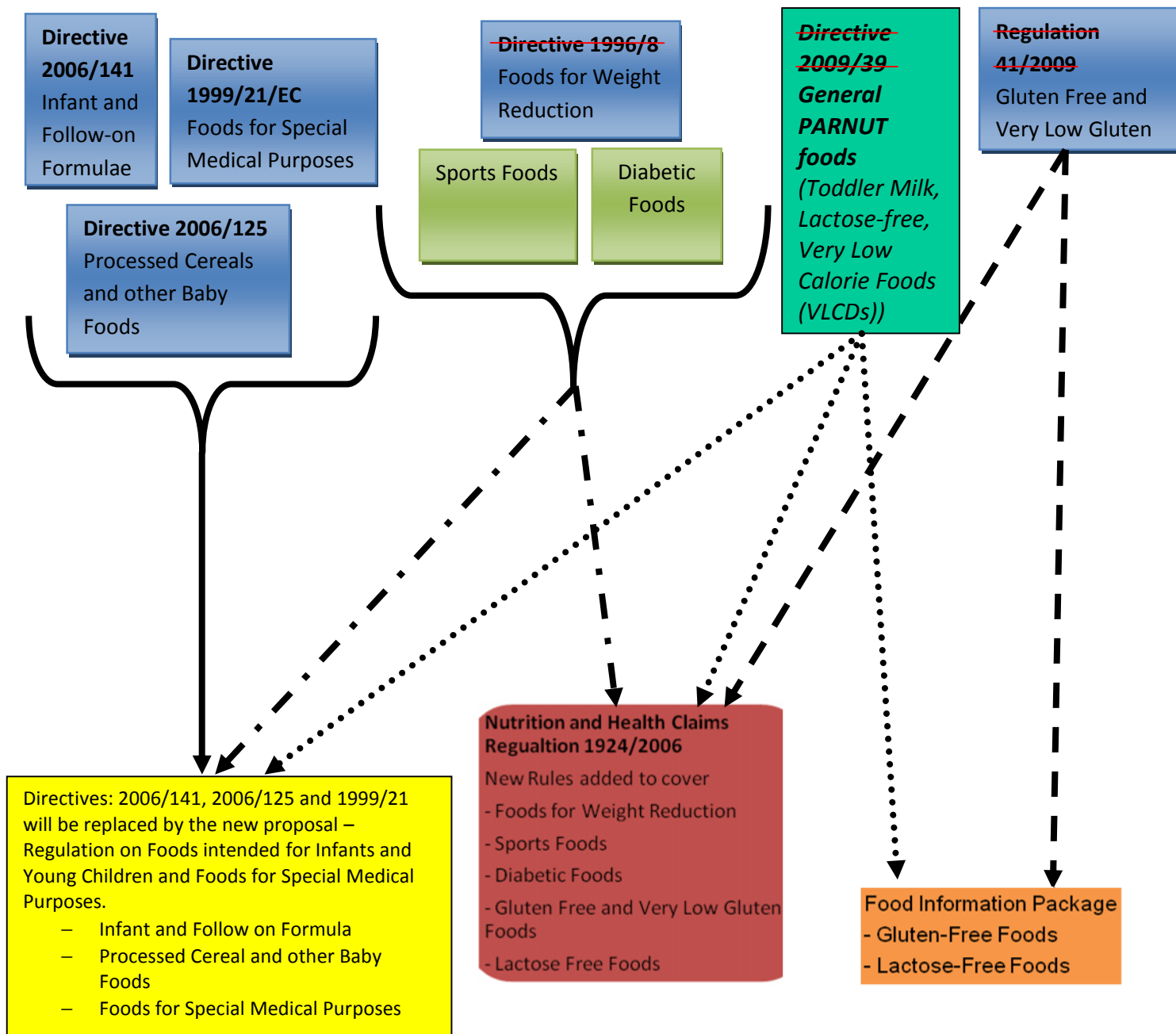


Figure 2 Proposed revision of PARNUTS Framework Directive 2009/39/EC and related specific legislation