

**REPORT ON CONSULTATION
FOR IRELAND ON PROPOSED
CHANGES TO LEGISLATION
REGULATING FOODS FOR
PARTICULAR NUTRITIONAL
USES (PARNUTS)**

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Executive Summary

BACKGROUND

PARNUTs are specifically produced foodstuffs designed to suit the particular nutritional need of specific consumer groups. They are *'clearly distinguishable from foodstuffs for normal consumption, are suitable for their claimed nutritional purposes and are marketed in such a way as to indicate such suitability'*.

A wide variety of PARNUTs exist on the European market. Currently, PARNUTs are regulated by a Framework Directive (2009/39/EC) and specific pieces of related legislation (five Directives and one Regulation) which set out specific rules for certain categories of PARNUTs. To simplify the regulation of PARNUTs, the European Commission proposed changes to the legislation governing PARNUTs in November 2011. These changes involved repealing the Framework Directive (2009/39/EC) and regulating PARNUTs under various pieces of food legislation. It was proposed that three specific Directives (Infant Formula and Follow-on Formula, Food Intended for Infants and Young Children and Foods for Special Medical Purposes (FSMPs)) would be combined into a single new Regulation called Food Intended for Infants and Young Children and Food for Special Medical Purposes. The following changes were also proposed:

1. Repeal the Directive on Foods for Weight Reduction (Directive 1996/8/EC) and regulate these foods under an amended Nutrition and Health Claims Regulation
2. Repeal the Regulation on 'gluten-free' and 'very low gluten' foods and regulate these foods under either:
 - a. An amended Nutrition and Health Claims Regulation (Reg EC No 1924/2006), or
 - b. The new Food Information to Consumers Regulation (Reg EC No 1169/2011)
3. Regulate lactose-free foods under either:
 - a. An amended Nutrition and Health Claims Regulation, or
 - b. The Food Information to Consumers Regulation
4. Regulate toddler milks under an amended Nutrition and Health Claims Regulation
5. Regulate very low calorie diets (VLCDs) either under:
 - a. An amended Nutrition and Health Claims Regulation, or
 - b. As a Food for Special Medical Purposes under the new Regulation 'Food Intended for Infants and Young Children and Food for Special Medical Purposes'
6. Not set European rules governing sports foods and diabetic foods

Many stakeholders would be affected by the changes proposed including consumers, food businesses, healthcare professionals and food law regulators. Therefore, a national public consultation on the proposed changes was carried out on behalf of the Department of Health (Food Unit) by the Food Safety Authority of Ireland (FSAI) in November 2011 to seek the views of stakeholders. The data gathered in the consultation were used to inform the Irish position from January 2012 onwards at the European Council working party meetings on the revision of PARNUTs legislation (15th July 2011 – 2nd April 2012).

Since the consultation was carried out, much progress has been made at a European level and a final proposal is now being discussed by the European Parliament, Commission and Presidency. This report details the results of the public consultation and also provides updates on where the discussions on the various issues currently stand (28th June 2012).

APPROACHES USED FOR THE CONSULTATION PROCESS

A short online survey was live on the FSAI website from 15th November 2011 to 15th December, 2011. The survey asked questions which were devised based on the legislative changes which were proposed at that time (November 2011), with a focus on the issues that were deemed by the FSAI to be most pertinent to Ireland. An information note detailing the proposed legislative changes was also available on the FSAI website.

MAIN FINDINGS

- Submissions were received from 41 consumers, 13 industry and 21 health professionals. In general, the responses were diverse and a high proportion of respondents selected the 'don't know' response to the questions posed.
- There was no consensus amongst respondents about whether the framework should be discarded or not.
- The category representing the largest proportion of respondents at 42%, did not agree with combining the three Directives (on Infant formula, Food Intended for Infants and Young Children and Foods for Special Medical Purposes) into the single new Regulation.
- Of the respondents who expressed an opinion regarding the regulation of lactose, more agreed with lactose being regulated under the Food Information to Consumers Regulation (Reg EU No 1169/2011).
- Of the respondents who expressed an opinion on the regulation of VLCDs, a small majority felt that VLCDs should be categorised as FSMPs and regulated in the new Regulation.
- A slight majority felt that toddler milks should be regulated under the Regulation on Nutrition and Health Claims.
- The majority of respondents felt that the terms 'gluten-free' and 'very low-gluten' should be regulated under the new Food Information to Consumers Regulation (Reg EU No 1169/2011).
- There was no consensus amongst respondents as to whether foods for weight reduction should be regulated under the Regulation on Nutrition and Health Claims.
- The majority felt that foods which are labelled as being suitable for diabetics should be regulated under the Nutrition and Health Claims Regulation.
- A small majority felt that sports foods should be regulated under the Nutrition and Health Claims Regulation.
- The results of this consultation were published in the FSAI January/February 2012 Newsletter which is widely circulated and was also published on the FSAI website.

IRISH POSITION THROUGHOUT EU DISCUSSIONS ON PARNUTS REVISION

At the Council Working Party meetings, Ireland supported the repeal of the PARNUTs framework and the proposed changes on 'gluten-free'; 'lactose-free'; foods for weight reduction and diabetic foods. However, Ireland did express concerns with regard to the following food categories:

SPORTS FOODS

Ireland expressed concern relating to the inappropriate use of sports foods by teenagers and young people and potential issues with unsafe ingredients (stimulants and prohibited substances). Ireland suggested that further consideration be given to the option proposed by other Member States, whereby a selected group of products within the category of foods for sportspeople would be regulated within the scope of the new Regulation

VLCDs

Ireland agreed with several other Member States who, due to safety concerns, expressed the view that all VLCDs should be regulated within the new Regulation as opposed to some of these products being regulated under the Nutrition and Health Claims Regulation. Ireland expressed concern that the proposed Regulation does not appear to cover those VLCD regimens which recommend consumption of low calorie foods in addition to meal replacement products. Ireland agreed with a proposal that the nutritional composition of VLCD regimens, which recommend consumption of low calorie foods in addition to meal replacement products, should be regulated to ensure the regimens are nutritionally adequate and safe. This is of particular concern due to the vulnerability of consumers of these regimens to risks of nutritional deficiencies and other negative health effects

TODDLER MILKS

Ireland expressed the view that the nutritional composition of toddler milks should be regulated to ensure adequate nutrients are provided by these milks which are staple foods in the diets of young children. These milks (also known as 'growing-up milks') are milk-based drinks marketed as being particularly suited for children aged 12-36 months. These products are not covered by the specific measures applying to foods intended for infants and young children. In agreement with the majority of other Member States, Ireland's position was that the European Food Safety Authority (EFSA) should determine the compositional, food safety and other criteria necessary to adequately regulate toddler milks. However, an additional suggestion proposed by Ireland outlined an interim measure whereby the compositional criteria established for follow-on formula could be used temporarily to cover toddler milks. Ireland therefore proposed that the best way of regulating toddler milks was to do so under Directive 2006/141/EC. For toddler milks that are already on the market which do not meet the compositional criteria for follow-on formula, Ireland suggested these products could remain on the market through derogation as a temporary measure until the nutritional composition criteria for toddler milks are agreed by EFSA and come into force

CURRENT SITUATION ON REVISION OF PARNUTS

The PARNUTs Framework is going to be repealed, and much work has been undertaken by the European Commission, Council and Member States on drafting a new Regulation called 'Food Intended for Infants and Young Children and Food for Special Medical Purposes'. The changes which were proposed by the European Council in the draft Regulation are as following:

Lactose – The term 'lactose-free' will be regulated in the new Food Information to Consumers Regulation (Reg 1169/2011)

VLCDs – VLCDs will be regulated under the category of 'Total Diet Replacement for Weight Control' in the new draft Regulation Food Intended for Infants and Young Children and Food for Special Medical Purposes (where Total Diet Replacement for Weight Control means 'food (e)specially formulated for use in energy-restricted diets for weight reduction which, when used as instructed by the food business operator, replace the whole total daily diet')

Toddler milks – Toddler milks will not be regulated under the new draft Regulation. However, the Commission will consult with EFSA and subsequently produce a report on the desirability of special provisions regarding the composition, labelling and other types of requirements, if appropriate, of milk-based drinks and similar products intended for young children. This report may be accompanied with a legislative proposal for these milks. Transitional measures will allow these milks to continue to be marketed under the PARNUTs rules until such time as the Commission's report is prepared

Gluten – The rules on the use of the statements 'gluten-free' and 'very low gluten' will be transferred from where they currently are (Reg (EC) No 41/2009) to the new Food Information to Consumers Regulation (Reg 1169/2011)

Foods for weight reduction – The statement '*Meal replacement for weight control*' used on products intended to replace part of the daily diet will be regulated solely by Regulation (EC) No 1924/2006 on Nutrition and Health Claims and companies will be obliged to comply with the conditions of use laid down therein

Sports foods – Sports foods will not be regulated under the new draft Regulation. However, the Commission will consult with EFSA and subsequently produce a report on whether special rules are needed on composition, labelling, etc for food intended for sportspeople. The report will particularly evaluate whether specific provisions are needed to ensure the protection of vulnerable consumers, such as children and young people who use sports foods in their diet. This report may be accompanied with a legislative proposal for these foods

Diabetic foods – European rules governing diabetic foods are not being set

Following a vote on 14th June 2012, the European Parliament adopted its first reading position which proposed 83 amendments to the proposed Regulation on 21st June 2012. The European Parliament called on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text and it instructed its President to forward its position to the Council, the Commission and the national parliaments. The main changes in the amendments are suggestions to include food for people intolerant to gluten and food intended for use in low calorie diets (LCD) and very low calorie diets (VLCD) within the scope of the Regulation. Other suggestions include a request for the Commission to clarify the status of 'lactose-free' under general food law and a request for 'food for special medical purposes' to specifically include formula intended for low birth-weight and pre-term infants.

Chapter 1. Proposed Changes to the PARNUTs Legislation In Europe

1.1 INTRODUCTION

Foods for Particular Nutritional uses (also known as PARNUTs) are a variety of foods that due to their composition, meet the needs of special groups of the population, for example, infants and those under medical supervision.

The definition of PARNUTs is: *foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability* (Directive 2009/39/EC).

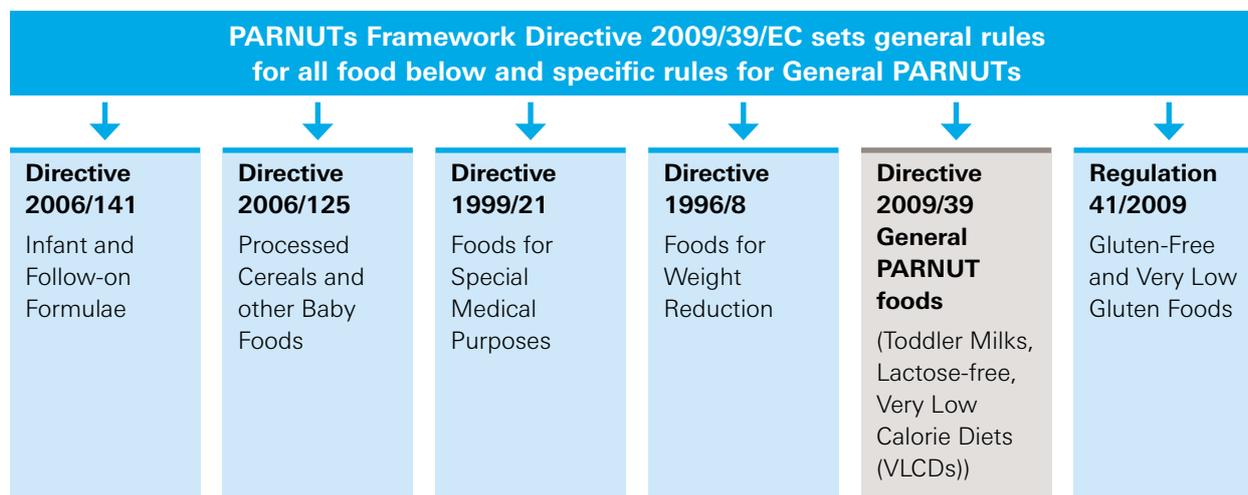
Examples of PARNUTs are:

- Infant and follow-on formulas
- Processed cereals and other baby foods
- Foods for special medical purposes (sip feeds, specialised food products)
- 'Gluten-free' and 'very low gluten' foods
- Foods for weight reduction and very low calorie diets
- Sports foods
- Diabetic foods
- Toddler milks
- Lactose-free foods

1.2 CURRENT LEGISLATIVE POSITION

Current legislation regulating PARNUTs includes the PARNUTS Framework Directive (2009/39/EC) and related specific legislation which sets out specific rules for certain categories of PARNUTs (5 Directives and 1 Regulation) (see Figure 1).

Figure 1. PARNUTs Framework Directive 2009/39/EC and Related Specific Legislation¹



1.3 PROPOSED CHANGES AS OF NOVEMBER 2011

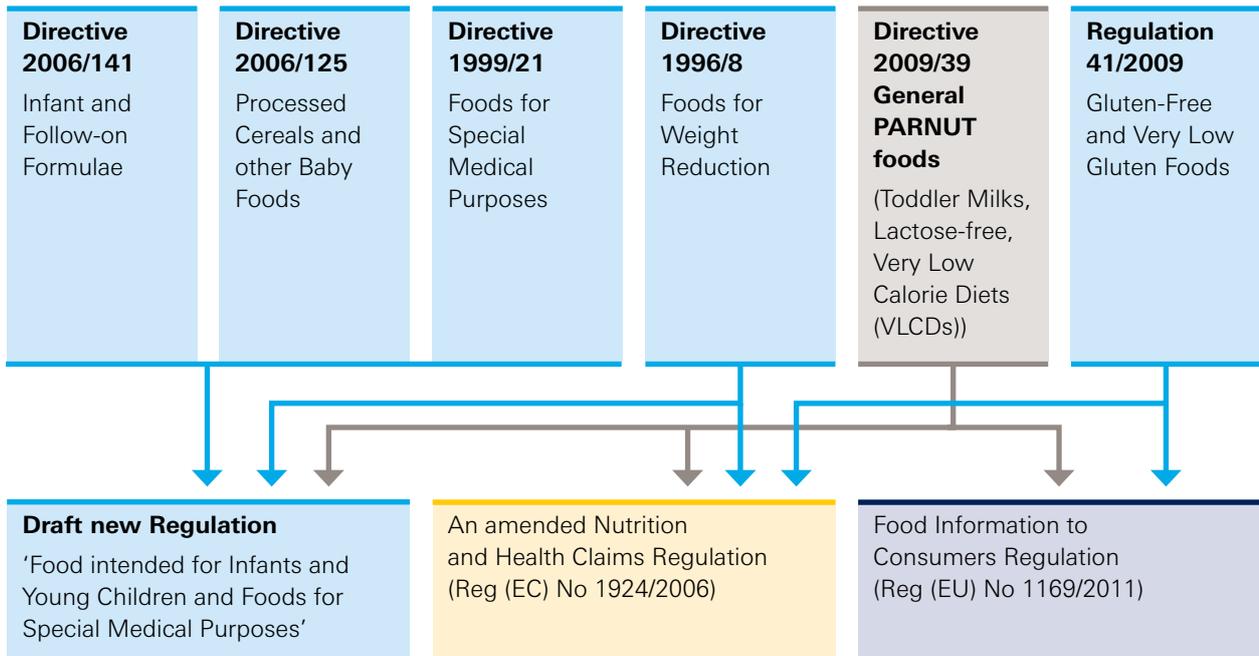
Ireland, other EU Member States and the European Commission are in the process of revising how PARNUTs are regulated. The European Commission developed a proposal to simplify the way in which PARNUTs are regulated. Changes to the legislation proposed at the time of the consultation (in November 2011) were:

- 1) Repeal the PARNUTs Framework Directive
- 2) Combine three specific Directives (Infant Formula and Follow-on Formula, Processed Cereal-based Foods and Baby Foods for Infants and Young Children and Foods for Special Medical Purposes (FSMPs)) into a single new Regulation called Food Intended for Infants and Young Children and Food for Special Medical Purposes
- 3) Repeal the Directive on Foods for Weight Reduction and regulate these foods under an amended Nutrition and Health Claims Regulation
- 4) Regulate toddler milks under an amended Nutrition and Health Claims Regulation
- 5) Regulate lactose-free foods under either a) an amended Nutrition and Health Claims Regulation or b) the Food Information to Consumers Regulation
- 6) Regulate very low calorie diets (VLCDs) either under a) an amended Nutrition and Health Claims Regulation or b) as a Food for Special Medical Purposes under the new Regulation 'Food Intended for Infants and Young Children and Food for Special Medical Purposes'
- 7) Repeal the Regulation on 'gluten-free' and 'very low gluten' foods and regulate these foods under either a) an amended Nutrition and Health Claims Regulation or b) the new Food Information to Consumers Regulation
- 8) Do not set European rules governing sports foods and diabetic foods

These proposed changes are reflected in **Figure 2**.

¹ It was envisaged in the Framework Directive that specific rules would be set for 'foods intended to meet the expenditure of intense muscular effort, especially for sportspeople' and 'foods for persons suffering from carbohydrate metabolism disorders (diabetes)', however, these were never set.

Figure 2. Proposed options per the Revision of PARNUTS Framework Directive 2009/39/EC and Related Specific Legislation



Chapter 2. Consultation

2.1 APPROACHES USED

The consultation took the form of an online survey on the FSAI website (<http://www.fsai.ie/legislation/consultations.html>) (see **Appendix 1**) which was live from Tuesday 15th November, 2011 until Thursday 15th December, 2011. Questions were devised based on the legislative changes which were proposed at that time (November 2011, see Figure 2), with a focus on the issues that were deemed to be most pertinent to Ireland by the FSAI. An information note which incorporated the information in chapter 1 was available on the FSAI website (<http://www.fsai.ie/uploadedFiles/Legislation/Consultations/Info-Parnuts-20111115.pdf>.)

The opening of the consultation was advertised by press release which was issued on Tuesday 15th November. There is a core set of people who subscribe to all FSAI consultations and these people were notified by email of the consultation. Also, a number of consumer agencies and companies whose work relates to PARNUTs were contacted directly via email to inform them of the consultation (see **Appendix 2**). The online survey asked questions on the main aspects of the proposed changes as well as detailed questions on how specific foods (currently regulated under PARNUTs) could be regulated in the future.

2.2 RESULTS

Seventy-five submissions were received from a range of stakeholders (see **Appendix 3**).

2.2.1 Responses to questions on the main proposed changes

There was no consensus amongst respondents about whether the framework should be discarded or not (see **Table 1**). A significant proportion of respondents (39%) didn't know if the PARNUTs framework should be discarded, many of whom (64%) were consumers who stated that they were confused and had concerns over the protection of vulnerable groups. Many healthcare professionals stated that they were also confused about the implications of discarding the framework.

The group representing the largest category of respondents (42%) did not agree with combining the three Directives (on Infant Formula, Food Intended for Infants and Young Children and Foods for Special Medical Purposes) into the single new Regulation. Most of these respondents (69%) were consumers who were concerned about whether the strict rules on marketing infant formula would still apply. Of those who didn't express an opinion either way (16%), most were consumers (92%) who stated they were confused and concerned about whether the strict rules on marketing infant formula would still apply. Health care professionals expressed the concern that infant formula classified as a Food for Special Medical Purposes (FSMP) wouldn't have to follow the strict rules on marketing infant formula (see **Table 2**).

Table 1. Should the PARNUTs Framework be Discarded?

Response rate	Response	Respondents profile	Main reasons given for response
99% (n71)	Yes 32% (n23)	30% Consumers (n7)	Simplification (n11)
		35% Industry (n8)	Harmonisation (n5)
		35% Health care professionals (n8)	Concerns re: vulnerable groups (n4)
	No 28% (n20)	65% Consumers (n13)	Concerns re: vulnerable groups (n2)
		20% Industry (n4)	Concerns re: vulnerable group (coeliacs) (n4)
		15% Health care professionals (n3)	Concerns re: vulnerable group (infants) (n3)
	Don't know 39% (n28)	64% Consumers (n18)	*
		4% Industry (n1)	
		32% Health care professionals (n9)	

* Reasons were mostly concerns about the protection of vulnerable groups, and confusion was expressed about the possible implications

Percentages were subjected to rounding and do not always equate to 100%.

Table 2. Do You Agree to Combine Three Directives into the New Regulation?

Response rate	Response	Respondents profile	Main reasons given for response
93% (n70)	Yes 35% (n26)	23% Consumers (n6)	Concern re: vulnerable group (infants) (n3)
		27% Industry (n7)	Legislative concerns (n2)
		50% Health care professionals (n13)	Consider to be appropriate regulation (n3) Simplification (n2)
	No 42% (n32)	69% Consumers (n22)	Concern re: vulnerable group (n13)
		16% Industry (n5)	Consider to be inappropriate Regulation (n7)
		16% Health care professionals (n5)	Legislative concerns (n2)
	Don't know 16% (n12)	92% Consumers (n11)	*
		0% Industry (n0)	
		8% Health care professionals (n1)	

* Reasons were mostly concerns about the protection of vulnerable groups, and confusion was expressed about the possible implications

Percentages were subjected to rounding and do not always equate to 100%.

2.2.2 Responses to questions on specific issues

Lactose

Of respondents who expressed opinions on the questions on lactose, more respondents felt that the term 'lactose-free' should be regulated under the Food Information to Consumers Regulation compared to under an amended Nutrition and Health Claims Regulation (n24 vs n12). Of those who didn't express an opinion either way for regulating 'lactose-free', most were consumers who stated they didn't understand the implications.

On balance, it appears that more respondents agree with lactose being regulated under the Food Information Regulation (Reg EU No 1169/2011) (see **Table 3**).

Table 3. Responses to Questions on the Options for Regulating 'Lactose-free'

Question	Response rate	Response	Respondents profile	Main reasons given for response	
Should lactose-free foods be regulated under the Food Information Regulation (option 1)?	73% (n55)	Yes (44%) (n24)	38% Consumers (n9)	Clarity on lactose would be provided (n5) Consider to be appropriate regulation (n4) Concern re: vulnerable group (n2) Comments not clear (n2)	
			17% Industry (n4)		
			46% Health care professionals (n11)		
		No (16%) (n9)	33% Consumers (n3)	56% Industry (n5)	Consider to be inappropriate regulation (n2)
				11% Health care professionals (n1)	
				Don't know (40%) (n22)	
		5% Industry (n1)			
		18% Health care professionals (n4)			
		OR Should lactose-free foods be regulated under Nutrition and Health Claims (option 2)?	61% (n46)	Yes (26%) (n12)	25% Consumers (n3)
42% Industry (n5)					
33% Health care professionals (n4)					
No (30%) (n14)	29% Consumers (n4)			36% Industry (n5)	Consider to be inappropriate regulation (n6) Comments not clear (n3)
				36% Health care professionals (n5)	
				Don't know (44%) (n20)	
0% Industry (n0)					
15% Health care professionals (n3)					

* Reasons mostly expressed confusion about the possible implications

Percentages were subjected to rounding and do not always equate to 100%.

Very low calorie diets (VLCDs)^{1a}

Very low calorie diets are complete meal replacement diets for weight reduction comprising liquid shakes, soups and possibly snack bars that provide between 450 and 800 calories per day. The average weight loss on these diets is between 1.5 and 2.5kg per week^{1b}

Of respondents who expressed opinions to the questions on VLCDs, a small majority (n18 vs n14) felt that VLCDs should be categorised as FSMPs and regulated in the new Regulation due to concerns about the safety of these products. Many respondents who felt that it was inappropriate to regulate VLCDs under Nutrition and Health Claims stated that it was because of safety concerns and lack of compositional rules. Of those who didn't express an opinion either way to either of the options given, most were consumers who stated they were confused about the implications or concerned about potential mis-use of VLCDs (see **Table 4**).

Table 4. Responses to Questions on the Options for Regulating VLCDs

Question	Response rate	Response	Respondents profile	Main reasons given for response
Should VLCDs be regulated under Nutrition and Health Claims (Regulation 1924/2006)?	61% (n46)	Yes 30% (n14)	57% Consumers (n8)	No reasons given
			29% Industry (n4)	
			14% Health care professionals (n2)	
		No 33% (n15)	27% Consumers (n4)	Safety concerns (n8)
			7% Industry (n1)	
			67% Health care professionals (n10)	
		Don't know 37% (n17)	59% consumers (n10)	*
			18% Industry (n3)	
			24% Health care professionals (n4)	

^{1a} Many VLCDs available over the counter on the Irish market contain only 400 calories per day and recommend additional consumption of low calorie foods such as salad and vegetables. VLCDs should only be used by obese persons. The side effects associated with the use of VLCDs range from hair loss to cardiac arrhythmias.

^{1b} National Task Force on the Prevention and Treatment of Obesity, National Institutes of Health (1993) JAMA 270, 967–974

Question	Response rate	Response	Respondents profile	Main reasons given for response
QR Should VLCDs should be categorised as FSMP and regulated in the new draft proposal	61% (n46)	Yes 39% (n18)	28% Consumers (n5)	Safety concerns (n5) Comments not clear (n2)
			6% Industry (n1)	
			67% Health care professionals (n12)	
		No 30% (n14)	29% Consumers (n4)	Inappropriate to regulate as FSMPs (n4) Comments not clear (n3)
			36% Industry (n5)	
			36% Health care professionals (n5)	
		Don't know 30% (n14)	64% Consumers (n9)	*
			21% Industry (n3)	
			14% Health care professionals (n2)	

* Reasons mostly expressed confusion about the possible implications

Percentages were subjected to rounding and do not always equate to 100%.

Toddler milks²

Toddler milks (also known as ‘growing-up milks’) are milk-based drinks marketed as being particularly suited for children aged 12-36 months. These products are not covered by the specific measures applying to foods intended for infants and young children.

Of respondents who expressed an opinion, slightly more (n28 vs n25) felt that toddler milks should be regulated under the Regulation on Nutrition and Health Claims. Of those who didn’t express an opinion either way (n12), the majority (n11) were consumers, some of whom stated that they felt that toddler milks are unnecessary products and were concerned about how toddler milks are marketed (see **Table 5**).

Table 5. Should Toddler Milks be Regulated Under Nutrition and Health Claims (Regulation 1924/2006)?

Response rate	Response	Respondents profile	Main reasons given for response
89% (n65)	Yes 42% (n28)	62% Consumers (n18)	Consider it an unnecessary product (n5) Concern about unsubstantiated claims (n2)
		21% Industry (n5)	
		17% Health care professionals (n5)	
	No 37% (n25)	36% Consumers (n9)	Consider to be inappropriate regulation (n6) Concern re: marketing of products (n5) Consider it an unnecessary product (n4) Legislative concerns (n5) Comments not clear (n2) Safety concerns (n3) Concern re: vulnerable group (n2)
		20% Industry (n5)	
		44% Health care professionals (n11)	
	Don’t know 21% (n12)	92% Consumers (n11)	*
		0% Industry (n0)	
		8% Health care professionals (n1)	

* Reasons were mostly concerns about the protection of vulnerable groups, and confusion was expressed about the possible implications

Percentages were subjected to rounding and do not always equate to 100%.

² Note on toddler milks: Toddler milks can provide up to a third of a child’s total daily energy intake and we believe that the nutritional composition of toddler milks needs to be regulated to ensure they provide adequate amounts of the key nutrients provided by milk in a young child’s diet. The FSAI conducted an analysis of the declared nutritional composition of the six toddler milks on the Irish market and found that all toddler milks for children aged 1+ (stage 1) in powder format met the nutritional criteria laid down for follow-on formula and the level of key nutrients in toddler milks for children aged 2+ (stage 2) were close to follow-on formula or cows’ milk (see Appendix 4).

'Gluten-free'

Of respondents who expressed opinions to the questions on 'gluten-free', the majority (n36 vs n11) felt that the terms 'gluten-free' and 'very low gluten' should be regulated under the new Food Information to Consumers Regulation as they considered this the appropriate solution. Of those who didn't express an opinion either way, most were consumers, some of whom stated they didn't understand the implications (see **Table 6**).

Table 6. Responses to Questions on Regulatory Options for 'Gluten-free'

Question	Response rate	Response	Respondents profile	Main reasons given for response	
Should 'gluten-free' and 'very low gluten' foods be regulated under the New Food Information Regulation?	63% (n47)	Yes 77% (n36)	36% Consumers (n13)	Consider to be appropriate Regulation (n6) Option makes sense (n2) Safety concerns (n2) Comments not clear (n2)	
			19% Industry (n7)		
			44% Health care professionals (n16)		
		No 4% (n2)	50% Consumers (n1)	50% Industry (n1)	No reasons given
				% Health care professionals (n)	
		Don't know 19% (n9)	67% Consumers (n6)	11% Industry (n1)	*
				22% Health care professionals (n2)	
OR Should 'gluten-free' and 'very low gluten' foods be regulated under Nutrition and Health Claims (Regulation 1924/2006)?	60% (n45)	Yes 24% (n11)	55% Consumers (n6)	Comments not clear (n2)	
			18% Industry (n2)		
			27% Health care professionals (n3)		
		No 60% (n27)	30% Consumers (n8)	22% Industry (n6)	Consider to be inappropriate regulation (n2) Inappropriate ('gluten-free' claims would be restricted to 'healthy' food) (n6) Inappropriate regulation for gluten ('gluten-free' claims on alcohol above 1.2% would not be allowed) (n3) Safety concerns (n2) Comments not clear (n6)
				48% Health care professionals (n13)	
		Don't know 16% (n7)	57% Consumers (n4)	14% Industry (n1)	*
				29% Health care professionals (n2)	

* Reasons mostly expressed confusion about the possible implications

Percentages were subjected to rounding and do not always equate to 100%.

Foods for weight reduction

Foods for weight reduction include ‘meal replacement for weight control’ and ‘total diet replacement for weight control’ and are currently governed by specific rules under Directive 96/8/EC.

There was no consensus amongst respondents as to whether foods for weight reduction should be regulated under the Regulation on Nutrition and Health Claims. Of those who answered ‘no’, many stated that safety was a key concern. Of those who didn’t express an opinion either way, some respondents commented that they didn’t understand or could not clearly imagine what the implications would be (a respondent from industry was concerned about the sector becoming burdened with unnecessary information) (see **Table 7**).

Table 7. Should Foods for Weight Reduction be Regulated Under Nutrition and Health Claims (Regulation 1924/2006)?

Response rate	Response	Respondents profile	Main reasons given for response
64% (n48)	Yes 35% (n17)	47% Consumers (n8)	Appropriate regulation for these foods (to inform consumer) (n2)
		18% Industry (n3)	
		35% Health care professionals (n6)	
	No 35% (n17)	29% Consumers (n5)	Safety concerns (n11) Consider to be inappropriate regulation (n3)
		18% Industry (n3)	
		53% Health care professionals (n9)	
	Don’t know 29% (n14)	57% Consumers (n8)	*
		21% Industry (n3)	
		21% Health care professionals (n3)	

* Reasons mostly expressed confusion about the possible implications
 Percentages were subjected to rounding and do not always equate to 100%.

Diabetic foods

Of those who expressed an opinion, the majority (n25) felt that foods which are labelled as being suitable for diabetics should be regulated under the Nutrition and Health Claims Regulation. Of those who didn't express an opinion either way, some commented that they felt these products are unnecessary and some stated that they did not understand the issue (see **Table 8**).

Table 8. Should Diabetic Foods be Regulated Under Nutrition and Health Claims (Regulation 1924/2006)?

Response rate	Response	Respondents profile	Main reasons given for response
60% (n45)	Yes 56% (n25)	52% Consumers (n13)	Consider to be appropriate legislation (n3) Consider to be unnecessary product (n2) Comments not clear (n2)
		16% Industry (n4)	
		32% Health care professionals (n8)	
	No 13% (n6)	33% Consumers (n2)	Consider to be unnecessary product (n2) Consider to be inappropriate regulation (n2)
		0% Industry (n0)	
		67% Health care professionals (n4)	
	Don't know 31% (n14)	50% Consumers (n7)	*
		14% Industry (n2)	
		36% Health care professionals (n5)	

* Reasons were mostly 'don't understand' and 'unnecessary products'

Percentages were subjected to rounding and do not always equate to 100%.

Sports foods

Of respondents who expressed opinions to the questions on sports foods, a small majority (n19 vs n14) felt that sports foods should be regulated under the Nutrition and Health Claims Regulation. Of those who didn't express an opinion either way on the options given, most were consumers and some commented that they didn't understand the issue completely but they had concerns about safety (see **Table 9**).

Table 9. Responses to Questions on Regulatory Options for Sports Foods

Question	Response rate	Response	Respondents profile	Main reasons given for response
Should sports foods be regulated under Nutrition and Health Claims Regulation (Regulation 1924/2006)?	60% (n45)	Yes 42% (n19)	47% Consumers (n9)	Comments not clear (n2)
			26% Industry (n5)	
			26% Health care professionals (n5)	
		No 24% (n11)	27% Consumers (n3)	Safety concerns (n5)
			27% Industry (n3)	
			46% Health care professionals (n5)	
		Don't know 33% (n15)	53% Consumers (n8)	*
			7% Industry (n1)	
			40% Health care professionals (n6)	
<i>OR</i> Should sports foods should be regulated in the new draft Regulation?	53% (n40)	Yes 35% (n14)	57% Consumers (n8)	Safety concerns (n3)
			7% Industry (n1)	
			36% Health care professionals (n5)	
		No 33% (n13)	15% Consumers (n2)	Consider to be inappropriate regulation (n2) Comments not clear (n2)
			39% Industry (n5)	
			46% Health care professionals (n6)	
		Don't know 33% (n13)	62% Consumers (n8)	*
			15% Industry (n2)	
			23% Health care professionals (n3)	

* Reasons mostly expressed confusion about the possible implications and safety concerns

Percentages were subjected to rounding and do not always equate to 100%.

2.2.3 Discussion

In general, the responses were diverse and a high proportion of respondents did not express reasons for their responses when answering the questions. There was no consensus amongst respondents about whether the framework should be discarded or not. The category representing the largest proportion of respondents did not agree with combining the three Directives (on Infant Formula, Food Intended for Infants and Young Children and Foods for Special Medical Purposes) into the single new Regulation. Of the respondents who expressed an opinion regarding the regulation of lactose, more agreed with lactose being regulated under the Food information to Consumers Regulation. Of the respondents who expressed an opinion on the regulation of VLCDs, a small majority felt that VLCDs should be categorised as FSMPs and regulated in the new Regulation. A slight majority felt that toddler milks should be regulated under the Regulation on Nutrition and Health Claims. The majority of respondents felt that the terms 'gluten-free' and 'very low gluten' should be regulated under the new Food Information to Consumers Regulation. There was no consensus amongst respondents as to whether foods for weight reduction should be regulated under the Regulation on Nutrition and Health Claims. The majority felt that foods which are labelled as being suitable for diabetics should be regulated under the Nutrition and Health Claims Regulation. A small majority felt that sports foods should be regulated under the Nutrition and Health Claims Regulation.

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Appendix 1: Questionnaire Used in Online Survey

SECTION 1

Please enter your name:

E-Mail:

Click which box best describes you:

- Consumer
- Consumer Agency Representative
- Industry
- Industry Agency Representative
- Health Professional
- Legal Expert
- Other

Do you live in the Republic of Ireland?

- Yes
- No

SECTION 2

Please complete any of the questions that are relevant to you - do not worry about leaving questions blank.

If you come across a set of questions that do not apply to you - use the 'next page' button to skip to the next set of questions

Proposal to discard the PARNUTs Framework (2009/39/EC)

Advantages

This will simplify how foods are regulated under nutrition related legislation. Incompatibilities will not arise between the PARNUTs Framework and other nutrition law such as Nutrition and Health Claims (Regulation 1924/2006).

Disadvantages

It is unclear where General PARNUTs, currently regulated under the PARNUTs Framework will be regulated in the future.

There may be implications for Research and Development.

Q1. Do you agree that the PARNUTs framework should be discarded?

- Yes
- No
- Don't know

Please outline why you agree

Please outline why you disagree *(include alternative suggestions if possible)*

Please outline why you are uncertain *(include alternative suggestions if possible)*

Proposal to merge the specific rules of three Directives, into a new regulation – *Food Intended for Infants and Young Children and Foods for Special Medical Purposes*. The three 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)

Advantages

This proposal maintains specific rules contained in all three Directives

This new regulation will not be incompatible with other nutrition-related legislation.

Q2. Do you agree with merging the legislation regulating Infant Formula and Follow-on Formula, Food Intended for Infants and Young Children and Foods for Special Medical Purposes under new regulation – *Food Intended for Infants and Young Children and Foods for Special Medical Purposes*?

- Yes
- No
- Don't know

Please outline why you agree

Please outline why you disagree *(include alternative suggestions if possible)*

Please outline why you are uncertain *(include alternative suggestions if possible)*

**Proposal to regulate lactose-free foods (currently under the PARNUTs Framework Directive):
 OPTION 1 regulate lactose-free foods under the New Food Information Regulation**

Advantage

In the New Food Information Regulation specific rules have been laid down for foods that cause allergic reactions e.g. nuts, wheat. Additional rules on Lactose-free foods could be easily included in this legislation.

Q3. Do you agree with OPTION 1 that Lactose-free foods should be regulated under the New Food Information Regulation?

- Yes
- No
- Don't know

Please outline why you agree

Please outline why you disagree

(include alternative suggestions if possible)

Please outline why you are uncertain

(include alternative suggestions if possible)

**Proposal to regulate lactose-free foods (currently under the PARNUTs Framework Directive):
 OPTION 2 regulate lactose-free foods under Nutrition and Health Claims (Regulation 1924/2006)**

Disadvantage

Nutrition and Health Claims Regulation makes provision for claims only on foods that are inherently healthy (containing limited amounts of saturated fat, salt and sugar). Consumers who need to follow lactose-free diets require information on the lactose content of all food products irrespective of whether they are inherently healthy or not.

Q4. Do you agree with OPTION 2 that lactose-free foods should be regulated under Nutrition and Health Claims (Regulation 1924/2006)?

- Yes
- No
- Don't know

Please outline why you agree

Please outline why you disagree

(include alternative suggestions if possible)

Please outline why you are uncertain

(include alternative suggestions if possible)

Q4. For the regulation of lactose-free foods, which option would you prefer?

- Option 1
- Option 2
- Don't know

Please outline why you chose Option 1

Please outline why you chose Option 2

Please outline why you are uncertain *(include alternative suggestions if possible)*

Proposal to regulate Very Low Calorie Diets (currently under the PARNUTs Framework Directive): OPTION 1 regulate Very Low Calorie Diets under Nutrition and Health Claims (Regulation 1924/2006)

Advantage

There are practical advantages for using one set of rules (Regulation 1924/2006) to cover all food products that contribute to losing weight. Specific conditions of use would be set on a case-by-case basis.

Disadvantage

The Nutrition and Health Claims regulation assesses the validity of the claimed effect and does not consider safety issues

Q6. Do you agree with OPTION 1 that Very Low Calorie Diets should be regulated under Nutrition and Health Claims (Regulation 1924/2006)?

- Yes
- No
- Don't know

Please outline why you agree

Please outline why you disagree *(include alternative suggestions if possible)*

Please outline why you are uncertain *(include alternative suggestions if possible)*

Proposal to regulate Very Low Calorie Diets (currently under the PARNUTs Framework Directive): OPTION 2 regulate Very Low Calorie Diets as Foods for Special Medical Purposes (FSMPs) under the new draft regulation (*Foods Intended for infants and Young Children and Foods for Special Medical Purposes*)

Advantage

The legislation on FSMPs considers safety issues.

Q7. Do you agree with OPTION 2 that Very Low Calorie Diets should be categorised as FSMP and regulated in the new draft proposal

- Yes
- No
- Don't know

Please outline why you agree

Please outline why you disagree *(include alternative suggestions if possible)*

Please outline why you are uncertain *(include alternative suggestions if possible)*

Q8. For the regulation of Very Low Calorie Diets, which option would you prefer?

- Option 1
- Option 2
- Don't know

Please outline why you chose Option 1

Please outline why you chose Option 2

Please outline why you are uncertain *(include alternative suggestions if possible)*

Proposal to regulate Toddler Milks (currently under the PARNUTs Framework Directive): regulate Toddler Milks under Nutrition and Health Claims (Regulation 1924/2006)

Disadvantage

Toddlers are young children (less than 36 months) who are a nutritionally vulnerable group due to their small body size and growth and development. Nutrition and Health Claims Regulation does not make provisions for the minimum and maximum level of nutrients and other substances. Compositional criteria are generally regulated for young children due to their vulnerability and requirement for growth and development.

Q9. Do you agree that Toddler Milks should be regulated under Nutrition and Health Claims (Regulation 1924/2006)?

- Yes
- No
- Don't know

Please outline why you agree

Please outline why you disagree

(include alternative suggestions if possible)

Please outline why you are uncertain

(include alternative suggestions if possible)

Proposal to discard specific rules for 'Gluten-Free' and 'Very Low Gluten' Foods (Regulation 41/2009): OPTION 1 regulate 'Gluten-Free' and 'Very Low Gluten' Foods under the New Food Information Regulation

Advantage

In the New Food Information Regulation, specific rules have been laid down for foods that cause allergic reactions e.g. nuts, wheat. Additional rules for 'Gluten-Free' and 'Very Low Gluten' could be included in this legislation.

Q10. Do you agree with OPTION 1 that 'Gluten-Free' and 'Very Low Gluten' Foods should be regulated under the New Food Information Regulation?

- Yes
- No
- Don't know

Please outline why you agree

Please outline why you disagree

(include alternative suggestions if possible)

Please outline why you are uncertain

(include alternative suggestions if possible)

Proposal to discard specific rules for 'Gluten-Free' and 'Very Low Gluten' Foods (Regulation 41/2009): OPTION 2 regulate 'Gluten-Free' and 'Very Low Gluten' Foods under Nutrition and Health Claims (Regulation 1924/2006)

Disadvantages

Nutrition and Health Claims Regulation makes provision for claims only on foods that are inherently healthy (containing limited amount of saturated fat, salt and sugar). Consumers who need to follow gluten-free or very low gluten diets require information on the gluten content of all food products irrespective of whether they are inherently healthy or not.

Nutrition and Health Claims do not permit claims to be authorised on foods that contain more than 1.2% of alcohol. Consumers who need to follow gluten-free or very low gluten diets require information on the gluten content of all alcohol beverages.

Q11. Do you agree with OPTION 2 that Gluten-Free and Very Low Gluten Foods should be regulated under Nutrition and Health Claims (Regulation 1924/2006)?

- Yes
- No
- Don't know

Please outline why you agree

Please outline why you disagree *(include alternative suggestions if possible)*

Please outline why you are uncertain *(include alternative suggestions if possible)*

Q12. For the regulation of Gluten-free and Very Low Gluten, which option would you prefer?

- Option 1
- Option 2
- Don't know

Please outline why you chose Option 1

Please outline why you chose Option 2

Please outline why you are uncertain *(include alternative suggestions if possible)*

Proposal to discard specific rules for Foods for Weight Reduction (Directive 1996/8) and to regulate these under Nutrition and Health Claims (Regulation 1924/2006).

Advantage

There are practical advantages for using one set of rules (Regulation 1924/2006) to cover all food products that contribute to losing weight. Specific conditions of use would be set on a case-by-case basis.

Disadvantage

The Nutrition and Health Claims regulation assesses the validity of the claimed effect and does not consider safety issues.

Q13. Do you agree that Foods for Weight Reduction should be regulated under Nutrition and Health Claims (Regulation 1924/2006)?

- Yes
- No
- Don't know

Please outline why you agree

Please outline why you disagree

(include alternative suggestions if possible)

Please outline why you are uncertain

(include alternative suggestions if possible)

Proposal to regulate diabetic foods (specific rules have never been set) under Nutrition and Health Claims (Regulation 1924/2006).

Advantage

Specific conditions of use would be set on a case-by-case basis.

Q14. Do you agree that Diabetic Foods should be regulated under Nutrition and Health Claims (Regulation 1924/2006)?

- Yes
- No
- Don't know

Please outline why you agree

Please outline why you disagree

(include alternative suggestions if possible)

Please outline why you are uncertain

(include alternative suggestions if possible)

**Proposal to regulate sports foods (specific rules have never been set):
 Option 1. Regulate under Nutrition and Health Claims (Regulation 1924/2006).**

Advantage

Specific conditions of use would be set on a case-by-case basis.

Disadvantage

The Nutrition and Health Claims regulation assesses the validity of the claimed effect and does not consider safety issues.

Q15. Do you agree with option 1 that Sports Foods should be regulated under Nutrition and Health Claims (Regulation 1924/2006)?

- Yes
- No
- Don't know

Please outline why you agree

Please outline why you disagree

(include alternative suggestions if possible)

Please outline why you are uncertain

(include alternative suggestions if possible)

Proposal to regulate Sports Foods (specific rules have never been set): Option 2. Regulate Sports Foods under the new draft regulation (*Foods Intended for infants and Young Children and Foods for Special Medical Purposes*)

Advantage

Regulating these foods under the new proposal would facilitate consideration of safety issues.

Q16. Do you agree with option 2 that Sports Foods should be regulated in the new draft regulation?

- Yes
- No
- Don't know

Please outline why you agree

Please outline why you disagree

(include alternative suggestions if possible)

Please outline why you are uncertain

(include alternative suggestions if possible)

Please provide any general comments or suggestions you may have on the proposed changes to PARNUTs legislation.

Q17. If you have any further comments on the proposed changes to PARNUTs legislation, please outline these below:

Appendix 2: Agencies Contacted About Consultation

Abbott Laboratories	Local Authority Vets
Ardyss Internationals	Mead Johnson Nutritionals
Beverage Council of Ireland	Medinutrix
Bord Bia	Medisource
Bruce Dayala	National Breastfeeding Coordinator
Coeliac Society of Ireland	National Dairy Council
Danone Baby Nutrition	Nutricia
Department of Agriculture, Food and the Marine	Nutrition Society
Department of Health	Official Food Microbiology Laboratories
Diabetes Society	Pfizer
Food and Drink Industry Ireland	Pharma Nord
Fresenius Kabi	Public Analyst's Laboratories
Giuliani Internationals	Sea-Fisheries Protection Authority
Health Service Executive: Environmental Health Officers	SMA Nutrition Pfizer
Irish Business and Employers Confederation	UCB Pharma
Irish Nutrition and Dietetic Institute	Vegenat
KoRa Healthcare	World Food
Lakeland Dairies	Wyeth Nutritionals
	Yasoo Health

Appendix 3: Profile of Respondents

	Number of respondents	% total
Consumers	41	55
Industry	13	17
Health Professionals	21	28
TOTAL	75	100

Appendix 4: An Analysis of the Declared Nutritional Composition of the Six Toddler Milks on the Irish Market

Ireland's submission to EU on PARNUTs revision (March 2012)

Toddler milks marketed in Ireland in 2012; variations in nutritional composition compared with minimum and maximum criteria in follow-on formula legislation (Directive 2006/141/EC). Full fat cows' milk composition included for information.

Nutrient	Follow-on-formula Minimum – Maximum values	Brand 1	Brand 1	Brand 2	Brand 2	Brand 3	Full fat cows' milk
		Stage 1 1+ yrs	Stage 2 2+ yrs	Stage 1 1-2 yrs	Stage 2 2-3 yrs	1-3 yrs	
Format (powder or ready-to-feed liquid)		Powder	R.T.F*	Powder	Powder	Powder	
Energy kcal/100ml	60 – 70	✓	✓	50	✓	50	66
Vitamin D3 µg/100kcal	1 – 3	✓	✓	3.4	✓	3.4	Trace
Calcium mg/100kcal	50 – 140	✓	✓	220	✓	220	179
Phosphorus mg/100kcal	25 – 90	✓	✓	133	✓	133	141
Magnesium mg/100kcal	5 – 15	✓	✓	20	✓	20	17
Iron mg/100kcal	0.6 – 2	✓	✓	2.4	✓	2.4	0.046
Zinc mg/100kcal	0.5 – 1.5	✓	✓	1.8	✓	1.8	0.06
Copper µg/100kcal	35 – 100	✓	✓	118	✓	118	Trace
Taurine mg/100kcal	Max 12	✓	14	✓	✓	✓	N/A

* R.T.F = ready-to-feed (liquid)

✓ = meets min – max values as laid down by Directive 2006/141/EC



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