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"A" ITEM NOTE

from : Permanent Representatives Committee (Part 1)
to : Council

No. Cion prop. : 12099/11 DENLEG 98 AGRI 480 SAN 137 CODEC 1180
No. prev. doc. : 10084/12 DENLEG 48 AGRI 327 SAN 113 CODEC 1341

Subject : Proposal for a Regulation of the European Parliament and of the Council on food intended for **infants and young children** and on food for **special medical purposes**
– *General approach*

1. The proposal for a Regulation of the European Parliament and of the Council on food intended for infants and young children and on food for special medical purposes (Proposal)¹ was submitted by the Commission on 24 June 2011 on the basis of Article 114 of the Treaty on the Functioning of the European Union (TFEU).
2. The European Economic and Social Committee has issued its opinion on 26 October 2011².
3. The ENVI Committee of the European Parliament voted its first reading report on 26 April 2012³.

¹ 12099/11 (COM(2011)353 final).

² NAT/518 – CESE 1604/2011.

³ A7-0059/2012.

4. After examination of the Proposal by the Working Party on Foodstuffs at a number of meetings, Coreper agreed by qualified majority, at its meeting on 8 May 2012, to give a mandate to the Presidency to negotiate with the European Parliament with the aim to reach a first reading agreement.
5. On 9 May 2012, the Presidency was informed by the Rapporteur (Mrs Ries, ALDE -BE), that the European Parliament had decided to adopt its position at first reading at the Plenary session in 11-14 June and thus, not to engage in negotiations with the Council at this stage of the ordinary legislative procedure.
6. IT is opposed to the text as set out in the Annex to this note, DE abstains and UK and FR maintain Parliamentary scrutiny reservations.
7. In view of the above, the Council is invited to agree on a general approach on the basis of the text set out in the Annex to this note.

* * *

In the text annexed, the additions and modifications to the Commission's proposal are highlighted in ***bold italics***. The deletion of entire recital(s), paragraph(s), Article(s) in the Commission's proposal is indicated by *(deleted)*.

Proposal for a
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on food intended for infants and young children, food for special medical *purposes and total diet replacement for weight control*.
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,
Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,
Having regard to the proposal from the European Commission,
After transmission of the draft legislative act to the national *parliaments*,
Having regard to the opinion of the European Economic and Social Committee,
Acting in accordance with the ordinary legislative procedure¹,

Whereas:

- (1) Article 114 of the Treaty on the Functioning of the European Union (TFEU) provides that measures having as their object the establishment and functioning of the internal market and which concern *inter alia* health, safety and consumer protection must take as a base a high level of protection taking account in particular of any new development based on scientific facts.
- (2) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.

¹ Position of the European Parliament of ... and the position of the Council at first reading of ...

- (3) Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses² lays down general rules on the composition and preparation of such foods that are specially designed to meet the particular nutritional requirements of the persons to whom they are intended. The majority of the provisions laid down in that Directive date back to 1977 and should therefore be reviewed.
- (4) Directive 2009/39/EC establishes a common definition for 'foodstuffs for particular nutritional uses' and general labelling requirements, including that such foods should bear an indication of their suitability for the claimed nutritional purposes.
- (5) The general composition and labelling requirements laid down in Directive 2009/39/EC are complemented by a number of non-legislative Union acts, which are applicable to specific categories of food. In that respect, Commission Directive 2006/141/EC of 22 December 2006 lays down harmonised rules with respect to infant formulae and follow-on formulae³, whereas Commission Directive 2006/125/EC of 5 December 2006 lays down certain harmonised rules with respect to processed cereal-based foods and baby foods for infants and young children⁴. Similarly, harmonised rules are also laid down by Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction⁵, Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes⁶ and Commission Regulation (EC) No 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable people intolerant to gluten⁷.
- (6) In addition, Council Directive 92/52/EEC of 18 June 1992 lays down harmonised rules with respect to infant formulae and follow-on formulae intended for export to third countries⁸.

² OJ L 124, 20.5.2009, p. 21.

³ OJ L 401, 30.12.2006. p. 1.

⁴ OJ L 339, 6.12.2006, p. 16.

⁵ OJ L 55, 6.3.1996, p. 22.

⁶ OJ L 91, 7.4.1999, p. 29.

⁷ OJ L 16, 21.1.2009, p. 3.

⁸ OJ L 179, 1.7.1992, p. 129.

(7) Directive 2009/39/EC foresees that specific provisions could be adopted regarding the two following specific categories of food falling within the definition of foodstuffs for particular nutritional uses: 'food intended to meet the expenditure of intense muscular effort, especially for sportsmen' and 'food for persons suffering from carbohydrate metabolism disorders (diabetes)'. *As regards special provisions for food for persons suffering from carbohydrate metabolism disorders (diabetes)*, a Commission report⁹ concludes that the scientific basis for setting specific compositional requirements is lacking. *With regard to food intended to meet the expenditure of intense muscular effort, especially for sportsmen, no successful conclusion could be reached as regard the development of specific provisions due to widely diverging views among the Member States and stakeholders concerning the scope of the specific legislation, the number of sub-categories of the food to be included, the criteria for establishing composition requirements and the potential impact on innovation in product development. Therefore, specific rules should not be developed at this stage. Meanwhile, based on the submission of requests by food business operators, relevant claims have been assessed to be included under the rules set out in Regulation (EC) No 1924/2006 on nutrition and health claims.*

(7a) However, different views exist on whether additional rules would be needed to ensure an adequate protection of the consumers of food intended for sportsmen, also called food intended to meet the expenditure of intense muscular effort. The Commission should, therefore, be invited, after consulting the Authority, to submit to the European Parliament and the Council a report on the desirability of special provisions for food intended for sportsmen with regard to composition, labelling and, if appropriate, other types of requirements. The consultation of the Authority should take into account the report of the Scientific Committee on Food of 28 February 2001 on composition and specification of food intended to meet the expenditure of intense muscular effort, especially for sportsmen. In its report, the Commission should, in particular, evaluate whether special provisions are needed to ensure the protection of vulnerable consumers, such as children and young people who use food intended for sportsmen in their diet.

⁹ COM (2008) 392 Report from the Commission to the European Parliament and the Council on foods for persons suffering from carbohydrate metabolism disorders (diabetes), Brussels, 26.6.2008.

- (8) Directive 2009/39/EC also requires a general notification procedure at national level for food presented by food business operators as falling under the definition of 'foodstuffs for particular nutritional uses' and for which no specific provisions are laid down in Union law, prior to their placing on the Union market, in order to facilitate the efficient monitoring of such food by the Member States.
- (9) A report from the Commission to the European Parliament and the Council on the implementation of that notification procedure¹⁰ showed that difficulties may arise from different interpretations of the definition of foodstuffs for particular nutritional uses which appeared to be open to different interpretations by the national authorities. It therefore concluded that a revision of the scope of Directive 2009/39/EC would be required to ensure a more effective and harmonised implementation of the Union legislation.
- (10) A study report¹¹ concerning the revision of the legislation on foodstuffs for particular nutritional uses confirms the findings of the Commission report on the implementation of the notification procedure and indicates that an increasing number of foodstuffs are today marketed and labelled as foodstuffs suitable for particular nutritional uses, due to the broad definition laid down in Directive 2009/39/EC. The study report also points out that the type of food regulated under that legislation differs significantly between Member States; similar food could at the same time be marketed in different Member States as food for particular nutritional uses and/or as food for normal consumption, ***including food supplements***, addressed to the population in general or to certain sub-groups thereof such as pregnant women, postmenopausal women, older adults, growing children, adolescents, variably active individuals and others. This state of affairs undermines the functioning of the internal market, creates legal uncertainty for competent authorities, food business operators and consumers, while the risks of marketing abuse and distortion of competition cannot be ruled out.

¹⁰ Report from the Commission to the European Parliament and the Council on the implementation of Article 9 of Council Directive 89/398/EEC on the approximation of the laws of the member States relating to foodstuffs intended for particular nutritional uses, COM (2008)393, dated 27.6.2008.

¹¹ An analysis of the European, social and environmental impact of the policy options for the revision of the Framework Directive on dietetic foods – Study report Agra CEAS Consulting, dated 29.4.2009.

- (11) It appears that other Union acts recently adopted are more adapted to an evolving and innovative food market than Directive 2009/39/EC. Of particular relevance and importance in that respect are: Directive 2002/46/EC of the European Parliament and the Council of 10 June on the approximation of the laws of the Member States relating to food supplements¹², Regulation (EC) No 1924/2006 of the European Parliament and the Council of 20 December 2006 on nutrition and health claims made on foods¹³ and Regulation (EC) No 1925/2006 of the European Parliament and the Council of 20 December 2006 on the addition of vitamins and minerals and other substances to foods¹⁴. Furthermore, the provisions of these Union acts would adequately regulate a number of the categories of food covered by Directive 2009/39/EC with less administrative burden and more clarity as to the scope and objectives.
- (12) Moreover, experience shows that certain rules included in or adopted under Directive 2009/39/EC are no longer effective to ensure the functioning of the internal market.
- (13) Therefore, the concept of “foodstuffs for particular nutritional uses” should be abolished and Directive 2009/39/EC should be replaced by the present act. To simplify its application and to ensure consistency throughout the Member States, the present act should take the form of a Regulation.
- (14) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety¹⁵ establishes common principles and definitions for Union food law in order to ensure a high level of health protection and the effective functioning of the internal market. It establishes the principles of risk analysis in relation to food and establishes the structures and mechanisms for the scientific and technical evaluations which are undertaken by the European Food Safety Authority (hereinafter referred to as 'the Authority'). Therefore, certain definitions laid down in that Regulation must also apply in the context of the present Regulation. Moreover, for the purpose of this Regulation, the Authority should be consulted on all matters likely to affect public health.

¹² OJ L 183, 12.7.2002, p. 51.

¹³ OJ L 404, 30.12.2006, p. 9.

¹⁴ OJ L 404, 30.12.2006, p. 26.

¹⁵ OJ L 31, 1.2.2002, p. 1.

(15) A limited number of categories of food constitutes the sole source of nourishment of certain groups of the population or represent a partial source of nourishment; such categories of food are vital for the management of certain conditions and/or are essential to maintain the intended nutritional adequacy for certain well-established vulnerable groups of the population. Those categories of food include infant formulae and follow-on formulae, processed cereal-based food and baby food and food for special medical purposes. Experience has shown that the provisions laid down in Commission Directive 2006/141/EC, Commission Directive 2006/125/EC, as well as Commission Directive 1999/21/EC ensure the free movement of such food in a satisfactory manner, while ensuring a high level of protection of public health. It is therefore appropriate that this Regulation focuses on the general compositional and information requirements for infant formula and follow-on formulae, processed cereal-based food and baby food for infants and young children and to food for special medical purposes, taking into account Commission Directive 2006/141/EC, Commission Directive 2006/125/EC and Commission Directive 1999/21/EC.

(15a) In addition, in view of the growing rates of people with overweight and obesity problems, an increasing number of food is placed on the market as total diet replacement for weight control, including food the energy content of which is very low, commonly named as very low calorie diet products. Given the nature of the food in question it would be appropriate to set certain specific provisions for it. Experience has shown that the relevant provisions laid down in Commission Directive 96/8/EC ensure the free movement of food presented as total daily diet replacement for weight control in a satisfactory manner while ensuring a high level of protection of public health. It is therefore appropriate that this Regulation focuses on the general composition and information requirements for food intended to replace the whole of the daily diet including food the energy content of which is very low taking into account the relevant provisions of Commission Directive 96/8/EC.

(16) *This Regulation should establish, among others, definitions of infant formulae and follow-on formulae, processed cereal-based food and baby food, food for special medical purposes and total diet replacement for weight control, taking into account relevant provisions in Commission Directive 2006/141/EC, Commission Directive 2006/125/EC, Commission Directive 1999/21/EC and Commission Directive 1996/8/EC.*

(16a) *The nutritional requirements of low birth weight and/or preterm infants depend on the medical condition of the infant, in particular on his weight in comparison with that of an infant in good health, and on the number of weeks the infant is premature. It is to be decided on a case by case basis whether the infant's condition requires the consumption under medical supervision of a formula adapted for the dietary management of his specific condition.*

(17) It is important that ingredients used in the manufacture of the categories of food covered by this Regulation are appropriate to satisfy the nutritional requirements of, and are suitable for the persons to whom they are intended and that their nutritional adequacy has been established by generally accepted scientific data. Such adequacy should be demonstrated through a systematic review of the available scientific data.

(17a) *The use of pesticides in products of plant and animal origin intended for infants and young children should be restricted as far as possible. A prohibition of their use in the production of such products would not necessarily guarantee that they are free from such pesticides, since some pesticides contaminate the environment and their residues may be found in the products concerned. Therefore, the maximum residues levels in the products concerned should be set at the lowest achievable level consistent with good agricultural practices for each pesticide with a view to protect those vulnerable groups of the population.*

(17b) Limitations or bans of certain pesticides equivalent to those currently established by the annexes to the Directives 2006/141/EC and 2006/125/EC should be taken into account in delegated acts. Those limitations or bans should be updated regularly, with particular attention to be paid to pesticides containing active substances, safeners or synergists classified in accordance with Regulation (EC) No 1272/2008 as mutagen category 1A or 1B, carcinogen category 1A or 1B, toxic for reproduction category 1A or 1B, considered to have endocrine disrupting properties that may cause adverse effects in humans.

(18) General labelling requirements are laid down in ***Regulation (EU) No 1169/2011*** of the European Parliament and of the Council ***of 25 October 2011***¹⁶. Those general labelling requirements should, as a general rule, apply to the categories of food covered by this Regulation. However, this Regulation should also provide for additional requirements to, or derogations from, the provisions of ***Regulation (EU) No 1169/2011***, where necessary, in order to meet the specific objectives of this Regulation.

(18a) The labelling, presentation or advertising of foods falling under the scope of this regulation should not attribute properties to such foods for the prevention, treatment or cure of human disease or imply such properties. Foods for special medical purposes, however, are intended for the dietary management of patients with a limited, impaired or disturbed capacity, for example, to take an ordinary food because of a specific disease, disorder or medical condition. Reference to the dietary management of diseases, disorders or medical conditions for which the product is intended should not be considered as attribution of a property for the prevention, treatment or cure of human disease.

¹⁶ OJ L 304, 22.11.2011, p.18.

(19) This Regulation should provide the criteria for the establishment of the specific compositional and information requirements for infant formula, follow-on formula, processed cereal-based food and baby food, food for special medical purposes **and total diet replacement for weight control**, taking into account Commission Directive 2006/141/EC, Commission Directive 2006/125/EC, Commission Directive 1999/21/EC **and Commission Directive 96/8/EC**. In order to lay down the specific compositional and information requirements with respect to the categories of food covered by this Regulation, including for additional labelling requirements to, or derogations from, the provisions of **Regulation (EU) No 1169/2011** and for the authorisation of nutrition and health claims, the power to adopt acts in accordance with Article 290 of the TFEU should be delegated to the Commission. **Furthermore, in order to enable consumers to benefit rapidly from technical and scientific progress, especially in relation to innovative products, and thus to stimulate innovation, the power to adopt acts in accordance with Article 290 TFEU should also be delegated to the Commission for the purpose of a regular update of the requirements applying to infant formula and follow-on formula, processed cereal-based food and baby food for infants and young children, food for special medical purposes and total diet replacement for weight control, taking into account all relevant data, including data provided by interested parties.** It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

(19a) There is an increasing number of milk-based drinks and similar products on the Union market which are promoted as being particularly suited for children between one and three years. These products, which can be derived from protein of animal or vegetable origin such as, for example, cows' milk, goats' milk, soy or rice are often marketed as 'growing up milks' or 'toddlers' milks' or with similar terminology. These products are not covered by the specific existing measures applying to foods intended for infants and young children. Different views exist on whether these products respond to specific nutritional requirements of the population they target. The Commission should therefore, after consulting the Authority, present to the European Parliament and to the Council a report on the desirability of special provisions regarding the composition, labelling and other types of requirements, if appropriate, of these milk-based drinks and similar products intended for young children. The Commission may accompany this report with a legislative proposal.

(19b) It is appropriate to establish and update a Union list of vitamins, minerals, amino acids, carnitine, taurine, nucleotides, choline and inositol that may be added to infant formula and follow-on formula, processed cereal-based food and baby food for infants and young children, food for special medical purposes and total diet replacement for weight control subject to criteria laid down in this Regulation.

(19c) In order to take into account technical progress, scientific developments or consumers' health, the power to adopt acts in accordance with Article 290 TFEU should also be delegated to the Commission in respect of extending the Union list to additional categories of substances that have a nutritional or physiological effect. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

- (20) *In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to decide whether or not a given food falls within the scope of this Regulation and to which category of food under the scope it belongs, as well as to establish and to update, by applying the criteria laid down in this Regulation, a Union list of vitamins, minerals, amino acids, carnitine, taurine, nucleotides, choline and inositol.* Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers¹⁷ The Commission should adopt immediately applicable implementing acts, where, in duly justified cases relating to public health, imperative grounds of urgency so require.
- (21) *The substances falling within the scope of Regulation (EC) No 258/97 should not be added to the foods covered by this Regulation unless such substances fulfil the conditions for being placed on the market under Regulation (EC) 258/97 in addition to the conditions set out in accordance with this Regulation. When, for a substance that has been used in accordance with this Regulation, there is a significant change in the production method or a change in particle size, for example through nanotechnology, this substance should be considered different from the one that has been used in accordance with this Regulation and should be re-evaluated under Regulation (EC) No 258/97.*
- (22) *(deleted)*
- (23) *(deleted)*
- (24) Council Directive 92/52/EEC states that infant formulae and follow-on formulae exported or re-exported from the European Union have to comply with Union law unless otherwise required by the importing country. This principle has already been established for food in Regulation (EC) No 178/2002. For the sake of simplification and legal certainty, Directive 92/52/EEC should therefore be repealed.

¹⁷ OJ L 55, 28.2.2011, p. 13.

- (25) Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods¹⁸ establishes the rules and conditions for the use of nutrition and health claims on food. Those rules should apply as a general rule to the categories of food covered by this Regulation, unless otherwise specified in this Regulation or non-legislative acts adopted pursuant to this Regulation.
- (26) Currently, ***the rules on the use of the statements 'gluten-free' and 'very low gluten' are specified in Commission Regulation (EC) No 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten¹⁹. That Regulation harmonises the information that is provided to consumers on the absence or reduced presence of gluten in foods and sets specific rules for foods that are specially processed, prepared or manufactured to reduce the gluten content of one or more gluten containing ingredients and other foods that are made exclusively from ingredients naturally free of gluten. Regulation (EU) No 1169/2011 on the provision of food information to consumers sets out rules on information to provide on the presence in all foods, including non-prepacked foods, of ingredients, such as gluten containing ingredients, with a scientifically proven allergenic or intolerant effect to enable consumers, particularly those suffering from a food allergy or intolerance such as gluten intolerant people, to make informed choices which are safe for them. For the sake of clarity and consistency, the rules on the use of the statements 'gluten-free' and 'very low gluten' should also be regulated under Regulation (EU) No 1169/2011. It is necessary that the acts pursuant to Regulation (EU) No 1169/2011, transferring the rules on the use of the statements 'gluten-free' and 'very low gluten' as regulated under Regulation (EU) No 41/2009 be completed prior to the application of this Regulation.***

¹⁸ OJ L 404, 30.12.2006, p. 9.

¹⁹ OJ L 14, 20.1.2009, p. 5.

- (26a) Labelling and compositional rules indicating the absence or reduced presence of lactose in food are currently not harmonised at Union level. Those indications are, however, important for people who are intolerant to lactose. As mentioned above, Regulation (EU) No 1169/2011 sets out rules on information to provide on substances with a scientifically proven allergenic or intolerant effect, to enable consumers, such as lactose intolerant people, to make informed choices which are safe for them. For the sake of clarity and consistency, the establishment of rules on the use of the statements indicating the absence or reduced presence of lactose in food should be regulated under Regulation (EU) No 1169/2011.**
- (27) 'Meal replacement for weight control' **intended to replace part of the daily diet is** considered as food for particular nutritional uses and **is currently** governed by specific rules adopted under Directive 96/8/EC. However, more and more food intended for the general population has appeared on the market carrying similar declarations which are presented as health claims for weight control. In order to eliminate any potential confusion **within this group** of food marketed for weight control and in the interests of legal certainty and coherence of Union legislation, such statements should be regulated solely by Regulation (EC) No 1924/2006 and comply with requirements therein. It is necessary that technical adaptations pursuant to Regulation (EC) No 1924/2006, incorporating the health claims referring to the body weight control for food presented as 'meal replacement for weight control' and associated conditions of use as regulated by Directive 96/8/EC be completed prior to the entry into application of this Regulation.
- (28) Since the objectives of the actions to be taken cannot be sufficiently achieved by the Member States and can therefore be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (29) Adequate transitional measures are necessary to enable food business operators to adapt to the requirements of this Regulation.

HAVE ADOPTED THIS REGULATION:

CHAPTER I
SUBJECT MATTER AND DEFINITIONS

Article 1

Subject matter

1. This Regulation establishes compositional and information requirements for the following categories of food:
 - (a) infant formula and follow-on formula;
 - (b) processed cereal-based food and baby food for infants and young children;
 - (c) food for special medical purposes;
 - (d) ***total diet replacement for weight control.***

2. This Regulation provides the rules for the establishment and update of a Union list of vitamins, minerals, ***amino acids, carnitine, taurine, nucleotides, choline and inositol*** that ***may*** be added to the categories of food referred to in paragraph 1 (“Union list”).

Article 2

Definitions

1. For the purposes of this Regulation, the following definitions shall apply:
 - (a) the definitions of 'food', '***retail***' and 'placing on the market' set out ***respectively*** in Articles 2 and ***Article 3(7) and (8)*** of Regulation (EC) No 178/2002;
 - (b) the definitions of 'labelling' and '***prepacked food***' set out ***respectively*** in points (e) and (j) of Article 2(2) of Regulation (EU) No 1169/2011; and
 - (c) the definitions of 'nutrition claim' and 'health claim' set out ***respectively*** in points (4) and (5) of Article 2(2) of Regulation (EC) No 1924/2006.
 - (d) *(deleted)*.

2. The following definitions shall also apply:

- (a) 'Authority' means the European Food Safety Authority established by Regulation (EC) No 178/2002;
- (b) 'infants' means children under the age of 12 months;
- (c) 'young children' means children between one and three years;
- (d) 'infant formula' means food used by infants during the first months of life and satisfying by itself the nutritional requirements of such infants until the introduction of appropriate complementary feeding;
- (e) 'follow-on formula' means food used by infants when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet of such infants;
- (f) 'processed cereal-based food' means food:
 - (i) intended to fulfil the particular requirements of infants in good health while they are being weaned, and of young children in good health as a supplement to their diet and/or for their progressive adaptation to ordinary food and
 - (ii) pertaining to **one of** the following four categories:
 - simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids;
 - cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid;
 - pastas which are to be used after cooking in boiling water or other appropriate liquids;
 - rusks and biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids;

- (g) 'baby food' means food intended to fulfil the particular requirements of infants in good health while they are being weaned, and of young children in good health as a supplement to their diet and/or for their progressive adaptation to ordinary food, excluding:
- (i) processed cereal-based food and
 - (ii) milk intended for young children;
- (h) 'food for special medical purposes' means food *specifically processed or formulated and* intended for the dietary management of patients to be used under medical supervision. It is intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein *or metabolites*, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet.
- (i) *'total diet replacement for weight control' means food (e)specifically 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.*

3. (deleted)

Article 2a

Interpretation decisions

In order to ensure the uniform implementation of this Regulation, the Commission may adopt implementing acts to decide:

- *whether or not a given food falls within the scope of this Regulation;*
- *to which specific category referred to in Article 1(1) a given food belongs.*

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 14(2).

CHAPTER II
PLACING ON THE MARKET

Article 3

Placing on the market

1. Food referred to in Article 1(1) may be placed on the market only if it complies with this Regulation.
2. Food referred to in Article 1(1) shall only be allowed on the retail market in the form of ***prepacked*** food.
3. Member States may not ***restrict or forbid the placing on the market of food which complies with this Regulation*** for reasons related to ***its*** composition, manufacturing, presentation or labelling.

Article 4

(deleted)

Article 5

(deleted)

Article 6

(deleted)

CHAPTER III REQUIREMENTS

SECTION 1 GENERAL REQUIREMENTS

Article 7

Introductory provisions

1. Food referred to in Article 1(1) shall comply with any requirement of Union law applicable to food.
2. The requirements laid down in this Regulation shall prevail over any other conflicting requirement of Union law applicable to food.

Article 8

Opinions of the Authority

The Authority shall provide scientific opinions in accordance with Articles 22 and 23 of Regulation (EC) No 178/2002 for the purpose of application of *this* Regulation. ***These opinions will serve as the scientific basis for any Union measure adopted pursuant to this Regulation which is likely to have an effect on public health.***

Article 9

General composition and information requirements

1. The composition of food referred to in Article 1(1) shall be such that it is appropriate to satisfy the nutritional needs of and it is suitable for the persons to whom it is intended, in accordance with generally accepted scientific data.

2. Food referred to in Article 1(1) shall not contain any substance in such quantity as to endanger the health of the persons to whom they are intended.
- 2a. *Without prejudice to Article 3, food referred to in Article 1(1) may contain substances covered by Article 1 of Regulation (EC) No 258/97 concerning novel foods and novel food ingredients, provided that those substances fulfil the conditions for placing on the market under Regulation (EC) No 258/97.*
3. The labelling, presentation and advertising of food referred to in Article 1(1) shall provide information *for the appropriate use of the food*, and *shall* not be misleading, *nor attribute properties to such products for the prevention, treatment or cure of human disease, or imply such properties.*
4. *Paragraph 3 shall not prevent* the dissemination of any useful information or recommendations *exclusively intended for* persons having qualifications in medicine, nutrition, pharmacy or other *health care* professionals responsible for maternal and child care.

SECTION 2

SPECIFIC REQUIREMENTS

Article 10

Specific composition and information requirements

1. *(deleted)*
2. Subject to the general requirements of Articles 7 and 9 and taking into account any technical and scientific progress, the Commission shall be empowered to adopt delegated *acts* in accordance with Article 15, with respect to the following:
 - (a) the specific compositional requirements of food referred to in Article 1(1), *with the exception of requirements as set out in accordance with Article 11;*

- (b) the specific requirements on the use of pesticides in *products of plant and animal origin* intended for the production of food *referred to in Article 1(1)* and on pesticides residues in such food;
- (c) the specific requirements on labelling, presentation and advertising of food referred to in Article 1(1), including the authorisation of nutrition and health claims thereof;
- (d) the notification for the placing on the market of a food referred to in Article 1(1) in order to facilitate the efficient official monitoring of such food on the basis of which food *business* operators shall notify the competent authority of the Member State(s) where the product is being marketed;
- (e) the requirements on promotional and commercial practices relating to infant formulae; and,
- (f) the requirements on information to be provided on infant and young child feeding in order to ensure adequate information on appropriate feeding practices.

Those delegated acts shall be adopted no later than²⁰ [...].

3. Subject to the *general* requirements of Articles 7 and 9 and taking into account relevant technical and scientific progress, *including data provided by interested parties in relation to innovative products*, the Commission *shall be empowered to adopt delegated acts aimed at updating the delegated acts* mentioned in paragraph 2 in accordance with Article 15.

Where in the case of emerging health risks, imperative grounds of urgency so require, the procedure provided in Article 16 shall apply to delegated acts adopted pursuant to this paragraph.

²⁰ *2 years after the date of the entry into force of this Regulation.*

Article 10a

Milk-based drinks and similar products intended for young children

By²¹ [...], the Commission shall, after consulting the Authority, present to the European Parliament and to the Council 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. The Commission may accompany this report with a legislative proposal.

Article 10b

Foods intended for sportsmen

By²² [...], the Commission shall, after consulting the Authority, present to the European Parliament and to the Council a report on the desirability of special provisions for food intended for sportsmen with regard to composition, labelling and, if appropriate, other types of requirements. In its report, the Commission shall, in particular, evaluate whether specific provisions are needed to ensure the protection of vulnerable consumers, such as children and young people who use food intended for sportsmen in their diet. The Commission may accompany this report with a legislative proposal.

CHAPTER IV

UNION LIST OF PERMITTED SUBSTANCES

Article 11

Union list of permitted substances

1. Vitamins, minerals, amino acids, *carnitine, taurine, nucleotides, choline and inositol* may be added to food referred to in Article 1(1), provided that *they are included in the Union list*.

²¹ 2 years after the date of the entry into force of this Regulation.

²² 2 years after the entry into force of this Regulation.

2. ***Substances belonging to the categories listed in paragraph 1 shall be included in the Union list, provided that, on the basis of generally accepted scientific data, they meet each of the following criteria:***
- a) they do not pose a safety concern to the health of the consumer;
 - b) they are *bio*-available for use by human body;
 - c) ***they do have a nutritional or physiological effect;***
 - d) ***they are suitable for the persons to whom the category (categories) of food referred to in Article 1(1) are intended for.***
3. ***For the purposes of taking into account technical progress, scientific developments or consumers' health, the Commission shall be empowered to adopt delegated acts in accordance with Article 15 to provide for additional categories of substances that have a nutritional or physiological effect to the categories referred to in paragraph 1 of this Article.***
4. ***Substances belonging to categories not listed in paragraph 1 may still be added to food referred to in Article 1(1), provided that they satisfy the requirements set out in Articles 7 and 9, the criteria set out in Article 11(2), and, where applicable, the requirements established in accordance with Article 10.***
5. ***The entry of a substance into the Union list shall include:***
- ***the name, the description of the substance and, where appropriate, the specification of its form;***
 - ***where appropriate, the conditions of use;***
 - ***the purity criteria.***
6. ***No later than ²³[...], the Commission shall establish, by means of implementing acts, the Union list referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 14(2).***

The Commission shall, pursuant to paragraphs 7 to 12, update the Union list.

²³ ***2 years after the date of the entry into force of this Regulation.***

7. *"Updating the Union list" means:*
- (a) *adding a substance to the Union list;*
 - (b) *removing a substance from the Union list;*
 - (c) *adding, removing or amending the specifications, conditions of use, or the applicable purity criteria associated with the presence of a substance on the Union list.*
8. *The updating of the Union list may be initiated either on the initiative of the Commission or following an application. Applications may be made by a Member State or by an interested party, who may also represent several interested parties (hereinafter referred to as the applicant). Applications shall be submitted to the Commission. Where the Commission starts the procedure to update the Union list on its own initiative, the Commission shall inform the Member States.*
9. *The application shall include:*
- (a) *the name and the address of the applicant;*
 - (b) *the name and a clear description of the substance;*
 - (c) *the composition of the substance;*
 - (d) *the proposed use of the substance and conditions thereof;*
 - (e) *a systematic review of the scientific data and appropriate studies performed following generally accepted expert guidance on the design and conduct of such studies;*
 - (f) *scientific evidence demonstrating the quantity of the substance which does not endanger the health of the persons to whom it is intended and its suitability for the intended uses;*
 - (g) *scientific evidence demonstrating that the substance is bio-available for use by the human body and has a nutritional or a physiological effect;*
 - (h) *a summary of the content of the application;*
 - (i) *the production method;*
 - (j) *where applicable, the analysis method;*
 - (k) *the purity criteria.*

10. *Within 2 months of receiving an application to update the Union list, the Commission shall send to the applicant a written acknowledgement, stating the date of receipt, and informing him whether the submitted application contains all the elements provided for in paragraph 9 in order to be admissible. Where one or more of the elements provided for in paragraph 9 are missing, the Commission shall inform the applicant, setting a period for their submission. Where at the end of that period, the applicant has not submitted the missing elements, the application is considered inadmissible.*
11. *Where an application does not meet the conditions of this Article, the Commission shall decide not to proceed with the update of the Union list and shall inform the applicant and the Member States accordingly indicating the reasons for its decision.*
12. *Where an application or initiative of the Commission to update the Union list meets the conditions of this Article, the Commission shall, by means of implementing acts, update the Union list. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 14(2).*

On duly justified grounds of extreme urgency relating to emerging health risks, the Commission shall adopt immediately applicable implementing acts updating the Union list in accordance with Article 14(3).

Article 12

Confidential information relating to applications

1. Among the information provided in the application referred to in Article 11, confidential treatment may be given to information the disclosure of which might significantly harm the competitive position of the applicant.

2. Information relating to the following shall not, in any circumstances, be regarded as confidential:
 - (i) the name and address of the applicant;
 - (ii) the name and description of the substance;
 - (iii) the justification for the use of the substance in or on specific food;
 - (iv) information that is relevant to the assessment of the safety of the substance;
 - (v) where applicable, the analysis method(s) used by the applicant.
3. Applicants shall indicate which of the information provided they wish to be treated as confidential. Verifiable justification *shall* be given in such cases.
4. The Commission shall decide after consulting with the applicants which information can remain confidential and shall notify applicants, the Member States *and the Authority* accordingly.
5. After being made aware of the Commission's position, applicants shall have three weeks in which to withdraw their application so as to preserve the confidentiality of the information provided. Confidentiality shall be preserved until this period expires.
6. *The Commission, the Member States and the Authority shall keep confidential all the information identified as confidential under the previous paragraphs.*

Notwithstanding the previous subparagraph, the Commission shall make public such information where this is appropriate in order to protect human health, animal health or the environment.

CHAPTER V
CONFIDENTIALITY

Article 13

Access to documents

The Commission shall apply Regulation (EC) No 1049/2001 to applications for access to any document covered by the present Regulation.

CHAPTER VI
PROCEDURAL PROVISIONS

Article 14

Committee

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health ***established by Regulation (EC) No 178/2002***. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request.

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

Article 15

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power *to adopt delegated acts* referred to in Articles 10 *and 11(3)* shall be conferred *on the Commission* for a period of time *of 5 years from the entry into force of this Regulation. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*
3. The delegation of powers referred to in Articles 10 *and 11(3)* may be revoked at any time by the European Parliament or by the Council. A decision *to revoke* shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act adopted pursuant to Articles 10 *and 11(3)* shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of *two* months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by *two* months at the initiative of the European Parliament or *of* the Council.

Article 16
Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.
2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 15. In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or *by* the Council.

CHAPTER VII
FINAL PROVISIONS

Article 17

Repeal

1. Directive 2009/39/EC is repealed from²⁴ [...]. References to the repealed acts shall be construed as references to this Regulation.
 - 1a. Directive 92/52/EEC and Regulation (EC) No 41/2009 are repealed from²⁵ [...].***
 - 1b. Without prejudice to the first subparagraph of paragraph 2, Directive 96/8/EC shall not apply to foods presented as replacement for one or more meals of the daily diet from²⁶ [...].***

²⁴ 3 years after the date of the entry into force of this Regulation.

²⁵ 3 years after the date of the entry into force of this Regulation.

²⁶ 3 years after the date of the entry into force of this Regulation.

2. **Directives 96/8/EC, 2006/141/EC, 2006/125/EC, 1999/21/EC** and Regulation (EC) No 953/2009 are repealed from ***the date of application of the delegated acts referred to in Article 10(2) and of the implementing acts referred to in the first subparagraph of Article 11(6).***

The delegated acts referred to in Article 10(2) and the implementing acts referred to in the first subparagraph of Article 11(6) shall apply from the same date.

In case of conflict between Directives 96/8/EC, 2006/141/EC, 2006/125/EC, 1999/21/EC, Regulation (EC) No 953/2009 and this Regulation, provisions of this Regulation shall prevail.

Article 18

Transitional measures

1. Food ***covered by Article 1(1) which does not comply***~~ing~~ with this Regulation but ***complies*** with Directives 2009/39/EC, 96/8/EC, ***2006/141/EC, 2006/125/EC, 1999/21/EC and Regulation (EC) No 953/2009, which is placed on the market or labelled before***²⁷ [...] may continue to be marketed after that date until stocks ***of such food*** are exhausted.

Where the date of application of the delegated and implementing acts referred to in Article 17(2) is after²⁸ [...], food covered by Article 1(1) which ***complies with this Regulation, Regulation (EC) No 953/2009, Directives 96/8/EC, 2006/141/EC, 2006/125/EC and 1999/21/EC but does not comply with the delegated and implementing acts referred to in Article 17(2), and which is placed on the market or labelled before the date of application of those delegated and implementing acts, may continue to be marketed after that date until stocks of such food are exhausted.***

²⁷ 3 years after the date of the entry into force of this Regulation.

²⁸ 3 years after the date of the entry into force of this Regulation.

2. ***Food which is not covered by Article 1(1) of this Regulation but which is placed on the market or labelled in accordance with Directives 2009/39/EC, 96/8/EC, Regulations (EC) 41/2009 and (EC) 953/2009 before²⁹[...] may continue to be marketed after that date until stocks of such food are exhausted.***

Article 19

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from³⁰ [...], ***with the exception of Articles 14 to 16, as well as the power conferred on the Commission in Articles 10(2), 10(3), 11(3), 11(6) and 11(12) which shall apply from the date of entry into force.***

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at ...,

For the European Parliament

For the Council

The President

The President

²⁹ ***3 years after the date of the entry into force of this Regulation.***

³⁰ ***3 years after the entry into force.***