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EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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I

*(Acts whose publication is obligatory)*

# COMMISSION DIRECTIVE 2006/141/EC

## of 22 December 2006

## on infant formulae and follow-on formulae and amending Directive 1999/21/EC

**(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses [1], and in particular Article 4(1) thereof,

After consulting the European Food Safety Authority (the Authority),

Whereas:

(1) Directive 89/398/EEC concerns foodstuffs intended for particular nutritional uses. The specific provisions applicable to certain groups of foods for particular nutritional uses are laid down by specific Directives.

(2) Commission Directive 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae [2] is a specific Directive adopted pursuant to Directive 89/398/EEC. That Directive has been substantially amended several times [3]. Since further amendments are to be made, it should be recast in the interests of clarity.

(3) In the light of discussions in international fora, in particular Codex Alimentarius, in relation to the timing of the introduction of complementary foods into the diet of infants, it is appropriate to amend the current definitions of infant formulae and follow-on formulae and certain provisions on the labelling of follow-on formulae in Directive 91/321/EEC.

(4) Infant formula is the only processed foodstuff which wholly satisfies the nutritional requirements of infants during the first months of life until the introduction of appropriate complementary feeding. In order to safeguard the health of such infants it is necessary to ensure that the only products marketed as suitable for such use during the period would be infant formulae.

(5) The essential composition of infant formulae and follow-on formulae must satisfy the nutritional requirements of infants in good health as established by generally accepted scientific data.

(6) The requirements concerning the essential composition of infant formulae and follow-on formulae should include detailed provisions on the protein content. Notwithstanding that traditionally different appropriate conversion factors have been used for the calculation of the protein content from the nitrogen content of different protein sources, recent scientific advice indicates that for the specific purposes of calculating the protein content of infant formulae and follow-on formulae it is appropriate to use a single conversion factor adapted to these products. As infant formulae and follow-on formulae are sophisticated products that are specially formulated for their intended purpose, additional essential requirements on protein, including minimum and maximum levels of protein and minimum levels of certain amino acids, should be established. The protein requirements specified in this Directive should relate to the final products as such, prepared ready for consumption.

[1] OJ L 186, 30.6.1989, p. 27. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).
[2] OJ L 175, 4.7.1991, p. 35. Directive as last amended by the 2003 Act of Accession.
[3] See Annex X, Part A.

(7) On the basis of such data, the essential composition of infant formulae and follow-on formulae manufactured from cows' milk proteins and soya proteins alone or in a mixture, as well as infant formulae based on protein hydrolysates, can already be defined. The same is not true for preparations based wholly or partly on other sources of protein. For this reason specific rules for such products, if necessary, should be adopted at a later date.

(8) It is important that ingredients used in the manufacture of infant formulae and follow-on formulae are suitable for the particular nutritional use by infants and that their suitability has been demonstrated, when necessary, by appropriate studies. Guidance on the design and conduct of appropriate studies has been published by expert scientific groups such as the Scientific Committee on Food, the UK Committee on the Medical Aspects of Food and Nutrition Policy, and the European Society for Paediatric Gastroenterology, Hepatology and Nutrition. Such guidance should be taken into consideration when ingredients are introduced into infant formulae or follow-on formulae.

(9) A number of the substances that may be used in the manufacture of infant formulae and follow-on formulae may also be used in foodstuffs as food additives. In that context, purity criteria have already been or are to be adopted at Community level in accordance with Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption ([1]). Those purity criteria should apply to those substances whatever the purpose of their use in foodstuffs.

(10) Pending the adoption of purity criteria for substances for which such criteria have not yet been adopted at Community level, and in order to ensure a high level of protection for public health, generally acceptable purity criteria recommended by international organisations or agencies, such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA) or European Pharmacopoeia (EUP), should apply. In addition, Member States should be permitted to maintain national rules setting stricter purity criteria.

([1]) OJ L 40, 11.2.1989, p. 27. Directive as last amended by Regulation (EC) No 1882/2003.

(11) Given the particular nature of infant formula, additional means to those usually available to monitoring bodies should be available in order to facilitate efficient monitoring of those products.

(12) Infant formulae based on protein hydrolysates are distinct from semi-elemental diet products based on high degree hydrolysates used for the dietary management of diagnosed medical conditions, which are not covered by this Directive.

(13) This Directive reflects current knowledge about the products concerned. Any amendment, to allow innovation based on scientific and technical progress, should be decided by the procedure referred to in Article 13(2) of Directive 89/398/EEC.

(14) Maximum levels for pesticide residues set out in relevant Community legislation, in particular Council Directive 76/895/EEC of 23 November 1976 relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables ([2]), in Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals ([3]), in Council Directive 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin ([4]), and in Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables ([5]), should apply without prejudice to specific provisions set out in this Directive.

(15) Taking into account the Community's international obligations, in cases where the relevant scientific evidence is insufficient, the precautionary principle referred to in Article 7 of 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 safety ([6]) allows the Community to provisionally adopt measures on the basis of available pertinent information, pending an additional assessment of risk and a review of the measure within a reasonable period of time.

([2]) OJ L 340, 9.12.1976, p. 26. Directive as last amended by Commission Directive 2006/92/EC (OJ L 311, 10.11.2006, p. 31).
([3]) OJ L 221, 7.8.1986, p. 37. Directive as last amended by Directive 2006/92/EC.
([4]) OJ L 221, 7.8.1986, p. 43. Directive as last amended by Commission Directive 2006/62/EC (OJ L 206, 27.7.2006, p. 27).
([5]) OJ L 350, 14.12.1990, p. 71. Directive as last amended by Directive 2006/92/EC.
([6]) OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 3).

(16) On the basis of the two opinions given by the Scientific Committee for Food on 19 September 1997 and 4 June 1998, there are at present doubts as to the adequacy of existing acceptable daily intake (ADI) values of pesticides and pesticide residues for the protection of the health of infants and young children. Therefore, as far as foodstuffs for particular nutritional uses intended for infants and young children are concerned, it is appropriate to adopt a very low common limit for all pesticides. This very low common limit should be fixed at 0,01 mg/kg which normally is in practice the minimum detectable level.

(17) Severe limitations on pesticide residues should be required. With careful selection of raw materials, and given that infant formulae and follow-on formulae undergo extensive processing during their manufacture, it is feasible to produce products containing very low levels of pesticide residues. However, in the case of a small number of pesticides or metabolites of pesticides even a maximum residue level of 0,01 mg/kg might, under worst-case intake conditions, allow infants and young children to exceed the ADI. This is the case for pesticides or metabolites of pesticides with an ADI lower than 0,0005 mg/kg body weight.

(18) This Directive should establish the principle of the prohibition of the use of these pesticides in the production of agricultural products intended for infant formulae and follow-on formulae. However, this prohibition does not necessarily guarantee that products are free from such pesticides, since some pesticides contaminate the environment and their residues may be found in the products concerned.

(19) Most of the pesticides which have ADI values lower than 0,0005 mg/kg body weight are already prohibited in the Community. The prohibited pesticides should not be detectable in infant formulae and follow-on formulae by state-of-the-art analytical methods. However, some pesticides degrade slowly and still contaminate the environment. They might be present in infant formulae and follow-on formulae even if they have not been used. For the purposes of control, a harmonised approach should be followed.

(20) Pending Commission decisions on whether they satisfy the safety requirements of Article 5 of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [1], the continued use of authorised pesticides should be permitted as long as their residues comply with the maximum residue levels established in this Directive. The latter should be set at levels ensuring that their respective ADI values are not exceeded by infants and young children under worst-case intake conditions.

(21) The Annexes to this Directive dealing with pesticides should be amended following the completion of the review programme being carried out under Directive 91/414/EEC.

(22) Pursuant to Article 7(1) of Directive 89/398/EEC, the products covered by this Directive are subject to the general rules laid down by Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs [2]. This Directive adopts and expands upon the additions and exceptions to those general rules, where it is appropriate, in order to promote and protect breast feeding.

(23) In particular, the nature and destination of the products covered by this Directive require nutritional labelling showing the energy value and principal nutrients they contain. On the other hand, the method of use should be specified in accordance with point 9 of Article 3(1) and Article 11(2) of Directive 2000/13/EC, in order to prevent inappropriate uses likely to be detrimental to the health of infants.

(24) Given the nature of infant formulae and follow-on formulae the detailed rules as to nutrient declaration on the labelling need to be clarified in order to avoid any problems which may arise from the application of other relevant Community legislation.

(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 food [3] establishes the rules and conditions for the use of nutrition and health claims concerning foods. However, Article 1(5) of that Regulation states that it shall apply without prejudice to, in particular, Directive 89/398/EEC and directives adopted relating to foodstuffs for particular nutritional uses.

(26) It is appropriate to set out specific conditions for the use of nutrition and health claims concerning infant formulae in this Directive. In this respect, it is necessary, in order to supply objective and scientifically verified information, to define the conditions under which nutrition and health claims are authorised, and to establish a list of authorised claims. In accordance with the third subparagraph of Article 4(1) of Directive 89/398/EEC, modification of that list of nutrition and health claims should be adopted, when necessary, after consultation of the Authority.

[1] OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2006/85/EC (OJ L 293, 24.10.2006, p. 3).

[2] OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15) .

[3] OJ L 404, 30.12.2006, p. 9.

(27) In an effort to provide better protection for the health of infants, the rules of composition, labelling and advertising laid down in this Directive should be in conformity with the principles and the aims of the International Code of Marketing of Breast-milk Substitutes adopted by the 34th World Health Assembly, bearing in mind the particular legal and factual situations existing in the Community.

(28) Given the important role which information on infant feeding plays in choosing, by pregnant women and mothers of infants, the type of nourishment provided to their children, it is necessary for Member States to take appropriate measures in order that this information ensures an adequate use of the products in question and is not counter to the promotion of breast feeding.

(29) This Directive does not concern the conditions of sale of publications specialising in baby care and of scientific publications.

(30) Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes [1] lays down compositional and labelling requirements for dietary foods for special medical purposes. The Annex to that Directive sets out values for minerals in nutritionally complete foods intended for use by infants. There has been new scientific advice as regards the minimum level of manganese in foods intended for infants. Therefore, it is appropriate to amend the levels of manganese in dietary foods for special medical purposes intended for infants set out in that Annex. Directive 1999/21/EC should therefore be amended accordingly.

(31) Due to the specific nature of dietary foods for special medical purposes intended for infants and to the necessity to assess the new formulation of such products, manufacturers require a longer period to adapt their products to the essential composition that derive from the new requirements set out in this Directive.

(32) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive change as compared with the earlier Directive. The obligation to transpose the provisions which are unchanged arises under the earlier Directive.

[1] OJ L 91, 7.4.1999, p. 29. Directive as amended by the 2003 Act of Accession.

(33) This Directive should be without prejudice to the obligations of the Member States relating to the time limits for transposition into national law of the Directives set out in Annex X, Part B.

(34) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

This Directive is a 'specific Directive' within the meaning of Article 4(1) of Directive 89/398/EEC and lays down compositional and labelling requirements for infant formulae and follow-on formulae intended for use by infants in good health in the Community.

It also provides for Member States to give effect to principles and aims of the International Code of Marketing of Breast-milk Substitutes dealing with marketing, information and responsibilities of health authorities.

*Article 2*

For the purposes of this Directive, the definitions of 'claim', 'nutrition claim', 'health claim' and 'reduction of disease risk claim' in Article 2(2)(1), (4), (5) and (6) of Regulation (EC) No 1924/2006 shall apply.

The following definitions shall also apply:

(a) 'infants' means children under the age of 12 months;

(b) 'young children' means children aged between one and three years;

(c) 'infant formulae' means foodstuffs intended for particular nutritional use by infants during the first months of life and satisfying by themselves the nutritional requirements of such infants until the introduction of appropriate complementary feeding;

(d) 'follow-on formulae' means foodstuffs intended for particular nutritional use by infants when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet of such infants;

(e) 'pesticide residue' means the residue in infant formulae and follow-on formulae of a plant protection product, as defined in point 1 of Article 2 of Directive 91/414/EEC, including its metabolites and products resulting from its degradation or reaction.

*Article 3*

Infant formulae and follow-on formulae may be marketed within the Community only if they comply with this Directive.

No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life until the introduction of appropriate complementary feeding.

*Article 4*

Infant formulae and follow-on formulae shall not contain any substance in such quantity as to endanger the health of infants and young children.

*Article 5*

Infant formulae shall be manufactured from protein sources defined in point 2 of Annex I and other food ingredients, as the case may be, whose suitability for particular nutritional use by infants from birth has been established by generally accepted scientific data.

Such suitability shall be demonstrated through a systematic review of the available data relating to the expected benefits and to safety considerations as well as, where necessary, appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

*Article 6*

Follow-on formulae shall be manufactured from protein sources defined in point 2 of Annex II and other food ingredients, as the case may be, whose suitability for particular nutritional use by infants aged over six months has been established by generally accepted scientific data.

Such suitability shall be demonstrated through a systematic review of the available data relating to the expected benefits and to safety considerations as well as, where necessary, appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

*Article 7*

1. Infant formulae shall comply with the compositional criteria set out in Annex I taking into account the specifications in Annex V.

In the case of infant formulae manufactured from cows' milk proteins defined in point 2.1 of Annex I with a protein content between the minimum and 0,5 g/100 kJ (2 g/100 kcal), the suitability of the infant formula for the particular nutritional use by infants shall be demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

In the case of infant formulae manufactured from protein hydrolysates defined in point 2.2 of Annex I with a protein content between the minimum and 0,56 g/100 kJ (2,25 g/100 kcal), the suitability of the infant formula for the particular nutritional use by infants shall be demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies and shall be in accordance with the appropriate specifications set out in Annex VI.

2. Follow-on formulae shall comply with the compositional criteria set out in Annex II taking into account the specifications set out in Annex V.

3. In order to make infant formulae and follow-on formulae ready for use, nothing more shall be required, as the case may be, than the addition of water.

4. The prohibitions and limitations on the use of food ingredients in infant formulae and follow-on formulae set out in Annexes I and II shall be observed.

*Article 8*

1. Only the substances listed in Annex III may be used in the manufacture of infant formulae and follow-on formulae in order to satisfy the requirements on:

(a) mineral substances;

(b) vitamins;

(c) amino acids and other nitrogen compounds;

(d) other substances having a particular nutritional purpose.

2. Purity criteria for substances, as provided for in Community legislation concerning the use of substances listed in Annex III, in the manufacture of foodstuffs for purposes other than those covered by this Directive, shall apply.

3. For those substances for which no purity criteria have been provided for in Community legislation, generally acceptable purity criteria recommended by international bodies shall apply until the adoption of such criteria at Community level.

However, national rules setting stricter purity criteria than those recommended by international bodies may be maintained.

*Article 9*

1. To facilitate the efficient official monitoring of infant formulae, when a food business operator places an infant formula on the market he shall notify the competent authority of the Member States where the product is being marketed by forwarding to it a model of the label used for the product.

2. The competent authorities for the purposes of this Article are those referred to in Article 9(4) of Directive 89/398/EEC.

*Article 10*

1. Infant formulae and follow-on formulae shall not contain residues of individual pesticides at levels exceeding 0,01 mg/kg of the product as proposed ready for consumption or as reconstituted according to the instructions of the manufacturer.

Analytical methods for determining the levels of pesticide residues shall be generally acceptable standardised methods.

2. The pesticides listed in Annex VIII shall not be used in agricultural products intended for the production of infant formulae and follow-on formulae.

However, for the purpose of controls:

(a) pesticides listed in Table 1 of Annex VIII are considered not to have been used if their residues do not exceed a level of 0,003 mg/kg. This level, which is considered to be the limit of quantification of the analytical methods, shall be kept under regular review in the light of technical progress;

(b) pesticides listed in Table 2 of Annex VIII are considered not to have been used if their residues do not exceed a level of 0,003 mg/kg. This level shall be kept under regular review in the light of data on environmental contamination.

3. By way of derogation from paragraph 1, for the pesticides listed in Annex IX, the maximum residue levels specified therein shall apply.

4. The levels referred to in paragraphs 2 and 3 shall apply to the products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers.

*Article 11*

Except as provided for in Article 12, the name under which infant formulae and follow-on formulae are sold shall be, respectively:

— *in Bulgarian*: 'храни за кърмачета' and 'преходни храни',

— *in Spanish*: 'Preparado para lactantes' and 'Preparado de continuación',

— *in Czech*: 'počáteční kojenecká výživa' and 'pokračovací kojenecká výživa',

— *in Danish*: 'Modermælkserstatning' and 'Tilskudsblanding',

— *in German*: 'Säuglingsanfangsnahrung' and 'Folgenahrung',

— *in Estonian*: 'imiku piimasegu' and 'jätkupiimasegu',

— *in Greek*: 'Παρασκεύασμα για βρέφη' and 'Παρασκεύασμα δεύτερης βρεφικής ηλικίας',

— *in English*: 'infant formula' and 'follow-on formula',

— *in French*: 'Préparation pour nourrissons' and 'Préparation de suite',

— *in Italian*: 'Alimento per lattanti' and 'Alimento di proseguimento',

— *in Latvian*: 'Mākslīgais maisījums zīdaiņiem' un 'Mākslīgais papildu ēdināšanas maisījums zīdaiņiem',

— *in Lithuanian*: 'mišinys kūdikiams iki papildomo maitinimo įvedimo' and 'mišinys kūdikiams, įvedus papildomą maitinimą',

— *in Hungarian*: 'anyatej-helyettesítő tápszer' and 'anyatej-kiegészítő tápszer',

— *in Maltese*: 'formula tat-trabi' and 'formula tal-prosegwiment',

— *in Dutch*: 'Volledige zuigelingenvoeding' and 'Opvolgzuigelingenvoeding',

— *in Polish*: 'preparat do początkowego żywienia niemowląt' and 'preparat do dalszego żywienia niemowląt',

— *in Portuguese*: 'Fórmula para lactentes' and 'Fórmula de transição',

— *in Romanian*: 'preparate pentru sugari' and 'preparate pentru copii de vârstă mică',

— *in Slovak*: 'počiatočná dojčenská výživa' and 'následná dojčenská výživa'.

— *in Slovenian*: 'začetna formula za dojenčke' and 'nadaljevalna formula za dojenčke',

— *in Finnish*: 'Äidinmaidonkorvike' and 'Vieroitusvalmiste',

— *in Swedish*: 'Modersmjölksersättning' and 'Tillskottsnäring'.

*Article 12*

The name under which infant formulae and follow-on formulae manufactured entirely from cows' milk proteins are sold, shall be respectively:

— *in Bulgarian*: 'млека за кърмачета' and 'преходни млека',

— *in Spanish*: 'Leche para lactantes' and 'Leche de continuación',

— *in Czech*: 'počáteční mléčná kojenecká výživa' and 'pokračovací mléčná kojenecká výživa',

— *in Danish*: 'Modermælkserstatning udelukkende baseret på mælk' and 'Tilskudsblanding udelukkende baseret på mælk',

— *in German*: 'Säuglingsmilchnahrung' and 'Folgemilch',

— *in Estonian*: 'Piimal põhinev imiku piimasegu' and 'Piimal põhinev jätkupiimasegu',

— *in Greek*: 'Τάλα για βρέφη' and 'Τάλα δεύτερης βρεφικής ηλικίας',

— *in English*: 'infant milk' and 'follow-on milk',

— *in French*: 'Lait pour nourrissons' and 'Lait de suite',

— *in Italian*: 'Latte per lattanti' and 'Latte di proseguimento',

— *in Latvian*: 'Mākslīgais piena maisījums zīdaiņiem' un 'Mākslīgais papildu ēdināšanas piena maisījums zīdaiņiem',

— *in Lithuanian*: 'pieno mišinys kūdikiams iki papildomo maitinimo įvedimo' and 'pieno mišinys kūdikiams įvedus papildomą maitinimą',

— *in Hungarian*: 'tejalapú anyatej-helyettesítő tápszer' and 'tejalapú anyatej-kiegészítő tápszer',

— *in Maltese*: 'ħalib tat-trabi' and 'ħalib tal-prosegwiment',

— *in Dutch*: 'Volledige zuigelingenvoeding op basis van melk' or 'Zuigelingenmelk' and 'Opvolgmelk',

— *in Polish*: 'mleko początkowe' and 'mleko następne',

— *in Portuguese*: 'Leite para lactentes' and 'Leite de transição',

— *in Romanian*: 'lapte pentru sugari' and 'lapte pentru copii de vârstă mică';

— *in Slovak*: 'počiatočná dojčenská mliečna výživa' and 'následná dojčenská mliečna výživa',

— *in Slovenian*: 'začetno mleko za dojenčke' and 'nadaljevalno mleko za dojenčke',

— *in Finnish*: 'Maitopohjainen äidinmaidonkorvike' and 'Maitopohjainen vieroitusvalmiste',

— *in Swedish*: 'Modersmjölksersättning uteslutande baserad på mjölk' and 'Tillskottsnäring uteslutande baserad på mjölk'.

*Article 13*

1. The labelling shall bear, in addition to those provided for in Article 3(1) of Directive 2000/13/EC, the following mandatory particulars:

(a) in the case of infant formulae, a statement to the effect that the product is suitable for particular nutritional use by infants from birth when they are not breast fed;

(b) in the case of follow-on formulae, a statement to the effect that the product is suitable only for particular nutritional use by infants over the age of six months, that it should form only part of a diversified diet, that it is not to be used as a substitute for breast milk during the first six months of life and that the decision to begin complementary feeding, including any exception to six months of age, should be made only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care, based on the individual infant's specific growth and development needs;

(c) in the case of infant formulae and follow-on formulae, the available energy value, expressed in kJ and kcal, and the content of proteins, carbohydrates and lipids, expressed in numerical form, per 100 ml of the product ready for use;

(d) in the case of infant formulae and follow-on formulae, the average quantity of each mineral substance and of each vitamin mentioned in Annexes I and II respectively, and where applicable of choline, inositol and carnitine, expressed in numerical form, per 100 ml of the product ready for use;

(e) in the case of infant formulae and follow-on formulae, instructions for appropriate preparation, storage and disposal of the product and a warning against the health hazards of inappropriate preparation and storage.

2. The labelling may bear the following particulars:

(a) for infant formulae and follow-on formulae the average quantity of nutrients mentioned in Annex III when such declaration is not covered by paragraph 1(d) of this Article, expressed in numerical form, per 100 ml of the product ready for use;

(b) for follow-on formulae in addition to numerical information, information on vitamins and minerals included in Annex VII, expressed as a percentage of the reference values given therein, per 100 ml of the product ready for use.

3. The labelling of infant formulae and follow-on formulae shall be designed to provide the necessary information about the appropriate use of the products so as not to discourage breast feeding.

The use of the terms 'humanised', 'maternalised', 'adapted', or similar terms shall be prohibited.

4. The labelling of infant formulae shall, in addition, bear the following mandatory particulars, preceded by the words 'Important Notice' or their equivalent:

(a) a statement concerning the superiority of breast feeding;

(b) a statement recommending that the product be used only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care.

5. The labelling of infant formulae shall not include pictures of infants, nor shall it include other pictures or text which may idealise the use of the product. It may, however, have graphic representations for easy identification of the product and for illustrating methods of preparation.

6. The labelling of infant formulae may bear nutrition and health claims only in the cases listed in Annex IV and in accordance with the conditions set out therein.

7. Infant formulae and follow-on formulae shall be labelled in such a way that it enables consumers to make a clear distinction between such products so as to avoid any risk of confusion between infant formulae and follow-on formulae.

8. The requirements, prohibitions and restrictions referred to in paragraphs 3 to 7 shall also apply to:

(a) the presentation of the products concerned, in particular their shape, appearance or packaging, the packaging materials used, the way in which they are arranged and the setting in which they are displayed;

(b) advertising.

*Article 14*

1. Advertising of infant formulae shall be restricted to publications specialising in baby care and scientific publications. Member States may further restrict or prohibit such advertising. Such advertisements for infant formulae shall be subject to the conditions laid down in Article 13(3) to (7) and Article 13(8)(b) and contain only information of a scientific and factual nature. Such information shall not imply or create a belief that bottle-feeding is equivalent or superior to breast feeding.

2. There shall be no point-of-sale advertising, giving of samples or any other promotional device to induce sales of infant formula directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales.

3. Manufacturers and distributors of infant formulae shall not provide, to the general public or to pregnant women, mothers or members of their families, free or low-priced products, samples or any other promotional gifts, either directly or indirectly via the health care system or health workers.

*Article 15*

1. Member States shall ensure that objective and consistent information is provided on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition covering the planning, provision, design and dissemination of information and their control.

2. Member States shall ensure that informational and educational materials, whether written or audiovisual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children, shall include clear information on all the following points:

(a) the benefits and superiority of breast feeding;

(b) maternal nutrition and the preparation for and maintenance of breast feeding;

(c) the possible negative effect on breast feeding of introducing partial bottle feeding;

(d) the difficulty of reversing the decision not to breast feed;

(e) where needed, the proper use of infant formulae.

When such materials contain information about the use of infant formulae, they shall include the social and financial implications of its use, the health hazards of inappropriate foods or feeding methods, and, in particular, the health hazards of improper use of infant formulae. Such material shall not use any pictures which may idealise the use of infant formulae.

3. Member States shall ensure that donations of informational or educational equipment or materials by manufacturers or distributors shall be made only on request and with the written approval of the appropriate national authority or within guidelines given by that authority for this purpose. Such equipment or materials may bear the donating company's name or logo, but shall not refer to a proprietary brand of infant formulae and shall be distributed only through the health care system.

4. Member States shall ensure that donations or low-price sales of supplies of infant formulae to institutions or organisations, whether for use in the institutions or for distribution outside them, shall only be used by or distributed for infants who have to be fed on infant formulae and only for as long as required by such infants.

*Article 16*

In the Annex to Directive 1999/21/EC, the row relating to manganese set out in the second part of Table I concerning minerals, is replaced by the following:

| | | | | |
|---|---|---|---|---|
| 'Manganese (µg) | 0,25 | 25 | 1 | 100' |

*Article 17*

The new requirements set out in Article 7(1) and (2) of this Directive shall not apply mandatorily to dietary foods for special medical purposes intended specifically for infants, as referred to in point 4 of the Annex to Directive 1999/21/EC, until 1 January 2012.

*Article 18*

1. Member States shall adopt and publish, by 31 December 2007 at the latest, the laws, regulations and administrative provisions necessary to comply with Articles 2, 3 and 5 to 17 and Annexes I to VII. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions in such a way as to:

— permit trade in products complying with this Directive by 1 January 2008 at the latest,

— without prejudice to Article 17, prohibit, with effect from 31 December 2009 trade in products which do not comply with this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directive repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

*Article 19*

Directive 91/321/EEC, as amended by the Directives listed in Annex X, Part A, is repealed with effect from 1 January 2008, without prejudice to the obligations of the Member States relating to the time limits for transposition into national law of the Directives listed in Annex X, Part B.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex XI.

*Article 20*

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

*Article 21*

This Directive is addressed to the Member States.

Done at Brussels, 22 December 2006.

*For the Commission*
Markos KYPRIANOU
*Member of the Commission*

*ANNEX I*

**ESSENTIAL COMPOSITION OF INFANT FORMULAE WHEN RECONSTITUTED AS INSTRUCTED BY THE MANUFACTURER**

The values set out in this Annex refer to the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.

1. ENERGY

| Minimum | Maximum |
|---|---|
| 250 kJ/100 ml<br>(60 kcal/100 ml) | 295 kJ/100 ml<br>(70 kcal/100 ml) |

2. PROTEINS

(Protein content = nitrogen content × 6,25)

2.1 **Infant formulae manufactured from cows' milk proteins**

| Minimum ([1]) | Maximum |
|---|---|
| 0,45 g/100 kJ<br>(1,8 g/100 kcal) | 0,7 g/100 kJ<br>(3 g/100 kcal) |

([1]) Infant formulae manufactured from cows' milk protein with a protein content between the minimum and 0,5 g/100 kJ (2 g/100 kcal) shall be in accordance with the second subparagraph of Article 7(1).

For an equal energy value, the infant formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex V). Nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together if the methionine:cystine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2. The ratio of methionine:cystine may be greater than 2 but shall not be greater than 3 provided that the suitability of the product for the particular nutritional use by infants is demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

2.2 **Infant formulae manufactured from protein hydrolysates**

| Minimum ([1]) | Maximum |
|---|---|
| 0,45 g/100 kJ<br>(1,8 g/100 kcal) | 0,7 g/100 kJ<br>(3 g/100 kcal) |

([1]) Infant formulae manufactured from protein hydrolysates with a protein content between the minimum and 0,56 g/100 kJ (2,25 g/100 kcal) shall be in accordance with the third subparagraph of Article 7(1).

For an equal energy value, the infant formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex V). Nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together if the methionine:cystine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2. The ratio of methionine:cystine may be greater than 2 but shall not be greater than 3 provided that the suitability of the product for the particular nutritional use by infants is demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

The L-carnitine content shall be at least equal to 0,3 mg/100 kJ (1,2 mg/100 kcal).

2.3 **Infant formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins**

| Minimum | Maximum |
|---|---|
| 0,56 g/100 kJ<br>(2,25 g/100 kcal) | 0,7 g/100 kJ<br>(3 g/100 kcal) |

Only protein isolates from soya shall be used in manufacturing these infant formulae.

For an equal energy value the infant formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex V). Nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together if the methionine:cystine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2. The ratio of methionine:cystine may be greater than 2 but shall not be greater than 3 provided that the suitability of the product for the particular nutritional use by infants is demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

The L-carnitine content shall be at least equal to 0,3 mg/100 kJ (1,2 mg/100 kcal).

2.4 In all cases, amino acids may be added to infant formulae solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose.

3. TAURINE

If added to infant formulae, the amount of taurine shall not be greater than 2,9 mg/100 kJ (12 mg/100 kcal).

4. CHOLINE

| Minimum | Maximum |
|---|---|
| 1,7 mg/100 kJ<br>(7 mg/100 kcal) | 12 mg/100 kJ<br>(50 mg/100 kcal) |

5. LIPIDS

| Minimum | Maximum |
|---|---|
| 1,05 g/100 kJ<br>(4,4 g/100 kcal) | 1,4 g/100 kJ<br>(6,0 g/100 kcal) |

5.1 The use of the following substances shall be prohibited:

— sesame seed oil,

— cotton seed oil.

5.2 **Lauric acid and myristic acid**

| Minimum | Maximum |
|---|---|
| — | separately or as a whole:<br>20 % of the total fat content |

5.3 The *trans* fatty acid content shall not exceed 3 % of the total fat content.

5.4 The erucic acid content shall not exceed 1 % of the total fat content.

5.5 **Linoleic acid (in the form of glycerides = linoleates)**

| Minimum | Maximum |
|---|---|
| 70 mg/100 kJ<br>(300 mg/100 kcal) | 285 mg/100 kJ<br>(1 200 mg/100 kcal) |

5.6 The alpha-linolenic acid content shall not be less than 12 mg/100 kJ (50 mg/100 kcal).

The linoleic:alpha-linolenic acid ratio shall not be less than 5 nor greater than 15.

5.7 Long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids (LCP) may be added. In that case their content shall not exceed:

— 1 % of the total fat content for n-3 LCP, and

— 2 % of the total fat content for n-6 LCP (1 % of the total fat content for arachidonic acid (20:4 n-6))

The eicosapentaenoic acid (20:5 n-3) content shall not exceed that of docosahexaenoic (22:6 n-3) acid content.

The docosahexaenoic acid (22:6 n-3) content shall not exceed that of n-6 LCP.

6. PHOSPHOLIPIDS

The amount of phospholipids in infant formulae shall not be greater than 2 g/l.

7. INOSITOL

| Minimum | Maximum |
|---|---|
| 1 mg/100 kJ<br>(4 mg/100 kcal) | 10 mg/100 kJ<br>(40 mg/100 kcal) |

8. CARBOHYDRATES

| Minimum | Maximum |
|---|---|
| 2,2 g/100 kJ<br>(9 g/100 kcal) | 3,4 g/100 kJ<br>(14 g/100 kcal) |

8.1 Only the following carbohydrates may be used:

— lactose,

— maltose,

— sucrose,

— glucose,

— malto-dextrins,

— glucose syrup or dried glucose syrup,

— pre-cooked starch

— gelatinised starch

} naturally free of gluten.

8.2 **Lactose**

| Minimum | Maximum |
|---|---|
| 1,1 g/100 kJ | — |
| (4,5 g/100 kcal) | — |

This provision shall not apply to infant formulae in which soya protein isolates represent more than 50 % of the total protein content.

8.3 **Sucrose**

Sucrose may only be added to infant formulae manufactured from protein hydrolysates. If added, the sucrose content shall not exceed 20 % of the total carbohydrate content.

8.4 **Glucose**

Glucose may only be added to infant formulae manufactured from protein hydrolysates. If added, the glucose content shall not exceed 0,5 g/100 kJ (2 g/100 kcal).

8.5 **Pre-cooked starch and/or gelatinised starch**

| Minimum | Maximum |
|---|---|
| — | 2 g/100 ml, and 30 % of the total carbohydrate content |

9. FRUCTO-OLIGOSACCHARIDES AND GALACTO-OLIGOSACCHARIDES

Fructo-oligosaccharides and galacto-oligosaccharides may be added to infant formulae. In that case their content shall not exceed: 0,8 g/100 ml in a combination of 90 % oligogalactosyl-lactose and 10 % high molecular weight oligofructosyl-saccharose.

Other combinations and maximum levels of fructo-oligosaccharides and galacto-oligosaccharides may be used in accordance with Article 5.

10. MINERAL SUBSTANCES

10.1 **Infant formulae manufactured from cows' milk proteins or protein hydrolysates**

| | Per 100 kJ | | Per 100 kcal | |
|---|---|---|---|---|
| | Minimum | Maximum | Minimum | Maximum |
| Sodium (mg) | 5 | 14 | 20 | 60 |
| Potassium (mg) | 15 | 38 | 60 | 160 |
| Chloride (mg) | 12 | 38 | 50 | 160 |
| Calcium (mg) | 12 | 33 | 50 | 140 |
| Phosphorus (mg) | 6 | 22 | 25 | 90 |
| Magnesium (mg) | 1,2 | 3,6 | 5 | 15 |
| Iron (mg) | 0,07 | 0,3 | 0,3 | 1,3 |
| Zinc (mg) | 0,12 | 0,36 | 0,5 | 1,5 |
| Copper (µg) | 8,4 | 25 | 35 | 100 |

| | Per 100 kJ | | Per 100 kcal | |
|---|---|---|---|---|
| | Minimum | Maximum | Minimum | Maximum |
| Iodine (µg) | 2,5 | 12 | 10 | 50 |
| Selenium (µg) | 0,25 | 2,2 | 1 | 9 |
| Manganese (µg) | 0,25 | 25 | 1 | 100 |
| Fluoride (µg) | — | 25 | — | 100 |

The calcium:phosphorus ratio shall not be less than 1 nor greater than 2.

10.2 **Infant formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins**

All requirements of point 10.1 shall apply, except for those concerning iron and phosphorus, which shall be as follows:

| | Per 100 kJ | | Per 100 kcal | |
|---|---|---|---|---|
| | Minimum | Maximum | Minimum | Maximum |
| Iron (mg) | 0,12 | 0,5 | 0,45 | 2 |
| Phosphorus (mg) | 7,5 | 25 | 30 | 100 |

11. VITAMINS

| | Per 100 kJ | | Per 100 kcal | |
|---|---|---|---|---|
| | Minimum | Maximum | Minimum | Maximum |
| Vitamin A (µg-RE) (1) | 14 | 43 | 60 | 180 |
| Vitamin D (µg) (2) | 0,25 | 0,65 | 1 | 2,5 |
| Thiamin (µg) | 14 | 72 | 60 | 300 |
| Riboflavin (µg) | 19 | 95 | 80 | 400 |
| Niacin (µg) (3) | 72 | 375 | 300 | 1 500 |
| Pantothenic acid (µg) | 95 | 475 | 400 | 2 000 |
| Vitamin $B_6$ (µg) | 9 | 42 | 35 | 175 |
| Biotin (µg) | 0,4 | 1,8 | 1,5 | 7,5 |
| Folic Acid (µg) | 2,5 | 12 | 10 | 50 |
| Vitamin $B_{12}$ (µg) | 0,025 | 0,12 | 0,1 | 0,5 |
| Vitamin C (mg) | 2,5 | 7,5 | 10 | 30 |
| Vitamin K (µg) | 1 | 6 | 4 | 25 |
| Vitamin E (mg α-TE) (4) | 0,5/g of polyunsaturated fatty acids expressed as linoleic acid as corrected for the double bonds (5) but in no case less than 0,1 mg per 100 available kJ | 1,2 | 0,5/g of polyunsaturated fatty acids expressed as linoleic acid as corrected for the double bonds (5) but in no case less than 0,5 mg per 100 available kcal | 5 |

(1) RE = all trans retinol equivalent.
(2) In the form of cholecalciferol, of which 10 µg = 400 i.u. of vitamin D.
(3) Preformed niacin.
(4) α-TE = d-α-tocopherol equivalent.
(5) 0,5 mg α-TE/1 g linoleic acid (18:2 n-6); 0,75 mg α-TE/1 g α-linolenic acid (18:3 n-3); 1,0 mg α-TE/1 g arachidonic acid (20:4 n-6); 1,25 mg α-TE/1 g eicosapentaenoic acid (20:5 n-3); 1,5 mg α-TE/1 g docosahexaenoic acid (22:6 n-3).

12. NUCLEOTIDES

The following nucleotides may be added:

| | Maximum [1] | |
|---|---|---|
| | (mg/100 kJ) | (mg/100 kcal) |
| cytidine 5′-monophosphate | 0,60 | 2,50 |
| uridine 5′-monophosphate | 0,42 | 1,75 |
| adenosine 5′-monophosphate | 0,36 | 1,50 |
| guanosine 5′-monophosphate | 0,12 | 0,50 |
| inosine 5′-monophosphate | 0,24 | 1,00 |

[1] The total concentration of nucleotides shall not exceed 1,2 mg/100 kJ (5 mg/100 kcal).

*ANNEX II*

**ESSENTIAL COMPOSITION OF FOLLOW-ON FORMULAE WHEN RECONSTITUTED AS INSTRUCTED BY THE MANUFACTURER**

The values set out in this Annex refer to the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.

1. ENERGY

| Minimum | Maximum |
|---|---|
| 250 kJ/100 ml<br>(60 kcal/100 ml) | 295 kJ/100 ml<br>(70 kcal/100 ml) |

2. PROTEINS

(Protein content = nitrogen content × 6,25)

2.1 **Follow-on formulae manufactured from cows' milk proteins**

| Minimum | Maximum |
|---|---|
| 0,45 g/100 kJ<br>(1,8 g/100 kcal) | 0,8 g/100 kJ<br>(3,5 g/100 kcal) |

For an equal energy value, the follow-on formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex V). Nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together if the methionine:cystine ratio is not greater than 3, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2.

2.2 **Follow-on formulae manufactured from protein hydrolysates**

| Minimum | Maximum |
|---|---|
| 0,56 g/100 kJ<br>(2,25 g/100 kcal) | 0,8 g/100 kJ<br>(3,5 g/100 kcal) |

For an equal energy value, the follow-on formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex V). Nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together if the methionine:cystine ratio is not greater than 3, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2.

2.3 **Follow-on formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins**

| Minimum | Maximum |
|---|---|
| 0,56 g/100 kJ<br>(2,25 g/100 kcal) | 0,8 g/100 kJ<br>(3,5 g/100 kcal) |

Only protein isolates from soya shall be used in manufacturing these formulae.

For an equal energy value the follow-on formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex V). Nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together if the methionine:cystine ratio is not greater than 3, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2.

2.4 In all cases, amino acids may be added to follow-on formulae solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose.

3. TAURINE

If added to follow-on formulae, the amount of taurine shall not be greater than 2,9 mg/100 kJ (12 mg/100 kcal).

4. LIPIDS

| Minimum | Maximum |
|---|---|
| 0,96 g/100 kJ<br>(4,0 g/100 kcal) | 1,4 g/100 kJ<br>(6,0 g/100 kcal) |

4.1 The use of the following substances shall be prohibited:

— sesame seed oil,

— cotton seed oil.

4.2 **Lauric acid and myristic acid**

| Minimum | Maximum |
|---|---|
| — | separately or as a whole:<br>20 % of the total fat content |

4.3. The *trans* fatty acid content shall not exceed 3 % of the total fat content.

4.4 The erucic acid content shall not exceed 1% of the total fat content.

4.5 **Linoleic acid (in the form of glycerides = linoleates)**

| Minimum | Maximum |
|---|---|
| 70 mg/100 kJ<br>(300 mg/100 kcal) | 285 mg/100 kJ<br>(1 200 mg/100 kcal) |

4.6 The alpha-linolenic acid content shall not be less than 12 mg/100 kJ (50 mg/100 kcal).

The linoleic:alpha-linolenic acid ratio shall not be less than 5 nor greater than 15.

4.7 Long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids (LCP) may be added. In that case their content shall not exceed:

— 1 % of the total fat content for n-3 LCP, and

— 2 % of the total fat content for n-6 LCP (1 % of the total fat content for arachidonic acid (20:4 n-6))

The eicosapentaenoic acid (20:5 n-3) content shall not exceed that of docosahexaenoic (22:6 n-3) acid content.

The docosahexaenoic (22:6 n-3) acid content shall not exceed that of n-6 LCP.

5. PHOSPHOLIPIDS

The amount of phospholipids in follow-on formulae shall not be greater than 2 g/l.

6. CARBOHYDRATES

| Minimum | Maximum |
|---|---|
| 2,2 g/100 kJ<br>(9 g/100 kcal) | 3,4 g/100 kJ<br>(14 g/100 kcal) |

6.1 The use of ingredients containing gluten shall be prohibited.

6.2 **Lactose**

| Minimum | Maximum |
|---|---|
| 1,1 g/100 kJ<br>(4,5 g/100 kcal) | — |

This provision shall not apply to follow-on formulae in which soya protein isolates represent more than 50 % of the total protein content.

6.3 **Sucrose, fructose, honey**

| Minimum | Maximum |
|---|---|
| — | separately or as a whole:<br>20 % of the total carbohydrate content |

Honey shall be treated to destroy spores of *Clostridium botulinum*.

6.4 **Glucose**

Glucose may only be added to follow-on formulae manufactured from protein hydrolysates. If added, the glucose content shall not exceed 0,5 g/100 kJ (2 g/100 kcal).

7. FRUCTO-OLIGOSACCHARIDES AND GALACTO-OLIGOSACCHARIDES

Fructo-oligosaccharides and galacto-oligosaccharides may be added to follow-on formulae. In that case their content shall not exceed: 0,8 g/100 ml in a combination of 90 % oligogalactosyl-lactose and 10 % high molecular weight oligofructosyl-saccharose.

Other combinations and maximum levels of fructo-oligosaccharides and galacto-oligosaccharides may be used in accordance with Article 6.

8. MINERAL SUBSTANCES

8.1 **Follow-on formulae manufactured from cows' milk proteins or protein hydrolysates**

| | Per 100 kJ | | Per 100 kcal | |
|---|---|---|---|---|
| | Minimum | Maximum | Minimum | Maximum |
| Sodium (mg) | 5 | 14 | 20 | 60 |
| Potassium (mg) | 15 | 38 | 60 | 160 |
| Chloride (mg) | 12 | 38 | 50 | 160 |
| Calcium (mg) | 12 | 33 | 50 | 140 |
| Phosphorus (mg) | 6 | 22 | 25 | 90 |
| Magnesium (mg) | 1,2 | 3,6 | 5 | 15 |
| Iron (mg) | 0,14 | 0,5 | 0,6 | 2 |
| Zinc (mg) | 0,12 | 0,36 | 0,5 | 1,5 |
| Copper (μg) | 8,4 | 25 | 35 | 100 |
| Iodine (μg) | 2,5 | 12 | 10 | 50 |
| Selenium (μg) | 0,25 | 2,2 | 1 | 9 |
| Manganese (μg) | 0,25 | 25 | 1 | 100 |
| Fluoride (μg) | — | 25 | — | 100 |

The calcium:phosphorus ratio in follow-on formulae shall not be less than 1,0 nor greater than 2,0.

8.2 **Follow-on formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins**

All requirements of point 8.1 shall apply, except for those concerning iron, and phosphorus, which shall be as follows:

| | Per 100 kJ | | Per 100 kcal | |
|---|---|---|---|---|
| | Minimum | Maximum | Minimum | Maximum |
| Iron (mg) | 0,22 | 0,65 | 0,9 | 2,5 |
| Phosphorus (mg) | 7,5 | 25 | 30 | 100 |

9. VITAMINS

| | Per 100 kJ | | Per 100 kcal | |
|---|---|---|---|---|
| | Minimum | Maximum | Minimum | Maximum |
| Vitamin A (µg-RE) (1) | 14 | 43 | 60 | 180 |
| Vitamin D (µg) (2) | 0,25 | 0,75 | 1 | 3 |
| Thiamin (µg) | 14 | 72 | 60 | 300 |
| Riboflavin (µg) | 19 | 95 | 80 | 400 |
| Niacin (µg) (3) | 72 | 375 | 300 | 1 500 |
| Pantothenic acid (µg) | 95 | 475 | 400 | 2 000 |
| Vitamin $B_6$ (µg) | 9 | 42 | 35 | 175 |
| Biotin (µg) | 0,4 | 1,8 | 1,5 | 7,5 |
| Folic Acid (µg) | 2,5 | 12 | 10 | 50 |
| Vitamin $B_{12}$ (µg) | 0,025 | 0,12 | 0,1 | 0,5 |
| Vitamin C (mg) | 2,5 | 7,5 | 10 | 30 |
| Vitamin K (µg) | 1 | 6 | 4 | 25 |
| Vitamin E (mg α-TE) (4) | 0,5/g poly-unsaturated fatty acids expressed as linoleic acid as corrected for the double bonds (5) but in no case less than 0,1 mg per 100 available kJ | 1,2 | 0,5/g poly-unsaturated fatty acids expressed as linoleic acid as corrected for the double bonds (5) but in no case less than 0,5 mg per 100 available kcal | 5 |

(1) RE = all *trans* retinol equivalent.
(2) In the form of cholecalciferol, of which10 µg = 400 i.u. of vitamin D.
(3) Preformed niacin.
(4) α-TE = d-α-tocopherol equivalent.
(5) 0,5 mg α-TE/1 g linoleic acid (18:2 n-6); 0,75 mg α-TE/1 g α-linolenic acid (18:3 n-3); 1,0 mg α-TE/1 g arachidonic acid (20:4 n-6); 1,25 mg α-TE/1 g eicosapentaenoic acid (20:5 n-3); 1,5 mg α-TE/1 g docosahexaenoic acid (22:6 n-3).

10. NUCLEOTIDES

The following nucleotides may be added:

| | Maximum (1) | |
|---|---|---|
| | (mg/100 kJ) | (mg/100 kcal) |
| cytidine 5′-monophosphate | 0,60 | 2,50 |
| uridine 5′-monophosphate | 0,42 | 1,75 |
| adenosine 5′-monophosphate | 0,36 | 1,50 |
| guanosine 5′-monophosphate | 0,12 | 0,50 |
| inosine 5′-monophosphate | 0,24 | 1,00 |

(1) The total concentration of nucleotides shall not exceed 1,2 mg/100 kJ (5 mg/100 kcal).

*ANNEX III*

**NUTRITIONAL SUBSTANCES**

1. **Vitamins**

| Vitamin | Vitamin formulation |
|---|---|
| Vitamin A | Retinyl acetate |
| | Retinyl palmitate |
| | Retinol |
| Vitamin D | Vitamin $D_2$ (ergocalciferol) |
| | Vitamin $D_3$ (cholecalciferol) |
| Vitamin $B_1$ | Thiamin hydrochloride |
| | Thiamin mononitrate |
| Vitamin $B_2$ | Riboflavin |
| | Riboflavin-5′-phosphate, sodium |
| Niacin | Nicotinamide |
| | Nicotinic acid |
| Vitamin $B_6$ | Pyridoxine hydrochloride |
| | Pyridoxine-5′-phosphate |
| Folate | Folic acid |
| Pantothenic acid | D-pantothenate, calcium |
| | D-pantothenate, sodium |
| | Dexpanthenol |
| Vitamin $B_{12}$ | Cyanocobalamin |
| | Hydroxocobalamin |
| Biotin | D-biotin |
| Vitamin C | L-ascorbic acid |
| | Sodium L-ascorbate |
| | Calcium L-ascorbate |
| | 6-palmityl-L-ascorbic acid (ascorbyl palmitate) |
| | Potassium ascorbate |
| Vitamin E | D-alpha tocopherol |
| | DL-alpha tocopherol |
| | D-alpha tocopherol acetate |
| | DL-alpha tocopherol acetate |
| Vitamin K | Phylloquinone (Phytomenadione) |

2. **Mineral substances**

| Mineral substances | Permitted salts |
|---|---|
| Calcium (Ca) | Calcium carbonate |
| | Calcium chloride |
| | Calcium salts of citric acid |
| | Calcium gluconate |
| | Calcium glycerophosphate |
| | Calcium lactate |
| | Calcium salts of orthophosphoric acid |
| | Calcium hydroxide |
| Magnesium (Mg) | Magnesium carbonate |
| | Magnesium chloride |
| | Magnesium oxide |
| | Magnesium salts of orthophosphoric acid |
| | Magnesium sulphate |
| | Magnesium gluconate |
| | Magnesium hydroxide |
| | Magnesium salts of citric acid |
| Iron (Fe) | Ferrous citrate |
| | Ferrous gluconate |
| | Ferrous lactate |
| | Ferrous sulphate |
| | Ferric ammonium citrate |
| | Ferrous fumarate |
| | Ferric diphosphate (Ferric pyrophosphate) |
| | Ferrous bisglycinate |
| Copper (Cu) | Cupric citrate |
| | Cupric gluconate |
| | Cupric sulphate |
| | Copper-lysine complex |
| | Cupric carbonate |
| Iodine (I) | Potassium iodide |
| | Sodium iodide |
| | Potassium iodate |
| Zinc (Zn) | Zinc acetate |
| | Zinc chloride |
| | Zinc lactate |
| | Zinc sulphate |
| | Zinc citrate |
| | Zinc gluconate |
| | Zinc oxide |

| Mineral substances | Permitted salts |
|---|---|
| Manganese (Mn) | Manganese carbonate |
| | Manganese chloride |
| | Manganese citrate |
| | Manganese sulphate |
| | Manganese gluconate |
| Sodium (Na) | Sodium bicarbonate |
| | Sodium chloride |
| | Sodium citrate |
| | Sodium gluconate |
| | Sodium carbonate |
| | Sodium lactate |
| | Sodium salts of orthophosphoric acid |
| | Sodium hydroxide |
| Potassium (K) | Potassium bicarbonate |
| | Potassium carbonate |
| | Potassium chloride |
| | Potassium salts of citric acid |
| | Potassium gluconate |
| | Potassium lactate |
| | Potassium salts of orthophosphoric acid |
| | Potassium hydroxide |
| Selenium (Se) | Sodium selenate |
| | Sodium selenite |

3. **Amino acids and other nitrogen compounds**

| |
|---|
| L-cystine and its hydrochloride |
| L-histidine and its hydrochloride |
| L-isoleucine and its hydrochloride |
| L-leucine and its hydrochloride |
| L-lysine and its hydrochloride |
| L-cysteine and its hydrochloride |
| L-methionine |
| L-phenylalanine |
| L-threonine |
| L-tryptophan |
| L-tyrosine |
| L-valine |
| L-carnitine and its hydrochloride |
| L-carnitine-L-tartrate |
| Taurine |

| |
|---|
| Cytidine 5′-monophosphate and its sodium salt |
| Uridine 5′-monophosphate and its sodium salt |
| Adenosine 5′-monophosphate and its sodium salt |
| Guanosine 5′-monophosphate and its sodium salt |
| Inosine 5′-monophosphate and its sodium salt |

4. **Other nutritional substances**

| |
|---|
| Choline |
| Choline chloride |
| Choline citrate |
| Choline bitartrate |
| Inositol |

*ANNEX IV*

## NUTRITION AND HEALTH CLAIMS FOR INFANT FORMULAE AND CONDITIONS WARRANTING A CORRESPONDING CLAIM

1. NUTRITION CLAIMS

| Nutrition claim related to | Conditions warranting the nutrition claim |
|---|---|
| 1.1 Lactose only | Lactose is the only carbohydrate present. |
| 1.2 Lactose free | Lactose content is not greater than 2,5 mg/100 kJ (10 mg/100 kcal). |
| 1.3 Added LCP or an equivalent nutrition claim related to the addition of docosahexaenoic acid | The docosahexaenoic acid content is not less than 0,2 % of the total fatty acid content. |
| 1.4 Nutrition claims on the addition of the following optional ingredients: | |
| 1.4.1 taurine | Voluntarily added at a level that would be appropriate for the intended particular use by infants and in accordance with the conditions set out in Annex I. |
| 1.4.2 fructo-oligosaccharides and galacto-oligosaccharides | |
| 1.4.3 nucleotides | |

2. HEALTH CLAIMS (INCLUDING REDUCTION OF DISEASE RISK CLAIMS)

| Nutrition claim related to | Conditions warranting the health claim |
|---|---|
| 2.1 Reduction of risk to allergy to milk proteins. This health claim may include terms referring to reduced allergen or reduced antigen properties. | (a) Objective and scientifically verified data as proof to the claimed properties must be available;<br>(b) The infant formulae shall satisfy the provisions set out in point 2.2 of Annex I and the amount of immunoreactive protein measured with methods generally acceptable as appropriate shall be less than 1 % of nitrogen containing substances in the formulae;<br>(c) The label shall indicate that the product must not be consumed by infants allergic to the intact proteins from which it is manufactured unless generally accepted clinical tests provide proof of the infant formulae's tolerance in more than 90 % of infants (confidence interval 95 %) hypersensitive to proteins from which the hydrolysate is manufactured;<br>(d) The infant formulae administered orally must not induce sensitisation, in animals, to the intact proteins from which the infant formulae are manufactured. |

*ANNEX V*

**INDISPENSABLE AND CONDITIONALLY INDISPENSABLE AMINO ACIDS IN BREAST MILK**

For the purpose of this Directive, the indispensable and conditionally indispensable amino acids in breast milk, expressed in mg per 100 kJ and 100 kcal, are the following:

| | Per 100 kJ [1] | Per 100 kcal |
|---|---|---|
| Cystine | 9 | 38 |
| Histidine | 10 | 40 |
| Isoleucine | 22 | 90 |
| Leucine | 40 | 166 |
| Lysine | 27 | 113 |
| Methionine | 5 | 23 |
| Phenylalanine | 20 | 83 |
| Threonine | 18 | 77 |
| Tryptophan | 8 | 32 |
| Tyrosine | 18 | 76 |
| Valine | 21 | 88 |

[1] 1 kJ = 0,239 kcal.

*ANNEX VI*

**Specification for the protein content and source and the processing of protein used in the manufacture of infant formulae with a protein content less than 0,56 g/100 kJ (2,25 g/100 kcal) manufactured from hydrolysates of whey proteins derived from cows' milk protein**

1. **Protein content**

Protein content = nitrogen content × 6,25

| Minimum | Maximum |
|---|---|
| 0,44 g/100 kJ | 0,7 g/100 kJ |
| (1,86 g/100 kcal) | (3 g/100 kcal) |

2. **Protein source**

Demineralised sweet whey protein derived from cows' milk after enzymatic precipitation of caseins using chymosin, consisting of:

(a) 63 % caseino-glycomacropeptide free whey protein isolate with a minimum protein content of 95 % of dry matter and protein denaturation of less than 70 % and a maximum ash content of 3 %; and

(b) 37 % sweet whey protein concentrate with a minimum protein content of 87 % of dry matter and protein denaturation of less than 70 % and a maximum ash content of 3,5 %.

3. **Protein processing**

Two-stage hydrolysis process using a trypsin preparation with a heat-treatment step (from 3 to 10 minutes at 80 to 100 °C) between the two hydrolysis steps.

*ANNEX VII*

**REFERENCE VALUES FOR NUTRITION LABELLING FOR FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN**

| Nutrient | Labelling reference value |
|---|---|
| Vitamin A | (µg) 400 |
| Vitamin D | (µg) 7 |
| Vitamin E | (mg TE) 5 |
| Vitamin K | (µg) 12 |
| Vitamin C | (mg) 45 |
| Thiamin | (mg) 0,5 |
| Riboflavin | (mg) 0,7 |
| Niacin | (mg) 7 |
| Vitamin $B_6$ | (mg) 0,7 |
| Folate | (µg) 125 |
| Vitamin $B_{12}$ | (µg) 0,8 |
| Pantothenic acid | (mg) 3 |
| Biotin | (µg) 10 |
| Calcium | (mg) 550 |
| Phosphorus | (mg) 550 |
| Potassium | (mg) 1 000 |
| Sodium | (mg) 400 |
| Chloride | (mg) 500 |
| Iron | (mg) 8 |
| Zinc | (mg) 5 |
| Iodine | (µg) 80 |
| Selenium | (µg) 20 |
| Copper | (mg) 0,5 |
| Magnesium | (mg) 80 |
| Manganese | (mg) 1,2 |

*ANNEX VIII*

**PESTICIDES WHICH SHALL NOT BE USED IN AGRICULTURAL PRODUCTION INTENDED FOR THE PRODUCTION OF INFANT FORMULAE AND FOLLOW ON FORMULAE**

*Table 1*

| Chemical name of the substance (residue definition) |
|---|
| Disulfoton (sum of disulfoton, disulfoton sulfoxide and disulfoton sulfone expressed as disulfoton) |
| Fensulfothion (sum of fensulfothion, its oxygen analogue and their sulfones, expressed as fensulfothion) |
| Fentin, expressed as triphenyltin cation |
| Haloxyfop (sum of haloxyfop, its salts and esters including conjugates, expressed as haloxyfop) |
| Heptachlor and *trans*-heptachlor epoxide, expressed as heptachlor |
| Hexachlorobenzene |
| Nitrofen |
| Omethoate |
| Terbufos (sum of terbufos, its sulfoxide and sulfone, expressed as terbufos) |

*Table 2*

| Chemical name of the substance |
|---|
| Aldrin and dieldrin, expressed as dieldrin |
| Endrin |

*ANNEX IX*

**SPECIFIC MAXIMUM RESIDUE LEVELS OF PESTICIDES OR METABOLITES OF PESTICIDES IN INFANT FORMULAE AND FOLLOW-ON FORMULAE**

| Chemical name of the substance | Maximum residue level (mg/kg) |
|---|---|
| Cadusafos | 0,006 |
| Demeton-S-methyl/demeton-S-methyl sulfone/oxydemeton-methyl (individually or combined, expressed as demeton-S-methyl) | 0,006 |
| Ethoprophos | 0,008 |
| Fipronil (sum of fipronil and fipronil-desulfinyl, expressed as fipronil) | 0,004 |
| Propineb/propylenethiourea (sum of propineb and propylenethiourea) | 0,006 |

*ANNEX X*

PART A

**Repealed Directive, with list of its successive amendments**

(referred to in Article 19)

Commission Directive 91/321/EEC (OJ L 175, 4.7.1991, p. 35).

Point XI.C.IX.5 of Annex I to the 1994 Act of Accession, p. 212.

Commission Directive 96/4/EC (OJ L 49, 28.2.1996, p. 12).

Commission Directive 1999/50/EC (OJ L 139, 2.6.1999, p. 29).

Commission Directive 2003/14/EC (OJ L 41, 14.2.2003, p. 37).

Point 1.J.3 of Annex II to the 2003 Act of Accession, p. 93.

PART B

**List of time limits for transposition into national law**

(referred to in Article 19)

| Directive | Time limit for transposition | Permission of trade in products complying with this Directive | Prohibition of trade in products not complying with this Directive |
|---|---|---|---|
| 91/321/EEC | | 1 December 1992 | 1 June 1994 |
| 96/4/EC | 31 March 1997 | 1 April 1997 | 31 March 1999 |
| 1999/50/EC | 30 June 2000 | 30 June 2000 | 1 July 2002 |
| 2003/14/EC | 6 March 2004 | 6 March 2004 | 6 March 2005 |

*ANNEX XI*

**CORRELATION TABLE**

| Directive 91/321/EEC | This Directive |
|---|---|
| Article 1(1) | Article 1 |
| Article 1(2) | Article 2 |
| Article 2 | Article 3 |
| Article 3(1) | Article 5 |
| Article 3(2) | Article 6 |
| Article 3(3) | Article 7(4) |
| Article 4 | Article 7(1) to (3) |
| Article 5(1), first subparagraph | Article 8(1) |
| Article 5(1), second subparagraph | Article 8(2) and (3) |
| Article 5(2) | — |
| — | Article 9 |
| Article 6(1), first sentence | Article 4 |
| Article 6(1), second sentence | — |
| Article 6(2) | Article 10(1) |
| Article 6(3)(a), introductory phrase | Article 10(2), introductory phrase |
| Article 6(3)(a)(i) | Article 10(2)(a) |
| Article 6(3)(a)(ii) | Article 10(2)(b) |
| Article 6(3)(b), first subparagraph | Article 10(3) |
| Article 6(3)(b), second subparagraph | — |
| Article 6(3)(c) | Article 10(4) |
| Article 6(4) | — |
| Article 7(1), first subparagraph | Article 11 |
| Article 7(1), second subparagraph | Article 12 |
| Article 7(2)(a) | Article 13(1)(a) |
| Article 7(2)(b) | — |
| Article 7(2)(c) | Article 13(1)(b) |
| Article 7(2)(d) | Article 13(1)(c) |

| Directive 91/321/EEC | This Directive |
|---|---|
| Article 7(2)(e) | Article 13(1)(d) |
| Article 7(2)(f) | Article 13(1)(e) |
| Article 7(2a) | Article 13(2) |
| Article 7(3) | Article 13(3) |
| Article 7(4) | Article 13(4) |
| Article 7(5) | Article 13(5) |
| Article 7(6) | Article 13(6) |
| — | Article 13(7) |
| Article 7(7) | Article 13(8) |
| Article 8 | Article 14 |
| Article 9 | Article 15 |
| Article 10 | — |
| — | Article 16 |
| — | Article 17 |
| — | Article 18 |
| — | Article 19 |
| — | Article 20 |
| Article 11 | Article 21 |
| Annexes I to V | Annexes I to V |
| Annex VI | — |
| Annex VII | — |
| — | Annex VI |
| Annexes VIII to X | Annexes VII to IX |
| — | Annex X |
| — | Annex XI |

II

*(Acts whose publication is not obligatory)*

# COMMISSION

## COMMISSION DECISION

**of 19 January 2005**

**on State aid which Italy plans to grant to agricultural undertakings in Sicily**

*(notified under document number C(2005) 52)*

**(Only the Italian text is authentic)**

(2006/967/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular the first subparagraph of Article 88(2) thereof,

Having called on interested parties to submit their comments pursuant to the provision cited above [1] and having regard to their comments,

Whereas:

### I. PROCEDURE

(1) By letter dated 15 December 1999, registered on 20 December 1999, the Italian Permanent Representation to the European Union notified the Commission of Regional Law No 22/1999 on emergency measures in the agricultural sector (hereinafter 'Law No 22/1999') in accordance with Article 88(3) of the EC Treaty.

(2) By letters dated of 6 October 2000, registered on 9 October 2000, 1 February 2001, registered on 5 February 2001, and 30 July 2001, registered on 1 August 2001, the Italian Permanent Representation to the European Union sent the Commission the further information requested from the Italian authorities by letters dated 23 February 2000, 20 November 2000 and 27 March 2001.

(3) By letter dated 25 September 2001, the Commission informed Italy that it had decided to initiate the procedure laid down in Article 88(2) of the EC Treaty in respect of the aid.

(4) The Commission Decision to initiate the procedure was published in the *Official Journal of the European Communities* [2]. The Commission invited the third parties concerned to submit their comments on the aid in question.

(5) The Commission did not receive any comments from interested parties.

(6) On 29 November 2001 the Commission and the Italian authorities met in Brussels.

(7) By letter dated 29 April 2002, registered on 30 April 2002, Italy sent the Commission further information on the planned aid.

### II. DETAILED DESCRIPTION OF THE AID

(8) The measures originally planned under the Regional Law in question are set out in points 9 to 21, broken down by Article:

*Article 1: Extension of agricultural loans*

(9) The article provides for agricultural credit institutes to extend until 31 December 2000 agricultural loans due for repayment in 1998 and 1999. Such extensions would be subject to the reference rate applicable at the date the loans fall due, with any related charges being borne by the borrowers. Extension of the agricultural loans does not entail government action but is a matter for the contractual parties (farmers and credit institutes). However, Italy has undertaken not to apply this measure.

[1] OJ C 315, 9.11.2001, p. 12.

[2] See footnote 1.

*Article 2: Renegotiation of agricultural loans*

(10) The article provides for institutes offering special conditions for loans ([3]), and the borrowers, to request the renegotiation of these loans where their reference rate is above the rate applicable at the time of the entry into force of the law. The agricultural loans qualifying for renegotiation will continue to benefit from the subsidy on the outstanding interest payments, even where the negotiating institute receives a request to accept early repayment of the loan.

*Article 3: Agri-environmental measures*

(11) The article provides for the payment of agri-environmental aid that had been granted to the region of Sicily under Regulation (EEC) No 2078/92 on agricultural production methods compatible with the requirements of the protection of the environment and the maintenance of the countryside ([4]) but which did not qualify for funding by the European Union. It relates to agri-environmental measures set out in the programme drawn up by the Region of Sicily for 1999 and which had already been notified to farmers when the Commission declared such expenditure inadmissible under the co-financing provisions of the Regulation (EEC) No 2078/92. The funding requirement comprises LIT 25 billion (EUR 12 911 420), as against a budget allocation of LIT 10 billion (EUR 5 160 000).

(12) Sicily's agri-environmental programme had been approved by the Commission ([5]) up until the end of 1999, whereas for the majority of Italian regions the programmes had been approved up to 1998. In March 1998 the Commission had decided to make the continuation of any programmes due to expire (or any amendments) conditional upon the submission of evaluations of programmes already carried out.

(13) In October 1998 Sicilian farmers had undertaken the commitments in question, thus incurring expenditure and losing income.

(14) In November 1998 the Commission refused to underwrite new agri-environmental commitments until an evaluation had been carried out ([6]). The Commission stated that a definitive decision on this matter would be taken following a discussion with the competent authorities in the Member States. Sicily submitted the evaluation report in January 1999.

(15) In May 1999 the Commission announced its Decision not to fund the measures A1, B, D1, E and F of the Sicilian agri-environmental plan ([7]), because the evaluation had not supplied sufficient information for a judgement to be made on the socioeconomic and environmental impact of these measures. Furthermore, there had been no amendment of the programme to address the shortcomings highlighted by the evaluation.

(16) Italy plans to grant the same types of aid as set out in the approved agri-environmental programme and in accordance with the same criteria, at the rate of 50 % of the planned amounts. This percentage reflects the effective duration of the commitments, in other words from October 1998 to May 1999 (six months instead of one year).

*Article 4: Measures to promote greenhouse crops*

(17) The article provides for aid to promote greenhouse crops, comprising 40 % of the cost of soil sterilisation, 50 % of the purchase price of sterilisation equipment and a subsidy of LIT 250/kg for the purchase of plastic sheeting for tunnel greenhouses. The Italian authorities have noted their intention to use, as the legal basis for this measure, Article 49 of Law 86/82 of 5 August 1982 (hereinafter 'Law 86/1982'), already approved by the Commission as aid intended to compensate for losses caused by adverse weather conditions. The budget for this measure is LIT 20 billion (EUR 10 329 000).

*Article 5: Co-financing of the national citrus cultivation plan*

(18) The article includes a budget provision for action under the national citrus cultivation plan. After excluding this measure from the dossier, the Commission approved the aid as part of aid C 65/A/2001 by Decision SG(2003) 232301 of 15 October 2003.

*Article 6: Crop protection associations*

(19) The article provides for the grant to crop protection associations of aid to cover 50 % of the expenditure incurred by an insurance fund covering its members' crops. The aid comprises a contribution to both insurance premiums and the management costs of the associations (0,5 % of the sum insured), up to a maximum expenditure of LIT 100 million (EUR 51 645) per association.

([3]) Conditions as set out in the Regional Law No 13 of 25 March 1986 and in the regional laws providing for the State to subsidise interest payments due on agricultural loans.
([4]) OJ L 215, 30.7.1992, p. 85.
([5]) Decisions C(97) 3089 of 14 November 1997 and C(94) 2494 of 10 October 1994.
([6]) Memorandum No 43244 of 6 November 1998.
([7]) Note 27373 of 4 May 1999.

*Article 7: Upgrading of livestock farming*

(20) The article provides for funding for the measure set out in Article 11 of Regional Law No. 40 of 7 November 1997 (hereinafter 'Law No 40-1997'). This measure was studied during the examination of file NN 37/98 and approved by Commission letter SG(2002) 233136 dated 11 December 2002.

(21) Granting of the above aid is subject to approval by the Commission.

III. **REASONS FOR INITIATING PROCEEDINGS**

The Commission had initiated proceedings in respect of the scheme in question for the reasons set out at points 22 to 29:

(22) **Article 1 (extension of agricultural loans)**: despite Italy's assurances that the measure would not be applied, it had not been officially removed from the wording of the law, and the information provided was too limited to enable its compatibility to be assessed.

(23) **Article 2 (renegotiation of agricultural loans)**: the Italian authorities had stated that the loans subject to renegotiation were those granted under a regional law (Regional Law No 13 of 25 March 1986, hereinafter 'Law No 13/1986', approved by the Commission ([8]) and some national laws ([9]). It was not clear whether the national legal basis of the measure had been notified to the Commission and approved by it. If the loans with special conditions to be renegotiated under this measure were considered to constitute illegal and incompatible aid, any increase in the intensity of the aid would also be incompatible.

(24) Furthermore, it could not be inferred from the wording whether the renegotiation of the loans would simultaneously bring about the alignment of the rates of aid with those provided for by the Community Guidelines on State aid in the agriculture sector ([10]) (hereinafter 'the Guidelines'). According to the aid scheme, such an alignment would have had to be made by 30 June 2000 or 31 December 2001 at the latest.

(25) **Article 3 (agri-environmental measures)**: for the purposes of excluding any possible overcompensation of the additional costs and loss of income sustained by farmers as a result of the adoption of agri-environmental commitments, it could not be inferred from the available information whether the maximum amounts and conditions had been observed. These are:

(a) Council Regulation (EC) No 1257/1999 on support for rural development from the European Agricultural Guidance and Guarantee Fund (EAGGF) and amending and repealing certain Regulations ([11]), and

(b) Commission Regulation (EC) No 1750/1999 laying down detailed rules for the application of Council Regulation (EC) No 1257/1999 on support for rural development from the European Agricultural Guidance and Guarantee Fund (EAGGF) ([12]).

(26) **Article 4 (measures in favour of greenhouse crops)**: regarding the application of point 11.3 of the Guidelines (aid to compensate farmers for losses caused by adverse weather conditions), it would seem that only aid to purchase material to rebuild tunnel greenhouses would meet the requirements of the Guidelines. However, aid for soil sterilisation or purchasing sterilising machinery would not seem to be admissible as the Guidelines permit compensation only for damage caused to buildings and machinery by adverse weather conditions. Furthermore, Italy had not provided guarantees that any compensation received from insurance policies, and any costs not incurred by farmers, would be deducted from the aid.

(27) Regarding the application of point 4.1 of the Guidelines (aid for investments in agricultural holdings), the conditions of that point have not been satisfied: expenditure on soil sterilisation would not seem to be included among the forms of eligible expenditure in point 4.1.1.5, the rate of aid (50 %) for the purchase of machinery exceeds the maximum permitted rate (40 %) in areas which are not less-favoured (point 4.1.1.2), and respect for the eligibility criteria laid down by point 4.1.1.3 of the Guidelines has not been demonstrated.

(28) **Article 5 (co-financing of the national citrus cultivation plan)**: the funding envisaged by the Article was to finance the national citrus cultivation plan, a plan which was still being examined by the Commission. Therefore, at that stage of the procedure, it was not yet possible to consider financing of the plan admissible.

([8]) Decision C(97) 1785 of 17 July 1997 (co-financing decision).
([9]) Article 4 of Law No 286/89, Article 4 of Law No 31/91, Article 2 of Law No 237/93.
([10]) OJ C 28, 1.2.2000, p. 2.
([11]) OJ L 160, 26.6.1999, p. 80. Regulation as last amended by Regulation (EC) No 567/2004 (OJ L 90, 27.3.2004, p. 1).
([12]) OJ L 214, 13.8.1999, p. 31. Regulation repealed by Regulation (EC) No 445/2002 (OJ L 74, 15.3.2002, itself repealed by Regulation (EC) No 817/2004 (OJ L 153, 30.4.2004)).

(29) **Article 6 (crop protection associations)**: a contribution to the associations' management costs did not seem to satisfy some of the criteria of point 14 of the Guidelines, particularly with regard to the general availability of the services, the limiting of administrative costs for non-members, and the requirement to account separately for the expenditure relating to the subsidised services.

## IV. COMMENTS SUBMITTED BY ITALY

(30) By letter dated 29 April 2002 Italy provided the following information and clarifications:

(31) **Article 1 (extension of agricultural loans)**: Italy specified that the provision in question had been repealed by Article 1(2) of Regional Law No 28 of 23 December 2000 (hereinafter 'Law No 28/2000'). Italy also emphasised that the provision had never been notified, as the extension of agricultural loans did not entail government action and instead was a matter for the contractual parties, and as the responsibilities regarding the extension of the loans rested entirely with the farmers.

(32) **Article 2 (renegotiation of agricultural loans)**: Italy specified that the possibility of renegotiation would concern only loans financed on the basis of the regional law (Article 2(3) of Regional Law No 13/86) within the period of validity of the approved scheme. Italy indicated, furthermore, that the aim of the provision is to bring the rate applied to loans previously entered into by farmers below the so-called 'usurious rate', as defined by Law No 108 of 1996. In many cases, the loans in question have reference rates which are far higher than the usurious rate, and are two or three times higher than the prevailing market rate. The aim of the renegotiations is to align the old reference rates with current market rates. As a result of the article in question, the institutions granting aid would be able to renegotiate the relevant loans, resulting in savings of public resources. The regional government has undertaken not to change the extent of the state aid in grant-equivalent terms of the initial measure. The fact that up-dated aid instalments due will benefit the borrower means that, in cases where the loan is settled early, the reduction of aid causes the borrower to receive a lower amount than that which was originally granted, and thus the equivalent aid is also lower.

(33) **Article 3 (agri-environmental measures)**: Italy pointed out that the prohibition on assuming new agri-environmental commitments for programmes expiring at the end of 1998 in the absence of an evaluation (November 1998), as well as the decision not to co-finance certain measures (May 1999), had both occurred after farmers had agreed (in October 1998) to the commitments in question. It should be noted, in the case of Sicily, that the commitments which have been challenged are not 'new five-year commitments'. Rather, they come within the framework of the Sicilian agri-environmental programme which is still valid given that it was approved by the Commission until the end of 1999, and not just until 1998 as was the case for the other regions.

(34) **Article 4 (measures in favour of greenhouse crops)**: Italy has undertaken to limit the aid solely to the purchase of plastic sheeting to cover tunnel greenhouses. In order to avoid any risk of overcompensation, Italy has also undertaken that, wherever a farmer has entered into an insurance contract providing cover for damage caused by adverse weather conditions, it would subtract, from the compensation payable, any sums received, as well as any ordinary expenditure not incurred by the farmer.

(35) **Article 6 (crop-protection associations)**: Italy undertook to abrogate the contribution towards the associations' day-to-day management costs.

## V. ASSESSMENT OF THE AID

(36) The provision at Article 1 has been repealed (see point (9)) and measures provided for by Articles 5 and 7 were approved within the framework of other aid schemes (see paragraphs (18) and (20)). Therefore, the following assessment concerns only Articles 2, 3, 4 and 6 of Law No 22/1999.

### V.1. Existence of aid within the meaning of Article 87(1) of the Treaty

(37) Under Article 87(1) of the Treaty, any aid granted by a Member State or through State resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods is, in so far as it affects trade between Member States, incompatible with the common market.

(38) The final wording of Article 2 of the Regional Law provides for the renegotiation of agricultural loans with special conditions within the meaning of Law No 13/86 (a scheme authorised by the Commission [13]) during the validity period of the said scheme (31 December 1997). The Italian authorities claim that no renegotiation of farm loans took place. Since, under Article 2(3) of the Regional Law, such renegotiations had to be completed within 18 months of the date of entry into force of the law, the Commission considers it unnecessary to consider the measure.

[13] See note 7.

(39) The Commission reserves the right to verify that the national legislation cited in the original notification, even where not directly applicable to the article of the law in question, has been properly notified to and approved by the Commission in so far as it concerns State aid.

(40) Articles 3, 4 and 6 of the Regional Law under examination correspond to the definition of aid in Article 87(1) of the Treaty, due to the fact that they give:

(a) economic advantages (unrecoverable financial assistance)

(b) to certain undertakings (Sicilian agricultural undertakings)

(c) financed by public (regional) resources, and

(d) have the potential to affect trade, given Italy's place in the agriculture sector (for example, in 1999 Italy exported agricultural products to other Member States to a total value of EUR 10 258 million, while imports from other Member States were valued at EUR 15 271 million ([14])).

V.2. **Compatibility of the aid**

(41) The prohibition referred to in Article 87(1) of the Treaty is not absolute. In order to be considered compatible with the common market, the measures referred to in Articles 3, 4 and 6 of the law in question must qualify for one of the derogations provided for in Article 87(2) and (3) of the Treaty.

(42) The only possible derogation in the case in point is laid down in Article 87(3)(c), according to which aid may be considered compatible with the common market if it is found to facilitate the development of certain economic activities or of certain economic areas, where such aid does not adversely affect trading conditions to an extent contrary to the common interest.

(43) In interpreting this derogation, the Commission in dealing with the agricultural sector first of all checks whether Commission Regulation (EC) No 1/2004 on the application of Articles 87 and 88 of the EC Treaty to State aid to small and medium-sized enterprises active in the production, processing and marketing of agricultural products ([15]) is applicable. If this Regulation does not apply, the Commission refers to the Community Guidelines on State aid in the agricultural sector ([16]).

(44) Regulation (EC) No 1/2004 is not applicable in the case in point, since the scheme is not restricted to small and medium-sized agricultural undertakings. The Commission has therefore referred to points 5.3 (agri-environmental commitments) and 11 (compensation for damage caused by bad weather) of the Guidelines.

V.2.1. *Agri-environmental measures*

(45) The Commission takes note of the fact that the agri-environmental commitments in question had already been given by the farmers at the time of the Commission's doubts, and then its final decision that such commitments should not be considered eligible for Community co-financing and that, consequently, the farmers had already incurred expenses and lost revenue at the time of the Decision.

(46) Furthermore, these commitments were part of an agri-environmental programme approved by the Commission until 1999 and thus complied in concept with the requirements of Regulation (EC) No 1257/1999.

(47) In order to assess the compatibility with the common market of State aids in connection with agri-environmental commitments, the Commission applies point 5.3 of the Guidelines.

(48) This point says that State aids may be deemed compatible if they are granted in accordance with the criteria applicable to agri-environmental measures co-financed under Articles 22 to 24 of Regulation (EC) No 1257/1999. In the case in point, this condition cannot be met in the light of what was said in paragraph 46.

(49) It is nevertheless necessary to examine why the Commission decided not to co-finance such measures, with a view to excluding any administrative shortcomings or irregularities indicating, for example, any overcompensation of farmers.

(50) The Commission's communications, as well as internal correspondence of the relevant departments, reveal nothing which can indicate, on the part of the Region of Sicily, any irregular administration or overcompensation of farmers. The reasoning adopted by the Commission (see paragraph 15) for the failure to agree to co-financing concerned the need to take account of the outcome of the assessment of the programme as a result of changes designed to improve it.

([14]) *Source*: Eurostat. Separate data for individual regions are not available.

([15]) OJ L 1, 3.1.2004, p. 1.

([16]) OJ C 28, 1.2.2000, p. 2.

(51) Italy plans to grant aid in the same ways and according to the same criteria as the approved agri-environmental programme at a rate of 50 % of the planned amounts. This percentage matches *pro rata temporis* the actual duration of the commitments (six months). The Italian authorities have shown that the scale of the aid is such as not to result in overcompensation of costs but rather, in the case of certain measures, does not succeed in covering the greater burdens stemming from commitments which have already been honoured. Indeed, when the farmers were informed (May 1999) that there would be no co-financing, the bulk of the cultivation operations had already been carried out in compliance with the commitments given (preparatory work, seeds, fertilisers, spring treatment, pruning). The farmers had also incurred the costs of technical consultations and administrative and technical documentation. The costs and lost revenue incurred during the six months in question thus represented more than 50 % of the total for a whole farming year.

(52) However, the information available to the Commission does not make it possible to verify whether the Region of Sicily conducted the proper checks to ensure that farmers complied with their agri-environmental commitments in 1999 and whether such checks proved positive.

(53) The Commission therefore believes that the State aid in question should be considered compatible with the common market only in so far as Italy can prove that the checks referred to in paragraph 52 were conducted between October 1998 and May 1999 and proved positive.

V.2.2. *Measures in favour of greenhouse crops*

(54) In the final version of the measure the aid in question will be granted to greenhouse farmers who have suffered from adverse weather conditions in accordance with Article 49 of Law No 86/1982, which extends to crops grown under cover the benefits of Law No 37/1974. However, only the costs of purchasing plastic sheeting for tunnel greenhouses will be considered eligible.

(55) Article 49 of Law No 86/92 was approved by the Commission since it concerned aid intended to compensate the damage caused to greenhouses and plastic sheetings by the severe storms and heavy hail showers occurring in areas where greenhouse cultivation is the main form of farming.

(56) Aid intended to compensate damage caused to buildings and equipment by adverse weather conditions can be authorised on the basis of point 11.3 of the Guidelines up to 100 % of actual costs, with no minimum threshold being applied. However, point 11.3.6 of the Guidelines lays down that, in order to avoid excessive compensation, any sums received from insurance schemes and normal costs not incurred by farmers must be deducted from the amount of the aid. Furthermore, in accordance with point 11.3.1 of the Guidelines, the aid measures must be accompanied by appropriate meteorological information.

(57) As outlined in paragraph 34, Italy has indicated that the eligible expenses were limited to the cost of replacing plastic sheeting. Furthermore, Italy promised to deduct from aid amounts any sums paid under insurance schemes and normal costs not incurred.

(58) In addition, Italy provided the meteorological documentation concerning the bad weather in question.

(59) The Commission therefore believes that the measure in question can be considered compatible with the common market.

V.2.3. *Crop protection associations*

(60) In the final version of the measure, Italy will grant aid equivalent to 50 % of insurance premiums for damage caused by natural disasters in the case of policies taken out by crop protection associations. These associations are private bodies set up by farmers themselves with a view to increasing their own bargaining power when taking out insurance contracts.

(61) Point 11.5 of the Guidelines allows aid to be granted up to 80 % of the cost of insurance premiums covering losses caused by natural disasters or exceptional occurrences, and up to 50 % of the cost of such premiums when the insurance also covers other losses caused by adverse weather conditions or losses caused by animal or plant diseases.

(62) In the case in point, the type of aid and the maximum aid intensity comply with point 11.5 of the Guidelines.

(63) The Commission therefore believes that the measure in question can be considered compatible with the common market.

## VI. **CONCLUSIONS**

(64) The measure referred to in Article 2 of Law No 22/99 does not constitute aid within the meaning of Article 87(1) of the Treaty.

(65) The measure referred to in Article 3 of the above law is compatible with the common market within the meaning of Article 87(3)(c) of the Treaty only in so far as Italy can prove that the proper checks of farmers' compliance were conducted between October 1998 and May 1999 and that such checks proved positive.

(66) The measures referred to in Articles 4 and 6 of the above law are compatible with the common market within the meaning of Article 87(3)(c) of the Treaty,

HAS ADOPTED THIS DECISION:

*Article 1*

Article 2 of Regional Law No 22/1999, which Italy intends to implement for the benefit of agricultural undertakings in Sicily, does not constitute aid within the meaning of Article 87(1) of the Treaty.

*Article 2*

The measure referred to in Article 3 of Regional Law No 22/1999, which Italy intends to implement for the benefit of agricultural undertakings in Sicily, is compatible with the common market, provided that the conditions laid down in Article 4 of this Decision are complied with.

*Article 3*

The measures referred to in Articles 4 and 6 of Regional Law No 22/1999, which Italy intends to implement for the benefit of agricultural undertakings in Sicily, are compatible with the common market. The implementation of these measues is therefore authorised.

*Article 4*

Within two months of notification of this Decision, Italy shall provide the information which can prove that the relevant authorities conducted checks between October 1998 and May 1999 on the compliance by farmers with the agri-environmental commitments given in connection with the environmental programme of the Region of Sicily and which were not eligible for Community co-financing and that such checks proved positive.

*Article 5*

This Decision is addressed to the Italian Republic.

Done at Brussels, 19 January 2005.

*For the Commission*

Mariann FISCHER BOEL

*Member of the Commission*

# COMMISSION DECISION

## of 15 December 2006

## implementing Council Regulation (EC) No 21/2004 as regards guidelines and procedures for the electronic identification of ovine and caprine animals

*(notified under document number C(2006) 6522)*

**(Text with EEA relevance)**

(2006/968/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 21/2004 of 17 December 2003 establishing a system for the identification and registration of ovine and caprine animals and amending Regulation (EC) No 1782/2003 and Directives 92/102/EEC and 64/432/EEC [1], and in particular Article 9(1) thereof,

Whereas:

(1) Regulation (EC) No 21/2004 provides that each Member State is to establish a system for the identification and registration of ovine and caprine animals in accordance with that Regulation.

(2) Regulation (EC) No 21/2004 also provides that all animals on a holding born after 9 July 2005 are to be identified by two means of identification. The first means of identification are eartags and the second means of identification are set out in point 4 of Section A of the Annex to that Regulation. One of the second means of identification is an electronic transponder. In addition, Article 9 of Regulation (EC) No 21/2004 provides that, as from 1 January 2008 or another date that may be fixed by the Council, electronic identification as a second means of identification is to be obligatory for all animals.

(3) Regulation (EC) No 21/2004 provides for the adoption by the Commission of guidelines and procedures for the implementation of the electronic identification in order to improve its implementation. Those guidelines and procedures should be applied for those animals for which electronic identification is already used as the second means of identification and for all animals as from the date provided for in Article 9(3) of that Regulation.

(4) In order to ensure that the identifiers to be applied to ovine and caprine animals for the purpose of Regulation (EC) No 21/2004 are readable in all Member States, minimum requirements concerning certain conformance and performance tests should be laid down in this Decision for the approval of identifiers.

(5) In order to provide guidance to the Member States as regards readers, minimum requirements concerning certain conformance and performance tests should be laid down in this Decision taking into account that Regulation (EC) No 21/2004 does not foresee that every operator must possess a reader.

(6) Due to the different geographic conditions and husbandry systems under which ovine and caprine animals are kept in the Community, the Member States should have the possibility to require additional performance tests taking into account their specific national conditions.

(7) The International Organization for Standardization (ISO) has published standards dealing with aspects of radio frequency identification (RFID) of animals. In addition, the International Committee on Animal Recording (ICAR) has developed procedures aimed to verify the compliance of certain RFID characteristics with ISO standards. Those procedures have been published in the International Agreement on Recording Practices in the version as approved by the ICAR General Assembly, June 2004. The ISO standards are accepted and used internationally and should therefore be taken into account in this Decision.

(8) The Joint Research Centre (JRC) of the Commission has developed Technical Guidelines specifying tests for assessing the performance and reliability of RFID devices that are published on the JRC website as JRC technical standards. The essential elements of those guidelines should be taken into account in this Decision.

(9) The European Committee for Standardisation (CEN) has published technical standards dealing with the accreditation of test laboratories. Those standards (EN standards) are accepted and used internationally and should therefore be taken into account in this Decision.

(10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

[1] OJ L 5, 9.1.2004, p. 8.

HAS ADOPTED THIS DECISION:

*Article 1*

The Annex to this Decision sets out the guidelines and procedures for the electronic identification of animals:

(a) for the second means of identification, as provided for in Article 4(2)(b) of Regulation (EC) No 21/2004 and referred to in the fourth indent of point 4 of Section A of the Annex to that Regulation; and

(b) provided for in the first subparagraph of Article 9(3) of Regulation (EC) No 21/2004.

*Article 2*

This Decision shall apply from the 20th day following that of its publication in the *Official Journal of the European Union*.

*Article 3*

This Decision is addressed to the Member States.

Done at Brussels, 15 December 2006.

*For the Commission*

Markos KYPRIANOU

*Member of the Commission*

*ANNEX*

**Guidelines and procedures for the approval of identifiers and readers for the electronic identification of ovine and caprine animals pursuant to Regulation (EC) No 21/2004**

CHAPTER I

**Definitions**

For the purpose of these Guidelines, the following definitions shall apply:

(a) 'Country code' means a 3-digit numeric code representing the name of a country in accordance with ISO standard 3166;

(b) 'National identification code' means a 12-digit numeric code to identify an individual animal at national level;

(c) 'Transponder code' means the 64-bit electronic code programmed in the transponder and containing *inter alia* the country code and national identification code and used for the electronic identification of animals;

(d) 'Identifier' means a read-only passive transponder applying the HDX- or FDX-B technology as defined in ISO standards 11784 and 11785 and incorporated in different means of identification as referred to in Annex A of Regulation (EC) No 21/2004;

(e) 'Reader' means a synchronising or non-synchronising transceiver which is, at least, capable of:

(i) reading identifiers; and

(ii) displaying the country code and the national identification code;

(f) 'Synchronising transceiver' means a transceiver, which fully complies with ISO standard 11785 and is able to detect the presence of other transceivers;

(g) 'Non-synchronising transceiver' means a transceiver, which does not comply with clause 6 of ISO standard 11785 and is not able to detect the presence of other transceivers.

CHAPTER II

**Identifiers**

1. The competent authority shall only approve the use of identifiers which have at least been tested, with favourable results, in accordance with the methods specified in the International Agreement on Recording Practices of the International Committee on Animal Recording (ICAR Recording Guidelines), as referred to in the following points (a) and (b), on their:

(a) conformance with the ISO standards 11784 and ISO 11785, in accordance with the method specified in Section 10.2.6.2.1, 'Conformance evaluation of RFID devices, Part 1: ISO 11784/11785 — conformance of transponders including granting and use of a manufacturer code'; and

(b) achievement of performance at the reading distances as laid down in the third indent of Section A.6 of the Annex to Regulation (EC) No 21/2004, in accordance with the method specified in Section 10, Appendix 10.5 'Performance evaluation of RFID devices, Part 1: ISO 11784/11785 — performance of transponders' which shall include measurements of:

(i) the activation field strength;

(ii) the dipole moment; and

(iii) the bit length stability for FDX-B and frequency stability for HDX.

2. The tests referred to in point 1 shall be carried out on a minimum quantity of 50 identifiers of each model to be tested.

3. The structure of the transponder code shall be in accordance with ISO standard 11784 and the descriptions set out in the following table:

| Bit(s) No | No of digits | No of combinations | Description |
|---|---|---|---|
| 1 | 1 | 2 | This bit indicates whether the identifier is used for animal identification or not. In all animal applications this bit shall be '1' |
| 2-4 | 1 | 8 | Retagging counter (0 to 7). |
| 5-9 | 2 | 32 | User Information field. This bit shall contain '04' codifying the CN-code for sheep and goats in accordance with Chapter 1, Section I, Part II of the Annex to Council Regulation (EEC) No 2658/87 ([1]). |
| 10-15 | 2 | 64 | Empty — All zeros (reserved zone for future applications). |
| 16 | 1 | 2 | This bit indicates the presence or not of a data block (for the use in animals this bit shall be '0' = no data block). |
| 17-26 | 4 | 1 024 | Country code as defined in point (a) of Chapter 1 |
| 27-64 | 12 | 274 877 906 944 | National identification code as defined in point (b) of Chapter 1. If the national identification code is less than 12 digits, the space between the national identification code and the country code shall be completed with zeros. |

([1]) OJ L 256, 7.9.1987, p. 1.

4. The competent authority may require additional tests for robustness and endurance of identifiers according to the procedures described in Part 2 of the Technical Guidelines of the Joint Research Centre of the Commission (JRC).

5. The competent authority may require other performance criteria to ensure the functionality of identifiers under the specific geographic, climatic and management conditions of the Member State concerned.

## CHAPTER III

## **Readers**

1. The competent authority shall only approve the use of readers which have at least been tested on their conformance with ISO standards 11784 and 11785, with favourable results, in accordance with the methods specified in the ICAR Recording Guidelines, as referred to in the following points (a) and (b), by the conformance test for:

(a) synchronising transceivers in conformity with the methods specified in Section 10.3.5.2 'Conformance evaluation of RFID devices, Part 2: ISO 11784/11785 — conformance of transceivers'; or

(b) non-synchronising transceivers in conformity with the methods specified in Section 10.4.5.2 'Conformance evaluation of RFID devices, Part 3: Conformance test for non-synchronising transceivers for reading ISO 11784/11785 transponders'.

2. The competent authority may require:

(a) additional tests on mechanical and thermal robustness and endurance of readers according to the procedures described in Part 2 of Technical Guidelines of the JRC; and

(b) electromagnetic performance tests as specified in the ICAR Recording Guidelines, Section 10, Appendix 10.6.2 'Performance evaluation of RFID devices, Part 2: ISO 11784/11785 — performance of handheld transceivers'.

CHAPTER IV

**Test laboratories**

1. The competent authority shall designate test laboratories for carrying out the tests provided for in Chapters II and III.

However, the competent authority may only designate laboratories that operate and are assessed and accredited in accordance with the following European standards ('EN standards') or equivalent standards:

(a) EN ISO/IEC 17025 'General requirements for the competence of testing and calibration laboratories';

(b) EN 45002 'General criteria for the assessment of testing laboratories'; and

(c) EN 45003 'Calibration and testing laboratory accreditation system — General requirements for operation and recognition'.

2. Member States shall draw up and keep up-to-date lists of test laboratories designated by the competent authorities and make such information available to the other Member States and the public on a website.

**NOTICE TO READERS**

From 1 January 2007, the structure of the Official Journal will be modified in the direction of a clearer classification of the acts published which preserves, nevertheless, essential continuity.

The new structure, with examples illustrating its use in the classification of acts, can be consulted on the EUR-Lex site on the following address:

http://eur-lex.europa.eu/en/index.htm