Statutory Instrument

S.I. No. 142 of 2000

European Communities (Processed Cereal-Based Foods and Baby Foods for Infants and Young Children) Regulations, 2000

I, Micheál Martin, Minister for Health and Children, in exercise of the powers conferred on me by section 3 of the European Communities Act, 1972 (No. 27 of 1972), having regard to Council Directive 89/398/EEC[1] of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses as amended by Directive 96/84/EC[2] of the European Parliament and of the Council of 19 December 1996 and Directive 1999/41/EC[3] of the European Parliament and of the Council of 7 June 1999 and for the purpose of giving effect to Commission Directive 96/5/EC[4] of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children as amended by Commission Directive 98/36/EC[5] of 2 June 1998 and Commission Directive 1999/39/EC[6] of 6 May 1999, hereby make the following Regulations:

[6] OJ No. L124, 18.5.99, p.8

[5] OJ No. L167, 12.6.98, p.23

[4] OJ No. L49, 28.2.96, p.17

[3] OJ No.172, 8.7.99, p.38

[2] OJ No. L48, 19.2.97, p.20

[1] OJ No. L186, 30.6.89, p.27

1. These Regulations may be cited as the European Communities (Processed Cereal-Based Foods and Baby Foods for Infants and Young Children) Regulations, 2000.

2. (1) In these Regulations-

"the Act of 1998" means the Food Safety Authority of Ireland Act, 1998 (No. 29 of 1998);

"Annex" means an Annex to the Directive;

"authorised officer" means a person appointed as an authorised officer under Regulation 15;

"the Directive" means Commission Directive 96/5/EC[7] of 16 February 1996 on processed cereal-based foods and baby foods for infants and young

children as amended by Commission Directive 98/36/EC[8] of 2 June 1998 and Commission Directive 1999/39/EC[9] of 6 May 1999;

[9] OJ No. L124, 18.5.99, p.8

[8] OJ No. L167, 12.6.98, p.23

[7] OJ No. L49, 28.2.96, p.17

"functional area" in relation to a health board established under section 4(1) of the Health Act, 1970 (No. 1 of 1970), means the functional area of the health board as specified in the Health Board Regulations, 1970 (S.I. No. 170 of 1970) and in relation to the Eastern Regional Health Authority established under section 7 of the Health (Eastern Regional Health Authority) Act, 1999 (No. 13 of 1999) ("the Act of 1999"), means the functional area of the Authority as specified in section 7(4) of the Act of 1999;

"health board" means a health board established under section 4(1) of the Health Act, 1970 (No. 1 of 1970) and the Eastern Regional Health Authority established under section 7 of the Act of 1999;

"infants" means children under the age of twelve months;

"pesticide residue" means the residue in processed cereal-based foods and baby foods of a plant protection product, as defined in point 1 of Article 2 of Council Directive 91/414/EEC[10], including its metabolites and products resulting from its degradation or reaction;

[10] OJNo. L230, 19.8.91, p.1

"to market" includes to supply (whether or not for profit), offer for sale, expose for sale and have in possession for sale, and cognate words shall be construed accordingly;

"young children" means children aged between one and three years.

(2) A word or expression that is used in these Regulations and that is also used in the Directive has, unless the context otherwise requires, the same meaning in these Regulations that it has in the Directive.

(3) (a) A reference in these Regulations to a Regulation is to a Regulation of these Regulations, unless it is indicated that reference to some other Regulations is intended.

(b) A reference in these Regulations to a paragraph or subparagraph is to the paragraph or subparagraph of the provision in which the reference occurs, unless it is indicated that reference to some other provision is intended.

3. These Regulations relate to foodstuffs for particular nutritional use fulfilling the particular requirements of infants and young children in good health and are intended for use by infants while they are being weaned, and by young children as a supplement to their diet and/or for their progressive adaptation to ordinary food. They comprise of:

(1) "Processed cereal-based foods" which are divided into the following four categories:

(a) simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids;

(b) cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid;

(c) pastas which are to be used after cooking in boiling water or other appropriate liquids;

(d) rusks and biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids.

(2) "Baby foods" other than processed cereal-based foods.

4. These Regulations do not apply to milks intended for young children.

5. The products referred to in Regulation 3 may be marketed only if they comply with the provisions laid down in these Regulations and the Directive.

Composition of Processed Cereal-Based Foods and Baby Foods

6. Processed cereal-based foods and baby foods shall be manufactured from ingredients whose suitability for particular nutritional use by infants and young children has been established by generally accepted scientific data.

7. (1) Processed cereal-based foods must comply with the compositional criteria specified in Annex I.

(2) Baby foods which are described in Annex II must comply with the compositional criteria specified therein.

(3) Only the nutritional substances listed in Annex IV may be added in the manufacture of processed cereal-based foods and baby foods.

(4) Notwithstanding paragraph (3), a substance listed in Annex VI shall not be added in the manufacture of processed cereal-based foods and baby foods in a quantity that is greater than the maximum permitted level for that substance as specified in that Annex

8. Processed cereal-based foods and baby foods shall not contain any substance in such quantity as is likely to endanger the health of infants and young children.

9. (1) Processed cereal-based foods and baby foods shall not contain a pesticide residue at a level exceeding 0.01 mg/kg.

(2) The level specified in paragraph (1) applies to processed cereal-based foods and baby foods as proposed ready for consumption or as reconstituted according to the instructions of the manufacturer.

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

(4) This Regulation shall come into operation on the 1st day of July, 2000.

Labelling of Processed Cereal-Based Foods and Baby Foods

10. The labelling of foodstuffs as set out in Regulation 3 shall bear the following particulars in addition to EU and general food labelling requirements:

(a) A statement as to the appropriate age from which the product may be used, with regard to its composition, texture or other particular properties. The stated age may not be less than four months for any product.

(b) Products recommended for use from the age of four months may indicate that they are suitable from that age unless independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care, advise otherwise.

(c) If the indicated age from which the product may be used is below six months, the label must contain information as to the presence or absence of gluten.

(d) The available energy value expressed in kJ and kcal, and the protein, carbohydrate and lipid content, expressed in numerical form, per 100 g or 100 ml of the product as sold and, where appropriate, per specified quantity of the product as proposed for consumption.

(e) The average quantity of each mineral substance and of each vitamin governed by a specific level in Annex I and Annex II respectively, expressed in numerical form, per 100g or 100ml of the product as sold and, where appropriate, per specified quantity of the product as proposed for consumption.

(f) Instructions for appropriate preparation, when necessary, and a statement as to the importance of following those instructions.

11. The labelling of foodstuffs as set out in Regulation 3 may bear:

(a) The average quantity of the nutrients set out in Annex IV when such declaration is not covered by the provisions of Regulation 10 (e), expressed in numerical form, per 100g or 100ml of the product as proposed for consumption.

(b) In addition to numerical information, information on vitamins and minerals shown in Annex V, expressed as a percentage of the reference values given therein, per 100g or 100ml of the product as sold, and where appropriate, per specified quantity of the product as proposed for consumption, provided that the quantities present are at least equal to 15% of the reference values.

Application of Act of 1998.

12. These Regulations shall be deemed to be food legislation for the purposes of the Act of 1998 and the enforcement provisions contained in that Act shall accordingly apply for the purpose of ensuring compliance with these Regulations.

Application of Regulations of 1998.

13. (1) Without prejudice to Regulation 12, the powers contained in the European Communities (Official Control of Foodstuffs) Regulations, 1998 (S.I. No. 85 of 1998), as amended, may be exercised for the purpose of ensuring compliance with these Regulations.

(2) An official certificate given in accordance with sub-article (1) of article 14 of the said Regulations of 1998, as amended, may be adduced in evidence in a prosecution under these Regulations and shall be prima facie evidence of the matters contained therein, until the contrary is proved.

Enforcement of these Regulations before entry into a service contract.

14. Without prejudice to Regulations 12 and 13, before entry into a service contract by a health board with the Food Safety Authority of Ireland under the Act of 1998, the powers contained in Regulations 15 to 19 may be exercised for the purpose of ensuring compliance with these Regulations.

Authorised Officers

15. (1) The Chief Executive Officer of a health board may appoint in writing such and so many officers of the health board as he or she thinks fit to be authorised officers for the purposes of ensuring compliance with these Regulations in the functional area of the health board.

(2) A person appointed as an authorised officer under the European Communities (Processed Cereal - Based Foods and Baby Foods for Infants and Young Children) Regulations, 1998 (S.I. No. 241 of 1998) and holding office as an authorised officer immediately before the making of these Regulations shall continue in office as if appointed under this Regulation.

(3) An authorised officer shall be furnished with a certificate of his appointment as an authorised officer and, when exercising any power conferred on an authorised officer under these Regulations, shall, if requested by any person affected, produce the certificate to that person.

16. (1) An authorised officer may for the purpose of ensuring that these Regulations are being complied with -

(a) require any employee of the health board, a former employee of the health board or any person otherwise currently or previously retained by the health board, or any person who carries or has carried on any trade, business or activity to which these Regulations relate or any person currently or previously employed in connection with that trade, business or activity to produce to him or her such records, and in the case of such information in a non-legible form to reproduce it in a permanent legible form, or to give him or her such information, as the officer may reasonably require in relation to any entries in such records,

(b) at all reasonable times enter any premises, subject to paragraph (2), at which there are reasonable grounds to believe that any trade, business or activity in connection with the production, processing, disposal, manufacture, exportation, importation, storage, distribution, sale, marketing or labelling for the purposes of marketing of any product to which these Regulations apply is or has been carried on, or that records in relation to such trade, business or activity are kept, and search and inspect the premises and any product, label or records found in or on the premises,

(c) secure for later inspection any premises or any part thereof in which such product, label or records are kept or there are reasonable grounds for believing that such product, labels or records are kept,

(d) require any person in charge thereof or so employed therein, to produce to the officer such records and to give to the officer such information as the officer may reasonably require in relation to any entries in such records,

(e) inspect and take copies of or extracts from any such records (including in the case of information in a non-legible form a copy of or extract from such information in a permanent legible form),

(f) remove and retain the said product, labels or records for such period as may be reasonable for further examination or until the conclusion of any legal proceedings,

(g) as regards any product or any article or substance used in the manufacture or preparation of a product the officer finds at or in a premises, require any person in charge thereof or any person who appears to the officer to be in possession of the product or the article or substance, to supply without payment, for test, examination or analysis sufficient samples thereof,

(h) require any person to afford the officer such facilities and assistance within his or her control or responsibilities as are reasonably necessary to enable the officer to exercise any of the powers conferred on an authorised officer under this Regulation,

(i) require a person referred to in subparagraph (a) to give to the officer any information which the officer may reasonably require in regard to the trade, business or activity or in regard to the persons carrying on such trade, business or activity or employed in connection with that trade, business or activity,

(j) require any person referred to in subparagraph (a) by or on whose behalf data equipment is or has been used in relation to a business within the meaning of subparagraph (b) or any person having charge of, or otherwise concerned with the operation of, the data equipment or any associated apparatus or material, to afford the officer all reasonable assistance in relation to its use thereto,

(k) summon, at any reasonable time, any other person being or having been an employee of the health board or retained or having been retained by the health board or employed in connection with the trade, business or activity under examination by the health board to give to the officer any information which the officer may reasonably require in regard to that trade, business or activity and to produce to the officer any records which are in that person's power or control;

(l) examine any procedure connected with the manufacture of a product, and

(m) exercise such other powers as may be necessary to ensure that these Regulations are being complied with.

(2) An authorised officer shall not, other than with the consent of the occupier, enter a private dwelling unless he or she has obtained a warrant from the District Court under paragraph (5) authorising such entry.

(3) Where an authorised officer in the exercise of the officer's powers under this Regulation is prevented from entering any premises an application may be made to the District Court under paragraph (5) for a warrant authorising such entry.

(4) An authorised officer where he considers is necessary, may be accompanied by a member of the Garda Síochána when performing any powers conferred on an authorised officer under this Regulation.

(5) If a judge of the District Court is satisfied on the sworn information of an authorised officer that there are reasonable grounds for suspecting that there is information required by an authorised officer under this Regulation held on or in any premises or any part of any premises or there is a product which an authorised officer requires to inspect for purposes of these Regulations or that such inspection is likely to disclose evidence of a contravention of these Regulations, the judge may issue a warrant authorising an authorised officer, accompanied, if appropriate, by other authorised officers or by a member of the Garda Síochána, at any time or times within one month from the date of issue of the warrant, on production, if so requested, of the warrant, to enter, if need be by reasonable force, the premises and exercise all or any of the powers conferred on an authorised officer under this Regulation.

(6) An application under paragraph (5) shall be made to the judge of the District Court in whose district court district the premises is situated.

17. (1) Where a sample of any product, article or substance is supplied pursuant to paragraph (1)(g) of Regulation 16 and where the division of the sample is reasonably practicable, the authorised officer concerned may divide the sample into not more than three approximately equal parts each of which he shall mark in such a way as to identify it as a part of the sample taken by the officer. The authorised officer shall mark, seal and fasten each part in such a manner as its nature will permit, forward one part to a laboratory approved under the European Communities (Official Control of Foodstuffs) (Approved Laboratories) Order, 1998 (S.I. No. 95 of 1998), where it may be tested, examined or analysed for the purposes of these Regulations by an approved examiner, within the meaning of the European Communities (Official Control of Foodstuffs) Regulations, 1998, as amended, give or send one part to the seller, owner or person in apparent charge or control of the product, article or substance and retain the third part.

(2) Where an authorised officer takes a sample consisting of a product, article or substance contained in unopened containers and its division into parts—

(a) is not reasonably practicable, or

(b) might affect the composition or impede the proper analysis of the sample,

the provision of paragraph (1) as regards the division of samples into parts shall be deemed to be complied with if the authorised officer divides the containers into three lots and deals with each lot as if it were a sample as specified under paragraph (1).

18. (1) The approved examiner within the meaning of Regulation 17(1) or a person under his direction shall analyse as soon as possible any sample of a product, article or substance submitted to him in pursuance of these Regulations and the approved examiner shall certify to the person who submitted the sample to him the result of such analysis. If the sample is found to be diseased, contaminated or otherwise unfit for human consumption, the form of certificate set out in the Schedule to these Regulations or a certificate in like form shall be used.

(2) An official certificate given in accordance with paragraph (1) may be adduced in evidence in a prosecution under these Regulations and shall be *prima facie* evidence of the matters contained therein, until the contrary is proved.

19. Where a sample of a product, article or substance is taken by an authorised officer in pursuance of these Regulations for analysis by an approved examiner, and where the seller, owner or person in apparent charge or control of such item requests in writing the results of such analysis, the request shall be made to the health board in whose area the sample was taken and the health board shall comply with such request.

Offences

20. (1) A person who markets a product referred to in Regulation 3, which does not comply with these Regulations shall be guilty of an offence.

(2) A person who falsely represent himself to be an authorised officer shall be guilty of an offence.

(3) A person who -

(a) obstructs or interferes with an authorised officer in the exercise of the officer's powers under Regulation 16, or

(b) fails to comply with a request from an authorised officer under Regulation 16, or

(c) makes a statement to an authorised officer which the person knows is false or misleading,

shall be guilty of an offence.

(4) A person who is guilty of an offence under these Regulations shall be liable on summary conviction to a fine not exceeding £1,500 or at the discretion of the Court to imprisonment for a term not exceeding six months, or both.

21. Where an offence under these Regulations is committed by a body corporate or by a person acting on behalf of a body corporate and is proved to have been so committed with the consent, connivance or approval of, or to be attributable to any neglect on the part of any director, manager, secretary or any other officer of such body or a person who was purporting to act in any such capacity, such person shall also be guilty of an offence and shall be liable to be proceeded against and punished as if he were guilty of the first-mentioned offence.

Prosecutions

22. An offence under these Regulations may be prosecuted by the health board in whose functional area the offence was committed.

Revocation

23. (1) The European Communities (Processed Cereal-Based Foods and Baby Foods for Infants and Young Children) Regulations, 1998 (S.I. No. 241 of 1998), are hereby revoked.

(2) References in any other instrument to the Regulations revoked under paragraph (1) shall be construed as references to these Regulations, as appropriate.

Schedule

Form of official certificate to be given by an approved examiner to an authorised officer.

European Communities

(Processed Cereal-Based Foods and Baby Foods for Infants and Young Children) Regulations, 2000

Certificate of Analysis

To (1) .....

(1) Insert the name and address of the person submitting the sample for analysis.

I, the undersigned (2) .....

(2) Insert description (i.e. officer of Health Board etc.)

being the Approved Examiner for the purpose of Regulations 17 and 18 of the above Regulations certify that on

the ..... day of .....20.....

a sample marked (3) .....

(3) Insert particulars of marking (e.g. name, date etc.)
Date .....
Number .....
Weight or Measure (4) .....

(4) This may be left unanswered if the sample cannot be conveniently weighed or measured or the weight or measurement is not material to the result of analysis.

was submitted to me by you and I certify that the sample has been analysed/examined by me or under my direction (5) and as a result I am of the opinion that (6)

(6) Here the approved examiner should specify the result of the analysis having regard to the provision of relevant legislation.

(5) State whether the analysis was carried out by an approved examiner or under his direction by deleting appropriate words ("by me" or "under my direction").

Observations : (7)

(7) Here the approved examiner may insert, at his discretion, his opinion whether the analysis indicates any addition, abstraction, deficiency or the presence of foreign matter or other defect and whether the composition or quality is thereby affected; any physical, chemical or other properties bearing on the composition or quality of the article; whether the article is injurious to health or unfit for human consumption; whether and in what respect a label and description relating to the sample is incorrect or misleading; and he may add any other observations as he may consider relevant.

I further certify that the sample has undergone no change which would affect my opinion/observations expressed above.

Certified by me this ..... day of .....20.....

at (8) .....

(8) Insert the name and address of the laboratory carrying out the analysis/examination.

Name in BLOCK LETTERS ..... Status .....

Signature .....

_____

Official Stamp

NOTES

GIVEN under my official seal this 25th day of May, 2000

L.S.

Micheál Martin

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Minister for Health and Children

Explanatory Note

(*This note is not part of the Instrument and does not purport to be a legal interpretation).*

These Regulations give effect to Commission Directive 96/5/EC of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children as amended by Commission Directive 98/36/EC of 2 June 1998 and Commission Directive 1999/39/EC of 6 May 1999.

These Regulations revoke the European Communities (Processed Cereal-Based Foods and Baby Foods for Infants and Young Children) Regulations, 1998 (S.I. No. 241 of 1998.