Statutory Instrument

S.I. No. 379 of 2002.

European Communities (Foodstuffs Intended for Particular Nutritional Uses) Regulations, 2002

I, Micheal 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) and for the purposes of giving effect 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_t, and Commission Directive 2001/15/EC[4] of 15 February 2001, hereby make the following Regulations:-

PART I Preliminary

1. These Regulations may be cited as the European Communities (Foodstuffs Intended for Particular Nutritional Uses) Regulations, 2002, and, with the exception of Regulation 7(2), they shall come into operation on .....

2. (1) In these Regulations:

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

"approved examiner" for the purposes of these Regulations has the meaning assigned to it by the European Communities (Official Control of Foodstuffs) Regulations 1998 (S.I. No. 85 of 1998);

"authorised officer" means -

(a) an authorised officer appointed under Section 49 of the Act of 1998; or

(b) in relation to the functional area of a health board, a person or a person belonging to a class of persons, authorised by the chief executive officer of the health board concerned to perform the functions of an authorised officer under these Regulations.

"the Authority" means the Food Safety Authority of Ireland, established under Section 9 of the Act of 1998;

"certificate of an approved examiner" means a certificate given by an approved examiner of any test, examination or analysis made under these Regulations;

"controlled item" means

— foodstuff,

— food additives, vitamins, mineral salts, trace elements and other additives intended to be sold as such,

— materials and articles intended to come into contact with foodstuffs;

"the Directive" means Council Directive 89/398/EEC 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 of the European Parliament and of the Council of 19 December 1996 and Directive 1999/41/EC of the European Parliament and of the Council of 7 June 1999 and Commission Directive 2001/15/EC of 15 February 2001;

"foodstuffs for particular nutritional uses" has the meaning assigned to it by Regulation 3(2);

"foodstuff" includes any substance used for food or drink by man, and

(a) any substance which enters into or is used in the composition or preparation of human food.

(b) any substance which enters into or is used in the composition or preparation of any such substance aforesaid, and

(c) chewing gum and products of a similar composition and use

and references to foodstuff include as the context may require, references to a particular food particular foods or a class or classes of food;

"functional area" means

(a) in relation to a health board established under Section 4 of the Health Act, 1970, the functional area of the health board as specified in the Health Boards Regulations, 1970 (S.I. No. 170 of 1970);

(b) in relation to an Area Health Board established by Section 14(1) of the Health (Eastern Regional Health Authority) Act, 1999, the functional area of each Area Health Board as specified in Section 14(4) of the Act of 1999;

"functions" includes powers and duties and references to the performance of functions include references to the exercise of powers and the performance of duties;

"health board" means

(a) a board established under Section 4 of the Health Act, 1970, and/or

(b) an Area Health Board established by Section 14 of the Health (Eastern Regional Health Authority) Act, 1999);

"import" means importation from a country other than a Member State;

"Minister" means the Minister for Health and Children;

"official control of foodstuffs" hereinafter called "control of foodstuffs" means an inspection by authorised officers of the compliance of :-

- foodstuffs,

- food additives, vitamins, mineral salts, trace elements and other additives intended to be sold as such, or

- materials and articles intended to come into contact with food,

with provisions aimed at preventing risks to public health, guaranteeing fair commercial transactions or protecting consumer interests, including provisions on consumer information.

"official laboratory" means -

(a) a laboratory approved in writing by the Minister to analyse any samples of a controlled item taken by an authorised officer for the purposes of these Regulations, or

(b) a laboratory approved in writing by the Chief Executive Officer of a health board with the consent of the Minister to analyse any samples of a controlled item taken by an authorised officer for the purposes of these Regulations;

"place on the market" means —

(a) import,

(b) sell,

(c) offer or expose for sale,

(d) invite the making by a person of an offer to purchase,

(e) distribute free of charge

(f) supply for any of those purposes (whether or not for profit),

and cognate words shall be construed accordingly;

"premises" includes any place, building, aircraft, vehicle, railway wagon, container or vessel or temporary premises at or in or on which any trade, business or activity in connection with the production, preparation, processing, manufacture, exportation, importation, storage, distribution or sale of food is or has been carried on;

"Public Analyst" means an analyst appointed by a health board to carry out the duties of a public analyst for the functional area of the board or an analyst designated by a health board to be a public analyst for its functional area;

"specific Directive" means a Directive adopted pursuant to Article 4 of the Directive for the purposes of setting down specific provisions applicable to the groups of foods for particular nutritional uses listed in Schedule 1 of these Regulations;

(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 as 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 Regulation 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.

PART II General Provisions

3. (1) These Regulations concern foodstuffs intended for particular nutritional uses.

(2) "Foodstuffs for particular nutritional uses" are those foodstuffs which :

(a) are clearly distinguishable from foodstuffs for normal consumption, owing to their special composition or manufacturing process, and

(b) are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability.

(3) A particular nutritional use must fulfil the particular nutritional requirements of :

(a) certain categories of persons whose digestive processes or metabolism are disturbed; or

(b) certain categories of persons who are in a special physiological condition and who are therefore able to obtain special benefit from controlled consumption of certain substances in foodstuffs; or

(c) infants or young children in good health.

4. A person shall not manufacture, produce, process, prepare, distribute, or place on the market foodstuffs intended for particular nutritional uses unless that person complies with the provisions laid down in these Regulations and in the Directive.

5. (1) The nature or composition of the foodstuffs for particular nutritional uses referred to in Regulation 3 must be such that the foodstuffs are appropriate for the particular nutritional use intended;

(2) The foodstuffs for particular nutritional uses referred to in Regulation 3 must also comply with any mandatory provisions applicable to foodstuffs for normal consumption save as regards changes made to them to ensure their conformity with the requirements of Regulation 3;

(3) For the categories of substances added for specific nutritional purposes in foodstuffs for particular nutritional uses listed in the Annex to Commission Directive 2001/15/EC only the chemical substances mentioned under each category may be used in the manufacture of foodstuffs for particular nutritional uses covered by Directive 89/398/EEC, as amended;

(4) The use of those substances referred to at paragraph (3) shall be in conformity with any specific provisions concerning those substances that may be laid down in specific Directives provided for in Article 4(1) of the Directive;

(5) Without prejudice to European Parliament and Council Regulation (EC) No. 258/97[5], other substances added for specific nutritional purposes, not belonging to one of the categories listed in the Annex to Directive 2001/15/EC, may be used in the manufacture of foodstuffs for particular nutritional uses;

(6) The use of nutritional substances in foodstuffs for particular nutritional uses shall result in the manufacture of safe products that fulfil the particular nutritional requirements of the persons for whom they are intended as established by generally accepted scientific data.

6. (1) Purity criteria for substances listed in the Annex to Directive 2001/15/EC, and specified by Community legislation for their use in the manufacture of foodstuffs for purposes other than those covered by Directive 2001/15/EC, shall apply;

(2) For those substances listed in the Annex to Directive 2001/15/EC for which purity criteria are not specified by Community legislation, and until the adoption of such specifications, generally acceptable purity criteria recommended by international bodies shall apply.

7. (1) In relation to the categories of substances added for specific nutritional purposes in foodstuffs for particular nutritional uses listed in the Annex to Commission Directive 2001/15/EC, trade in foodstuffs for particular nutritional uses which comply with paragraphs (3), (4), (5) and (6) of Regulation 5, Regulation 6 and with Regulation 12(3) is permitted from the date of coming into operation of these Regulations;

(2) In relation to the categories of substances added for specific nutritional purposes in foodstuffs for particular nutritional uses listed in the Annex to Commission Directive 2001/15/EC, trade in foodstuffs for particular nutritional uses which do not comply with paragraphs (3), (4), (5) and (6) of Regulation 5, Regulation 6 or with Regulation 12(3) is prohibited with effect from 1 April 2004.

8. (1) Foodstuffs for particular nutritional uses referred to in sub-paragraphs (a) and (b) of Regulation 3(3) may be characterised as 'dietetic' or 'dietary';

(2) Directive 2000/13/EC[6] of the European Parliament and of the Council on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, shall apply to the foodstuffs for particular nutritional uses referred to in Regulation 3, subject to the additional requirements set out below :

(a) the designation under which any such foodstuff is sold shall be accompanied by an indication of its particular nutritional characteristics, save in the case of foodstuffs which fulfil the particular nutritional requirements referred to at Regulation 3(3)(c);

(b) in the case of foodstuffs for particular nutritional uses which fulfil the particular nutritional requirements referred to at Regulation 3(3)(c), the designation under which any such foodstuff is sold shall be accompanied by a reference to the purpose for which it is intended;

(c) in the case of the labelling of foodstuffs for particular nutritional uses for which no specific Directive has been adopted in accordance with Article 4 of the Directive, the labelling of such foodstuffs shall also include :

(i) the particular elements of the qualitative and quantitative composition or the special manufacturing process which gives the foodstuff its particular nutritional characteristics;

(ii) the carbohydrate, protein and fat content per 100 grams or 100 millilitres of the foodstuff as marketed and, where appropriate, per specified quantity of the foodstuff as proposed for consumption;

(iii) the available energy value expressed in kilojoules and kilocalories per 100 grams or 100 millilitres of the foodstuff as marketed and, where appropriate, per specified quantity of the foodstuff as proposed for consumption;

(iv) where the energy value is less than 50 kilojoules (12 kilocalories) per 100 grams or 100 millilitres of the foodstuff as marketed, these particulars may be replaced either by the words 'energy value less than 50 kilojoules (12 kilocalories) per 100 grams' or by the words 'energy value less than 50 kilojoules (12 kilocalories) per 100 millilitres'.

9. (1) The foodstuffs for particular nutritional uses referred to at Regulation 3 shall only be allowed on the retail market in pre-packaged form, and the packaging shall completely cover the foodstuffs;

(2) Without prejudice to paragraph (1), the Minister, after consultation with the Authority, may permit derogations from these provisions for the purposes of the retail trade provided that the foodstuff is accompanied by the particulars provided for in Regulation 8(2) at the time when it is put on sale.

10. (1) The labelling, and the labelling methods used, the presentation and the advertising of the foodstuffs for particular nutritional uses referred to in Regulation 3 must not attribute properties for the prevention, treatment or cure of human disease to such foodstuffs or imply such properties;

(2) Paragraph (1) shall not prevent the dissemination of any useful information or recommendations exclusively intended for persons having qualifications in medicine, nutrition or pharmacy.

11. The following shall be prohibited in the labelling, presentation and advertising of foodstuffs for normal consumption:

(1) the use of the adjectives 'dietetic' or 'dietary', whether alone or in conjunction with other words, to designate these foodstuffs;

(2) all other markings or any presentation likely to give the impression that such foodstuffs referred to in Regulation 3 are involved

12. (1) Where a foodstuff for a particular nutritional use which does not belong to one of the groups listed in Schedule 1 of these Regulations, is to be placed on the market for the first time in Ireland. the manufacturer, or where the foodstuff is manufactured in a third country, the importer, shall notify the Authority before the foodstuff is placed on the market Such notification shall be accompanied by

(a) a model of the label used for the foodstuff;
(b) an indication as to whether or not the foodstuff has been on the market in another Member State and, if so, the name of such Member State and the name of the competent authority which first received a notification pursuant to Article 9 of the Directive;

(2) Where necessary, the Authority may require the manufacturer or, where appropriate, the importer, to produce the scientific work and the data establishing the foodstuff's compliance with paragraphs (2) and (3) of Regulation 3 together with the information provided for in Regulation 8(2)(c)(i). If such work is contained in a readily available publication, a mere reference to this publication shall suffice.

(3) The Authority may require the manufacturer or, where appropriate, the importer, to produce the scientific work and the data establishing the use of substances added for specific nutritional purposes in compliance with Regulation 5(6). If such work is contained in a readily available publication, a mere reference to this publication shall suffice.

13. (1) The Minister, after consultation with the Authority, may by order impose temporary suspensions or restrictions on trade in a foodstuff intended for a particular nutritional use where he has detailed grounds for establishing that the foodstuff,

not belonging to any of the groups listed in Schedule 1, does not comply with paragraphs (2) and (3) of Regulation 3 or endangers human health, albeit freely circulating in one or more of the Member States:

(2) The Minister, after consultation with the Authority, may by order temporarily suspend or restrict the application of the provisions of a specific Directive, where, as a result of new information or of a reassessment of existing information made since the relevant specific Directive was adopted, he has detailed grounds for establishing that foodstuffs intended for particular nutritional uses endanger human health even though they comply with the relevant specific Directive.

PART III Enforcement

14. Control of foodstuffs shall be carried out in accordance with the provisions of these Regulations.

15. These Regulations shall be enforced by the Food Safety Authority of Ireland.

16. 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.

17. (1) Without prejudice to Regulation 16, 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 Regulation 14(1) 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.

18. Without prejudice to Regulations 16 and 17, before the European Communities (Foodstuffs Intended for Particular Nutritional Uses) Regulations, 2002 are added to Schedule 1 of the service contract entered into by a health board and the Authority under the Act of 1998, the powers contained in Regulations 19 to 24 may be exercised by health boards in their functional areas, for the purpose of ensuring compliance with these Regulations.

19. (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 Health (Foods for Particular Nutritional Uses) Regulations, 1991 (S.I. No. 331 of 1991) and holding office as an authorised officer immediately before the coming into operation 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;

(4) For the purpose of ensuring compliance with these Regulations after entry into a service contract by a health board with the Authority, the appointments referred to in paragraphs (1) and (2) shall continue in force.

20. (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 (3), 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 foodstuff 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 foodstuff, label or records found in or on the premises;

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

(d) 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).

(e) seize, remove, detain and or direct the withdrawal from the market of any foodstuff intended for sale for human consumption which is suspected by him to fail to comply with the provisions of these Regulations;

(f) remove and retain the said foodstuff, 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 foodstuff 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 foodstuff.

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

(2) Where an authorised officer has reasonable grounds for believing that a person has contravened any provision of these regulations and so informs such person, the authorised officer may require such person to state his name and address, and, if the authorised officer thinks it necessary, to produce corroborative evidence of his name and address.

(3) 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 (6) authorising such entry;

(4) 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 (6) for a warrant authorising such entry;

(5) An authorised officer, where he or she considers it necessary, may be accompanied by a member of the Garda Síochána when performing any powers conferred on an authorised officer under this Regulation;

(6) 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 foodstuff 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;

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

21. (1) An authorised officer may destroy or otherwise dispose of any foodstuff seized, removed and detained by him or her under Regulation 20(1)(e), with the consent of the owner or person responsible for the foodstuff or upon the granting of an order under paragraph (3).

(2) An authorised officer who has seized, removed and detained any foodstuff under Regulation 20(1)(e) may, on giving notice in writing to the owner or person responsible for the foodstuff apply to a judge of the District Court in whose district court district the foodstuff was seized for an order directing that the foodstuff be destroyed or otherwise disposed of as being a foodstuff which is not in compliance with these Regulations;

(3) A judge of the District Court to whom an application is made under paragraph (2) shall, if satisfied that such foodstuff does not comply with these Regulations order that it be destroyed or otherwise disposed of after such period, not exceeding 14 days, as may be specified in the order, as being a foodstuff which is not in compliance with these Regulations;

22. (1) An authorised officer may, for the purpose of these Regulations, purchase or take without payment a sample of any controlled item.

(2) An authorised officer may for the purpose of taking a sample of a controlled item open any receptacle.

(3) Where an authorised officer purchases or takes without payment, with the intention of of having it analysed by an approved examiner, a sample of a controlled item which is suspected by him to fail to comply with the provisions of any other Regulations applicable to such a controlled item, he may, by notice in writing to the seller, owner or person in apparent charge or control of such item (as the case may be) prohibit the removal of the controlled item except to any place which may be specified in the notice, during such period as may be specified in the notice, but not exceeding fourteen days from the date of the taking of the sample.

(4) Where an authorised officer purchases or takes without payment a sample of a controlled item with the intention of having it analysed by an approved examiner within the meaning of the European Communities (Official Control of Foodstuffs) Regulations, 1998, as amended, in an official laboratory approved under the European Communities (Official Control of Foodstuffs)(Approved Laboratories) Order, 1998 (S.I. No. 95 of 1998), he shall after purchasing or taking the sample forthwith notify the seller, owner or person in apparent charge or control of the controlled item (as the case may be) of his intention of having the sample analysed.

(5) Nothing in this Regulation shall authorise the examination or detention of a controlled item without the consent of an officer of the Revenue Commissioners where the duties of such officer in relation to such item have not been wholly discharged

23. (1) Where a sample of any product, article or substance is supplied pursuant to Regulation 20(1)(g) 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 so supplied;

(2) The authorised officer shall mark, seal and fasten each part in such a manner as its nature will permit, forward one part to an official laboratory where it may be tested, examined or analysed for the purposes of these Regulations by an approved examiner, 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;

(3) 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);

(4) In proceedings for an offence under these Regulations, the result of any test, examination or analysis of or report on a sample of a product, article or substance taken pursuant to these Regulations shall not be adduced unless before the proceedings were instituted the sample was divided as specified in paragraphs (1), (2) and (3) of this Regulation. The part, package or container retained by the authorised officer shall be produced at the hearing.

24. (1) The approved examiner 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;

(2) If the approved examiner finds that any sample analysed by him or her under paragraph (1) is not in compliance with these Regulations the form of certificate set out in Schedule 2 to these Regulations or a certificate in like form shall be used.

(3) 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.

25. Where a sample of a product, article or substance is taken by an authorised officer in pursuance of these Regulations for analysis by the 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 functional area the sample was taken, or the Food Safety Authority of Ireland, and the health board or the Food Safety Authority of Ireland shall comply with such request.

26. (1) A person who fails to comply with these Regulations shall be guilty of an offence;

(2) For the purposes of these Regulations, every contravention of a Regulation shall be deemed a separate contravention and every contravention of a paragraph shall also be deemed to be a separate contravention and shall carry the same penalty as for a single contravention of any Regulation of these Regulations;

(3) A person who falsely represents himself to be an authorised officer shall be guilty of an offence;

(4) A person who -

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

(b) fails or refuses to state his name or address in compliance with a requirement under these Regulations, or

(c) fails to comply with a request from an authorised officer under these Regulations, or

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

(e) gives in purported compliance with a requirement under these Regulations a name, an address or corroborative evidence which is false or misleading

shall be guilty of an offence

(5) A person who is guilty of an offence under these Regulations shall be liable on summary conviction to a fine not exceeding €1,900 or at the discretion of the Court to imprisonment for a term not exceeding six months, or both.

27. 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 or default 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.

28. An offence under these Regulations may be prosecuted by -

(1) the Food Safety Authority of Ireland, or

(2) a health board within whose functional area the offence was committed.

29. (1) Any person who forges, or utters knowing it to be forged, a certificate or other document purporting to be issued, granted or given under these Regulations (hereafter in this Regulation referred to as "a forged document"), is guilty of an offence;

(2) Any person who alters with intent to defraud or deceive, or who utters knowing it to be so altered, a certificate or other document issued, granted or

given under these Regulations (hereafter in this Regulation referred to as "an altered document"), is guilty of an offence;

(3) Any person who, without lawful authority, has in his or her possession a forged document or an altered document is guilty of an offence:

(4) Any person who, with intent to defraud or deceive -

(a) tampers with any thing so as to procure that any sample taken pursuant to these Regulations does not correctly represent the substance sampled, or

(b) tampers or interferes with any sample taken under these Regulations.

is guilty of an offence

30. (1) A notice or other document under these Regulations shall, subject to paragraph (2), be addressed to the person concerned by name, and may be served on or given to the person in one of the following ways:

(a) by delivering it to the person,

(b) by leaving it at the address at which the person ordinarily resides or, in a case in which an address for service has been furnished, at that address,

(c) by sending it by post in a prepaid registered letter to the address at which the person ordinarily resides or, in a case in which an address for service has been furnished, to that address,

(d) where the address at which the person ordinarily resides cannot be ascertained by reasonable inquiry and the notice, direction or other document relates to land, by delivering it to some person over 16 years of age resident or employed on the land or by affixing it in a conspicuous position on or near the land;

(2) It shall not be lawful for a person at any time during the period of 12 months after a direction or other document is affixed under sub-paragraph (d) of paragraph (1) to remove, damage or deface the notice, direction or other document without lawful authority;

(3) For the purposes of this Regulation, a company within the meaning of the Companies Acts. 1963 to 1999, shall be deemed to be ordinarily resident at its registered office, and every other body corporate and every unincorporated body shall be deemed to be ordinarily resident at its principal office or place of business.

31. (1) The Health (Foods for Particular Nutritional Uses) Regulations, 1991 (S.I. No. 331 of 1991) 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 1

Annex I of Council Directive 89/398/EEC as amended by Directive 1999/41/EC

- Groups of foodstuffs for particular nutritional uses for which specific provisions will be laid down by specific Directives

1. Infant formulae and follow-on formulae

2. Processed cereal-based foods and baby foods for infants and young children

3. Food intended for use in energy-restricted diets for weight reduction

4. Dietary foods for special medical purposes

5. Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen;

- Groups of foodstuffs for particular nutritional uses for which specific provisions will be laid down by a specific Directive dependant on the outcome of the procedure described in Article 4(b) of the Directive:

6. Foods for persons suffering from carbohydrate-metabolism disorders (diabetes).

Schedule 2

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

European Communities (Foodstuffs Intended for Particular Nutritional Uses) Regulations, 2002

Certificate of Analysis

To (1) .....

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

being the Approved Examiner for the purpose of Regulations 23 and 24 of the above Regulations certify that on

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

a sample marked (3) .....

Date .....

Number .....

Weight or Measure (4) .....

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)

Observations: (7)

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

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

at (8) .....

Name in BLOCK LETTERS .....

Status .....

Signature .....

_____

Official Stamp

NOTES

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

(2) Insert description (i.e. officer of health board etc.).

(3) Insert particulars of marking (e.g. name, date etc.).

(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.

(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").

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

(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.

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

Given under the Official Seal of the Minister for Health and Children this 23rd day of July, 2002.

Micheal Martin. T.D.

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 revoke The Health (Foods for Particular Nutritional Uses) Regulations, 1991 (S.I. No. 331 of 1991) and bring into effect new Regulations. The new Regulations give effect 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 as amended by Directive 96/84/EC of the European Parliament and of the Council of 19 December 1996, and Directive 1999/41/EC of the European Parliament and of the Council of 7 June 1999, and to Commission Directive 2001/15/EC of 15 February 2001 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses.

These Regulations, may be cited as the European Communities (Foodstuffs for Particular Nutritional Uses) Regulations, 2002, come into effect from the date they are signed by the Minister.