Statutory Instrument

S.I. No. 64 of 2001

European Communities (Dietary Foods for Special Medical Purposes) Regulations, 2001

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 purposes of giving effect to Commission Directive 1999/21/EC[4] of 25 March 1999 on dietary foods for special medical purposes, as amended by Corrigendum[5] of 5 January 2000, hereby make the following Regulations :

[5] OJ L 2, 5.1.2000, p. 79

[4] OJ L 91, 7.4.1999 p. 29

[3] OJ L 172, 8.7.1999 p. 38

[2] OJ L 48, 19.2.1997, p. 20

[1] OJ L 186, 30.6.1989, p. 27

PART I Preliminary

1. These Regulations may be cited as the European Communities (Dietary Foods for Special Medical Purposes) Regulations, 2001.

2. (1) In these Regulations -

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

"Annex" means the Annex to the Directive;

"approved examiner" 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,

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

(c) a member of the Garda Síochána;

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

"dietary foods for special medical purposes" means a category of foods for particular nutritional uses specifically processed or formulated and intended for the dietary management of patients and to be used under medical supervision. They are intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for particular nutritional uses, or by a combination of the two;

"the Directive" means Commission Directive 1999/21/EC of 25 March, 1999 on dietary foods for special medical purposes;

"Food Safety Authority" means the Food Safety Authority of Ireland established under section 9 of the Food Safety Authority of Ireland Act, 1998 (No. 29 of 1998);

"Foodstuff" means 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 the functional area of the health board as specified in the Health Board Regulations, 1970 (S.I. No. 170 of 1970);

(b) in relation to the Eastern Regional Health Authority, means its functional area as specified in section 7(4) of the Health (Eastern Regional Health Authority) Act, 1999 (No. 13 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;

"infants" means children under the age of 12 months;

"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,

- 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, or

(f) supply for any of those purposes,

and cognate words shall be construed accordingly;

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

(2) A word or expression which is used in these Regulations and which 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. Dietary foods for special medical purposes may be placed on the market only if they comply with the provisions laid down in these Regulations and the Directive.

4. Dietary foods for special medical purposes are classified in the following three categories :

(1) nutritionally complete foods with a standard nutrient formulation which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended;

(2) nutritionally complete foods with nutrient-adapted formulation specific for a disease, disorder or medical condition which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended;

(3) nutritionally incomplete foods with a standard formulation or a nutrient-adapted formulation specific for a disease, disorder or medical condition which are not suitable to be used as the sole source of nourishment.

The foods referred to in paragraphs (1) and (2) may also be used as a partial replacement or as a supplement to the patient's diet.

5. (1) The formulation of dietary foods for special medical purposes shall be based on sound medical and nutritional principles;

(2) The use of dietary foods for special medical purposes shall be safe and beneficial and effective in meeting the particular nutritional requirements of the persons for whom they are intended, as demonstrated by generally accepted scientific data and, subject to the provisions of this paragraph, shall be in accordance with the manufacturer's instructions;

(3) Dietary foods for special medical purposes must comply with the compositional criteria specified in the Annex to the Directive.

6. The name under which dietary foods for special medical purposes are to be sold shall be "Food(s) for special medical purposes". The information required to be given by these Regulations shall be given in the English language (unless other measures have been taken to ensure that the purchaser is informed) and may, in addition, be given in the Irish language or any other language.

7. The labelling of dietary foods for special medical purposes shall comply with the particulars referred to in Article 3 of Directive 79/112/EEC[6] and shall bear the following mandatory particulars, which must be conspicuous, clearly legible and indelible :

[6] OJ L33, 8.2.1979, p.1

(1) the available energy value expressed in kJ and kcal, and the content of protein, carbohydrate and fat, expressed in numerical form, per 100 g or per 100 ml of the product as sold and where appropriate per 100 g or per 100 ml of the product ready for use in accordance with the manufacturer's instructions. This information may be in addition be provided per serving as quantified on the label or per portion, provided that the number of portions contained in the package is stated;

(2) the average quantity of each mineral substance and each vitamin mentioned in the Annex present in the product, expressed in numerical form per 100 g or per 100 ml of the product as sold and where appropriate 100 g or 100 ml of the product ready for use in accordance with the manufacturer's instructions. This information may in addition be provided per serving as quantified on the label or per portion, provided that the number of portions contained in the package is stated;

(3) selectively the content of components of protein, carbohydrate and fat and/or of other nutrients and their components the declaration of which would be necessary for the appropriate intended use of the product, expressed in numerical form, per 100 g or per 100 ml of the product as sold and where appropriate per 100 g or per 100 ml of the product ready for use in accordance with the manufacturer's instructions. This information may in addition be provided per serving as quantified on the label or per portion, provided that the number of portions contained in the package is stated;

(4) information on the osmolality or the osmolarity of the product where appropriate;

(5) information on the origin and the nature of the protein and/or protein hydrolysates contained in the product.

8. The labelling shall in addition bear the following mandatory particulars, preceded by the words 'important notice' or their equivalent :

(1) a statement that the product must be used under medical supervision;

(2) statement as to whether the product is suitable for use as the sole source of nourishment ;

(3) a statement that the product is intended for a specific age group, as appropriate;

(4) where appropriate a statement that the product poses a health hazard when consumed by persons who do not have the diseases, disorders or medical conditions for which the product is intended.

9. The labelling of dietary foods for special medical purposes shall also include :

(1) The statement 'For the dietary management of ....' where the blank shall be filled in with the diseases, disorders or medical conditions for which the product is intended, as the case may be;

(2) where appropriate a statement concerning adequate precautions and contra-indications;

(3) a description of the properties and/or characteristics that make the product useful in particular, as the case may be, relating to the nutrients which have been increased, reduced, eliminated or otherwise modified and the rationale of the use of the product;

(4) where appropriate, a warning that the product is not for parenteral use.

10. The labelling of dietary foods for special medical purposes shall bear instructions for the appropriate preparation, the use and the storage of the product after the opening of the container, as appropriate.

11. When a dietary food for special medical purposes is placed on the market for the first time in Ireland, the manufacturer, or where a product is manufactured in a third country, the importer, shall notify the Food Safety Authority within seven days of the product being placed on the market of such placement. Such notification shall be accompanied by :

(1) a model of the label to be used for the product;

(2) a statement as to whether or not the product has been placed on the market in any other Member State, and, if so, the name of such Member State or States and the name of the recipients of the notifications of such placement;

(3) any other information the Food Safety Authority may require for the purpose of establishing compliance with these Regulations.

PART III Enforcement

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

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

14. 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.

15. (1) Without prejudice to Regulation 14, 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.

16. Without prejudice to Regulations 13, 14 and 15, before the European Communities (Dietary Foods for Special Medical Purposes) Regulations, 2001 are added to Schedule 1 of the service contract entered into by a health board or the Eastern Regional Health Authority, and the Food Safety Authority under the Act of 1998, the powers contained in Regulations 17 to 21 may be exercised by an authorised officer appointed under Regulation 17 for the purpose of ensuring compliance with these Regulations.

17. (1) The chief executive officer of a health board and the Regional Chief Executive of the Eastern Regional Health Authority 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) An authorised officer shall be furnished with a certificate of his or her 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;

(3) For the purposes of ensuring compliance with these Regulations, after entering into a service contract between the Food Safety Authority and a health board and/or the Eastern Regional Health Authority, the appointments referred to in paragraph (1) shall continue in force.

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

(a) 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 dietary foods for special medical purposes 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 dietary foods for special medical purposes, foodstuff, label or records found in or on the premises,

(b) 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,

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

(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) seize and detain any product which fails to comply with these Regulations or the Directive which he or she has reason to believe is unfit for human consumption,

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

(h) 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 foodstuff or the article or substance, to supply without payment, for test, examination or analysis sufficient samples thereof,

(i) 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,

(j) require a person referred to in subparagraph (b) 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,

(k) require any person referred to in subparagraph (b) by or on whose behalf data equipment is or has been used in relation to a business within the meaning of subparagraph (a) 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 in connection with such business,

(l) 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,

(m) examine any procedure connected with the manufacture of a product referred to in this Regulation, and

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

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

(5) In this Regulation "premises" means any place, ship or other vessel, aircraft, railway wagon or other vehicle, and includes a container used to transport foodstuffs.

(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 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 or members 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.

19. (1) An authorised officer may destroy or otherwise dispose of any product seized and detained by him or her under paragraph 1(f) of Regulation 18, with the consent of the owner or person responsible for the product or upon the granting of an order under paragraph (3).

(2) An authorised officer who has seized and detained any product under paragraph 1(f) of Regulation 18 may, on giving notice in writing to the owner or person responsible for the product apply to a judge of the District Court in whose district court district the product was seized for an order directing that the product be destroyed or otherwise disposed of as being a foodstuff or a dietary food for special medical purposes which is unfit for human consumption.

(3) A judge of the District Court to whom an application is made under paragraph (2) shall, if satisfied that such product does not comply with these

Regulations or the Directive and is unfit for human consumption, 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 or a dietary food for special medical purposes which is unfit for human consumption.

20. (1) Where a sample of any product, article or substance is supplied pursuant to paragraph (1)(h) of Regulation 18 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 or she 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 referred to in paragraph (1) 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, 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 is supplied with a sample consisting of a product, article or substance which is 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 provisions 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).

21. (1) The approved examiner or a person under his or her direction shall analyse as soon as possible any sample of a product, article or substance submitted to him or her in pursuance of these Regulations and the approved examiner shall certify to the person who submitted the sample to him or her the result of such analysis;

(2) If the approved examiner finds that any sample analysed by him or her under paragraph (1) is diseased, contaminated or otherwise unfit for human consumption he or she should set out his or her findings in the form of certificate set out in the Schedule to these Regulations or a certificate in like form;

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

22. 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 Eastern

Regional Health Authority or the health board in whose area the sample was taken and the Eastern Regional Health Authority or the health board shall comply with such request.

23. (1) A person who fails to comply with these Regulations (other than Regulations 18(2), 19, 20, 21, or 22) is guilty of an offence.

(2) A person who falsely represents himself or herself to be an authorised officer is 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 18,

(b) fails to comply with a request from an authorised officer under Regulation 18, or

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

is guilty of an offence.

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

24. 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 is also guilty of an offence and shall be liable to be proceeded against and punished as if he or she were guilty of the same offence.

25. (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.

26. (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.

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

(1) the health board, within whose functional area the offence was committed, or

(2) the Eastern Regional Health Authority, within whose functional area the offence was committed, or

(3) the Food Safety Authority of Ireland.

Schedule

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

European Communities (Dietary Foods for Special Medical Purposes) Regulations, 2001

Certificate of Analysis

To (1).....

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

being the Approved Examiner for the purpose of Regulations 21 and 22 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 affect 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 provision 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 my official seal this 1st. Day of March, 2001

Micheál Martin

Minister for Health and Children

Explanatory Note

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

These Regulations give effect to Council Directive 89/398/EEC of the Council 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 for the purposes of giving effect to Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes, as amended by Corrigendum of 5 January 2000.

The effect of these Regulations is to lay down compositional and labelling requirements, and general provisions for the sale in Ireland of dietary foods for special medical purposes.

These Regulations should be read together with the Directive.