S.I. No. 85/1998 — European Communities (Official Control of Foodstuffs) Regulations, 1998

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S.I. No. 85 of 1998.

EUROPEAN COMMUNITIES (OFFICIAL CONTROL OF FOODSTUFFS) REGULATIONS, 1998

I, BRIAN COWEN, 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) hereby make the following Regulations for the purpose of giving full effect to Council Directive 89/397/EEC[1] on the official control of foodstuffs and Council Directive 93/99/EEC[2] on the subject of additional measures concerning the official control of foodstuffs.

[1] OJ No. L186,30.6.1989, p.23

[2] OJ No. L290, 24.11.1993, p.14

Title, Commencement and Interpretation

1. These Regulations may be cited as the European Communities (Official Control of Foodstuffs) Regulations, 1998.

2. With the exception of Article 21, these Regulations shall come into operation on the first day of April, 1998. Article 21 of these Regulations shall come into operation on the first day of November, 1998.

3. (1) In these Regulations :

"Authorised Officer" means—

(*a*) an officer of the Minister who is authorised in writing by the Minister to be an authorised officer for the purposes of these Regulations; or

(*b*) an officer of a health board or of a local authority who is authorised in writing by the Chief Executive Officer of the health board to be an authorised officer for the purposes of these Regulations;

"Approved examiner" means a public analyst, or any person approved, or person of a class approved by the Minister to analyse a controlled item for the purposes of these Regulations;

"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;

"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;

"Health Board" means a health board established under Section 4 (1) of the Health Act, 1970 (No. 1 of 1970);

"Member State" means a Member State of the European Community;

"The Minister" means the Minister for Health and Children;

"Official Control of Foodstuffs" hereinafter called "control" 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;

"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) Any reference in these Regulations to a seller, owner or to a person in apparent charge or control of a controlled item shall in the case of a sample purchased from a vending machine be construed as a reference:

(*a*) where the name and address of such proprietor is stated on the machine and such address is in the State, to the proprietor of the machine;

(*b*) in other cases, to the occupier of the premises at or on which the machine stands or to which it is affixed.

(3) A word or expression that is used in these Regulations and is also used in Council Directives 89/397/EEC and 93/99/EEC has, unless the contrary intention appears, the meaning in these Regulations that it has in the Council Directives.

4. These Regulations shall have effect for the purposes of the Official Control of Foodstuffs.

5. (1) These Regulations shall be enforced and executed by health boards in their functional areas.

(2) Health boards shall:

(*a*) ensure that controlled items intended for consignment to another Member State are inspected with the same care as those intended for marketing in this country, and

(*b*) shall not exclude a controlled item from appropriate control on the grounds that it is intended for export outside the European Communities.

Control

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

7. Control shall comprise one or more of the following operations in accordance with the conditions laid down in Articles 8 to 10 and in the light of the examinations to be carried out:

(*a*) inspection;

(*b*) sampling and analysis;

(*c*) inspection of staff hygiene;

(*d*) examination of written and documentary material;

(*e*) examination of any verification systems set up by the undertaking and of the results obtained.

Inspection

8. (1) The following may be subject to inspection by an authorised officer in the enforcement and execution of these Regulations:

(*a*) the state and use which is made at the different stages enumerated in Article 9 (3) of the site, premises, offices, plant and plant surroundings, means of transport, machinery and equipment;

(*b*) raw materials, ingredients, technological aids and other products used for the preparation and production of foodstuffs;

(*c*) semi-finished products;

(*d*) finished products;

(*e*) materials and articles intended to come into contact with foodstuffs;

(*f*) cleaning and maintenance products and processes and pesticides;

(*g*) processes used for the manufacture or processing of foodstuffs;

(*h*) labelling and presentation of foodstuffs;

(*i*) preserving methods.

(2) The operations enumerated in sub-article (1) of this Article may where necessary be supplemented by:

(*a*) interviews with the head of the inspected undertaking and with persons working for that undertaking;

(*b*) the reading of values recorded by measuring instruments installed by the undertaking;

(*c*) inspections carried out by the health board, with its own instruments, of measurements taken with the instruments installed by the undertaking.

9. (1) Inspections shall be carried out:

(*a*) regularly and/or

(*b*) where non-compliance is suspected.

(2) Inspections shall be carried out using means proportionate to the end to be observed.

(3) Inspection shall cover all stages of production, manufacture, import, processing, storage, transport, distribution and trade.

(4) As a general rule, inspections shall be carried out without prior warning.

(5) The health board shall, in each case, select the stage or stages which it considers the

most appropriate for its examination from those listed in sub-article (3) of this Article.

10. (1) Persons who, in the exercise of their activity come into contact, whether directly or indirectly, with the materials and products referred to in sub-articles 8(1)(*b*) to (*f*) shall be subject to the hygiene inspection referred to in Article 7(*c*).

(2) The inspection referred to in sub-article (1) of this Article shall be carried out for the purpose of checking that the health standards concerning personal cleanliness and clothing are respected. Performance of this inspection shall be without prejudice to medical examinations.

Powers of Entry

11. In exercising his powers under Articles 6 to 10 of these Regulations an authorised officer may, at all reasonable times, enter—

(*a*) any premises in which he has reasonable grounds for believing that any controlled item is being produced, manufactured, imported, processed, stored, transported, distributed or traded;

(*b*) any railway wagon, vehicle, ship, vessel, aircraft or container in which he has reasonable grounds for believing that a controlled item is being transported for sale;

and there or at any other place carry out any or all of the following :

(i) interview the head of the undertaking or any person working for that undertaking;

(ii) take note of written and documentary material held by the natural and legal persons at the various stages enumerated in Article 9(3) above;

(iii) inspect and take copies of, or extracts from, any books, records, computerised data or other information submitted to him for examination;

(iv) take the reading of values recorded by measuring instruments installed by the undertaking;

(v) inspect with his own instruments measurements taken with the instruments installed by the undertaking;

(vi) make such other examinations, tests and inspections including the opening of any receptacle as may be necessary.

Sampling

12. (1) An authorised officer may, for the purposes 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 having it analysed by an approved examiner, a sample of a controlled item which is suspected by him—

(*a*) to be diseased, contaminated or otherwise unfit for human consumption, and/or

(*b*) 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 in an official laboratory, 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 Article 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.

13. (1) Where a sample of a controlled item is taken pursuant to these Regulations 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 the approved examiner in an official laboratory for analysis, give or send one part to the seller, owner or person in

apparent charge or control of the controlled item (as the case may be) and retain the third part.

(2) Where an authorised officer takes a sample consisting of a controlled item 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 sub-article (1) of this Article 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 sub-article (1) of this Article.

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

14. (1) The approved examiner or a person under his direction shall analyse as soon as possible any sample of a controlled item 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 sub-article (1) of this Article shall be *prima facie* evidence of the matters contained therein until the contrary is proved.

15. Where a sample of a controlled item 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 (as the case may be) requests in writing the results of such analysis, the following shall apply :

(*a*) Where the authorised officer is an officer of a health board or of a local authority 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.

(*b*) Where the authorised officer is an officer of the Minister, the request shall be made to the Minister who shall comply with such request.

Suspension of Business

16. (1) Whenever a chief executive officer of a health board has evidence that there is a grave and immediate danger that a foodstuff or foodstuffs intended for sale for human consumption may become so diseased, contaminated or otherwise unfit for human consumption as to be liable to cause serious illness if consumed, he may apply to the Justice of the District Court for a Closure Order prohibiting the operation of the food business and on such application such Justice may, as he thinks fit, grant, or refuse to grant, such an Order.

(2) A chief executive officer of a health board shall cause written notice of his intention to seek a Closure Order against a food business to be given to the proprietor of the said business before the date of the court hearing.

(3) A proprietor of a food business in respect of which a Closure Order is enforced may, at any time, apply to the Justice of the District Court for an annulment of the Closure Order and such District Justice may, as he thinks fit, confirm or annul the Closure Order.

(4) No person shall carry on a food business in respect of which an Order under this article is for the time being in force.

Enforcement

17. (1) An authorised officer may seize, remove, detain and/or direct the withdrawal from the market of any controlled item intended for sale for human consumption which is—

(*a*) suspected by him to be diseased, contaminated or otherwise unfit for human consumption, and/or

(*b*) suspected by him to fail to comply with the provisions of any other Regulations applicable to such a controlled item.

(2) With the consent in writing of the owner or person in apparent charge or control of such controlled item, or in accordance with an order of a Justice of the District Court under sub-article (4) of this Article destroy or otherwise dispose of same as to prevent it being used for human consumption.

(3) An authorised officer who has seized a controlled item in pursuance of the provisions of this Article may, on giving notice in writing to the owner or person responsible for such item of his intention to do so, apply to a Judge of the District Court

for an order directing that such item be destroyed or otherwise disposed of.

(4) A Judge of the District Court to whom the application is made for an order under sub-article (3) may, if satisfied that such item—

(*a*) is diseased, contaminated or otherwise unfit for human consumption, and/or

(*b*) fails to comply with the provisions of any other Regulations applicable to such a controlled item,

order that it be destroyed or otherwise disposed of after such period, not exceeding fourteen days, as may be specified in such order, and an authorised officer shall destroy or dispose of it accordingly.

18. (1) A person shall not wilfully obstruct or interfere with the exercise of a power by a person duly exercising such power as is specified in these Regulations.

(2) A person in charge of premises or of a railway wagon, vehicle, ship, vessel, aircraft or container shall—

(*a*) afford to an authorised officer such facilities and assistance as are reasonably necessary to enable the officer to perform his functions under these Regulations,

(*b*) produce to an authorised officer any books, documents, computerised data, written material as to verification systems or other records which he may reasonably require,

(*c*) give to an authorised officer any information which he may reasonably require regarding—

(i) any controlled item on the premises or in a wagon, vehicle, ship, vessel or aircraft,

(ii) any books, documents, computerised data, written material as to verification systems or other records produced to him pursuant to these Regulations,

(iii) the composition and use of any controlled item and the identity of the person from whom or the place from which any such controlled item was obtained and the person to whom and the place to which it was consigned or otherwise disposed of.

19. (1) 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.

(2) An authorised officer may require a member of the Garda Siochana to assist him in the exercise of any power conferred on him by these Regulations which involves the detention of any person, the bringing of any person to any place, the breaking open of any premises or any other action in which the use of force may be necessary and is lawful, and any member of the Garda Siochana so required shall comply with the requirement.

(3) A person who—

(*a*) fails or refuses to state his name or address in compliance with a requirement under this Article, or

(*b*) gives in purported compliance with a requirement under this Article a name, an address or corroborative evidence which is false or misleading

shall be guilty of an offence under this Article.

20. A person who has gained access to information by virtue of inspections made in the enforcement of Regulations shall not disclose such information unless it is necessary to do so for the purpose of the enforcement of these Regulations. Any person who contravenes this paragraph shall be guilty of an offence under this Article.

Official Laboratories

21. (1) All official laboratories shall comply with the general criteria for the operation of testing laboratories laid down in European Standard EN 45001 supplemented by standard operating procedures and the random audit of their compliance by quality assurance personnel, in accordance with the OECD principles No. 2 and 7 of good laboratory practice as set out in Section II of Annex 2 to the Decision of the Council of the OECD of 12 May, 1981 concerning the mutual acceptance of data in the assessment of chemicals.

(2) The Minister shall by Order, designate a body or bodies for the assessment of official laboratories. These bodies shall comply with the general criteria for laboratory accreditation bodies laid down in European Standard EN 45003.

(3) In assessing the official laboratories the designated body or bodies shall:

(*a*) apply the criteria laid down in European Standard EN 45002; and

(*b*) require the use of proficiency testing schemes as far as appropriate.

Laboratories meeting the assessment criteria shall be presumed to fulfil the criteria referred to in paragraph (1) of this Article.

Laboratories which do not meet the assessment criteria shall not be considered as official laboratories.

(4) The accreditation and assessment of testing laboratories referred to in this Article may relate to individual tests or groups of tests.

22. The validation of methods of analysis used within the context of official control of foodstuffs by the official laboratories shall comply whenever possible with the provisions of paragraphs 1 and 2 of the Annex to Council Directive 85/591/EEC[3] concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption.

[3]OJ No. L372, 31.12.1985, p.50

Cooperation and Assistance

23. (1) The health boards shall co-operate with the officials designated by the Commission of the European Union in accordance with Article 5 of Council Directive 93/99/EEC and shall give all the necessary assistance to enable them to accomplish their tasks.

(2) The health boards shall permit the officials designated by the Commission of the European Union in accordance with paragraph (1) of this Article to accompany the authorised officers, as defined in Article 3(1) of these Regulations, while carrying out the controls specified in Article 7 of these Regulations.

(3) The officials designated by the Commission of the European Union may, for the purposes of ensuring compliance with Directive 93/99/EEC and while accompanied by an authorised officer as defined in Article 3(1) of these Regulations, enter

(*a*) any premises in which there is reasonable grounds for believing that a controlled item is being produced, manufactured, imported, processed, stored, transported, distributed or traded;

(*b*) any railway wagon, vehicle, ship, vessel, aircraft or container in which there is reasonable grounds for believing that a controlled item is being transported for sale.

24. (1) The health boards shall afford each other, and in the case of other Member States, to the authorities of those Member States designated as competent authorities for the purposes of Council Directive 89/397/EEC and Council Directive 93/99/EEC, administrative assistance in all supervisory procedures in connection with legal provisions and quality standards applicable to foodstuffs and in all proceedings for infringements of the law applicable to foodstuffs.

(2) For the purpose of assistance to other Member States as required by this Article, the Department of Health and Children shall be the liaison body.

(3) Upon receiving a reasoned request, the health board concerned shall be responsible for ensuring that the requesting body is provided with all necessary information, except that which cannot be released because it is the subject of legal proceedings, enabling that requesting body to guarantee compliance with legal provisions and quality standards applicable to foodstuffs within its jurisdiction.

(4) The information and documents provided pursuant to paragraph (3) of this Article shall be forwarded without undue delay either through the Department of Health and Children or directly, as appropriate. When original documents cannot be sent, copies of the documents may be transmitted.

(5) When, during the exchange of information, it becomes clear that there may have been a case of non-compliance with Community laws or rules or with national law, the health board in whose functional area the alleged non-compliance has taken place shall, in due time, report back to the competent authority in the receiving or sending Member State, as appropriate

— on any action that may have been undertaken to deal with the alleged non-compliance, and also

— on any action which it has taken, including any action to try to prevent a re-occurrence of the alleged non-compliance.

Such a report may also be copied to the Commission of the European Union on the initiative of either the health board or of the competent authority in the other Member State.

(6) This Article shall apply without prejudice to Council Decision 89/45/EEC[4] on dangers arising from the use of consumer products and to Council Directive

92/59/EEC[5] on general product safety.

[4] OJ No. L17, 21.1.1989, p.51, as amended by Decision 90/352/EEC (OJ No. L173, 6.7.1990, p.49)

[5] OJ No. L228, 11.8.1992, p. 24

25. (1) Information forwarded pursuant to Article 24 of these Regulations, in whatever form, is covered by professional secrecy. In criminal proceedings taken in this jurisdiction, the information can be used only with the prior consent of the competent authority of the sending Member State in accordance with, for those Member States who are parties to them, the international conventions and agreements in force on mutual assistance in criminal affairs between Ireland and that sending Member State.

(2) Where a Member State requesting information in accordance with Article 24 of these Regulations has rules permitting free access by persons to information held by competent authorities, it shall reveal this fact at the time of the request to the appropriate authorities in Ireland or during the exchange of information if no such request occurs.

If the competent authority in the sending Member State indicates that the information involves matters of professional or commercial secrecy, the health board shall ensure that the information it has received is not divulged more widely than is provided under paragraph (1) of this Article.

Any health board which is requested to provide information in accordance with Article 24 to a competent authority in another Member State shall not be in a contravention of these Regulations for withholding the information if the competent authority in the other Member State is unable to restrict the giving out of the information to an extent more widely than is provided for in paragraph (1) of this Article.

(3) Any refusal by the health board to provide information according to the provisions of this Article must be justified.

Offences

26. (1) Any person who contravenes any article or sub-article of these Regulations shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding £1,000 or at the discretion of the Court, to imprisonment for a term not exceeding 6 months or to both.

(2) Where an offence under these Regulations is committed by a body corporate and the

offence is proved to have been committed with the consent or connivance of, or to be attributed to any neglect on the part of any director, secretary or other similar officer of the body, or other person who was purporting to act in any such capacity, he, as well as the body, shall be guilty of the offence.

(3) Notwithstanding Section 10(4) of the Petty Sessions (Ireland) Act, 1851, proceedings for an offence under these Regulations may be instituted within twelve months from the date of the offence or any time within twelve months from the date on which knowledge of the commission of the offence came to the attention of an authorised officer.

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

(*a*) the Minister, or

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

28. (1) 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 by these Regulations shall, if so requested by a person affected, produce the certificate for the inspection of the person.

(2) It shall be offence for a person falsely to represent himself to be an authorised officer.

29. A health board shall

(*a*) forward to the Minister such information as he may request in respect of the exercise of the functions conferred on it by or under these Regulations;

(*b*) comply with any directions given by the Minister from time to time as the exercise of its powers or the performance of its functions and duties under these Regulations.

Revocation

30. (1) The Health (Official Control of Food) Regulations, 1996 (S.I. No. 241 of 1996) are hereby revoked.

(2) References in another instrument to any of the Regulations revoked under sub-article (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 (Official Control of Foodstuffs) Regulations, 1998.

Certificate of Approved Examiner

To (1) ....

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

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

the ..... day of ..... 19 ....

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 ..... 19 ....

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 Minister for Health and Children / 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 the Official Seal of the Minister for Health and Children, this 31st day of March, 1998.

BRIAN COWEN,

Minister for Health and Children.

EXPLANATORY NOTE.

These Regulations are to be implemented by health boards in their functional areas. They set out the various items which are subject to inspection including the site, premises, offices, raw materials, semi-finished products, cleaners and materials coming into contact with foodstuffs.

These Regulations give full effect to Council Directive 89/397/EEC on the Official Control of Foodstuffs and Council Directive 93/99/EEC on the subject of Additional Measures Concerning the Official Control of Foodstuffs. The Regulations come into effect on 1 April, 1998, except for Article 21 which comes into effect on 1 November, 1998.
