S.I. No. 241 of 1996.
HEALTH (OFFICIAL CONTROL OF FOOD) REGULATIONS, 1996

The Minister for Health, in exercise of the powers conferred on him by sections 5 of the Health Act, 1947 (No. 28 of 1947), section 54 of that Act as amended by the European Communities (Health Act, 1947 Amendment of sections 54 and 61) Regulations, 1991, subsection (3) of section 38 of the Health Act, 1953 (No. 26 of 1953) and section 6 of the Health Act, 1970 (No. 1 of 1970), after consultation with the Minister for Enterprise and Employment and the Minister for Agriculture, Food and Forestry, hereby makes the following Regulations for the purpose of giving effect to Council Directive 89/397/EEC1 on the official control of foodstuffs and Council Directive 93/99/EEC2 on the subject of additional measures concerning the official control of foodstuffs.

1OJ No. L186, 30.6.1989, p.23

2OJ No. L290, 24.11.1993, p.l4

1. These Regulations may be cited as the Health (Official Control of Food) Regulations, 1996.

2. With the exception of Article 17, these Regulations shall come into operation on the first day of September, 1996. Article 17 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 food for the purpose of Regulations made under Part V of the Health Act, 1947;
"Certificate of an approved examiner" means a certificate given by an approved examiner of any test, examination or analysis made under these Regulations;
"The Minister" means the Minister for Health;
"Official Control of Food" hereinafter called "control" means an inspection by health boards through their authorised officers of the compliance of
– food,
– 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 and the sale to the prejudice of the purchaser of any food which is not of the nature, substance or quality demanded by the purchaser;
"Official laboratory" means –

(a) a laboratory approved in writing by the Minister to analyse any samples of food 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 food 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;
"Member State" means a Member State of the European Community.

(2) Any reference in these Regulations to a seller, owner or to a person in apparent charge or control of food 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.

4. These Regulations shall have effect for the purposes of any Regulations for the time being in force under Part V of the Health Act, 1947.

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

(2) Health boards shall:

(a) ensure that products 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 product from appropriate control on the grounds that it is intended for export outside the European Communities.

6. Control of food 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.

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 food;
(c) semi-finished products;
(d) finished products;

(e) materials and articles intended to come into contact with food;
(f) cleaning and maintenance products and processes and pesticides;
(g) processes used for the manufacture or processing of food;
(h) labelling and presentation of food;
(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;
(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.

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 food 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 food 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 containing food as may be necessary;
(vii) purchase or take without payment such samples of any food or of any of the products listed in Article 8(1)(b) to (f) of these Regulations which he finds in the course of his inspection.

12. 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 foods 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 food and the identity of the person from whom or the place from which any such food was obtained and the person to whom and the place to which it was consigned or otherwise disposed of.

13. (1) An authorised officer may for the purpose of Regulations made under Part V of the Health Act, 1947, purchase or take without payment a sample of any food.

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

(3) Where an authorised officer purchases or takes without payment, with the intention of having it analysed by an approved examiner, a sample of food which is suspected to be diseased, contaminated or otherwise unfit for human consumption or not to comply with Regulations made under Part V of the Health Act, 1947, he may, by notice in writing to the seller, owner or person in apparent charge or control of such food (as the case may be) prohibit the removal of the food 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 food 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 food (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 food without the consent of an officer of the Revenue Commissioners where the duties of such officer in relation to such food have not been wholly discharged.

14. (1) Where a sample is taken pursuant to these Regulations 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 food (as the case may be) and retain the third part.

(2) Where an authorised officer takes a sample consisting of a food contained in unopened containers and the division into parts of the food -

(a) is not reasonably practicable, or
(b) might affect the composition or impede the proper analysis of the contents,
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 any Regulations for the time being in force under Part V of the Health Act, 1947, the result of any test, examination or analysis of, or report on a sample 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 or container retained by the authorised officer shall be produced at the hearing.

15. (1) The approved examiner or a person under his direction shall analyse as soon as possible any sample of food 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 or not to comply with Regulations made under Part V of the Health Act, 1947, 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.

16. Where a sample of food 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 or such food (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.

17. (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 EN45003.

(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.

18. The validation of methods of analysis used within the context of official control of food by the official laboratories shall comply whenever possible with the provisions of paragraphs 1 and 2 of the Annex to Council Directive 85/591/EEC3 concerning the introduction of Community methods of sampling and analysis for the monitoring of food intended for human consumption.

3OJ No. L372, 31.12.1985, p.50

19. (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/EC 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 food 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 food is being transported for sale.
20. (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 food and in all proceedings for infringements of the law applicable to food.

(2) For the purpose of assistance to other Member States as required by this Article, the Department of Health 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 food 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 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 reoccurrence 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/EEC4 on dangers arising from the use of consumer products and to Council Directive 92/59/EEC5 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

21. (1) Information forwarded pursuant to Article 20 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 20 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 20 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.

22. (1) Any person who contravenes any Article or Sub-Article of these Regulations shall be guilty of an offence.

(2) Where an offence under these Regulations or any other Regulations for the time being in force under Part V of the Health Act, 1947 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, manager, 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.

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

(a) the Minister, or

(b) a health board within the functional area of which the offence was committed.

24. (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.

25. 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.

26. The Health (Official Control of Food) Regulations, 1991 (S.I. No. 332 of 1991) are hereby revoked.

SCHEDULE

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

HEALTH (OFFICIAL CONTROL OF FOOD) REGULATIONS, 1996. 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/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 on the

1st day of August, 1996.

MICHAEL NOONAN, T.D.,

MINISTER FOR HEALTH

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 food.

The Regulations carry forward the requirements of the 1991 Regulations which implemented Council Directive 89/397/EEC on the Official Control of Foodstuffs and incorporate the related provisions of Council Directive 93/99/EEC on the subject of Additional Measures Concerning the Official Control of Foodstuffs. The Regulations come into effect on 1st September, 1996, except for Article 17 which comes into effect on 1 November, 1998.