



## FOOD HYGIENE REGULATIONS 2007

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Statutory Document No. 2007/0594

*European Communities (Isle of Man) Act 1973***FOOD HYGIENE REGULATIONS 2007<sup>1</sup>**

*Laid before Tynwald: 16 October 2007*  
*Coming into Operation: in accordance with regulation 1*

In exercise of the powers conferred on the Council of Ministers by section 2B of the European Communities (Isle of Man) Act 1973<sup>1</sup>, and of all other enabling powers and after consultation as required by Article 9 of Regulation (EC) No. 178/2002<sup>2</sup> of the European Parliament and of Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, the following Regulations are hereby made: —

**Editorial Note:** This instrument, made under the European Communities (Isle of Man) Act 1973, is continued by virtue of section 6 of the European Union and Trade Act 2019.

**PART 1***Introduction***1 Citation and commencement**

These Regulations may be cited as the Food Hygiene Regulations 2007 and, subject to section 2B(9) of the European Communities (Isle of Man) Act 1973, shall come into operation on the day that they are made.

**2 Interpretation**

(1) In these Regulations —

“**the Act**” means the Food Act 1996<sup>3</sup>;

“**authorised officer**”, means any person (whether or not an officer of the Department) who is authorised by the Department in writing, either generally or specially, to act in matters arising under the Hygiene Regulations;

<sup>1</sup> 1973 c.14

<sup>2</sup> OJ No, L31, 1.2.2002, p.1- applied to the Island by SD 42/06

<sup>3</sup> 1996 c.8

“**the Community Regulations**” means Regulation 852/2004, Regulation 853/2004, Regulation 2073/2005, Regulation 2015/1375, Regulation 2017/185 and Regulation 2017/625 and the Regulation 2017/625 package insofar as it and they apply to food;<sup>2</sup>

“**Directive 2004/41**”, “**Regulation 178/2002**”, “**Regulation 852/2004**”, “**Regulation 853/2004**”, “**Regulation 1688/2005**”, “**Regulation 2073/2005**”, “**Regulation 2074/2005**”, “**Regulation 931/2011**”, “**Regulation 1169/2011**”, “**Regulation 28/2012**”, “**Regulation 208/2013**”, “**Regulation 210/2013**”, “**Regulation 579/2014**”, “**Regulation 2015/1375**”, “**Regulation 2017/185**”, “**Regulation 2017/625**”, “**Regulation 2018/329**”, “**Regulation 2019/66**”, “**Regulation 2019/626**”, “**Regulation 2019/627**”, “**Regulation 2019/628**”, “**Regulation 2019/1013**”, “**Regulation 2019/1014**”, “**Regulation 2019/1715**”, “**Regulation 2019/1793**”, “**Regulation 2019/1873**”, “**Regulation 2018/631**”, “**Regulation 2019/478**”, “**Regulation 2019/624**”, “**Regulation 2019/625**”, “**Regulation 2019/1012**”, “**Regulation 2019/1081**”, “**Regulation 2019/1602**” and “**Regulation 2019/1666**” [Revoked]<sup>3</sup>

“**Department**” means the Department of Local Government and the Environment; “**the Hygiene Regulations**” means these Regulations and the Community Regulations;

“**premises**” includes any establishment, any place, vehicle, stall or moveable structure and any ship or aircraft;

“**the Regulation 2017/625 package**” means Regulation 2017/625 and the other EU Regulations listed in Schedule 1 under the heading “The Regulation 2017/625 package”; and<sup>4</sup>

“**specified Community provision**” means any provision of the Community Regulations that is specified in Column 1 of Schedule 2 and whose subject-matter is described in Column 2 of that Schedule.

- (1A) Any reference in these Regulations to Directives or Regulations referred to in Schedule 1 have the meanings respectively given to them in that Schedule.<sup>5</sup>
- (2) Subject to paragraph (3), any expression other than one defined in paragraph (1) that is used both in these Regulations and in the Act has the meaning it bears in the Act.
- (3) Unless the context otherwise requires, any expression used both in these Regulations and in Regulation 178/2002 or the Community Regulations has the meaning that it bears in Regulation 178/2002 or the Community Regulations, as the case may be.
- (4) Where, apart from this paragraph, any period of less than seven days which is specified in these Regulations would include any day which is —
- (a) a Saturday, a Sunday, Christmas Day or Good Friday; or
  - (b) a day which is a bank holiday declared by Tynwald

that day shall be excluded from the period.

- (5) In these Regulations, any reference to an EU instrument defined in Schedule 1 is a reference to that instrument as amended from time to time.<sup>6</sup>

### **3 Presumptions that food is intended for human consumption**

- (1) The following paragraphs shall apply for the purposes of these Regulations.
- (2) Any food commonly used for human consumption shall, if placed on the market or offered, exposed or kept for placing on the market, be presumed, until the contrary is proved, to have been placed on the market or, as the case may be, to have been or to be intended for placing on the market for human consumption.
- (3) The following, namely –
- (a) any food commonly used for human consumption which is found on premises used for the preparation, storage, or placing on the market of that food; and
  - (b) any article or substance commonly used in the manufacture of food for human consumption which is found on premises used for the preparation, storage or placing on the market of that food,
- shall be presumed, until the contrary is proved, to be intended for placing on the market, or for manufacturing food for placing on the market, for human consumption.
- (4) Any article or substance capable of being used in the composition or preparation of any food commonly used for human consumption which is found on premises on which that food is prepared shall, until the contrary is proved, be presumed to be intended for such use.

### **4 Competent authority**

The competent authority for the purposes of the Community Regulations shall be the Department.

### **5 Enforcement**

These Regulations shall be enforced by the Department.

## PART 2

### *Main Provisions*

#### **6 Hygiene improvement notice**

- (1) If an authorised officer of the Department has reasonable grounds for believing that a food business operator is failing to comply with the Hygiene Regulations, he or she may by a notice served on that person (in these Regulations referred to as a “hygiene improvement notice”) —
  - (a) state the officer’s grounds for believing that the food business operator is failing to comply with the Hygiene Regulations;
  - (b) specify the matters which constitute the food business operator’s failure to comply;
  - (c) specify the measures which, in the officer’s opinion, the food business operator must take in order to secure compliance; and
  - (d) require the food business operator to take those measures, or measures which are at least equivalent to them, within such period (not being less than 14 days) as may be specified in the notice.
- (2) Any person who fails to comply with a hygiene improvement notice shall be guilty of an offence.

#### **7 Hygiene prohibition orders**

- (1) If —
  - (a) a food business operator is convicted of an offence under these Regulations; and
  - (b) the court by or before which he or she is so convicted is satisfied that the health risk condition is fulfilled with respect to the food business concerned,the court shall by an order impose the appropriate prohibition.
- (2) The health risk condition is fulfilled with respect to any food business if any of the following involves risk of injury to health (including any impairment, whether permanent or temporary), namely —
  - (a) the use for the purposes of the business of any process or treatment;
  - (b) the construction of any premises used for the purposes of the business, or the use for those purposes of any equipment; and
  - (c) the state or condition of any premises or equipment used for the purposes of the business.
- (3) The appropriate prohibition is —



- (a) in a case falling within sub-paragraph (a) of paragraph (2), a prohibition on the use of the process or treatment for the purposes of the business;
  - (b) in a case falling within sub-paragraph (b) of that paragraph, a prohibition on the use of the premises or equipment for the purposes of the business or any other food business of the same class or description; and
  - (c) in a case falling within sub-paragraph (c) of that paragraph, a prohibition on the use of the premises or equipment for the purposes of any food business.
- (4) If —
- (a) a food business operator is convicted of an offence under these Regulations; and
  - (b) the court by or before which he or she is so convicted thinks it proper to do so in all the circumstances of the case,
- the court may, by an order, impose a prohibition on the food business operator participating in the management of any food business, or any food business of a class or description specified in the order.
- (5) As soon as practicable after the making of an order under paragraph (1) or (4) (in these Regulations referred to as a “hygiene prohibition order”), the Department shall —
- (a) serve a copy of the order on the relevant food business operator; and
  - (b) in the case of an order made under paragraph (1), affix a copy of the order in a conspicuous position on such premises used for the purposes of the food business as they consider appropriate,
- and any person who knowingly contravenes such an order shall be guilty of an offence.
- (6) A hygiene prohibition order shall cease to have effect —
- (a) in the case of an order made under paragraph (1), on the issue by the Department of a certificate to the effect that they are satisfied that the food business operator has taken sufficient measures to secure that the health risk condition is no longer fulfilled with respect to the food business; and
  - (b) in the case of an order made under paragraph (4), on the giving by the court of a direction to that effect.
- (7) The Department shall issue a certificate under sub-paragraph (a) of paragraph (6) within three days of their being satisfied as mentioned in that sub-paragraph; and on an application by the food business operator for such a certificate, the Department shall —

- (a) determine, as soon as is reasonably practicable and in any event within 14 days, whether or not they are so satisfied; and
  - (b) if they determine that they are not so satisfied, give notice to the food business operator of the reasons for that determination.
- (8) The court shall give a direction under sub-paragraph (b) of paragraph (6) if, on an application by the food business operator, the court thinks it proper to do so having regard to all the circumstances of the case, including in particular the conduct of the food business operator since the making of the order; but no such application shall be entertained if it is made —
- (a) within six months of the making of the hygiene prohibition order; or
  - (b) within three months of the making by the food business operator of a previous application for such a direction.
- (9) Where a court of summary jurisdiction makes an order under paragraph (2) of regulation 8 with respect to any food business, paragraph (1) shall apply as if the food business operator had been convicted by the court of an offence under the Hygiene Regulations.
- (10) Where the commission of an offence by a food business operator leads to the conviction of another person pursuant to regulation 10, paragraph (4) shall apply in relation to that other person as it applies in relation to the food business operator and any reference in paragraph (5) or (8) to the food business operator shall be construed accordingly.

## **8 Hygiene emergency prohibition notices and orders**

- (1) If an authorised officer of the Department is satisfied that the health risk condition is fulfilled with respect to any food business he or she may by a notice served on the relevant food business operator (in these Regulations referred to as a “hygiene emergency prohibition notice”) impose the appropriate prohibition.
- (2) If a court of summary jurisdiction is satisfied, on the application of such an officer, that the health risk condition is fulfilled with respect to any food business, the court shall, by an order (in these Regulations referred to as a “hygiene emergency prohibition order”), impose the appropriate prohibition.
- (3) Such an officer shall not apply for a hygiene emergency prohibition order unless, at least one day before the date of the application, he or she has served notice on the relevant food business operator of his or her intention to apply for the order.
- (4) Paragraphs (2) and (3) of regulation 7 shall apply for the purposes of this regulation as they apply for the purposes of that regulation, but as if the

reference in paragraph (2) to risk of injury to health were a reference to imminent risk of injury.

- (5) As soon as practicable after the service of a hygiene emergency prohibition notice, an authorised officer of the Department shall affix a copy of the notice in a conspicuous position on such premises used for the purposes of the food business as he or she considers appropriate; and any person who knowingly contravenes such a notice shall be guilty of an offence.
- (6) As soon as practicable after the making of a hygiene emergency prohibition order, an authorised officer of the Department shall —
  - (a) serve a copy of the order on the relevant food business operator; and
  - (b) affix a copy of the order in a conspicuous position on such premises used for the purposes of the food business as he or she considers appropriate,and any person who knowingly contravenes such an order shall be guilty of an offence.
- (7) A hygiene emergency prohibition notice shall cease to have effect —
  - (a) if no application for a hygiene emergency prohibition order is made within the period of three days beginning with the service of the notice, at the end of that period; or
  - (b) if such an application is so made, on the determination or abandonment of the application.
- (8) A hygiene emergency prohibition notice or a hygiene emergency prohibition order shall cease to have effect on the issue by the Department of a certificate to the effect that they are satisfied that the food business operator has taken sufficient measures to secure that the health risk condition is no longer fulfilled with respect to the food business.
- (9) The Department shall issue a certificate under paragraph (8) within three days of their being satisfied as mentioned in that paragraph; and on an application by the food business operator for such a certificate, the Department shall —
  - (a) determine as soon as is reasonably practicable and in any event within 14 days whether or not they are so satisfied; and
  - (b) if they determine that they are not so satisfied, give notice to the food business operator of the reasons for that determination.
- (10) Where a hygiene emergency prohibition notice is served on a food business operator, the Department shall compensate that operator in respect of any loss suffered by reason of compliance with the notice unless —
  - (a) an application for a hygiene emergency prohibition order is made within the period of three days beginning with the service of the notice; and

- (b) the court declares itself satisfied, on the hearing of the application, that the health risk condition was fulfilled with respect to the food business at the time when the notice was served,

and any disputed question as to the right to or the amount of any compensation payable under this paragraph shall be determined by arbitration.

## 9 Remedial action notices and detention notices

- (1) Where it appears to an authorised officer of the Department that in respect of an establishment subject to approval under Article 4(2) of Regulation 853/2004 –
  - (a) any of the requirements of the Hygiene Regulations is being breached; or
  - (b) inspection under the Hygiene Regulations is being hampered,he or she may, by a notice in writing (in these Regulations referred to as a “remedial action notice”) served on the relevant food business operator or his duly authorised representative –
  - (c) prohibit the use of any equipment or any part of the establishment specified in the notice;
  - (d) impose conditions upon or prohibit the carrying out of any process; or
  - (e) require the rate of operation to be reduced to such extent as is specified in the notice, or to be stopped completely.
- (2) A remedial action notice shall be served as soon as practicable and shall state why it is being served.
- (3) If it is served under paragraph (1)(a), it shall specify the breach and the action needed to remedy it.
- (4) Any authorised officer of the Department whether or not he or she served the original remedial action notice shall, as soon as he or she is satisfied that such action has been taken, withdraw the notice by a further notice in writing served on the food business operator or his duly authorised representative.
- (5) An authorised officer of the Department may, at an establishment subject to approval under Article 4(2) of Regulation 853/2004, by a notice in writing (in this regulation referred to as a “detention notice”) served on the relevant food business operator or that operator’s duly authorised representative require the detention of any animal or food for the purpose of examination (including the taking of samples).
- (6) Any authorised officer of the Department whether or not he or she served the original detention notice shall, as soon as he or she is satisfied that the animal or food need no longer be detained, withdraw the notice by a

further notice in writing served on the food business operator or that operator's duly authorised representative.

- (7) Any person who fails to comply with a remedial action notice or a detention notice shall be guilty of an offence.

## 10 Offences due to fault of another person

Where the commission by any person of an offence under these Regulations is due to the act or default of some other person, that other person shall be guilty of the offence; and a person may be convicted of the offence by virtue of this regulation whether or not proceedings are taken against the first-mentioned person.

## 11 Defence of due diligence

- (1) In any proceedings for an offence under these Regulations, it shall, subject to paragraph (2), be a defence for the accused to prove that he or she took all reasonable precautions and exercised all due diligence to avoid the commission of the offence by him or herself or by a person under his or her control.
- (2) If in any case the defence provided by paragraph (1) involves the allegation that the commission of the offence was due to an act or default of another person, or to reliance on information supplied by another person, the accused shall not, without leave of the court, be entitled to rely on that defence unless —
- (a) at least seven clear days before the hearing; and
  - (b) where the accused has previously appeared before a court in connection with the alleged offence, within one month of his first such appearance,

the accused has served on the prosecutor a notice in writing giving such information identifying or assisting in the identification of that other person as was then in his or her possession .

## PART 3

### *Administration and enforcement*

## 12 Procurement of samples

An authorised officer of the Department may —

- (a) purchase a sample of any food, or any substance capable of being used in the preparation of food;
- (b) take a sample of any food, or any such substance, which —

- (i) appears to him or her to be intended for placing on the market or to have been placed on the market, for human consumption, or
- (ii) is found by him or her on or in any premises which he or she is authorised to enter by or under regulation 14;
- (c) take a sample from any food source, or a sample of any contact material, which is found by him or her on or in any such premises; and
- (d) take a sample of any article or substance which is found by him or her on or in any such premises and which he or she has reason to believe may be required as evidence in proceedings under any of the provisions of these Regulations.

### 13 Analysis etc. of samples

- (1) An authorised officer of the Department who has procured a sample under regulation 12 shall —
  - (a) if he or she considers that the sample should be analysed, submit it to be analysed by the Government Analyst, or
  - (b) if he or she considers that the sample should be examined, submit it to be examined by a food examiner.
- (2) A person, other than such an officer, who has purchased any food, or any substance capable of being used in the preparation of food, may submit a sample of it —
  - (a) to be analysed by the Government Analyst; or
  - (b) to be examined by a food examiner.
- (3) If, in any case where a sample is proposed to be or is submitted for analysis or examination under this regulation, the Government Analyst determines that he is for any reason unable to perform the analysis or examination, the sample shall be submitted or, as the case may be, sent by him to such other food analyst or examiner as he may determine.
- (4) The Government Analyst when he has analysed or examined a sample shall give to the person by whom it was submitted a certificate specifying the result of the analysis or examination.
- (5) Any certificate given by the Government Analyst under paragraph (4) shall be signed by him, but the analysis or examination may be made by any person acting under his direction.
- (6) In any proceedings under these Regulations, the production by one of the parties —
  - (a) of a document purporting to be a certificate given by the Government Analyst under paragraph (4); or

- (b) of a document supplied to him by the other party as being a copy of such a certificate,  
  
shall be sufficient evidence of the facts stated in it unless, in a case falling within sub- paragraph (a), the other party requires that the Government Analyst shall be called as a witness.
- (7) The certificate given by a food analyst or examiner under paragraph (4) shall be in the form set out in Schedule 8.

## 14 Powers of entry

- (1) An authorised officer of the Department shall, on producing, if so required, some duly authenticated document showing his or her authority, have a right at all reasonable hours –
  - (a) to enter any premises for the purpose of ascertaining whether there is or has been on the premises any contravention of the provisions of the Hygiene Regulations;
  - (b) to enter any premises, for the purpose of ascertaining whether there is on the premises any evidence of any such contravention ; and
  - (c) to enter any premises for the purpose of the performance by the Department of their functions under the Hygiene Regulations,but admission to any premises used only as a private dwelling-house shall not be demanded as of right unless 24 hours' notice of the intended entry has been given to the occupier.
- (2) If a justice of the peace, on sworn information in writing, is satisfied that there is reasonable ground for entry onto any premises for any such purpose as is mentioned in paragraph (1) or (2) and either –
  - (a) that admission to the premises has been refused, or a refusal is apprehended, and that notice of the intention to apply for a warrant has been given to the occupier; or
  - (b) that an application for admission, or the giving of such a notice, would defeat the object of the entry, or that the case is one of urgency, or that the premises are unoccupied or the occupier is temporarily absent,the justice may by warrant signed by him or her authorise the authorised officer to enter the premises, if need be by reasonable force.
- (3) Every warrant granted under this regulation shall continue in force for a period of one month.
- (4) An authorised officer entering any premises by virtue of this regulation, or of a warrant issued under it, may take with him such other persons as he or she considers necessary, and on leaving any unoccupied premises which he or she has entered by virtue of such a warrant shall leave them as effectively secured against unauthorised entry as he or she found them.

- (5) An authorised officer entering premises by virtue of this regulation, or of a warrant issued under it, may inspect any records (in whatever form they are held) relating to a food business and, where any such records are stored in any electronic form –
- (a) may have access to, and inspect and check the operation of, any computer and any associated apparatus or material which is or has been in use in connection with the records; and
  - (b) may require any person having charge of, or otherwise concerned with the operation of, the computer, apparatus or material to afford him or her such assistance as he or she may reasonably require.
- (6) Any officer exercising any power conferred by paragraph (5) may –
- (a) seize and detain any records which he or she has reason to believe may be required as evidence in proceedings under any of the provisions of these Regulations; and
  - (b) where the records are stored in any electronic form, require the records to be produced in a form in which they may be taken away.
- (7) If any person who enters any premises by virtue of this regulation, or of a warrant issued under it, discloses to any person any information obtained by him or her on the premises with regard to any trade secret, he or she shall, unless the disclosure was made in the performance of his or her duty, be guilty of an offence.
- (8) Nothing in this regulation authorises any person, except with the permission of the Department of Agriculture Fisheries and Forestry under the Animal Health Act 1996<sup>4</sup>, to enter any premises –
- (a) on which an animal or bird affected with any disease to which that Act applies is kept; and
  - (b) which is situated in a place declared under that Act to be infected with such a disease .

## 15 Obstruction etc. of officers

- (1) Any person who –
- (a) intentionally obstructs any person acting in the execution of the Hygiene Regulations; or
  - (b) without reasonable cause, fails to give to any person acting in the execution of the Hygiene Regulations any assistance or information which that person may reasonably require of him or her for the performance of his functions under the Hygiene Regulations,
- shall be guilty of an offence.
- (2) Any person who, in purported compliance with any such requirement as is mentioned in sub-paragraph (b) of paragraph (1) –

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<sup>4</sup> 1996 c.22



- (a) furnishes information which he knows to be false or misleading in a material particular; or
  - (b) recklessly furnishes information which is false or misleading in a material particular,
- shall be guilty of an offence.
- (3) Nothing in sub-paragraph (b) of paragraph (1) shall be construed as requiring any person to answer any question or give any information if to do so might incriminate him or her.

## 16 Time limit for prosecutions

No prosecution for an offence under these Regulations which is punishable under paragraph (2) of regulation 17 shall be begun after the expiry of —

- (a) three years from the commission of the offence; or
- (b) one year from its discovery by the prosecutor, whichever is the earlier.

## 17 Offences and penalties

- (1) Subject to paragraphs (4) and (5), any person who contravenes or fails to comply with any of the specified Community provisions shall be guilty of an offence.<sup>7</sup>
- (2) Subject to paragraph (3), a person guilty of an offence under these Regulations shall be liable —
  - (a) on summary conviction to a fine not exceeding £5000; or
  - (b) on conviction on information to custody for a term not exceeding two years, to a fine or to both.
- (3) A person guilty of an offence under regulation 15 shall be liable on summary conviction to a fine not exceeding £5000 or to custody for a term not exceeding three months or to both.
- (4) A person shall be considered not to have contravened or failed to comply with Article 4(2) of Regulation 852/2004 as read with paragraph 4 of Chapter IV of Annex II to that Regulation (bulk foodstuffs in liquid, granulate or powder form to be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs) provided the requirements of Schedule 3 are complied with.
- (5) A person is to be considered not to have contravened or failed to comply with Article 5(1) of Regulation 853/2004 if —
  - (a) in the case of a health mark —
    - (i) the health mark was applied to a product of animal origin in accordance with Article 5(1) before IP completion day; and

- (ii) the health mark complied with Article 5(1) as that Article applied immediately before IP completion day;
- (b) in the case of an identification mark –
  - (i) the identification mark was applied to a product of animal origin subject to Article 5(1) before IP completion day; or
  - (ii) the identification mark is applied to a product of animal origin in accordance with Article 5(1) as that Article applied immediately before IP completion day, no later than 21 months after IP completion day ends, using a label, wrapping or packaging bearing that identification mark which is owned by the food business operator immediately before IP completion day.<sup>8</sup>

## 18 Offences by bodies corporate

- (1) Where an offence under these Regulations which has been committed by a body corporate is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of –
  - (a) any director, manager, secretary or other similar officer of the body corporate; or
  - (b) any person who was purporting to act in any such capacity,he or she as well as the body corporate shall be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.
- (2) In sub-paragraph (a) of paragraph (1) “director”, in relation to any body corporate established by or under any enactment for the purpose of carrying on under national ownership any industry or part of an industry or undertaking, being a body corporate whose affairs are managed by its members, means a member of that body corporate.

## 19 Right of appeal

- (1) Any person who is aggrieved by –
  - (a) a decision of an authorised officer of the Department to serve a hygiene improvement notice;
  - (b) a decision of the Department to refuse to issue a certificate under paragraph (6) of regulation 7 or paragraph (8) of regulation 8; or
  - (c) a decision of an authorised officer of the Department to serve a remedial action notice,may appeal to a court of summary jurisdiction.
- (2) The period within which an appeal under paragraph (1) may be brought shall be –

- (a) one month from the date on which notice of the decision was served on the person desiring to appeal; or
- (b) in the case of an appeal against a decision to issue a hygiene improvement notice, the period specified in sub-paragraph (a) or, if it is shorter, the period specified in the notice pursuant to sub-paragraph (d) of paragraph (1) of regulation 6,

and the making of a complaint for an order shall be deemed for the purposes of this paragraph to be the bringing of the appeal.

## **20 Appeals to High Court**

A person who is aggrieved by —

- (a) the dismissal by a court of summary jurisdiction of an appeal to it under paragraph (1) of regulation 19; or
- (b) any decision of such a court to make a hygiene prohibition order or a hygiene emergency prohibition order,

may appeal to the High Court.

## **21 Appeals against hygiene improvement notices and remedial action notices**

- (1) On an appeal against a hygiene improvement notice or a remedial action notice, the court may cancel or affirm the notice and, if it affirms it, may do so either in its original form or with such modifications as the court may in the circumstances think fit.
- (2) Where any period specified in a hygiene improvement notice pursuant to sub-paragraph (d) of paragraph (1) of regulation 6 would otherwise include any day on which an appeal against that notice is pending, that day shall be excluded from that period.
- (3) Any appeal shall be regarded as pending for the purposes of paragraph (2) until it is finally disposed of, is withdrawn or is struck out for want of prosecution.

## **22 Application of section 7 of the Food Act 1996**

Section 7 of the Act (inspection and seizure of suspected food)<sup>5</sup> shall apply for the purposes of these Regulations.

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<sup>5</sup> Section 7 was amended by S.D. 163/06 and section 1(1) and (2) (definition of “food”) was substituted by S.D. 194/06

## PART 4

### *Miscellaneous and supplementary provisions*

#### **23 Application of section 38 of the Food Act 1996**

Section 38 of the Act (codes of practice) shall apply for the purposes of these Regulations.

#### **24 Revocation and suspension of designations and appointments**

(1) Subject to paragraphs (2) and (3), the Department may at any time revoke or suspend —

- (a) the appointment of an official veterinarian;
- (b) the designation of an approved veterinarian; or
- (c) the appointment of a Technician,

if it appears to the Department that the person in question is unfit to perform any of the functions of that post under the Hygiene Regulations.

(2) Where the Department revokes or suspends a designation or appointment under paragraph (1), the Department shall, as soon as practicable, give to the person whose designation or appointment has been revoked or suspended a notice in writing of the reasons for the revocation or suspension and shall afford him or her an opportunity of —

- (a) making representations in writing to the Department with regard to the revocation or suspension; or
- (b) being heard by a person nominated by the Department for the purpose pursuant to sub-paragraph (a) of paragraph (5).

(3) A notice given under paragraph (2) shall inform the person to whom it is given

- (a) of his or her right to make representations in writing;
- (b) of the manner in which and the time (not being less than 21 days from the giving of the notice) within which such representations may be made;
- (c) of his or her right to be heard; and
- (d) of the manner in which and the time (not being less than 21 days from the giving of the notice) within which he or she may apply for an opportunity to be heard.

(4) In the event of the person whose designation or appointment has been revoked or suspended making any representations (whether orally or in writing) under paragraph (3) the Department shall reconsider whether that person is unfit to perform any of the functions of the post held by him or her under the Hygiene Regulations and shall, as soon as practicable,

reconsider its decision to revoke or suspend the designation or appointment under paragraph (1) in the light of those representations.

- (5) Where a person requests the opportunity to be heard pursuant to subparagraph (b) of paragraph (2) —
  - (a) the Department shall nominate a person to determine the matter from the list established under paragraph (6);
  - (b) the person so nominated shall serve a notice on the person requesting the opportunity to be heard and the Department informing them of the time (not being less than 21 days from the giving of the notice) of the hearing; and
  - (c) the person so nominated shall, within 21 days of the hearing, notify the person requesting the opportunity to be heard and the Department of his or her decision.
- (6) The Department shall establish and maintain a list of people who may be nominated for the purposes of this regulation and shall consult those organisations appearing to it to represent official veterinarians, approved veterinarians and Technicians before including any person on the list.

## **25 Food which has not been produced, processed or distributed in accordance with the Hygiene Regulations**

- (1) On an inspection of any food, an authorised officer of the Department may certify that it has not been produced, processed or distributed in compliance with the Hygiene Regulations.
- (2) Where any food is certified as mentioned in paragraph (1) it shall be treated for the purposes of section 7 of the Act as failing to comply with food safety requirements.
- (3) Where any food certified as mentioned in paragraph (1) is part of a batch, lot or consignment of food of the same class or description, all the food in the batch, lot or consignment shall, until it is proved that it has been produced, processed or distributed in compliance with the Hygiene Regulations, be treated for the purposes of paragraph (2) as having been so certified.

## **26 Service of documents**

- (1) Any document which is required or authorised under the Hygiene Regulations to be served on a food business operator may be served —
  - (a) by delivering it to that person;
  - (b) in the case of an incorporated company or body, by delivering it to their secretary or registered agent at their registered or principal office, or by sending it in a prepaid letter addressed to him or her at that office; or

- (c) in the case of any other food business operator, by leaving it or sending it in a prepaid letter addressed to him or her at his or her usual or last known residence.
- (2) Where a document is to be served on a food business operator under the Hygiene Regulations and it is not reasonably practicable to ascertain the name and address of the person on whom it should be served, or the premises of the food business operator are unoccupied, the document may be served by addressing it to the food business operator concerned in the capacity of occupier of those premises (naming them), and –
- (a) by delivering it to some other person at the premises; and
  - (b) if there is no other person at the premises to whom it can be delivered, by affixing it or a copy of it to some conspicuous part of the premises.

**27 Bulk transport in sea-going vessels of liquid oils or fats and the bulk transport by sea of raw sugar**

Schedule 3 (bulk transport in sea-going vessels of liquid oils or fats and the bulk transport by sea of raw sugar) shall have effect.

**28 Temperature control requirements**

Schedule 4 (temperature control requirements) shall have effect.

**29 Direct supply by the producer of small quantities of meat from poultry or lagomorphs slaughtered on the farm**

Schedule 5 (direct supply by the producer of small quantities of meat from poultry or lagomorphs slaughtered on the farm) shall have effect.

**30 Restrictions on the placing on the market of raw milk and raw cream**

Schedule 6 (restrictions on the placing on the market of raw milk and raw cream) shall have effect.

**31 Consequential amendments**

The instruments specified in Schedule 7 are amended to the extent specified there.

**32 Revocation**

The instruments specified in Schedule 9 are revoked.

**MADE 11 JULY 2007**

**SCHEDULE 1<sup>9</sup>****DEFINITIONS OF LEGISLATION**

[Regulation 2(1) and (5)]

“Directive 2004/41” means Directive 2004/41/EC of the European Parliament and of the Council repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC<sup>6</sup>;

“Regulation 178/2002” means Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety<sup>7</sup> as read with Regulation 931/2011 and Regulation 208/2013;

“Regulation 852/2004” means Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs as read with Regulation 2073/2005<sup>8</sup> as read with Regulation 2073/2005 and Regulation 210/2013;

“Regulation 853/2004” means Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin as read with Directive 2004/41, Regulation 1688/2005, Regulation 2074/2005, Regulation 1020/2008 and Regulation 1162/2009<sup>9</sup> as read with Directive 2004/41, Regulation 1688/2005, Regulation 2074/2005 and 2017/185;

“Regulation 1688/2005” means Commission Regulation (EC) No 1688/2005 of 14 October 2005 implementing Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards special guarantees concerning salmonella for consignments to Finland and Sweden of certain meat and eggs<sup>10</sup>;

“Regulation 2073/2005” means Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs<sup>11</sup>;

“Regulation 2074/2005” means Commission Regulation (EC) No 2074/2005 laying down implementing measures for certain products under Regulation (EC)

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<sup>6</sup> OJ L 157, 30.4.2004, p. 33.

<sup>7</sup> OJ L 31, 1.2.2002, p. 1.

<sup>8</sup> OJ L 139, 30.4.2004, p. 1.

<sup>9</sup> OJ L 139, 30.4.2004, p. 55.

<sup>10</sup> OJ L 271, 15.10.2005, p.17.

<sup>11</sup> OJ L 338, 22.12.2005, p. 1.

No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004<sup>12</sup>;

“Regulation 931/2011” means Commission Implementing Regulation (EU) No 931/2011 of 19 September 2011 on the traceability requirements set by Regulation (EC) No 178/2002 of the European Parliament and of the Council for food of animal origin<sup>13</sup>;

“Regulation 1169/2011” means Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004<sup>14</sup>;

“Regulation 208/2013” means Commission Implementing Regulation (EU) No 208/2013 of 11 March 2013 on traceability requirements for sprouts and seeds intended for the production of sprouts<sup>15</sup>;

“Regulation 210/2013” means Commission Regulation (EU) No 210/2013 of 11 March 2013 on the approval of establishments producing sprouts pursuant to Regulation (EC) No 852/2004 of the European Parliament and of the Council<sup>16</sup>;

“Regulation 579/2014” means Commission Regulation (EU) No 579/2014 of 28 May 2014 granting derogation from certain provisions of Annex II to Regulation (EC) No 852/2004 of the European Parliament and of the Council as regards the transport of liquid oils and fats by sea<sup>17</sup>;

“Regulation 2015/1375” means Commission Implementing Regulation (EU) 2015/1375 of 10 August 2015 laying down specific rules on official controls for *Trichinella* in meat<sup>18</sup>;

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<sup>12</sup> OJ L 338, 22.12.2005, p. 27.

<sup>13</sup> OJ L 242, 20.9.2011, p. 2.

<sup>14</sup> OJ L 304, 22.11.2011, p. 18.

<sup>15</sup> OJ L 068, 12.3.2013, p. 16.

<sup>16</sup> OJ L 068, 12.3.2013, p. 24.

<sup>17</sup> OJ L 160, 29.5.2014, p. 14.

<sup>18</sup> OJ L 212, 11.8.2015, p. 7.



“Regulation 2017/185” means Commission Regulation (EU) 2017/185 of 2 February 2017 laying down transitional measures for the application of certain provisions of Regulations (EC) No 853/2004 and (EC) No 854/2004 of the European Parliament and of the Council<sup>19</sup>;

“Regulation 2017/625” means Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC and the Regulation 2017/625 package;

### **The Regulation 2017/625 package**

“Regulation 2019/624” means Commission Delegated Regulation (EU) 2019/624 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council<sup>20</sup>;

“Regulation 2019/625” means Commission Delegated Regulation (EU) 2019/625 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption<sup>21</sup>;

“Regulation 2019/626” means Commission Implementing Regulation (EU) 2019/626 of 5 March 2019 concerning lists of third countries or regions thereof authorised for the entry into the European Union of certain animals and goods intended for human consumption, amending Implementing Regulation (EU) 2016/759 as regards these lists<sup>22</sup>;

“Regulation 2019/627” means Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU)

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<sup>19</sup> OJ L 29, 3.2.2017, p. 21.

<sup>20</sup> OJ L 131, 17.5.2019, p. 1.

<sup>21</sup> OJ L 131, 17.5.2019, p. 18.

<sup>22</sup> OJ L 131, 17.5.2019, p. 31.

2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls<sup>23</sup>;

“Regulation 2019/628” means Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates<sup>24</sup>;

“Regulation 2019/1012” means Commission Delegated Regulation (EU) 2019/1012 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council by derogating from the rules on the designation of control points and from the minimum requirements for border control posts<sup>25</sup>;

“Regulation 2019/1013” means Commission Implementing Regulation (EU) 2019/1013 of 16 April 2019 on prior notification of consignments of certain categories of animals and goods entering the Union<sup>26</sup>;

“Regulation 2019/1014” means Commission Implementing Regulation (EU) 2019/1014 of 12 June 2019 to lay down detailed rules on minimum requirements for border control posts, including inspection centres, and for the format, categories and abbreviations to use for listing border control posts and control points<sup>27</sup>;

“Regulation 2019/1081” means Commission Delegated Regulation (EU) 2019/1081 establishing rules on specific training requirements for staff for performing certain physical checks at border control posts<sup>28</sup>;

“Regulation 2019/1602” means Commission Delegated Regulation (EU) 2019/1602 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council concerning the Common Health Entry Document accompanying consignments of animals and goods to their destination<sup>29</sup>;

“Regulation 2019/1666” means Commission Delegated Regulation (EU) 2019/1666 of 24 June 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards conditions for monitoring the transport and arrival of consignments of certain goods from the border control post of arrival to the establishment at the place of destination in the Union<sup>30</sup>;

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<sup>23</sup> OJ L 131, 17.5.2019, p. 51.

<sup>24</sup> OJ L 131, 17.5.2019, p. 101.

<sup>25</sup> OJ L 165, 21.6.2019, p. 4.

<sup>26</sup> OJ L 165, 21.6.2019, p. 8.

<sup>27</sup> OJ L 165, 21.6.2019, p. 10.

<sup>28</sup> OJ L 171, 26.6.2019, p. 1.

<sup>29</sup> OJ L 250, 30.9.2019, p. 6.

<sup>30</sup> OJ L 255, 4.10.2019, p. 1.

- “Regulation 2019/1715” means Commission Implementing Regulation (EU) 2019/1715 of 30 September 2019 laying down rules for the functioning of the information management system for official controls and its system components<sup>31</sup>;
- “Regulation 2019/1793” means Commission Implementing Regulation (EU) 2019/1793 of 22 October 2019 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council and repealing Commission Regulations (EC) No 669/2009, (EU) No 884/2014, (EU) 2015/175, (EU) 2017/186 and (EU) 2018/1660<sup>32</sup>;
- “Regulation 2019/1873” means Commission Implementing Regulation (EU) 2019/1873 of 7 November 2019 on the procedures at border control posts for a coordinated performance by competent authorities of intensified official controls on products of animal origin, germinal products, animal by-products and composite products<sup>33</sup>;
- “Regulation 2019/2007” means Commission Implementing Regulation (EU) 2019/2007 laying down rules for the application of Regulation (EU) 2017/625 of the European Parliament and of the Council as regards the lists of animals, products of animal origin, germinal products, animal by-products and derived products and hay and straw subject to official controls at border control posts and amending Decision 2007/275/EC<sup>34</sup>;
- “Regulation 2019/2074” means Commission Delegated Regulation (EU) 2019/2074 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards rules on specific official controls on consignments of certain animals and goods originating from, and returning to the Union following a refusal of entry by a third country<sup>35</sup>;
- “Regulation 2019/2122” means Commission Delegated Regulation (EU) 2019/2122 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards certain categories of animals and goods exempted from official controls at border control posts, specific controls on passengers’ personal luggage and on small consignments of goods sent to natural persons which are not intended to be placed on the market and amending Commission Regulation (EU) No. 142/2011<sup>36</sup>;
- “Regulation 2019/2123” means Commission Delegated Regulation (EU) 2019/2123 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards rules for the cases where and the

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<sup>31</sup> OJ L 261, 14.10.2019, p. 37.

<sup>32</sup> OJ L 277, 29.10.2019, p. 89.

<sup>33</sup> OJ L 289, 8.11.2019, p. 50.

<sup>34</sup> OJ L 312, 3.12.2019, p. 1.

<sup>35</sup> OJ L 316, 6.12.2019, p. 6.

<sup>36</sup> OJ L 321, 12.12.2019, p. 45.

conditions under which identity checks and physical checks on certain goods may be performed at control points and documentary checks may be performed at distance from border control posts<sup>37</sup>;

“Regulation 2019/2124” means Commission Delegated Regulation (EU) 2019/2124 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards rules for official controls of consignments of animals and goods in transit, transshipment and onward transportation through the Union, and amending Commission Regulations (EC) No. 798/2008, (EC) No. 1251/2008, (EC) No. 119/2009, (EU) No. 206/2010, (EU) No. 605/2010, (EU) No. 142/2011, (EU) No. 28/2012, Commission Implementing Regulation (EU) 2016/759 and Commission Decision 2007/777/EC<sup>38</sup>;

“Regulation 2019/2126” means Commission Delegated Regulation (EU) 2019/2126 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards rules for specific official controls for certain categories of animals and goods, measures to be taken following the performance of such controls and certain categories of animals and goods exempted from official controls at border control posts<sup>39</sup>;

“Regulation 2019/2129” means Commission Implementing Regulation (EU) 2019/2129 establishing rules for the uniform application of frequency rates for identity checks and physical checks on certain consignments of animals and goods entering the Union<sup>40</sup>;

“Regulation 2019/2130” means Commission Implementing Regulation (EU) 2019/2130 establishing detailed rules on the operations to be carried out during and after documentary checks, identity checks and physical checks on animals and goods subject to official controls at border control posts<sup>41</sup>;

“Regulation 2020/466” means Commission Implementing Regulation (EU) 2020/466 on temporary measures to contain risks to human, animal and plant health and animal welfare during certain serious disruptions of Member States’ control systems due to coronavirus disease<sup>42</sup>;

“Regulation 2020/1158” means Commission Implementing Regulation (EU) 2020/1158 on the conditions governing imports of food and feed originating in third countries following the accident at the Chernobyl nuclear power station<sup>43</sup>.

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<sup>37</sup> OJ L 321, 12.12.2019, p. 64.

<sup>38</sup> OJ L 321, 12.12.2019, p. 73.

<sup>39</sup> OJ L 321, 12.12.2019, p. 104.

<sup>40</sup> OJ L 321, 12.12.2019, p. 122.

<sup>41</sup> OJ L 321, 12.12.2019, p. 128.

<sup>42</sup> OJ L 098, 31.3.2020, p. 30.

<sup>43</sup> OJ L 257, 6.8.2020, p. 1.

## SCHEDULE 2

SPECIFIED COMMUNITY PROVISIONS<sup>10</sup>

[Regulations 2(1) and 17]

<i>1. Provision of retained EU law</i>	<i>2. Subject-matter</i>
Article 3 of Regulation 852/2004	Requirement that food business operators ensure that all stages of production, processing and distribution of food under their control satisfy the relevant hygiene requirements laid down in Regulation 852/2004.
Article 4(1) of Regulation 852/2004	Requirement that food business operators carrying out primary production and specified associated operations comply with the general hygiene provisions laid down in Part A of Annex 1 to Regulation 852/2004 and any specific requirements provided for in Regulation 853/2004.
Article 4(2) of Regulation 852/2004	Requirement that food business operators carrying out any stage of production, processing and distribution of food after those stages to which Article 4(1) applies comply with the general hygiene requirements laid down in Annex 2 to Regulation 852/2004 and any specific requirements provided for in Regulation 853/2004 and Regulation 579/2014.
Article 4(3) of Regulation 852/2004	Requirement that food business operators, as appropriate, adopt certain specific hygiene measures.
Article 5(1) of Regulation 852/2004	Requirement that food business operators put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.
Article 5(2) of Regulation 852/2004	Requirement that when any modification is made in the product, process, or any step, food business operators review the procedure referred to in Article 5(1) and make the necessary changes to it.
Article 5(4)(a) of Regulation 852/2004	Requirement that food business operators provide the competent authority with evidence of their compliance with Article 5(1).
Article 5(4)(b) of Regulation 852/2004	Requirement that food business operators ensure that any documents describing the procedures developed in accordance with Article 5 are up to date.
Article 5(4)(c) of Regulation 852/2004	Requirement that food business operators retain documents and records for an appropriate period.
Article 6(1) of Regulation 852/2004	Requirement that food business operators co-operate with the competent authorities in accordance with United Kingdom law.
Article 6(2), first paragraph, of Regulation 852/2004	Requirement that a food business operator notify the competent authority of each establishment under its control that carries out any of the stages of production, processing and distribution of food.

Article 6(2), second paragraph, of Regulation 852/2004	Requirement that food business operators ensure that the competent authority has up to date information on establishments.
Article 6(3) of Regulation 852/2004	Requirement that food business operators ensure that establishments are approved by the competent authority when approval is required.
Article 3(1) of Regulation 853/2004	Requirement that food business operators comply with the relevant provisions of Annexes 2 and 3 to Regulation 853/2004.
Article 3(2) of Regulation 853/2004	Requirement that food business operators do not use any substance other than potable water or, when Regulation 852/2004 or Regulation 853/2004 permits its use, clean water, to remove surface contamination from products of animal origin unless use of the substance has been approved.
Article 4(1) of Regulation 853/2004	Requirement that food business operators place products of animal origin on the market only if they have been prepared and handled exclusively in establishment – (a) that meet the relevant requirements of Regulation 852/2004, those of Annexes 2 and 3 of Regulation 853/2004 and other relevant requirements of food law; and (b) that the competent authority has registered or, where required in accordance with Article 4(2), approved.
Article 4(2) of Regulation 853/2004	Requirement that establishments handling those products of animal origin for which Annex 3 to Regulation 853/2004 lays down requirements do not operate unless the competent authority has approved them in accordance with Article 4(3).
Article 4(3) of Regulation 853/2004	Requirement that establishments subject to approval in accordance with Article 4(2) do not operate unless the competent authority has, in accordance with Regulation 2017/625 – (a) granted the establishment approval to operate following an on-site visit; or (b) provided the establishment with conditional approval. <sup>11</sup>
Article 4(4) of Regulation 853/2004	Requirement that food business operators co-operate with the competent authorities in accordance with Regulation 2017/625 including ensuring that an establishment ceases to operate if it is no longer approved. <sup>12</sup>

Article 5(1) of Regulation 853/2004	Requirement that food business operators do not place on the market a product of animal origin handled in an establishment subject to approval in accordance with Article 4(2) unless it has — (a) a health mark applied in accordance with Regulation 2017/625; or (b) when Regulation 2017/625 does not provide for the application of a health mark, an identification mark applied in accordance with Section 1 of Annex 2 to Regulation 853/2004. <sup>13</sup>
Article 5(2) of Regulation 853/2004	Requirement that food business operators apply an identification mark to a product of animal origin only if the product has been manufactured in accordance with Regulation 853/2004 in establishments meeting the requirements of Article 4.
Article 5(3) of Regulation 853/2004	Requirement that food business operators do not remove a health mark applied in accordance with Regulation 2017/625 from meat unless they cut or process it or work upon it in another manner. <sup>14</sup>
Article 6(1) and (2) of Regulation 853/2004	Requirement that food business operators ensure that importation of products of animal origin only takes place where certain conditions are met.
Article 6(3) of Regulation 853/2004	Requirement that food business operators importing products of animal origin shall ensure that — (a) products are made available for control upon importation in accordance with Council Directive 97/78/EC; (b) importation complies with the requirements of Council Directive 2002/99/EC; and (c) operations under their control that take place after importation are carried out in accordance with the requirements of Annex 3 to Regulation 853/2004.
Article 6(4) of Regulation 853/2004	Requirement that food business operators importing food containing both products of plant origin and processed products of animal origin ensure that the processed products of animal origin satisfy the requirements of paragraphs (1) to (3) of Article 6.
Article 7 of Regulation 853/2004	Requirement that food business operators ensure that certificates or other documents accompany consignments of products of animal origin when required in accordance with Annex 2 or 3 to Regulation 853/2004.
Article 7(1) of Regulation 2073/2005	Requirement that food business operators take the measures laid down in paragraphs (2) to (4) of Article 7 when the results of testing against the criteria set out in Annex 1 to Regulation 2073/2005 (microbiological criteria for foodstuffs) are unsatisfactory.

Article 9 of Regulation 2015/1375	Requirement that food business operators of holdings officially recognised as applying controlled housing conditions must inform the competent authority of any requirement of Annex 4 to Regulation 2015/1375 that is no longer fulfilled or of any other change that might affect the holdings' Trichinella status..
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**SCHEDULE 3****BULK TRANSPORT IN SEA-GOING VESSELS OF LIQUID OILS OR FATS AND  
THE BULK TRANSPORT BY SEA OF RAW SUGAR**

[Regulation 27]

*Offence*

1. A person who contravenes or fails to comply with any of the requirements of this Schedule shall be guilty of an offence.

*Liquid oils or fats*

2. [Revoked]<sup>15</sup>
3. [Revoked]<sup>16</sup>
4. [Revoked]<sup>17</sup>
5. [Revoked]<sup>18</sup>
6. [Revoked]<sup>19</sup>

*Raw sugar*

7. The bulk transport by sea of raw sugar which is not intended for use as food or as a food ingredient without a full and effective refining process is permitted in receptacles, containers or tankers that are not exclusively used for the transport of foodstuffs.
8. The receptacles, containers or tankers referred to in paragraph 7 shall be subject to the following conditions —
  - (a) prior to loading the raw sugar, the receptacle, container or tanker shall be effectively cleaned to remove residues of the previous cargo and other soiling and inspected to establish that such residues have been removed effectively; and
  - (b) the immediate previous cargo prior to the raw sugar shall not have been a bulk liquid.
9. A food business operator who is responsible for the transport of raw sugar by sea under paragraph 7 shall keep documentary evidence, accurately describing in detail the immediate previous cargo carried in the receptacle, container or tanker concerned, and the type and effectiveness of the cleaning process applied prior to the transport of the raw sugar.

10. The documentary evidence shall accompany the consignment of raw sugar during all stages of transport to the refinery and a copy shall be retained by the refinery. The documentary evidence shall be marked as follows in a clearly visible and indelible fashion, in one or more Community languages: “This product must be refined before being used for human consumption”.
11. On request, a food business operator responsible for the transport of the raw sugar or the refining process shall provide the enforcement authority with the documentary evidence referred to in paragraphs 9 and 10.
12. Raw sugar which has been transported by sea in receptacles, containers or tankers which are not exclusively reserved for the transport of foodstuffs shall be subjected to a full and effective refining process before being considered suitable for use as food or as a food ingredient.
13. In fulfilling his obligations under Article 5(1) of Regulation 852/2004 (hazard analysis and critical control points) in relation to the bulk transport of raw sugar by sea under paragraph 7, a food business operator who is responsible for the transport or refining of raw sugar shall —
- (a) consider the cleaning process undertaken prior to the loading of the sugar for transport by sea to be a critical control point as referred to in Article 5(2)(6) of Regulation 852/2004; and
  - (b) take into account the nature of the previous cargo which has been transported in any receptacle, container or tanker used for the transport of the sugar.

#### *Interpretation*

14. (1) For the purposes of this Schedule any words or expressions used both in this Schedule and in Commission Directive 98/28/EC granting a derogation from certain provisions of Directive 93/43/EEC on the hygiene of foodstuffs as regards the transport by sea of bulk raw sugar<sup>44</sup> shall bear the same meanings as they respectively have in those Directives.<sup>20</sup>
- (2) [Revoked]<sup>21</sup>

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<sup>44</sup> OJ No. L140, 12.5.98, p.10.

**SCHEDULE 4****TEMPERATURE CONTROL REQUIREMENTS**

[Regulation 28]

**1 Scope**

This Schedule does not apply in relation to —

- (a) any food business operation to which Regulation 853/2004 applies; or
- (b) any food business operation carried out on a ship or aircraft.

**2 Chill holding requirements**

- (1) Subject to sub-paragraph (2) and paragraph 3, any person who keeps any food —
  - (a) which is likely to support the growth of pathogenic micro-organisms or the formation of toxins; and
  - (b) with respect to which any commercial operation is being carried out, at or in food premises at a temperature above 8°C shall be guilty of an offence.
- (2) Sub-paragraph (1) shall not apply in relation to any food which, as part of a mail order transaction, is being conveyed to the final consumer.
- (3) Subject to paragraph 3, no person shall supply by mail order any food which —
  - (a) is likely to support the growth of pathogenic micro-organisms or the formation of toxins; and
  - (b) is being or has been conveyed by post or by a private or common carrier to the final consumer, at a temperature which has given rise to or is likely to give rise to a risk to health.

**3 General exemptions from the chill holding requirements**

Sub-paragraphs (1) and (3) of paragraph 2 shall not apply in relation to —

- (a) food which —
  - (i) has been cooked or reheated,
  - (ii) is for service or on display for sale, and
  - (iii) needs to be kept at or above 63°C in order to control the growth of pathogenic micro-organisms or the formation of toxins;

- (b) food which, for the duration of its shelf life may be kept at ambient temperatures with no risk to health;
- (c) food which is being or has been subjected to a process such as dehydration or canning intended to prevent the growth of pathogenic micro-organisms at ambient temperatures, but not where —
  - (i) after or by virtue of that process the food was contained in a hermetically sealed container, and
  - (ii) that container has been opened;
- (d) food which must be ripened or matured at ambient temperatures, but not when the process of ripening or maturation is completed;
- (e) raw food intended for further processing (including cooking) before human consumption, but only if that processing, if undertaken correctly, will render that food fit for human consumption;
- (f) food to which Council Regulation 1906/90 applies; and
- (g) food to which Council Regulation 1907/90 applies.

#### **4 Upward variation of the 8°C temperature by manufacturers etc.**

- (1) In any proceedings for an offence consisting of a contravention of subparagraph (1) of paragraph 2, it shall be a defence for the accused to prove that —
  - (a) a food business responsible for manufacturing, preparing or processing the food, including, where relevant, the accused, has recommended that it is kept
    - (i) at or below a specified temperature between 5°C and ambient temperatures, and
    - (ii) for a period not exceeding a specified shelf life;
  - (b) that recommendation has, unless the accused is that food business, been communicated to the accused either by means of a label on the packaging of the food or by means of some other appropriate form of written instruction;
  - (c) the food was not kept by the accused at a temperature above the specified temperature; and
  - (d) at the time of the commission of the alleged offence, the specified shelf life had not been exceeded.
- (2) A food business responsible for manufacturing, preparing or processing food shall not recommend that any food is kept —
  - (a) at or below a specified temperature between 5°C and ambient temperatures; and

- (b) for a period not exceeding a specified shelf life, unless that recommendation is supported by a well-founded scientific assessment of the safety of the food at the specified temperature.

## 5 Chill holding tolerance periods

- (1) In any proceedings for an offence consisting of a contravention of sub-paragraph (1) of paragraph 2, it shall be a defence for the accused to prove that the food
  - (a) was for service or on display for sale;
  - (b) had not previously been kept for service or on display for sale at a temperature above 5°C or, where a recommendation has been made pursuant to sub-paragraph (1) of paragraph 4, the recommended temperature; and
  - (c) had been kept for service or on display for sale for a period of less than four hours.
- (2) In any proceedings for an offence consisting of a contravention of sub-paragraph (1) of paragraph 2, it shall be a defence for the accused to prove that the food —
  - (a) was being transferred —
    - (i) from premises at which the food was going to be kept at or below 8°C or in appropriate circumstances the recommended temperature to a vehicle used for the purposes of a food business, or
    - (ii) to such premises from such a vehicle; or
  - (b) was kept at a temperature above 5°C or, in appropriate circumstances, the recommended temperature for an unavoidable reason, such as —
    - (i) to accommodate the practicalities of handling during and after processing or preparation,
    - (ii) the defrosting of equipment, or
    - (iii) temporary breakdown of equipment,and was kept at a temperature above 5°C or, in appropriate circumstances, the recommended temperature for a limited period only and that period was consistent with food safety.

## 6 Hot holding requirements

Any person who in the course of the activities of a food business keeps at or in food premises at a temperature below 63°C any food which —

- (a) has been cooked or reheated;

- (b) is for service or on display for sale; and
- (c) needs to be kept at or above 63°C in order to control the growth of pathogenic micro-organisms or the formation of toxins,

shall be guilty of an offence.

## 7 Hot holding defences

- (1) In any proceedings for an offence consisting of a contravention of paragraph 6, it shall be a defence for the accused to prove that —
  - (a) a well-founded scientific assessment of the safety of the food at temperatures below 63°C has concluded that there is no risk to health if, after cooking or re-heating, the food is held for service or on display for sale —
    - (i) at a holding temperature which is below 63°C, and
    - (ii) for a period not exceeding any period of time specified in that scientific assessment; and
  - (b) at the time of the commission of the alleged offence, the food was held in a manner which was justified in the light of that scientific assessment.
- (2) In any proceedings for an offence consisting of a contravention of paragraph 6, it shall be a defence for the accused to prove that the food —
  - (a) had been kept for service or on display for sale for a period of less than two hours; and
  - (b) had not previously been kept for service or on display for sale by that person.

## 8 Interpretation

In this Schedule —

“**Council Regulation 1906/90**” means Council Regulation (EEC) No. 1906/90 on certain marketing standards for poultry<sup>45</sup> as last amended by Council Regulation (EC) No. 1101/98 amending Regulation (EEC) No. 1906/90 on certain marketing standards for poultrymeat;<sup>46</sup>

“**Council Regulation 1907/90**” means Council Regulation (EEC) No. 1907/90 on certain marketing standards for eggs<sup>47</sup> as last amended by Council Regulation (EC) No. 2052/2003 amending Regulation (EEC) No. 1907/90 on certain marketing standards for eggs<sup>48</sup>;

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<sup>45</sup> OJ No. L173, 6.7.90, p.1.

<sup>46</sup> OJ No. L157, 30.5.98, p.12.

<sup>47</sup> OJ No. L173, 6.7.90, p.5.

<sup>48</sup> OJ No. L305, 22.11.2003, p.1.

“**recommended temperature**” means a specified temperature which has been recommended in accordance with sub-paragraph (1)(a)(i) of paragraph 4; and

“**shelf life**” means —

- (a) in relation to food for which a date of minimum durability is required in accordance with Article 9.1(f) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, as read with Article 24.1 and 24.2 of that Regulation, the period up to and including the required date of minimum durability;
- (b) in relation to food for which a “use by” date is required in accordance with Article 9.1(f) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council, as read with Article 24.1 and 24.2 of that Regulation, the period up to and including the required “use by” date; and
- (c) in relation to food which is not required to bear an indication of minimum durability or a “use by” date, the period for which the food can be expected to remain fit for sale if it is kept in a manner which is consistent with food safety.<sup>22</sup>

**SCHEDULE 5****DIRECT SUPPLY BY THE PRODUCER OF SMALL QUANTITIES OF MEAT FROM  
POULTRY OR LAGOMORPHS SLAUGHTERED ON THE FARM**

[Regulation 29]

**1 Scope**

The requirements of this Schedule apply in relation to the direct supply by the producer of small quantities of meat from poultry or lagomorphs that have been slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer.

**2 Requirements**

- (1) Where a producer supplies meat in the manner described in paragraph 1, he or she shall ensure that it bears a label or other marking clearly indicating the name and address of the farm where the animal from which it is derived was slaughtered.
- (2) The producer shall —
  - (a) keep a record in adequate form to show the number of birds and the number of lagomorphs received into, and the amounts of fresh meat despatched from, his or her premises during each week;
  - (b) retain the record for a period of one year; and
  - (c) make the record available to an authorised officer on request.

**3 Offence**

A producer who fails to comply with any of the requirements of paragraph 2 shall be guilty of an offence.



**SCHEDULE 6****RESTRICTIONS ON THE PLACING ON THE MARKET OF RAW MILK AND  
RAW CREAM**

[Regulation 30]

1. No person shall place on the market raw milk, or raw cream, intended for direct human consumption.
2. Any person who contravenes paragraph 1 above shall be guilty of an offence.
3. In any proceedings for an offence in respect of a contravention of paragraph 1 above, it shall be a defence for the accused to prove that the milk or cream in respect of which the offence is alleged to have been committed was intended for export —
  - (a) to England and that the milk or cream complies with the provisions of the Food Safety and Hygiene (England) Regulations 2013<sup>49,23</sup>
  - (b) to Scotland and that the milk or cream complies with the provisions of the Food Hygiene (Scotland) Regulations 2006<sup>50</sup>;
  - (c) to Wales and that the milk or cream complies with the provisions of the Food Hygiene (Wales) Regulations 2006<sup>51,24</sup>
  - (d) to Northern Ireland and that the milk or cream complies with the provisions of the Food Hygiene Regulations (Northern Ireland) 2006<sup>52,25</sup>
  - (e) to a Member State and that the milk or cream complies with Regulation 853/2004 and any national rules applicable in that member State made pursuant to Article 10.8(a) of Regulation 853/2004; or<sup>26</sup>
  - (f) to a third country which has legislation analogous to Regulation 853/2004 and that the milk or cream complies with that legislation.

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<sup>49</sup> SI 2013/2996.

<sup>50</sup> Scottish S.I. No. 3

<sup>51</sup> Welsh SI 2006/31.

<sup>52</sup> Northern Ireland S.R. 2006 No. 3.

**SCHEDULE 7**  
**CONSEQUENTIAL AMENDMENTS**

[Regulation 31]

**The Food Labelling Regulations 2004** <sup>53</sup>

1. The Food Labelling Regulations 2004 are amended as provided in paragraphs 2 and 3.
2. In Schedule 4 (Generic names in list of ingredients), in the description of “Ingredients” in column 3 of Part I (General) for Item 12 (“Meat” and the name of the animal species from which it comes, or a word which describes the meat by reference to the animal species from which it comes”) there appears a footnote reference (60) concerning the European Community definition of “mechanically recovered meat”. The wording of footnote 60 is substituted by the wording specified in paragraph 3.
3. The new wording for footnote 60 is:

60 The definition is currently the product obtained by removing the meat from flesh-bearing bones after boning or from carcasses of farmed birds (including birds that are not considered as domestic but which are farmed as domestic animals, but not including ratites) using mechanical means resulting in the loss or modification of the muscle fibre structure. 60.

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<sup>53</sup> SD 453/04



**SCHEDULE 9**  
**REVOCATIONS**  
[Regulation 32]

<b>Statute or Document</b>	<b>Reference</b>
The Minced Meat and Meat Preparations (Hygiene) Regulations 2001	SD 783/00
The Fresh Meat (Hygiene and Inspection) (No.2) Regulations 1997	SD 365/97
The Dairy Products (Hygiene) Regulations 1997	SD 97/97
The Food Safety (Fishery Products) (Derogations) Regulations 1993	SD 42/93
The Food Hygiene (General) Regulation 1978	GC 188/78
The Food Hygiene (Docks, Carriers, Etc.) Regulations 1978	GC 185/78

## ENDNOTES

### Table of Endnote References

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<sup>1</sup> The format of this legislation has been changed as provided for under section 75 of, and paragraph 2 of Schedule 1 to, the Legislation Act 2015. The changes have been approved by the Attorney General after consultation with the Clerk of Tynwald as required by section 76 of the Legislation Act 2015.

<sup>2</sup> Definition of “the Community Regulations” substituted by SD2019/0497.

<sup>3</sup> Definition revoked by SD2023/0284.

<sup>4</sup> Definition of “the Regulation 2017/625 package” inserted by SD2019/0497 and amended by SD2019/0512 with effect from 31/12/2020 at 23:00 and substituted by SD2023/0284.

<sup>5</sup> Para (1A) inserted by SD2019/0363 and substituted by SD2023/0284.

<sup>6</sup> Para (5) inserted by SD2023/0284.

<sup>7</sup> Para (1) amended by SD2020/0544 with effect from 31/12/2020 at 23:00.

<sup>8</sup> Para (5) inserted by SD2020/0544 with effect from 31/12/2020 at 23:00.

<sup>9</sup> Sch 1 substituted by SD2023/0284.

<sup>10</sup> Table substituted by SD2019/0374 with effect from 31/12/2020 at 23:00.

<sup>11</sup> Entry amended by SD2023/0284.

<sup>12</sup> Entry amended by SD2023/0284.

<sup>13</sup> Entry amended by SD2023/0284.

<sup>14</sup> Entry amended by SD2023/0284.

<sup>15</sup> Para 2 revoked by SD2019/0363.

<sup>16</sup> Para 3 revoked by SD2019/0363.

<sup>17</sup> Para 4 revoked by SD2019/0363.

<sup>18</sup> Para 5 revoked by SD2019/0363.

<sup>19</sup> Para 6 revoked by SD2019/0363.

<sup>20</sup> Subpara (1) amended by SD2019/0363.

<sup>21</sup> Subpara (2) revoked by SD2019/0363.

<sup>22</sup> Definition of “shelf life” substituted by SD2019/0363.

<sup>23</sup> Subpara (a) amended by SD2019/0363.

<sup>24</sup> Subpara (c) amended by SD2019/0363.

<sup>25</sup> Subpara (d) amended by SD2019/0363.

<sup>26</sup> Subpara (e) amended by SD2019/0374 with effect from 31/12/2020 at 23:00.