



STATUTORY INSTRUMENTS

S.I. No. 183 of 2009

EUROPEAN COMMUNITIES (CONTROL OF ANIMAL REMEDIES
AND THEIR RESIDUES) REGULATIONS 2009

(Prn. A9/0661)

EUROPEAN COMMUNITIES (CONTROL OF ANIMAL REMEDIES
AND THEIR RESIDUES) REGULATIONS 2009

I, BRENDAN SMITH, Minister for Agriculture, Fisheries and Food, in exercise of the powers conferred on me by section 3 of the European Communities Act, 1972 (No. 27 of 1972), for the purpose of giving effect to Council Directive 96/22/EC¹ of 29 April 1996, as amended by Directive 2003/74/EC² of the European Parliament and of the Council of 22 September 2003 and Directive 2008/97/EC³ of the European Parliament and of the Council of 19 November 2008 and Council Directive 96/23/EC⁴ of 29 April 1996, as amended by Council Regulation (EC) No. 806/2003⁵ of 14 April 2003, Regulation (EC) No. 882/2004⁶ of the European Parliament and of the Council of 29 April 2004 and Council Directive 2006/104/EC⁷ of 20 November 2006, hereby make the following Regulations:

Citation

1. These Regulations may be cited as the European Communities (Control of Animal Remedies and their Residues) Regulations, 2009.

Interpretation

2. (1) In these Regulations—

“Act” means the Animal Remedies Act, 1993 (No. 23 of 1993);

“animal” has the same meaning as it has in Section 2 of the Act and in the Animal Remedies Act (Section 2) Order 2005 (S.I. No. 733 of 2005);

“approved laboratory” means a laboratory designated as an approved laboratory in accordance with Regulation 13;

“authorised officer” means a person who is an authorised officer within the meaning of the Act;

“Council Directives” means Council Directive 96/22/EC of 29 April 1996 and Council Directive 96/23/EC of 29 April 1996, as amended;

“eartag” means an approved eartag within the meaning of the European Communities (Identification of Bovines) Regulations 2009 (S.I. No. 77 of 2009);

¹O.J. L 125 of 23.5.96

²O.J. L 262 of 14.10.2003

³O.J. L 318 of 28.11.2008

⁴O.J. L 125 of 23.5.96

⁵O.J. L 122 of 15.5.2003

⁶O.J. L 191 of 28.5.2004

⁷O.J. L 363 of 20.12.2006

*Notice of the making of this Statutory Instrument was published in
“Iris Oifigiúil” of 15th May, 2009.*

“establishment” means an establishment approved or requiring to be approved under the European Communities (Food and Feed Hygiene) Regulations 2005 (S.I. No. 910 of 2005);

“farm animal” means a domestic animal of the bovine, porcine, ovine, caprine or cervine species, a domestic soliped, poultry, or rabbit, including a wild animal of those species;

“identity card” means—

- (a) a cattle identity card or a passport within the meaning of the European Communities (Identification of Bovines) Regulations 2009 (S.I. No. 77 of 2009), or
- (b) an identification document within the meaning of the European Communities (Equine Stud Book and Competition) Regulations 2004 (S.I. No. 399/2004);

“maximum residue limit” has the same meaning as it has in Council Regulation (EEC) No. 2377/90⁸ of 26 June 1990;

“national reference laboratory” means a laboratory designated as a national reference laboratory in accordance with Regulation 13;

“official mark” means a mark in the form set out in the Schedule;

“prohibited animal remedy” means an animal remedy or ingredient for an animal remedy in respect of which, by virtue of these Regulations or the European Communities (Animal Remedies) (No. 2) Regulations (S.I. No. 786/2007), a licence, authorisation, registration or direction is required for the purpose of its administration to an animal or for other purposes and either—

- (a) such licence, authorisation, registration or direction has not been issued, or
- (b) where such licence, authorisation, registration or direction has been issued, a condition or other requirement, to which it is subject, has not been complied with or is no longer complied with;

“registered veterinary practitioner” means a veterinary practitioner registered under the Veterinary Practice Act 2005 (No. 22 of 2005);

“slaughter”, in relation to an animal, means slaughter for the purposes of the production of meat or other food intended for human or animal consumption.

(2) A word or expression that is used in these Regulations and that is also used in the Council Directives has, unless the contrary intention appears, the same meaning in these Regulations as it has in the Council Directives.

⁸OJ L 224. 18.8.1990

(3) A word or expression that is used in these Regulations and is also used in the Act or the European Communities (Animal Remedies) (No. 2) Regulations 2007 has, in these Regulations, unless the contrary intention appears, the same meaning as it has in the Act or in the European Communities (Animal Remedies) (No. 2) Regulations 2007.

Restriction on import, manufacture, sale or supply of certain animal remedies

3. (1) Subject to these Regulations, a person shall not manufacture, import, possess, sell or supply an animal remedy consisting of or containing—

(a) a stilbene, stilbene derivative, salt or ester of a stilbene or stilbene derivative, or a thyrostatic substance,

(b) a beta-agonist, or

(c) a substance having an oestrogenic, androgenic or gestagenic action.

(2) (a) Subject to sub-paragraph (b), a person may, in accordance with an animal remedies authorisation, import, possess, sell or supply an animal remedy consisting of or containing a substance to which paragraph (1) applies.

(b) A person shall not, except in accordance with a manufacturer's licence, manufacture or import from a state, other than a member state, an animal remedy consisting of or containing a substance to which paragraph (1) applies.

(3) A person shall not manufacture, import, sell, hire or otherwise supply or use, or have in his or her possession or under his or her control any plant, machinery, instrument, cartridge, container, utensil, label, package, package insert or other thing, made or adapted for use in connection with—

(a) the manufacture of a prohibited animal remedy,

(b) the administration of a prohibited animal remedy to a farm or aquaculture animal.

Prohibition on administration of stilbenes or oestradiol 17 β to a farm or aquaculture animal

4. (1) A person shall not administer, or cause to be administered to a farm or aquaculture animal, an animal remedy consisting of or containing—

(a) a substance to which Regulation 3(1)(a) applies, or

(b) oestradiol 17 β or its ester-like derivatives.

(2) A person shall not—

(a) import, export, sell, supply or slaughter an animal to which an animal remedy referred to in paragraph (1) has been administered,

- (b) import, export, sell or supply meat or other food derived from an animal referred to in subparagraph (a), or any meat product prepared from or with any such meat,
- (c) subject meat or other food referred to in subparagraph (b) to any manufacturing process, or
- (d) subject to Regulation 18(2), possess, or have under his or her control, an animal to which an animal remedy has been administered in contravention of paragraph (1), or meat, a meat product or other food derived from the animal.

Restriction on administration of certain substances to a farm or aquaculture animal.

5. (1) A person shall not administer, or cause to be administered to a farm or aquaculture animal, an animal remedy consisting of or containing a substance to which Regulation 3 (1) (b) or (c) applies, unless the administration is carried out in accordance with Regulation 8, 9 or 10.

(2) a person shall not—

- (a) import, export, sell, supply or slaughter an animal to which an animal remedy has been administered in contravention of paragraph (1),
- (b) import, export, sell or supply meat or other food derived from an animal referred to in subparagraph (a), or any meat product prepared from or with any such meat,
- (c) subject meat or other food referred to in subparagraph (b) to any manufacturing process, or
- (d) subject to Regulation 18(2), possess, or have under his or her control, an animal to which an animal remedy has been administered in contravention of paragraph (1), or meat, a meat product or other food derived from the animal.

Unlawful to sell or slaughter certain Animals, etc.

6. (1) A person shall not sell or slaughter a farm or aquaculture animal to which a prohibited animal remedy has been administered.

(2) A person shall not sell or slaughter a farm or aquaculture animal where there is present in the animal a quantity of an animal remedy in excess of the maximum residue limit.

(3) A person shall not sell meat, meat product or other food of animal origin that contains a quantity of an authorised animal remedy in excess of the maximum residue limit.

(4) A person shall not sell meat, a meat product or other food of animal origin that contains a prohibited animal remedy.

Detention of certain animals at establishments

7. (1) If an authorised officer has reasonable grounds for believing that a prohibited animal remedy has been administered to an animal presented for slaughter he or she shall—

- (a) direct that the animal be slaughtered separately from other animals at such time as he or she may specify, and
- (b) (i) issue a direction under Regulation 14 in respect of the meat, offal and carcase of the animal, or
- (ii) detain the meat, offal and carcase of the animal.

(2) If an authorised officer has reasonable grounds for believing that an authorised animal remedy has been administered to an animal presented for slaughter and that the withdrawal period in respect of the animal remedy has not expired he or she shall give a direction under Regulation 14 to the owner or occupier of the premises—

- (a) prohibiting the movement of the animal from the premises, and
- (b) prohibiting the sale or slaughter of the animal,

until such time as the authorised officer is satisfied that the quantity of the authorised animal remedy present in the animal no longer exceeds the maximum residue limit.

(3) If, having regard to Article 24(2) of Council Directive 96/23/EC of 29 April 1996, it would not be appropriate for an authorised officer to give a direction in accordance with paragraph (2), he or she may direct that the animal be slaughtered before the expiry of the period specified in paragraph (3) and give a direction under Regulation 14 to the owner or occupier of the premises prohibiting the movement or sale of all meat, meat products or other food derived from the animal until the authorised officer is satisfied that meat, meat products or other food does not contain a quantity of an authorised animal remedy in excess of the maximum residue limit.

(4) An authorised officer shall declare to be unfit for human consumption all meat, meat products or other food derived from an animal in which, at the time of its slaughter, there is present a quantity of an authorised animal remedy in excess of the maximum residue limit.

(5) An authorised officer shall declare to be unfit for human consumption all meat, meat products or other food of animal origin containing a quantity of an authorised animal remedy in excess of the maximum residue limit.

Administration of certain animal remedies for the purposes of therapeutic treatment

8. (1) A registered veterinary practitioner may, for therapeutic purposes and in accordance with the terms and conditions of an animal remedies authorisation, administer an animal remedy, consisting of or containing testosterone,

progesterone or derivatives thereof that readily yield the parent compound on hydrolysis after absorption at the site of application, to a farm animal,—

- (a) in the form of a vaginal spiral to treat ovarian dysfunction, or
- (b) by injection in any other case covered by this paragraph.

(2) A registered veterinary practitioner or, pursuant to a veterinary prescription, a person other than a registered veterinary practitioner, may, for therapeutic treatment and in accordance with the terms and conditions of an animal remedies authorisation, administer orally an animal remedy, consisting of or containing allyl trenbolone, to an equid.

(3) A farm animal (other than a bovine animal to whose ear an eartag has been affixed), to which an authorised animal remedy has been administered in accordance with this Regulation, shall be clearly identified by the owner or person in charge of the animal at the time the animal remedy is administered.

Administration of beta-agonists for the purposes of therapeutic treatment.

9. (1) A registered veterinary practitioner may, for the purpose of inducing tocolysis and in accordance with the terms and conditions of an animal remedies authorisation, administer, by injection, an animal remedy, consisting of or containing a beta-agonist, to a cow when calving.

(2) A registered veterinary practitioner or, pursuant to a veterinary prescription, a person, other than a registered veterinary practitioner, may, in accordance with the terms and conditions of an animal remedies authorisation, administer an animal remedy, consisting of or containing a beta-agonist, to an equid to induce tocolysis or to treat a respiratory problem, navicular disease or laminitis.

(3) The owner or person in charge of a farm animal (other than a bovine animal to whose ear an eartag has been affixed) to which an authorised animal remedy has been administered in accordance with this Regulation shall clearly identify the animal at the time the animal remedy is administered.

Administration of certain animal remedies for zootechnical purposes

10. (1) A registered veterinary practitioner or, pursuant to a veterinary prescription, a person other than a registered veterinary practitioner, may, in accordance with the terms and conditions of an animal remedies authorisation, administer an animal remedy consisting of or containing a substance having an oestrogenic (other than oestradiol 17 β or its ester-like derivatives), androgenic or gestagenic action to a farm animal to synchronise oestrus or prepare donors and recipients for the implantation of embryos.

(2) A registered veterinary practitioner or, pursuant to a veterinary prescription, a person other than a registered veterinary practitioner, may, in accordance with the terms and conditions of an animal remedies authorisation, administer an animal remedy, consisting of or containing a substance having an androgenic action, to an aquaculture animal aged not more than 3 months for the purposes of sex inversion.

(3) The owner or person in charge of a farm animal (other than a bovine animal to whose ear an eartag has been affixed), or an aquaculture animal, to which an authorised animal remedy has been administered in accordance with this Regulation shall clearly identify the animal at the time the animal remedy is administered.

Register of animal remedies administered

11. (1) A registered veterinary practitioner, to whom Regulation 8, 9 or 10 applies, shall cause to be established and maintained a register of animal remedies administered under those Regulations by him or her or by another person pursuant to a veterinary prescription issued by the registered veterinary practitioner.

(2) A registered veterinary practitioner shall, at the time of administering or prescribing an animal remedy pursuant to Regulation 8, 9, or 10, enter in the register maintained under this Regulation the—

- (a) nature of the treatment,
- (b) identity and quantity of animal remedy administered,
- (c) date of administration,
- (d) identity of the farm or aquaculture animal, and
- (e) date of expiry of the withdrawal period referred to in Regulation 40(2)(a)(ii) of the European Communities (Animal Remedies)(No. 2) Regulations 2007.

(3) If a person, other than a registered veterinary practitioner, administers an animal remedy to a farm or aquaculture animal, pursuant to Regulation 8, 9 or 10, he or she shall immediately inform the registered veterinary practitioner who issued the prescription in respect of the animal remedy of the fact and the registered veterinary practitioner shall enter the particulars specified in paragraph (2) in the register maintained under this Regulation.

(4) If a person, other than a registered veterinary practitioner, administers an animal remedy to a farm or aquaculture animal, pursuant to Regulation 8, 9 or 10, the registered veterinary practitioner shall enter in the register maintained under this Regulation (in addition to the particulars specified in paragraph (2)) the date of issue by him or her of the relevant prescription.

(5) A registered veterinary practitioner shall maintain an entry in a register maintained under this Regulation for a period of 5 years and shall make it available, on request, for inspection by an authorised officer.

Prohibition on administration

12. Notwithstanding Regulations 8, 9 or 10, a person shall not administer, or cause to be administered, an animal remedy, to which any of those Regulations apply, to—

- (a) a farm animal intended for fattening,
- (b) a castrate farm animal other than an equid, or
- (c) a reproductive farm animal during the fattening period at the end of its breeding life.

Laboratories

13. (1) The Minister may designate, by instrument in writing, a laboratory as an approved laboratory, and a person for the time being employed or engaged in the analysis of specimens at a laboratory so designated may perform the functions of an approved laboratory.

(2) The Minister may, in accordance with Article 14 of Council Directive 96/23/EC of 29 April 1996, designate, in the plan submitted by him or her under Article 5 of that Directive, a laboratory as a national reference laboratory, and a person for the time being employed or engaged in the analysis of specimens at a laboratory so designated may perform the functions of a national reference laboratory.

Restriction of movement of certain animals

14. (1) If—

- (a) an authorised officer has reasonable grounds for believing that, in relation to an animal, meat, meat product, other food of animal origin or an animal remedy, there has been a contravention of these Regulations,
- (b) an authorised officer receives a notification in writing from an approved laboratory or a national reference laboratory, that a specimen taken from an animal, meat, meat product or other food of animal origin was found, on analysis at the laboratory—
 - (i) to contain a prohibited animal remedy, or
 - (ii) to contain a residue of an animal remedy in excess of the maximum residue limit in respect thereof,
- (c) a prohibited animal remedy is found on land or premises, or
- (d) any plant, machinery, instrument, cartridge, container, utensil, label, package, insert or other thing to which Regulation 3(3) applies, is found on land or premises,

the authorised officer may give a direction, in accordance with paragraph (2), to—

- (i) the owner or occupier of—

(I) the land or premises on which the authorised officer has reasonable grounds for believing that the contravention referred to in paragraph (a) has taken place,

(II) the land or premises on which the specimen referred to in paragraph (b) was taken, or

(III) the land or premises to which paragraph (c) or (d) applies,

or

(ii) the owner or person in charge or control of—

(I) an animal, meat, meat product or other food of animal origin to which paragraph (a) or (b) applies, or

(II) an animal, meat, meat product or other food of animal origin found on land or premises to which paragraph (c) or (d) applies.

(2) A direction under paragraph (1) shall be in writing and may, subject to paragraph (5)—

(a) prohibit the movement of—

(i) all animals, meat, meat products, or other food of animal origin, or

(ii) such animal, meat, meat product or other food of animal origin as is specified in the direction,

from the land or premises or any part thereof as is specified in the direction,

(b) prohibit the movement of all animals, meat, meat products or other food of animal origin into the land or premises,

(c) prohibit the sale or slaughter of the animals as may be specified in the direction, or

(d) require the owner or occupier of the land or premises or the person in charge of or in control of the animal, meat, meat product or food to comply with such other restrictions relating to the movement of animals, meat, meat products or food of animal origin as may be specified in the direction for such period as may be specified in the direction.

(3) An authorised officer may, by direction in writing, amend or revoke a direction given by him or her under this Regulation, including a direction under this paragraph.

(4) A direction under this Regulation remains in force until it is revoked.

(5) Following an application in writing from the owner of an animal to which a direction under this Regulation applies, and on the taking from such animal by an authorised officer and analysis at an approved laboratory of such specimens as the authorised officer considers appropriate, an authorised officer may issue a permit allowing the movement of the animal concerned into or out of the land or premises or part thereof to which the direction relates, or the sale or slaughter of such animal.

(6) The costs of the taking and analysis of a specimen pursuant to paragraph (5) shall be borne by the owner of the animal concerned and shall be recoverable by the Minister—

- (a) in any court of competent jurisdiction as a simple contract debt, or
- (b) by deducting the costs from any sum due or becoming due from the Minister to the owner.

Testing of animals

15. (1) If an authorised officer receives notification in writing from an approved laboratory or a national reference laboratory that, on analysis at the laboratory concerned, a specimen taken by him or her from an animal was found to contain a prohibited animal remedy, an authorised officer may, in accordance with Article 17 of Council Directive 96/23/EC of 29 April 1996, take specimens from a statistically representative sample of the batch of animals to which the said animal belongs.

(2) If, in relation to not less than half of the specimens taken under paragraph (1), an authorised officer receives notification in writing from an approved laboratory or a national reference laboratory, that the specimens were found, on analysis at the laboratory concerned, to contain a prohibited animal remedy, an authorised officer may take specimens from the remaining animals in the batch referred to in paragraph (1).

(3) The costs of the taking and analysis of a specimen under this Regulation shall be borne by the owner or person in charge of the animal concerned and shall be recoverable by the Minister—

- (a) in any court of competent jurisdiction as a simple contract debt, or
- (b) by deducting the costs from any sum due or becoming due from the Minister to the owner.

(4) Paragraph (2) does not apply where the owner or person in charge of the animal consents to their destruction in accordance with Regulation 18.

Surrender of Identity Cards

16. (1) A person having in his or her possession, or under his or her control—

- (a) an identity card issued in respect of an animal on land or premises to which a direction under Regulation 14 applies, or

- (b) an identity card issued in respect of an animal to which a direction under that Regulation applies,

shall surrender the identity card to an authorised officer.

(2) The owner or occupier of land or premises to which a direction under Regulation 14 applies shall, at the request of an authorised officer, make a declaration, in writing, in the form specified, of the number and species of animals on the land or premises.

(3) The owner or person in charge or control of an animal to whom a direction under Regulation 14 is addressed shall, at the request of an authorised officer, make a declaration, in writing, in the form specified, of all land or premises of which he or she is the owner or occupier and the number and species of animals on such land or premises.

(4) If the owner or person in charge of an animal referred to in paragraph (1), or the owner or occupier of land on which such animal is for the time being kept, does not have in his or her possession or under his or her control the identity card in respect of the animal concerned, he or she shall, at the request of an authorised officer, furnish the authorised officer with the necessary details of the person and location at which the identity card can be obtained.

Marking of animals

17. (1) If an authorised officer receives notification in writing from an approved laboratory or a national reference laboratory that a specimen taken from an animal was found, on analysis at the laboratory concerned, to contain a prohibited animal remedy, the official mark in indelible form shall be affixed to the animal, from which the specimen was taken, in such manner as an authorised officer considers appropriate.

(2) If—

- (a) an authorised officer has reasonable grounds for believing that a residue of an authorised animal remedy exceeding the maximum residue limit is present in an animal,
- (b) a specimen taken from an animal is shown, on analysis at an approved laboratory, to contain a residue of an animal remedy exceeding the maximum residue limit,
- (c) an authorised officer has reasonable grounds for believing that a prohibited animal remedy has been administered to an animal,

the official mark (other than in indelible form) shall be affixed to the animal concerned in such manner as an authorised officer considers appropriate.

(3) A person shall not have in his or her possession or under his or her control an animal to which a mark has been affixed pursuant to this Regulation, unless that person is—

- (a) a person to whom a direction under Regulation 14 is addressed,
- (b) an authorised officer, or
- (c) a person authorised in that behalf by an authorised officer.

(4) A person shall not remove, or attempt to remove or obscure, other than in accordance with the instructions of an authorised officer, the official mark affixed under this Regulation.

(5) A person shall not move an animal to which the official mark is affixed from the land or premises at which it was affixed other than for the purpose of destroying such animal in accordance with Regulation 18.

(6) A person shall not sell or slaughter an animal to which the official mark is affixed.

Destruction of Animal where Illegal Treatment established

18. (1) If the official mark has been applied to an animal pursuant to Regulation 17 or if an authorised officer receives notification in writing from an approved laboratory or a national reference laboratory that a specimen taken from an animal was found, on analysis at the laboratory concerned, to contain a prohibited animal remedy, the authorised officer may destroy or cause to be destroyed the animal concerned and its carcase in such manner as he or she deems appropriate.

(2) Notwithstanding Regulations 4 and 5, a person may have in his or her possession or under his or her control an animal or carcase of an animal to which either of those Regulations apply for the purpose of complying with paragraph (1).

(3) The cost of destroying an animal or its carcase under this Regulation shall, subject to paragraph (4), be borne by the owner of the animal and may be recoverable by the Minister-

- (a) in any court of competent jurisdiction as a simple contract debt, or
- (b) by deducting the costs from any sum due or becoming due from the Minister to the owner.

(4) If the owner or person in charge of an animal destroyed under this Regulation is not the same person, both the owner and the person in charge of the animal shall be jointly and severally liable for the costs of the destruction of the animal and its carcase.

Unlawful to sell etc. an animal or animal product until certain conditions are met.

19. (1) A person shall not—

- (a) sell, slaughter or export an animal to which an animal remedy has been administered in accordance with Regulation 8, 9 or 10,

- (b) export or sell meat, a meat product or other food (or process such meat, meat product or other food) derived from an animal to which an animal remedy has been administered in accordance with Regulation 8, 9 or 10,

unless,

- (i) the withdrawal period pursuant to the relevant animal remedies authorisation has elapsed,
 - (ii) Regulation 42(2) and (3) of the European Communities (Animal Remedies) (No 2) Regulations 2007 is complied with, and
 - (iii) the Animal Remedies Record is available for inspection on request by an authorised officer.
- (2) (a) Notwithstanding paragraph (1), a person may, subject to subparagraph (b), import, export or sell a high-value horse, in particular, a racehorse, competition horse, circus horse or horse intended for stud purposes or for exhibition purposes, including a registered equid, to which an animal remedy consisting of or containing—
- (i) allyl trenbolone has been administered in accordance with Regulation 8(2), or
 - (ii) a beta-agonist has been administered in accordance with Regulation 9,
- before the end of the withdrawal period,
- (b) A person referred to in subparagraph (a) shall ensure that the certificate or passport in respect of the animal concerned specifies the nature, method and date of administration of the animal remedy.

Register of Certain Substances etc

20. (1) A person who engages in—

- (a) the manufacture of a substance to which Regulation 3 applies, or
- (b) the importation, purchase or sale of such substance,

shall establish and maintain a register containing the particulars specified in paragraph (2).

(2) A person to whom paragraph (1) applies shall enter in chronological order the following particulars in the register established and maintained by him or her under this Regulation—

- (a) the quantities of each substance referred to in paragraph (1) manufactured, imported, purchased or otherwise acquired by him or her,

- (b) the quantities of each such substance sold for or used in the manufacture of pharmaceutical or veterinary medicinal products, and
- (c) the name of the person to whom such quantities were sold or from whom they were purchased or otherwise acquired and the address at which he or she ordinarily resides.

(3) A person to whom this Regulation applies shall furnish the Minister with such particulars required to be entered in a register under this Regulation as the Minister may from time to time direct in such form as he or she may direct.

Self Monitoring

21. (1) The owner or person in charge of an approved establishment shall, not later than the 31st day of October in each year, prepare and submit to the Minister a plan, in respect of the following year, for the detection of substances, veterinary drugs and contaminants specified in Annex 1 to Council Directive 96/23/EC of 29 April 1996 in—

- (a) animals presented for slaughter,
- (b) meat, meat products or other food derived from such animals, and
- (c) milk, honey or eggs

at the establishment, and the plan shall, if approved by the Minister, be carried out by the owner or person in charge of the establishment in accordance with its terms.

(2) Without prejudice to the generality of paragraph (1), the Minister may direct that a plan prepared and submitted under this Regulation shall contain such provisions and comply with such requirements as are specified in the direction, including provisions and requirements relating to—

- (a) the form of the plan,
- (b) taking of specimens at an approved establishment as may be appropriate,
- (c) the manner in which the analysis of specimens is to be carried out,
- (d) the frequency with which testing is to be conducted,
- (e) the number, species and age of animals to be tested,
- (f) the foods of animal origin to be tested, and
- (g) measures to be taken by the owner or person in charge of the establishment concerned if a positive result is detected.

(3) A plan prepared and submitted under this Regulation shall comply with a direction given under paragraph (2).

(4) The Minister may approve a plan prepared and submitted under this Regulation.

(5) The Minister may within a period of 60 days of the submission of a plan to him or her under this Regulation require, by notice in writing, that the plan concerned be modified in such manner as he or she directs.

(6) If the Minister requires that a plan submitted under paragraph (1) be modified, the owner or person in charge of the establishment concerned shall modify the plan in accordance with directions of the Minister and shall, within a period of 30 days of receipt by him or her of a notice under paragraph (5), submit the plan as so modified to the Minister for approval by him or her.

(7) If the Minister does not, within a period of 60 days of the submission of a plan to him or her under paragraph (1)—

(a) approve,

(b) refuse approval of, or

(c) require under paragraph (6) the modification of,

the plan concerned, it, for the purposes of this Regulation, is deemed to have been approved by him or her.

(8) The owner or person in charge of an establishment shall, not later than the 31st day of March in each year, prepare and submit to the Minister a report, on the implementation in the immediately preceding year, of a plan approved by the Minister under this Regulation.

(9) Without prejudice to the generality of paragraph (8), a report submitted under that paragraph, shall, in respect of the year to which the report relates, include the following,

(a) the number and species of animals slaughtered at the establishment concerned,

(b) the name of the person responsible for ensuring the implementation of the plan at the establishment concerned,

(c) the number and species of animals from which specimens were taken and analysed under the plan,

(d) in the case of milk, honey or eggs, particulars of the specimens analysed under the plan,

(e) the number and species of animals found to be positive,

(f) particulars in relation to food of animal origin found to be positive,

- (g) the name of the person from whom each animal, or food of animal origin, was purchased, and the address at which he or she ordinarily resides, and
- (h) particulars of measures taken in respect of each animal or food of animal origin to which subparagraph (e) or (f) applies.

(10) The Minister may, by direction in writing, require the owner or person in charge of an establishment to take specific measures for the detection of substances, veterinary drugs and contaminants specified in the Annex referred to in paragraph (1), in animals presented for slaughter at the establishment concerned.

(11) If, in the carrying out of a plan under this Regulation, or the taking of measures pursuant to a direction under paragraph (10), a specimen taken from an animal or food of animal origin is found, on analysis, to be positive, the owner or person in charge of the establishment, at which such specimen was taken shall immediately inform the Minister or an authorised officer of that finding and of the name and address of the person who presented the animal concerned for slaughter, or food of animal origin concerned for processing, at such establishment.

Evidence by certificate in proceedings for an offence

22. (1) In proceedings for an offence consisting of a contravention of these Regulations, a certificate purporting to be signed by a person employed at an approved laboratory or a national reference laboratory, stating the capacity in which that person is so employed and stating any one or more of the following, namely—

- (a) that the person received a specimen submitted to the approved laboratory or the national reference laboratory,
- (b) that, for such period as is specified in the certificate, the person had in his or her custody a specimen so submitted,
- (c) that the person gave to such other person as is specified in the certificate a specimen so submitted, or
- (d) that the person carried out any procedure for the purpose of detecting the presence, in a specimen so submitted, of an animal remedy, or that the specimen concerned contained such animal remedy or such amount thereof as is specified in the certificate,

shall, unless the contrary is proved, be evidence of the matters stated in the certificate.

(2) In proceedings for an offence under these Regulations the court may, if it considers that the interests of justice so require, direct that oral evidence of the matters stated in a certificate under this Regulation be given, and the court may for the purpose of receiving oral evidence adjourn the proceedings to a later date.

(3) In any proceedings, evidence of an act of the institutions of the European Community may be given by production of a copy of the act certified by an officer of the Minister to be a copy of the act, and it is not necessary to prove the signature of the officer or that he or she is an officer of the Minister.

(4) Paragraph (3) is in addition to and not in substitution for the European Communities (Judicial Notice and Documentary Evidence) Regulations 1972 (S.I. No. 341 of 1972).

Forgery of Documents

23. (1) A person shall not forge or utter knowing it to be forged—

- (a) a register purporting to be established and maintained under these Regulations or a document purporting to be an extract therefrom (hereafter in this Regulation referred to as “a forged register”), or
- (b) a direction, permit or other document purporting to be issued, granted or given under these Regulations (hereafter in this Regulation referred to as “a forged document”).

(2) A person shall not alter, with intent to defraud or deceive, or utter knowing it to be so altered—

- (a) a register established and maintained under these Regulations or an extract therefrom (hereafter in this Regulation referred to as “an altered register”), or
- (b) a direction, permit or other document issued, granted or given under these Regulations (hereafter in this Regulation referred to as “an altered document”).

(3) A person shall not have, without lawful authority, in his or her possession a forged register, forged document, altered register or altered document.

Service of Documents

24. A direction or other document under these Regulations shall be addressed to the person concerned by name and may be served on or given to the person in one of the following ways—

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

Evidential Burden

25. In proceedings for an offence consisting of a contravention of these Regulations, it is not necessary to negative by evidence the existence of a marketing authorisation granted under Regulation (EC) No. 726/2004 and accordingly the onus of proving the grant or issue of such authorisation is on the defendant.

Persons not entitled to Community aid

26. (1) If the owner or person for the time being in charge of an establishment is convicted of an offence consisting of a contravention of Regulation 21(8), (9)(e), (f) or (g), or (11), or 23, or section 16 of the Act,—

- (a) the owner,
- (b) a company in which he or she has a controlling interest, or
- (c) in circumstances where the owner is a company, a related company,

is not entitled to receive Community aid for a period of 12 months commencing on the date of such conviction.

(2) In this Regulation, “company”, “holding company” and “subsidiary” have the same meaning as they have in the Companies Acts 1963 - 2006.

(3) In this Regulation, a person has a controlling interest in a company if circumstances exist whereby, were that person a company, the first-mentioned company would be that company’s subsidiary.

Implied condition in contract of sale

27. (1) In every contract of sale there shall be an implied condition on the part of the seller that all reasonable precautions have been taken and all due diligence has been exercised to ensure—

- (a) in the case of the sale of an animal, that the animal was not treated with any animal remedy and, in the case of an agreement to sell an animal, the animal was not so treated and will not be so treated prior to the time when the property is to pass, and
- (b) in the case of the sale of, or an agreement to sell, the carcase of any animal or food derived from any animal, that the animal had not been treated with any animal remedy,

other than in accordance with these Regulations.

(2) (a) Subject to sub-paragraph (b), any term of a contract implied by virtue of paragraph (1) may be negated or varied, by an express term in the contract, in so far as the first-mentioned term relates to an animal remedy—

- (i) which has been administered to an animal before being imported into the State, and
- (ii) in respect of which the Minister has granted an exemption from destruction,

but only if the express term is fair and reasonable and has been specifically brought to the attention of the buyer.

- (b) Sub-paragraph (a) does not apply to an animal imported into the State where the sale of the animal would not be in accordance with a condition imposed by the Minister on the exemption.

(3) Any term of a contract implied by virtue of paragraph (1) may not be negatived or varied in so far as it relates to an animal remedy other than in respect of an animal remedy to which paragraph (2) relates.

Inspection by authorised officers, etc.

28. (1) If an authorised officer or member of the Garda Síochána or an officer of Customs and Excise has reasonable cause to suspect that—

- (a) the manufacture, importation, preparation, handling, storage, transport, exportation, distribution, sale, supply or use of an animal remedy or any ingredient for an animal remedy is taking place or has taken place in, on, under or from any land, premises or in, on or from any vehicle,
- (b) an offence is being or has been committed under these Regulations in, on, under or from any land, premises or in, on or from any vehicle,
- (c) any land or premises is used for or in connection with the breeding, rearing, fattening, keeping, exhibiting, selling or transporting of animals,
- (d) any land or premises is an establishment or is used for or in connection with the slaughter of animals,
- (e) in, on, under or from any land or premises or in, on or from any vehicle, there is or was any animal of any species to which an animal remedy is being or has been administered or there is or was any food derived from such an animal or any carcase of such an animal, or
- (f) in, on, under or from any land or premises or in, on or from any vehicle, there is or was any animal remedy, or any ingredients for animal remedies, or any machinery, instruments or other thing used in the manufacture, preparation, handling, storage, transport, exportation, distribution, sale, supply or use of animal remedies or ingredients for animal remedies,

the authorised officer or member of the Garda Síochána or officer of Customs and Excise (in this section referred to as “the relevant person”) may, subject to paragraph (2), stop any such vehicle or enter (if necessary by force) any such land or premises, or land or premises used in connection with such land or premises, or any such vehicle, and there, or at any other place, and with such authorised officers, members of the Garda Síochána and officers of Customs and Excise (if any) as the relevant person considers appropriate—

- (i) search for and examine, inspect or test any animals, food derived from animals or carcasses of animals or anything believed to be

an animal remedy or an ingredient for an animal remedy or anything to which subparagraph (f) relates,

- (ii) take such specimens (including blood, urine, faeces, tissue or remains of implants) from any animals, food derived from animals or carcasses of animals, and may for that purpose perform or cause to be performed any procedure (including surgery) as is considered necessary on such animals, food or carcasses,
- (iii) take such reasonable samples of or from any substances or of or from a thing which may be considered appropriate for the purposes of these Regulations,
- (iv) seize and detain anything to which subparagraph (f) relates or anything which is believed to be or to contain an animal remedy or an ingredient for an animal remedy kept, used or intended to be used in contravention of the provisions of these Regulations,
- (v) search for and examine any document and take extracts from and copies of any such document,
- (vi) seize and detain an animal—
 - (I) in respect of which it is, with reasonable grounds, believed by the relevant person that a prohibited animal remedy or ingredient for an animal remedy has been administered to it in contravention of these Regulations, and
 - (II) in relation to which either or both—
 - (A) the relevant person is aware that an application has been made or will be made for the destruction of the animal, and
 - (B) the relevant person has reasonable grounds for believing that the animal has been or may be moved in contravention of any notice duly served,

in accordance with these Regulations,
- (vii) require any person who is suspected to be, or to have been engaged in the manufacture, preparation, handling, storage, transport, exportation, distribution, sale, supply or use of, or any person who is suspected to have possession or control of or to have kept or to keep, any animal remedy, ingredient for an animal remedy, animal, food derived from animals, carcasses of animals or anything to which subparagraph (f) relates, or any person who is suspected to be, or to have been, engaged in the breeding, rearing, fattening, keeping, exhibiting, selling or transporting or in the possession or control of any animal—

- (I) in the case of any documents in the possession or control of that person or any such remedy, ingredient, animal, food, carcase or thing, to produce them to the relevant person or any authorised officer, member of the Garda Síochána or officer of Customs and Excise,
 - (II) in the case of any information in relation to such document, remedy, animal, food, carcase or thing which may be required (including the source of that document, remedy, animal, food, carcase or thing), to furnish them to the relevant person or any authorised officer, member of the Garda Síochána or officer of Customs and Excise,
- (viii) require any person, being the owner or the person in charge of animals, or the owner or occupier of, or employed in or on, lands or premises so entered to give assistance, to carry out such instructions and to give such information as may be reasonably necessary for the purposes of subparagraphs (i) to (vii), and
- (ix) require any person who is for the time being in charge or control of any vehicle so stopped or entered—
- (I) to refrain from moving it, and
 - (II) to give assistance, to carry out such instructions and to give such information as may be reasonably necessary for the purposes of subparagraphs (i) to (vii).

(2) The functions of a relevant person under this Regulation may only be exercised in respect of a dwelling or so much of a vehicle or premises as constitutes a dwelling where the relevant person has reasonable cause to suspect that, before a search warrant could be sought in relation to the dwelling under Regulation 29, anything to which the said paragraph (1) relates—

(a) is being destroyed or disposed, or

(b) is likely to be destroyed or disposed.

(3) An authorised officer, member of the Garda Síochána or officer of Customs and Excise accompanying the relevant person may exercise all the functions conferred on the relevant person by virtue of paragraph (1) or (2).

(4) Nothing in these Regulations shall operate to prejudice any power to search, or to seize or detain property, which may, apart from these Regulations, be exercised by a member of the Garda Síochána or an officer of Customs and Excise.

Search warrant

29. (1) If a judge of the District Court is satisfied by information on oath of an authorised officer, member of the Garda Síochána or an officer of Customs and Excise that there is reasonable cause for suspecting that—

- (a) evidence of or relating to the commission or intended commission of an offence under these Regulations is to be found in, on or under any land or premises or in or on any vehicle and that such land, premises or vehicle or any part thereof consists of a dwelling, or
- (b) there is or was or is intended to be in, on or under any land or premises, in or on any vehicle and that such land, premises or vehicle or any part thereof consists of a dwelling, any animal remedy or ingredient for an animal remedy in relation to which a contravention of these Regulations, is being or has been or is intended to be committed, or
- (c) a document directly or indirectly relating to, or connected with, a transaction or dealing which was, or an intended transaction or dealing which would if carried out be, an offence under these Regulations, is in the possession or under the control of a person in, on or under any land or premises or in or on any vehicle and that such land, premises or vehicle or any part thereof consists of a dwelling,

the judge may issue a search warrant under this Regulation.

(2) A search warrant issued under this Regulation shall be expressed and operate to authorise a named authorised officer, named member of the Garda Síochána or named officer of Customs and Excise, accompanied by such authorised officers, members of the Garda Síochána and officers of Customs and Excise as the named officer or member thinks necessary, at any time or times within one month from the date of issue of the warrant, on production, if so requested, of the warrant to enter (if necessary by force) the land, premises or vehicle named in the warrant.

(3) Where any premises, land or vehicle is entered pursuant to a warrant issued under this section, an authorised officer, a member of the Garda Síochána or an officer of Customs and Excise so entering may—

- (a) stop and detain any person found in, on or under such land or premises, or in or on such vehicle, for the purpose of searching that person and to search or cause to be searched that person, and
- (b) exercise all or any of the powers referred to in Regulation 28.

Search of suspects, etc.

30. (1) If, with reasonable cause, a member of the Garda Síochána or an officer of Customs and Excise suspects that a person is in possession in contravention of these Regulations of an animal remedy or an ingredient for an animal remedy, the member or officer may without warrant—

- (a) search or cause to be searched by such a member or officer the person and, if the member or officer considers it necessary for that purpose, detain the person for such time as is reasonably necessary to carry out the search,

- (b) search or cause to be searched by such a member or officer any vehicle in which the member or officer suspects that such substance may be found and for the purpose of carrying out the search, if any such member or officer thinks fit, require the person who is, for the time being, in charge or control of the vehicle to bring it to a stop and when stopped to refrain from moving it or, in case the vehicle is already stationary, to refrain from moving it, or
- (c) seize and detain, or cause to be seized and detained by such a member or officer, anything found in the course of a search under this section which any such member or officer reasonably suspects to be something which might be required as evidence in proceedings for an offence under these Regulations.

(2) Where a member of the Garda Síochána or an officer of Customs and Excise (as the case may be) decides to search, or cause to be searched, a person under this section, the member or officer may require the person to accompany that member or officer to either a Garda Síochána station or a customs office for the purpose of being so searched at that station or office.

Power of arrest.

31. (1) Where, with reasonable cause, a member of the Garda Síochána suspects that—

- (a) an offence under these Regulations has been committed and so suspects a person of having committed the offence, or
- (b) a person is committing or has committed an offence under these Regulations in relation to the manufacture, importation, preparation, handling, storage, transport, exportation, distribution, sale, supply or use of any animal remedy or any ingredient for an animal remedy, the possession of which by such a person would be prohibited by these Regulations,

he or she may arrest the person without warrant.

(2) Where, with reasonable cause, a member of the Garda Síochána—

- (a) suspects that an offence under these Regulations has been committed or attempted, and
- (b) suspects a person of having committed the offence or having made the attempt,

he or she may arrest the person without warrant if—

- (i) with reasonable cause the member suspects that the person, unless arrested, either will abscond for the purposes of evading justice or will obstruct the course of justice, or

- (ii) having enquired of the person, the member has reasonable doubts as to the person's identity or place of abode, or
- (iii) having enquired of the person, the member knows that the person does not ordinarily reside in the State, or has reasonable doubts as to whether the person so resides.

(3) Nothing in sub-paragraphs (i), (ii) and (iii) of paragraph (2) shall apply where a person is required to accompany a member of the Garda Síochána or an officer of Customs and Excise to a Garda Síochána station or a customs office for the purpose of Regulation 30 and who fails to comply with the requirement.

Obstruction

32. A person shall not obstruct or impede an authorised officer, member of the Garda Síochána or officer of Customs and Excise in the due exercise of any of the functions conferred or exercisable by the authorised officer, member of the Garda Síochána or officer of Customs and Excise under these Regulations.

Impersonation of authorised officer, etc.

33. (1) A person shall not, with the intention to deceive—

- (a) purport to be, or
- (b) act in a manner that would lead another person to believe that he or she is

a person duly appointed as an authorised person, officer, inspector, examiner or other officer of the Minister or a person otherwise duly appointed by or with the authority of the Minister or of any other purported member of the Government exercising any functions of the Minister either—

- (i) generally, or
- (ii) for the purposes of these Regulations.

(2) A person shall not, without lawful excuse, have in his or her possession any document which—

- (a) has been,
- (b) purports to be, or
- (c) could lead another person to believe that it has been

duly issued for the purpose of identifying the person in possession of the document as a person duly authorised by, or a duly authorised officer, inspector, examiner or other officer of, the Minister or otherwise duly appointed by or with the authority of the Minister or, in the case of sub-paragraph (b) or (c), of any other purported member of the Government exercising any functions of the Minister either—

- (i) generally, or

(ii) for the purposes of these Regulations.

(3) In this Regulation, references to the Minister include the Department of Agriculture, Fisheries and Food and any Minister of State at that Department and references to a purported member of the Government include any purported Department of State and any Minister of State at such Department.

Offences and penalties

34. (1) A person who—

- (a) contravenes Regulation 3(1), (2)(b) or (3), 4(1) or (2), 5(1) or (2), 6(1), (2), (3) or (4), 8(3), 9(3), 10(3), 11(1), (2), (3), (4) or (5), 12, 16(1), (2), (3) or (4), 17(3), (4), (5) or (6), 19(1) or (2)(b), 20(1), (2) or (3), 21(1), (3), (6), (8), (9) or (11), 23(1), (2) or (3), 32, 33 or 33(1) or (2),
- (b) fails to comply with a direction, permit or requirement under Regulation 7(1), (2) or (3), 14(1), (2), (3) or (5), 21(3) or (11), 28 or 30(2), or
- (c) counsels, aids or abets a contravention of subparagraph (a) or (b),

commits an offence.

(2) A person who commits an offence to which paragraph 1 refers is liable—

- (a) on summary conviction, to a fine not exceeding €5,000 or to a term of imprisonment not exceeding 6 months, or to both, or
- (b) on conviction on indictment, to a fine not exceeding €500,000 or to a term of imprisonment not exceeding 3 years, or to both.

(3) A summary offence under these Regulations may be prosecuted by the Minister.

(4) If an offence under these Regulations has been committed by a body corporate and it is proved to have been so committed with the consent or connivance of or to be attributable to any neglect on the part of any person who, when the offence was committed, was a director, manager, secretary or other officer of the body corporate, or a person purporting to act in any such capacity, that person, as well as the body corporate, commits an offence and is liable to be proceeded against and punished as if guilty of the first-mentioned offence.

(5) If the affairs of a body corporate are managed by its members, paragraph (3) applies in relation to the acts and defaults of a member in connection with the functions of management as if the member is a director or manager of the body corporate.

Revocation and Saver

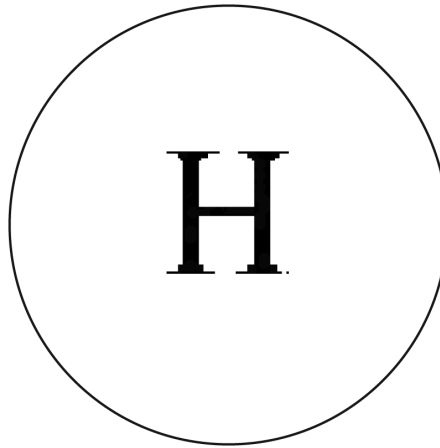
35. (1) The European Communities (Control of Animal Remedies and their Residues) Regulations 2007 (S.I. No. 143 of 2007) are revoked.

(2) A direction issued under Regulation 22 of the European Communities (Control of Animal Remedies and their Residues) Regulations 2007 is confirmed and may be dealt with as if given under the corresponding provision of these Regulations.

(3) If paragraph (2) would conflict with the constitutional right of any person, the operation of that paragraph is subject to such limitation as is necessary to secure that it does not so conflict, but is otherwise of full force and effect.

SCHEDULE

Official Mark



GIVEN under my Official Seal,
7 May 2009

BRENDAN SMITH.
Minister for Agriculture, Fisheries and Food.

EXPLANATORY NOTE

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

These Regulations implement in the State the provisions of Council Directive 96/22/EC of 29 April 1996 containing the prohibition in stockfarming of certain substances having hormonal or thyrostatic action and of beta agonists and Council Directive 96/23 of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ón
OIFIG DHÍOLTA FOILSEACHÁN RIALTAIS,
TEACH SUN ALLIANCE, SRÁID THEACH LAIGHEAN, BAILE ÁTHA CLIATH 2,
nó tríd an bpost ó
FOILSEACHÁIN RIALTAIS, AN RANNÓG POST-TRÁCHTA,
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