



STATUTORY INSTRUMENTS.

S.I. No. 193 of 2014



CONTROL ON ANIMAL VACCINES REGULATIONS 2014

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I, SIMON COVENEY, Minister for Agriculture, Food and the Marine in exercise of the powers conferred on me by sections 36 of the Animal Health and Welfare Act 2013 (No. 15 of 2013), for the purpose, inter alia, of giving further effect to Regulation 71 of Directive 2001/82/EC of the European Parliament and the Council of 6 November 2001¹, hereby make the following regulations:

Citation

1. These Regulations may be cited as the Control on Animal Vaccines Regulations 2014

Interpretation

2. In these Regulations—

"Act" means Animal Health and Welfare Act 2013 (No. 15 of 2013);

"animal remedy" has the same meaning as in the Animal Remedies Act 1993 (No. 23 of 1993);

"authorised animal remedy" means an animal remedy that is the subject of an animal remedies authorisation under the European Communities (Animal Remedies) (No.2) Regulations 2007;

"vaccine" means an animal remedy that may be administered to an animal to produce active or passive immunity or to diagnose the state of immunity.

Prohibition on certain vaccines, etc.

3. (1) A person shall not have in his or her possession or under his or her control, import, sell, supply or administer to an animal a vaccine that may be used to produce active or passive immunity to a disease specified in Schedule 1 or, to diagnose the state of immunity to the disease.

(2) A person shall not have in his or her possession or under his or her control, sell or supply an animal to which a vaccine, that may be used to produce active or passive immunity to a disease specified in Schedule 1 or to diagnose the state of immunity to the disease, has been administered.

Restriction on certain vaccines, etc.

4. (1) Subject to paragraph (3), a person shall not have in his or her possession or under his or her control, import, sell, supply or administer to an animal a vaccine that may be used to produce active or passive immunity to a

¹O.J. No. L 311 of 28.11.2001, p. 1

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 6th May, 2014.

disease specified in Schedule 2 or to diagnose the state of immunity to the disease except in accordance with a licence (“vaccine licence”).

(2) A person shall not have in his or her possession or under his or her control, sell or supply an animal to which a vaccine, that may be used to produce active or passive immunity to a disease specified in Schedule 2 has been administered or to diagnose the state of immunity to the disease, unless the vaccine—

- (a) was administered in accordance with a vaccine licence, or
- (b) is a vaccine to which paragraph (3) applies.

(3) A person may have in his or her possession or under his or her control, import, sell, supply or administer to an animal a marker vaccine (that is an authorised animal remedy) to produce active or passive immunity to a disease specified in Part 2 of Schedule 2 or to diagnose the state of immunity to the disease.

(4) The Minister may grant a licence, refuse an application or revoke a vaccine licence.

(5) An application for a vaccine licence shall be made in a form, be accompanied by any material and contain any particulars that the Minister specifies.

(6) The Minister shall not consider an application for a vaccine licence if the application does not contain all the material and particulars sought by the Minister.

(7) The Minister may attach conditions to a vaccine licence, revoke or vary a condition or attach a new condition.

(8) Without prejudice to the generality of paragraph (7), a condition to a vaccine licence may—

- (a) control the use of a vaccine to which the licence relates
- (b) specify the person or class of persons to whom a vaccine may be sold or supplied,
- (c) specify the person or classes of person who may administer a vaccine to an animal,
- (d) specify the animal or class of animal to which the vaccine may be administered,
- (e) specify records to be maintained,
- (f) bind the person to whom the vaccine licence is granted and such other person or classes of person as may be specified in the licence, and

(g) specify such other conditions as are, in the opinion of the Minister, necessary ancillary or desirable for a vaccine licence to have full effect.

(9) Without prejudice to the generality of paragraph (4), the Minister may refuse an application or revoke a vaccine licence if—

(a) the applicant or licensee has been convicted of, or committed, an offence, whether he or she has been convicted or not, under the Act,

(b) the applicant or licensee fails to comply with a condition attached to a licence,

(c) the applicant or licensee is not, in the opinion of the Minister, a fit and proper person to hold a licence,

(d) without prejudice to paragraph (3), in relation to the application, information required has not been furnished or information that is, in the opinion of the Minister, false or misleading in a material particular has been furnished, or

(e) it is necessary, in the opinion of the Minister—

(i) to give effect to an animal health strategy,

(ii) to prevent the risk or spread of disease,

(iii) to eradicate disease, or

(iv) is necessary, incidental, supplementary or consequential for the purposes of giving effect to an act of the institutions of the European Union relating to animal health or welfare.

(10) Without prejudice to the generality of paragraph (4), the Minister shall refuse an application or revoke a vaccine licence if the applicant or licensee has been convicted, on indictment, of an offence under the Act.

(11) Other than in the case of refusal under paragraph (10) or (12), if the Minister proposes to revoke a vaccine licence, or to refuse an application, he or she shall—

(a) notify the person concerned in writing of the proposal and of the reasons for the proposal, and that he or she may make representations to the Minister in relation to the proposal within 14 days of the notification,

(b) consider a representation made before deciding whether to proceed with, modify or annul the proposal, and

(c) notify the person concerned of the decision and the reasons for the decision.

(12) If the Minister is of the opinion that it is necessary to prevent the risk or spread of disease or to give effect to an Act of an institution of the European Union, he or she may revoke a vaccine licence in accordance with paragraph (13).

(13) If the Minister revokes a vaccine licence in accordance with this paragraph, he or she shall—

- (a) notify the person concerned in writing of the decision and the reasons for the decision, and that he or she may make representations to the Minister in relation to the decision within 14 days of the date of the notification,
- (b) consider a representation made, and
- (c) confirm, modify or annul the decision and notify the person concerned of the decision and the reasons for the decision.

(14) A person to whom a vaccine licence is granted shall make such returns to the Minister as and when, and in such form as, the Minister may direct.

(15) A person to whom a vaccine licence is granted shall make it available for inspection on request by an authorised officer.

(16) In paragraph (3) “marker vaccine” means a vaccine (inactivated or live) that is based on deletion technology that allows a distinction be made between a vaccinated and infected animal based on retrospective antibody response.

Limitation

5. Regulation 4 does not apply to the possession, control or administration of tuberculin or brucellin, designated by the Minister, to a bovine animal by a veterinary practitioner in the course of a test (within the meaning of the Bovine Tuberculosis (Attestation of State and General Provisions) Order 1989 (S.I. 308 of 1989) or the Brucellosis in Cattle (General Provisions) Order 1991 (S.I. No. 114 of 1991)), or to the possession, control, sale or supply of a bovine animal to which tuberculin or brucellin, designated by the Minister, has been administered in the course of a test.

Penal provisions

6. Regulation 3 and 4 (1), (2), (7), (14) and (15) are penal provisions to which section 36 (4) (b) of the Act applies.

Revocations and saver

7. (1) The instruments specified in Schedule 3 are revoked.

(2) These Regulations are in addition to and not in substitution for the European Communities (Animal Remedies) (No.2) Regulations 2007.

Schedule 1

Regulation 3

African horse sickness
African swine fever
Classical swine fever
Contagious bovine pleuropneumonia
Enzootic bovine leukosis
Epizootic haemorrhagic disease
Equine infectious anaemia
Foot-and Mouth disease
Goat pox
Lumpy skin disease
Maedi Visna
Peste des petits ruminants
Rift Valley fever
Rinderpest (cattle plague)
Sheep pox
Swine vesicular disease
Vesicular stomatitis

Schedule 2

Regulation 4

Part 1

Aujeszky's disease
Avian infectious laryngotracheitis
Avian influenza (including highly pathogenic avian influenza and low pathogenic avian influenza)
Avian mycoplasmosis (caused by *Mycoplasma gallisepticum*)
Bluetongue
Brucellosis in ruminants and swine
Equine encephalomyelitis (including Western Equine Encephalomyelitis and Eastern Encephalomyelitis)
Equine viral arteritis
Fowl typhoid (*Salmonella gallinarum*)
Paratuberculosis in ruminating animals (Johnes disease)
Pullorum disease (*Salmonella pullorum*)
Salmonellosis (caused by or involving *Salmonella enteritidis* or *Salmonella typhimurium*) in poultry
Swine influenza
Teschovirus encephalomyelitis
Transmissible gastro-enteritis (porcine respiratory corona virus)
Tuberculosis in ruminants
West Nile fever

Part 2

Infectious bovine rhinotracheitis

Schedule 3

Regulation 6(1)

Diseases of Animals Act 1966 (Control on Animal and Poultry Vaccines) Order 2002 (S.I. No. 528 of 2002);
Diseases of Animals Act 1966 (Control on Animal and Poultry Vaccines) (Amendment) Order 2003 (S.I. No. 159 of 2003);
Diseases of Animals Act 1966 (Control on Animal and Poultry Vaccines) (Amendment) Order 2004 (S.I. No. 508 of 2004);
Diseases of Animals Act 1966 (Control on Animal and Poultry Vaccines) (Amendment) Order 2007 (S.I. No. 765 of 2007);
Diseases of Animals Act 1966 (Control on Animal and Poultry Vaccines) (Amendment) Order 2009 (S.I. No. 323 of 2009);
Diseases of Animals Act 1966 (Control on Animal and Poultry Vaccines) (Amendment) Order 2010 (S.I. No. 289 of 2010);
Diseases of Animals Act 1966 (Control on Animal and Poultry Vaccines) (Amendment) Order 2013 (S.I. No. 379 of 2013).



GIVEN under my Official Seal,
17 April 2014.

SIMON COVENEY,
Minister for Agriculture, Food and the Marine.

EXPLANATORY NOTE

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

These Regulations continue existing arrangements with a number of modifications for the control on certain vaccines for animal health reasons.

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