

S.I. No. 528 of 2002

Diseases of Animals Act 1966 (Control on Animal and Poultry Vaccines) Order 2002

I, Joe Walsh, Minister for Agriculture and Food, in exercise of the powers conferred on me by sections 3 and 13 of the Diseases of Animals Act 1966 (No. 6 of 1966) (as adapted by the Agriculture, Food and Rural Development (Alteration of Name of Department and Title of Minister) Order 2002 (S.I. No. 306 of 2002)), for the purpose, *inter alia*, of giving further effect to Article 71 of Directive 2001/82/EC of the European Parliament and the Council of 6 November 2001¹, hereby order as follows:-

Citation

1. This Order may be cited as the Diseases of Animals Act 1966 (Control on Animal and Poultry Vaccines) Order 2002.

Interpretation

2. (1) In this Order –

"Act" means the Diseases of Animals Act 1966 (No. 6 of 1966);

"animal" includes poultry;

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

"authorised animal remedy" has the same meaning as in the Animal Remedies Regulations 1996 (S.I. No. 179 of 1996) (as amended by Article 3(a) of the Animal Remedies (Amendment) Regulations 2002 (S.I. No. 44 of 2002));

"authorised officer" means an authorised officer within the meaning of section 17A (inserted by section 2 of the Diseases of Animals (Amendment) Act 2001 (No. 3 of 2001)) of the Diseases of Animals Act 1966 (No. 6 of 1966);

"vaccine licence" means a licence granted under and in accordance with Article 4;

"marker vaccine" means a vaccine (inactivated or live) that allows a distinction be made between a vaccinated and a naturally infected animal;

"Minister" means the Minister for Agriculture and Food;

¹ O.J. No. L 311 of 28.11.2001, p. 1

"sell" includes offer, expose or keep for sale, invite an offer to buy, or distribute (whether for reward or not) and cognate words shall be construed accordingly;

“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.

(2) In this Order –

- (a) a reference to an Article, Schedule or part of a Schedule is to an Article of, Schedule to, or part of a Schedule to, this Order, unless it is indicated that reference to some other Order is intended, and
- (b) a reference to a paragraph or a subparagraph is a reference to the paragraph or subparagraph of the provision in which the reference occurs, unless it is indicated that reference to some other provision is intended.

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 the First Schedule or, subject to Article 7, to diagnose the state of immunity of an animal 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 the First Schedule 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 disease specified in the Second Schedule or, subject to Article 7, to diagnose the state of immunity of an animal to the disease except under and 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 the Second Schedule has been administered or to diagnose the state of immunity to the disease, unless the vaccine –

- (a) was administered under and 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 the Second Schedule or to diagnose the state of immunity to the disease.
- (4) The Minister may grant a vaccine 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 condition aforesaid 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 has failed 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 Communities relating to animal health or welfare.
- (10) Without prejudice to the generality of paragraph (4) or (9)(a), 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 therefor, 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 therefor.
- (12) If the Minister is of the opinion that it is necessary to prevent the risk of disease or to give effect to an Act of an institution of the European Communities, 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 therefor, 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 therefor.
- (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 from time to time direct.
- (15) A person to whom a vaccine licence is granted shall make it available for inspection on request by an authorised officer.

Forgery

- 5. (1) A person shall not forge or utter knowing it to be forged a licence purporting to be a vaccine licence or a document purporting to be an extract therefrom (hereafter in this Article referred to as "a forged licence").

(2) A person shall not alter with intent to defraud or deceive, or utter knowing it to be so altered a licence purporting to be a vaccine licence or a document purporting to be an extract therefrom (hereafter in this Article referred to as "an altered licence").

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

Amendment to First Schedule of Act

- 6. The First Schedule to the Act (substituted by the Diseases of Animals Act 1966 (First Schedule) Order 2001 (S.I. No. 469 of 2001)) is amended by the insertion, in Part III Class B after "15. Varroasis.", of –

- “16. For the purpose of giving effect to the Diseases of Animals Act 1966 (Control on Animal and Poultry Vaccines) Order 2002 (S.I. No. 528 of 2002), infectious bovine rhinotracheitis.
17. For the purpose of giving effect to the Diseases of Animals Act 1966 (Control on Animal and Poultry Vaccines) Order 2002 (S.I. No. 528 of 2002), infectious bursal disease (Gumboro disease).”.

Limitation

7. Article 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 surgeon 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.

Revocations and saver

8. (1) The Orders specified in the Third Schedule are revoked to the extent stated therein.
- (2) The Orders specified in the Fourth Schedule are revoked.
- (3) This Order is in addition to and not in substitution for the Animal Remedies Regulations 1996 (S.I. No. 179 of 1996).
- (4) This Order is without prejudice to the Rabies Order 1976 (S.I. No. 94 of 1976).

First Schedule

Article 3

African horse sickness

African swine fever

Bluetongue

Bovine leukosis

Contagious bovine pleuro-pneumonia

Equine encephalomyelitis

Foot and mouth disease

Infectious equine anaemia

Maedi visna

Rinderpest

Salmonellosis (caused by or involving salmonella enteritidis or salmonella typhimurium) in poultry

Sheep pox

Swine vesicular disease

Second Schedule

Article 4

Part 1

Brucellosis in ruminating animals and swine

Equine viral arteritis

Fowl pest in any of its forms, including Newcastle disease and fowl plague

Fowl typhoid

Infectious bursal disease (Gumboro disease)

Infectious laryngo-tracheitis

Johnes disease

Porcine respiratory and reproductive syndrome

Pullorum disease, otherwise known as bacillary white diarrhoea (salmonella pullorum)

Rabies

Rift valley fever

Swine fever

Swine influenza

Teschin fever

Transmissible gastro-enteritis

Tuberculosis in ruminating animals

Part 2

Aujeszky's disease

Infectious bovine rhinotracheitis

Third Schedule

Article 8(1)

Article 4 of the Bovine Tuberculosis (Attestation of the State and General Provisions) Order 1989 (S.I. No. 308 of 1989).

Article 4 of the Brucellosis in Cattle (General Provisions) Order 1991 (S.I. No. 114 of 1991).

Fourth Schedule

Article 8(2)

Anti-Swine Fever Serum and Swine Fever Vaccine (Restriction on Importation) Order 1957 (S.I. No. 228 of 1957).

Importation of Fowl Pest Vaccine (Prohibition) Order 1971 (S.I. No. 140 of 1971).

Importation of Infectious Bursal Disease (Gumboro Disease) Vaccine (Prohibition) Order 1978 (S.I. No. 275 of 1978).

Importation of Aujeszky's Disease Vaccine (Prohibition) Order 1980 (S.I. No. 166 of 1980).

GIVEN under my Official Seal,
14 November 2002

Joe Walsh
Minister for Agriculture and Food

Explanatory Note

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

This Order provides for controls on certain vaccines for animal health reasons.

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