General Scheme of the Veterinary Medicinal Products Medicated Feed and Fertilisers Regulation Bill 2022

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SCHEDULE

Part 1

ROUTES OF RETAIL

Part 2

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Long Title

An Act to make provision for the regulation of veterinary medicinal products and medicinal feed; to provide for the establishment of a national database to record veterinary prescriptions; to repeal the Animal Remedies Act 1993; to amend and extend the Fertilisers Feeding Stuffs and Mineral Mixtures Act 1955; and to provide for connected matters.

Be it enacted by the Oireachtas as follows:

Part 1

Preliminary

Short title and collective citation

1. This Act may be cited as the Veterinary Medicinal Products Medicated Feed and Fertilisers Regulation Act 2022.

(2) The Fertilisers Feeding Stuffs and Mineral Mixtures Act 1955 and *Part 4* may be cited together as *the Fertilisers Feeding Stuffs and Mineral Mixtures Acts 1955 and 2022*.

Repeals and dissolution

2. (1) The Animal Remedies Act 1993 is repealed.

(2) The provisions of the following Acts are repealed:

(a) section 41 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006;

(b) section 76 of the Animal Health and Welfare Act 2013; and

(c) section 17 of the Horse Racing Ireland Act 2016.

(3) The Animal Remedies Consultative Committee is dissolved.

(4) References after the passing of this Act in any enactment or instrument made under an enactment to an animal remedy (within the meaning of the Animal Remedies Act 1993) shall be construed as references to a veterinary medical product.

Expenses

3. The expenses incurred by the Minister in the administration of this Act shall, to such extent as may be sanctioned by the Minister for Public Expenditure and Reform, be paid out of moneys provided by the Oireachtas.

Part 2

Regulation of *veterinary medicinal products and medicated feed*

Chapter 1

Interpretation

Interpretation (Parts 2 and 3)

4. (1) In this Part and *Part 3*—

"animal" means a member of the kingdom *animale* other than a human being;

"authorised officer" means a person appointed or deemed to be appointed as an authorised officer under *section 36;*

"carcase" includes part of a carcase, whether edible or not, including blood and offal;

"document" includes any book and any other record, whether legible or in a machine readable form;

"functions" includes powers and duties;

"import" means import into the State from another Member State or a third country;

"export" means export from the State to another Member State or a third country;

"medicated feed" has the meaning assigned to it by Article 3(2)(a) of the Medicated Feed Regulation;

"Medicated Feed Regulation" means Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018[1];

"Minister" means Minister for Agriculture, Food and the Marine;

"national database" means the database established and maintained by the Minister under *section 7(1);*

"pharmacist" means a person registered as a pharmacist in the pharmacists' register under section 14 of the Pharmacy Act 2007;

"sale" includes offer, expose or keep for sale, invite or offer to buy, or distribute for reward and cognate words shall be construed accordingly;

[1] OJ No. L 4, 7.1. 2019, p. 1

"supply" includes giving without payment;

"veterinarian" means a veterinary practitioner registered under Part 4 of the Veterinary Practice Act 2005;

"veterinary medicinal product" has the meaning assigned to it by Article 4(1) of the VMP Regulation;

"VMP Regulation" means Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018[2].

(2) A word or expression that is used in this Part and is also used in the VMP Regulation or the Medicated Feed Regulation has, unless the contrary intention appears, the same meaning in this Part as it has in the VMP Regulation or the Medicated Feed Regulation.

Chapter 2

Veterinary medicinal products and medicated feed – prescriptions and dispensing – national database

Prohibitions

5. (1) A person who is not a veterinarian shall not issue a veterinary prescription.

(2) A person who issues a veterinary prescription in contravention of *subsection (1)* commits an offence.

(3) A person who is not a veterinarian, pharmacist or person permitted under regulations made under *subsection (4),* shall not dispense a veterinary medicinal product subject to a prescription.

(4) The Minister may by regulations permit a class of persons other than a veterinarian or pharmacist and whom he or she considers is qualified to do so to dispense a veterinary medicinal product subject to a prescription.

(5) A person who dispenses a veterinary prescription in contravention of *subsection (3)* commits an offence.

[2] OJ No. L 4, 7.1. 2019, p. 43

(6) Subject to *subsection (7),* a veterinary prescription shall be issued electronically and dispensed and recorded on or transmitted to the national database.

(7) The Minister may prescribe by regulations circumstances in which a veterinary prescription may be issued or dispensed other than using the national database.

(8) A person who commits an offence under *subsection (2)* or *(5)* is liable—

(a) on summary conviction, to a class A fine, or

(b) on conviction on indictment, to a fine not exceeding €100,000.

(9) A person who fails to comply with *subsection (6)* commits an offence and is liable on summary conviction to a class A fine.

Regulations – prescriptions and dispensing

6. (1) The Minister may make regulations in relation to the prescription and dispensing of veterinary medicinal products or medicated feed, including*, inter alia:*

(a) determining the maximum validity period of a prescription for a veterinary medicinal product, other than an antimicrobial;

(b) specifying elements in addition to those mentioned in Article 105(5) of the VMP Regulation that a veterinary prescription shall contain;

(c) where a veterinary medicinal product is prescribed, specifying a category or categories of product that the Minister is satisfied that any product in that category is of sufficiently similar characteristics with the product prescribed which may be dispensed in lieu of the product;

(d) requirements for the recording of prescriptions or dispensing of veterinary medicinal products or medicated feed;

(e) records to be kept by persons prescribing or dispensing veterinary medicinal products or medicated feed or administering such, including the form and manner in which they are kept;

(f) requirements in relation to the prescription for or dispensing of veterinary medicinal products or medicated feed which are not required to be recorded on the national database;

(g) the emergency dispensing of veterinary medicinal products without prescription by a retail pharmacy business (within the meaning of section 2 of the Pharmacy Act 2007) in the circumstances and for the period of time specified in the regulations.

(2) A person who contravenes or fails to comply with a provision of any regulations made under *subsection (1)* commits an offence and is liable on summary conviction to a class A fine.

National database

7. (1) The Minister shall establish and maintain a database ("national database") on which veterinary prescriptions and dispensing of veterinary prescriptions shall be recorded.

(2) Subject to *subsection (4), a* person who issues a veterinary prescription or dispenses a medicinal product or medicated feed on foot of a veterinary prescription shall record on, or cause to be transmitted to the national database the issuing of the prescription or dispensing of the product. The format of the recording and transmission to the national database shall be in accordance with any regulations made under *subsection (6).*

(3) The Minister shall cause to be electronically stored on the national database information obtained under *subsection (2)* for the purposes set out in *subsection (6)*.

(4) Information held on the national database—

(a) may be shared with the following persons:

(i) the Food Safety Authority of Ireland for the purpose of performing its regulatory functions ;

(ii) the Health Products Regulatory Authority in their role as a competent authority for the VMP Regulation;

(iii) the Veterinary Council of Ireland for purposes related to fitness to practice hearings;

(iv) Bord Bia for the purpose of quality assurance inspections and processes;

(v) the European Commission for the purpose of audit and control;

(vi) the European Court of Auditors for the purpose of audit and control;

(vii) such other persons specified by the Minister in regulations to comply with this Part and end user obligations under the VMP Regulation and the Medicated Feed Regulation and having regard to the need to adequately safeguard public and animal health and the environment.

(b) may be accessed by the following persons:

(i) the Minister;

(ii) veterinarians and persons engaged on their behalf for the purposes of using the national database to the extent necessary for the issuing and dispensing of veterinary prescriptions for their own clients;

(iii) dispensers and persons engaged on their behalf to the extent necessary for the purposes of using the national database when dispensing a veterinary prescription;

(iv) keepers and owners of animals subject to a veterinary prescription to the extent necessary for animals under their care;

(v) such other persons specified by the Minister in regulations to comply with this Part and end user obligations under the VMP Regulation and the Medicated Feed Regulation and having regard to the need to adequately safeguard public and animal health and the environment.

(5) The Minister may make regulations in relation to the operation of the national database including*, inter alia*—

(a) specifying the manner, method or form of recording information on the national database*;*

(b) determining the form of an electronic prescription or notification of the existence of a prescription on the national database;

(c) if recorded on another database, requiring that the information is transmitted to and from the national database in a readable and compatible form as specified in the regulations,

(d) specifying the period of time within which such prescriptions or dispensing must be recorded or shared with the national database,

(e) providing for the registration of veterinarians or other specified persons on the national database, and

(f) providing for the prescription and dispensing protocols in circumstances as determined by the Minister where the national database is unavailable to users.

(6) The Minister may process information held on the national database for the following:

(a) monitoring, evaluating or reporting the volume of sales, level and frequency of use of veterinary medicinal products or medicated feed or certain classes of such, or in specific animals or in different species of animals in the State;

(b) developing or implementing national or European policy relating to the use of veterinary medicinal products or medicated feed or certain classes of such in specific animals or in different species of animals in the State;

(c) determining the types of diseases or ailments in respect of which specific types of veterinary medicinal products or medicated feed are prescribed or dispensed;

(d) evaluating or determining the persons or class of persons prescribing, dispensing or using veterinary medicinal products or medicated feed or certain classes of such in the State and the level and frequency of prescribing, dispensing or use by such persons;

(e) monitoring or evaluating the scientific justification provided for prescribing veterinary medicinal products or medicated feed or certain classes of such for use in specific animals or in different species of animals;

(f) evaluating or identifying if certain locations in the State are more prevalent to animal diseases or ailments;

(g) the administration, control and enforcement of this Part, the VMP Regulation, the Medicated Feed Regulation or Regulation 625/2017 of the European Parliament and of the Council of 15 March 2013[3];

(h) such other purposes, to comply with this Part or end user obligations under the VMP Regulation or the Medicated Feed Regulation and having regard to the need to adequately safeguard public and animal health and the environment, as specified in regulations made by the Minister.

(7) A person who fails to comply with a *subsection (2)* commits an offence and is liable on summary conviction to a class A fine.

Prescriptions under Article 105 of VMP Regulation and Article 16 of Medicated Feed Regulation

8. (1) A veterinary prescription issued under Article 105 of the VMP Regulation or Article 16 of the Medicated Feed Regulation shall be issued in such form as prescribed, electronically or on paper, for a prescribed class or classes of animals in regulations made by the Minister.

(2) A medicinal product prescribed under Article 105 of the VMP Regulation or Article 16 of the Medicated Feed Regulation shall not be supplied unless the prescription has been issued electronically or in such other manner as prescribed in regulations made by the Minister.

(3) A person who fails to comply with *subsection (1)* or *(2)* commits an offence and is liable on summary conviction to a class A fine.

Chapter 3

Rules on retail

Purpose of Chapter 3

9. The purpose of this Chapter is to determine the rules on retail as required under Article 103(1) of the VMP Regulation unless otherwise provided in that Article.

Definitions (Chapter 3)

10. In this Chapter—

"manufacturing authorisation" means a manufacturing authorisation granted under Chapter VI of the VMP Regulation;

"marketing authorisation" means a marketing authorisation granted under Chapter II of the VMP Regulation;

"pharmacy" means a retail pharmacy business within the meaning of the Pharmacy Act 2007;

"Register" means the Companion Animal Medicine Retailers' Register established under *section 21;*

"Regulations of 2007" means European Communities (Animal Remedies) (No. 2) Regulations 2007 (S. I. No. 786 of 2007);

"retail" includes sell or supply;

"retailer's licence" means a veterinary medicinal product retailer's licence granted under *section 18;*

"route of retail" means the person who may retail a veterinary medicinal product and the manner of its retail from the options set out in *Part 1* of the Schedule and designated in the terms of the marketing authorisation relating to the product*;*

"retail responsible person" means a person deemed as such under *section 20*;

"special import licence" means a licence granted under *section 26(1);*

"veterinary nurse" means a veterinary nurse registered under Part 8 of the Veterinary Practice Act 2005;

"wholesale distribution authorisation" means a wholesale distribution authorisation granted under Article 100 of the VMP Regulation.

Route of retail

11. (1) The routes of retail for veterinary medicinal products which may be designated in the terms of a marketing authorisation are from the options set out in *Part 1* of the Schedule and the symbols that may be used denoting them are set out in *Part 2* of the Schedule.

(2) A competent authority, where it grants a marketing authorisation, shall—

(a) as a condition of authorisation of a veterinary medicinal product, designate the route of retail for the product from the options set out in *paragraph 1, 2, 3 or 4* of *Part 1* of the Schedule, and

(b) specify that the route of retail designated shall appear in the package leaflet or on the packaging relating to the product.

(3) Notwithstanding *subsections (1)* and *(2),* a veterinary medicinal product designated 'not subject to a prescription' by the European Commission may be retailed:

(a) by a pharmacist from a pharmacy,

(b) by a veterinarian where the animal to which the product is to be administered is under his or her care,

(c) from a premises to which a retailer's licence relates, or

(d) in the case of companion animal medicine, from the premises of a person entered in the Register.

Restriction on retail of veterinary medicinal products

12. (1) *A* person shall not retail a veterinary medicinal product except in accordance with the route of retail designated under *section 11* in the terms of the marketing authorisation relating to the product.

(2) The Minister may make regulations specifying the categories of veterinary medicinal products designated "prescription only" under *paragraph 1* or "prescription only exempt" under *paragraph 2* of *Part 1* of the Schedule that a retail responsible person may retail.

(3) A person shall not, unless authorised by the relevant competent authority, possess or retail a veterinary medicinal product if the label or package leaflet as required under section 13, relating to the product has been altered or removed.

(4) A person who fails to comply with *subsection (1)* commits an offence and is liable—

(a) on summary conviction, to a class A fine, or

(b) on conviction on indictment, to a fine not exceeding €300,000.

(5) A person who fails to comply with *subsection (3)* commits an offence and is liable—

(a) on summary conviction, to a class A fine, or

(b) on conviction on indictment, to a fine not exceeding €25,000.

Labelling of veterinary medicinal products

13. (1) A veterinarian, or a person who retails a veterinary medicinal product designated under *paragraph 1* of *Part 1* of the Schedule to be "prescription only" shall, subject to *subsection (2),* affix to the packaging of the product, at the time of retail, in a manner that does not obscure the

information required by its marketing authorisation, a label mentioning at least the following in relation to the product—

(a) supplier information,

(b) prescription identification information,

(c) details of the prescribing veterinary practitioner,

(d) the date of retail,

(e) the dosage and duration of treatment (unless indicated on a proprietary label),

(f) withdrawal period (unless indicated on a proprietary label),

(g) special import licence information, if applicable, and

(h) and any other information specified in regulations made by the Minister necessary to safeguard public and animal health and the environment.

(2) If the packaging of a veterinary medicinal product is not large enough to affix a label to it, a label containing the information required under *subsection (1)* may be affixed to the outer package of the product when dispensed.

(3) A person who fails to comply with *subsection (1)* commits an offence and is liable on summary conviction to a class A fine.

Prohibition on retail of a veterinary medicinal product after expiry date

14. (1) A person shall not retail a veterinary medicinal product after the date specified by the manufacturer as the expiry date.

(2) A person who fails to comply with *subsection (1)* commits an offence and is liable on summary conviction to a class A fine.

Exemption from manufacturing authorisation

15. A manufacturing authorisation shall not be required for—

(a) the dividing of or changes in outer packaging of veterinary medicinal products, where the quantity to be supplied is less than that available in the smallest proprietary pack size and, where those processes are carried out by a pharmacist, veterinarian or for certain categories of veterinary medicinal products other persons specified by the Minister in regulations, solely for retail directly to the public or

(b) the extemporaneous preparation, in accordance with Article 112, 113 or 114 of the VMP Regulation, of a veterinary medicinal product or magistral formula (provided it is not prepared in advance) by—

(i) a veterinarian for the treatment of an animal under his or her care, or

(ii) a pharmacist for the purposes of dispensing a veterinary medicinal product in accordance with a veterinary prescription.

Labelling veterinary medicinal products retailed out of their original outer packaging

16. (1) A person who retails a veterinary medicinal product that has been divided and is not in its original outer packaging shall label the product or ensure that it is labelled when retailed with, at least the following information:

(a) the proprietary name of the product,

(b) the words “for animal treatment only”,

(c) the species to be treated,

(d) the manner of administration,

(e) the dosage and duration of treatment,

(f) the name of the person to whom the product is retailed,

(g) the name and business address of the retailer,

(h) precautions regarding administration of the product and any withdrawal period,

(i) special import licence information, if applicable, and

(j) any other information specified in regulations made by the Minister necessary to safeguard public and animal health and the environment.

(2) A person who fails to comply with *subsection (1)* commits an offence and is liable on summary conviction to a class A fine.

Restriction on use of premises.

17. (1) A person shall not use a premises to store a veterinary medicinal product for the purpose of retail unless the premises is—

(a) a premises in respect of which a retailer's licence relates,

(b) a premises owned or operated by a person entered in the Register,

(c) a pharmacy, or

(d) a premises to which a certificate of suitability granted under section 19 of the Veterinary Practice Act 2005 applies.

(2) The Minister may by regulations specify the conditions and circumstances within which a premises referred to in *subsection (1)* may be used to store a veterinary medicinal product for the purpose of retail having regard to the need to adequately safeguard public and animal health and the environment.

(3) A person who fails to comply with *subsection (1)* or regulations made under *subsection (2)* commits an offence and is liable on summary conviction to a class A fine.

Veterinary medicinal product retailer's licence

18. (1) The Minister may on application grant a licence, to be known as a veterinary medicinal product retailer's licence, and in this Chapter referred to as a retailer's licence to a person, where he or she is satisfied that the applicant for the licence has suitable premises, equipment and staff and suitable arrangements for record-keeping, handling, storage, dispensing and retail of a veterinary medicinal product or class of veterinary medicinal product, to retail the veterinary medicinal product from those premises. The Minister may issue guidelines as to that which he or she considers to be suitable for the purposes of an application under this subsection.

(2) A retailer's licence—

(a) relates to the premises specified in the licence,

(b) remains in force while the holder satisfies the conditions of the grant of the licence, and

(c) does not entitle the holder of the licence to retail a veterinary medicinal product from a premises the subject of a wholesale distribution authorisation.

(3) A person, other than a veterinarian supplying their own clients or a pharmacist from a pharmacy shall not retail a veterinary medicinal product from a premises unless the person holds a retailer's licence to retail the product from premises mentioned in the licence.

(4) A person who fails to comply with *subsection (3)* commits an offence and is liable—

(a) on summary conviction, to a class A fine, or

(b) on conviction on indictment, to a fine not exceeding €300,000.

(5) (a) The holder of a retailer's licence shall –

(i) have at his or her disposal, during hours of retail, the services of at least one retail responsible person for the purposes of selling veterinary medicinal products, and

(ii) ensure that a veterinary medicinal product, other than a companion animal medicine, is not retailed from the premises of the holder other than by a retail responsible person.

(b) A person who fails to comply with this subsection commits an offence and is liable on summary conviction to a class A fine.

(6) A retailer's licence may apply to veterinary medicinal products generally, to veterinary medicinal products of a particular class or description, or to one or more veterinary medicinal products, specified in the licence.

(7) The holder of an animal remedies merchant's licence granted under Regulation 31 of the Regulations of 2007 which was in force on 27 January 2022 is deemed to have continued in force after that day and, if in force on the passing of this Act, to be the holder of a retailer's licence under this Regulation.

Obligations of holder of retailer's licence

19. (1) The holder of a retailer's licence shall obtain a veterinary medicinal product only from a holder of a wholesale distribution authorisation authorised to distribute veterinary medicinal products or a holder of a manufacturing authorisation authorised to manufacture the product.

(2) A person who fails to comply with *subsection (1)* commits an offence and is liable on summary conviction to a class A fine.

(3) The holder of a retailer's licence when retailing a veterinary medicinal product shall —

(a) ensure that a retail responsible person provides advice to the end user on the appropriate storage, administration, contra indications, withdrawal period, disposal of the veterinary medicinal product and procedures for reporting suspected adverse events,

(b) ensure that a retail responsible person obtains the consent of the end user before dispensing to him or her a product in accordance with regulations made for the purposes of *section 6 (1) (c* and shall ensure the end user is fully advised of any product differences to the prescribed product including withdrawal periods,

(c) not retail the product except to a veterinarian or an end user of the product,

(d) comply with any advertising requirements of Section 4 of Chapter VII of the VMP Regulation or guidance provided by the Minister in relation to veterinary medicinal products,

(e) provide and maintain premises, equipment and staff and have in operation arrangements necessary to avoid deterioration of the product and to notify the Minister within 7 days of a material change in the premises, equipment, staff or arrangements of the holder,

(f) permit inspections by authorised officers and make available information required to satisfy the Minister that the conditions of the licence are being complied with,

(g) immediately withdraw, if directed by the Minister, the European Medicines Agency, the Health Products Regulatory Authority, the marketing authorisation holder or the

wholesale distribution authorisation holder, from retail any quantity, and, in so far as is practicable, immediately recall any quantity sold or supplied of—

(i) a batch or part of a batch of a product that does not conform with a marketing authorisation or the strength, quality or purity does not conform with the specification of that veterinary medicinal product, or

(ii) a product that has given rise to unacceptable adverse events, unacceptable environmental safety or consumer safety concerns or a negative benefit or risk balance as decided by the person so directing,

(h) report any suspected adverse events as defined in Article 73(2) of the VMP Regulation, that they are made aware of, to the marketing authorisation holder of the veterinary medicinal product or the competent authority concerned designated under Article 137 of the VMP Regulation,

(i) have in place the necessary systems to receive from those that they retail to, the veterinary medicinal product that is unused or expired for the return to the person from whom they purchased that product and in addition take steps to ensure that customers are aware of the arrangements,

(j) ensure the premises of the holder and the retail and storage of veterinary medicinal products conform with the conditions in the holder's licence,

(k) in addition to keeping records of veterinary medicinal products requiring a veterinary prescription, keep records of such products not subject to veterinary prescription, and

(l) comply with such further obligations specified in regulations by the Minister having regard in particular to the need to adequately safeguard public and animal health.

(4) Where the Minister considers that the holder of a retailer's licence is not complying with the obligations of a holder under *subsection (3),* the Minister shall notify the holder of this and require the holder to comply with the obligation in accordance with the notification within such time as specified in the notification. If the holder of the licence does not comply with the notification or does not comply with it to the satisfaction of the Minister, the Minister may withdraw the licence indefinitely or until the holder complies with the notification and *section 35(6)* applies to any proposed withdrawal.

Training

20. (1) A person, other than a veterinarian, veterinary nurse or pharmacist, shall undergo a training course of a standard approved of by the Minister, including at appropriate intervals, in the proper and safe handling and storage of veterinary medicinal products to be responsible for the retail of such veterinary medicinal products.

(2) The Minister may require persons to undergo continual training in the proper and safe handling and storage of veterinary medicinal products to be responsible for the retail of such products, and upon request, furnish to the Minister satisfactory evidence that they have successfully completed the training.

(3) A person who has undertaken a course of training in accordance with *subsection (1)* shall, upon request, furnish to the Minister satisfactory evidence that they have successfully completed the course.

(4) Where, in the opinion of the Minister, a person, has successfully completed a training course under *subsection (1)* the Minister shall issue the person with a certificate of suitability for the retail or veterinary medicinal products and the person is referred to in this Chapter as a retail responsible person.

(5) The Minister may require a retail responsible person to undergo additional training, if the Minister considers it necessary.

(6) The Minister may refuse to certify a person to be a retail responsible person if, notwithstanding that the person has successfully completed an approved training course, the person has been convicted of an offence under this Part or the VMP Regulation or Medicated Feed Regulation.

(7) The Minister may withdraw the certification of a retail responsible person if, upon inspection it is found that the person has been convicted of an offence under this Part or the VMP Regulation or Medicated Feed Regulation or is not retailing veterinary medicinal products in accordance with the certification.

(8) (a) Where the Minister proposes to withdraw certification from a person as a retail responsible person, the Minister shall notify the person of the proposal. The person may within such period as the Minister allows in the notification, being not less than 14 days, make representations in writing to the Minister in relation to the proposal. The Minister, having considered any representations so made, may withdraw the certification or let the certification stand with or without conditions and notify the person of the decision.

(b) If the decision is to withdraw certification, the person may within 14 days of being notified of the decision, appeal to a judge of the District Court in whose district he or she carries on the business of the retail of veterinary medicinal products. On hearing the appeal, the judge may confirm the decision of the Minister or allow the appeal. The decision of the court is final save that an appeal on a point of law lies to the High Court.

(c) A decision of the Minister to withdraw certification takes effect on the notification of the decision to the person. The person, if making an appeal under *paragraph (b),* may apply to the court where the appeal is lodged to have the decision suspended until the appeal is determined or withdrawn.

Companion animal medicine retailers' register

21. (1) The Minister shall establish and maintain a register of retailers of veterinary medicinal products designated "companion animal medicine" under *paragraph 4* of *Part 1* of the Schedule to be known as the Companion Animal Medicine Retailers' Register and in this Chapter referred to as the Register.

(2) A person retailing or intending to retail veterinary medicinal products designated companion animal medicines may apply to the Minister to be entered on the Register.

(3) An application for entry in the Register shall be—

(a) in such form and manner as the Minister decides ,and

(b) accompanied by such non-refundable fee as the Minister specifies in regulations.

(4) A person who, when applying for registration in the Register, furnishes information to the Minister knowing it to be false or misleading in any material respect commits an offence and shall be liable on summary conviction to a class A fine.

(5) (a) A person shall not retail a veterinary medicinal product designated companion animal medicine except from premises of a person registered in the Register.

(b) A person who fails to comply with this subsection commits an offence and is liable on summary conviction to a class A fine.

(6) (a) The Minister may require a person entered in the Register to undergo or to ensure that an employee of the person undergoes training that the Minister considers to be adequate in the proper and safe handling and storage of veterinary medicinal products so they are responsible for the retail of such veterinary medicinal products.

(b) A person entered in the Register who fails to comply with a requirement of the Minister under this subsection may be removed by the Minister from the Register in accordance with *subsection (9).*

(7) A person registered in the Register shall comply with the storage requirements for a veterinary medicinal product specified in the labelling and packaging leaflet accompanying the product.

(8) This section does not apply to—

(*a*) a veterinarian,

(b) a veterinary nurse,

(c) a pharmacist,

(d) the holder of a retailer's licence, or

(e) the holder of a wholesale distribution authorisation.

(9) (a) The Minister—

(ii) where he or she considers that an applicant for registration in the Register should not be entered in the Register or a person entered in the Register is not complying with this section, may remove the person from the Register,

(ii) if considering refusing an application for registration in or the removal of a person from the Register, notify the person of the proposal. The notification shall allow the person to make representations to the Minister against the proposal within such period as the Minister allows in the notification, being not less than 14 days, of the person being notified, and

(iii) having considered any representations so made, may enter the person in the Register, refuse the application or remove the person from the Register and notify the person of his or her decision.

(b) If the decision is to refuse an application for registration in or remove the person from the Register, the person may within 14 days of being notified appeal to a judge of the District Court in whose district he or she carries on the business of the retail of veterinary medicinal products. On hearing the appeal, the judge may confirm the refusal for registration in or removal of the person from the Register or allow the appeal. The decision of the court is final save that an appeal on a point of law lies to the High Court.

(c) A decision of the Minister to remove the person from the Register takes effect on the date of notification of the decision to the person. The person, if making an appeal under *paragraph (b),* may apply to the court where the appeal is lodged to have the decision suspended until the appeal is determined or withdrawn.

(10) A person entered in the Register maintained under Regulation 33 of the Regulations of 2007 on 27 January 2022 is deemed to be entered in the Register.

Record-keeping for veterinarian, pharmacist and retailer's licence holder.

22. (1) A veterinarian, pharmacist or the holder of a retailer's licence shall, in addition to the records to be kept in accordance with Article 103(3) of the VMP Regulation, keep detailed records of any transaction of veterinary medicinal products not subject to a prescription, other than those with the route of retail designated companion animal medicine.

(2) A person who fails to comply with *subsection (1)* commits an offence and is liable on summary conviction to a class A fine.

Fixed premises.

23. (1) A person shall not retail a veterinary medicinal product other than from a fixed premises.

(2) *Subsection (1)* does not apply to the retail of a veterinary medicinal product in the course of the provision of a veterinary service by a veterinarian for the treatment of an animal under his or her care.

(3) A person shall not, other than under and in accordance with a licence granted by the Minister on application made to him or her in that behalf, make a visit from house to house to collect, solicit or obtain an order for a veterinary medicinal product.

(4) *Subsection (3)* does not apply in the case of a visit made by the representative of a wholesale distribution authorisation holder to any of the following persons at his or her place of business—

(a) a veterinarian,

(b) a pharmacist,

(c) the holder of a retailer's licence, or

(d) a person registered in the Register.

(5) The Minister shall not grant a licence under *subsection (3)* unless the applicant is—

(a) the holder of a retailer's licence, or

(b) a pharmacist.

(6) A licence granted under *subsection (3)* may only relate to a veterinary medicinal product that may be retailed as a condition of a marketing authorisation as referred to in *paragraph 3* or *4* of *Part 1* of the Schedule.

(7) A person who fails to comply with *subsection (1)* or *(3)* commits an offence and is liable—

(a) on summary conviction, to a class A fine, or

(b) on conviction on indictment, to a fine not exceeding €100,000.

(8) The holder of a licence granted under Regulation 36(3)(b) of the Regulations of 2007 which was in force on 27 January 2022 is deemed to have continued in force after that day and, if in force on the passing of this Act, to be the holder of a licence under this Regulation.

(9) In this section—

"house" includes land or other premises;

"fixed premises" does not include a vehicle, trailer, caravan, or other thing which may be transported on, in or attached to a vehicle or a tent, awning, hut, shed or an unroofed or temporary structure or stall or a yard, field, roadway or casual trading area.

Retail at distance

24. (1) A person shall not retail to another person in another Member State or a third country a veterinary medicinal product subject to a prescription at a distance.

(2) Subject to *subsection (3*), a person shall not purchase from another person in another Member State or a third country a veterinary medicinal product subject to a prescription at a distance.

(3) *Subsection (2)* does not apply to a veterinarian purchasing a veterinary medicinal product from another Member State for the purpose of administering it to animals under his or her care or supplying the product to his or her own clients.

(4) A person shall not purchase from another person in a third country a veterinary medicinal product not subject to a prescription, unless in accordance with procedures as laid out by the competent authority concerned as permitted by Article 106(3) of VMP Regulation.

(5) A person who fails to comply with *subsection (1), (2)* or *(4)* commits an offence and is liable—

(a) on summary conviction, to a class A fine, or

(b) on conviction on indictment, to a fine not exceeding €100,000.

(6) The Minister may, having regard to the need to adequately safeguard public and animal health or the environment, make regulations specifying the conditions and circumstance within which the holder of a retailer's licence, pharmacist or veterinarian may retail a veterinary medicinal product at a distance to a person in the State.

(7) A person who fails to comply with regulations made under *subsection (6)* commits an offence and is liable on summary conviction to a class A fine.

(8) In this section "at a distance" means that the service is provided without the parties being simultaneously present.

Internet retail

25. (1) A person shall not retail to another person in another Member State or a third country a veterinary medicinal product subject to a veterinary prescription over the internet.

(2) Subject to *subsection (3),* a person shall not purchase from another person in another Member State or a third country a veterinary medicinal product subject to a prescription over the internet.

(3) *Subsection (2)* does not apply to a veterinarian purchasing a veterinary medicinal product from another Member State for the purpose of administering it to animals under his or her care or supplying his or her own clients.

(4) A person shall not purchase from another person in a third country a veterinary medicinal product not subject to a prescription, unless in accordance with procedures as laid out by the competent authority concerned as permitted by Article 106(3) of VMP Regulation.

(5) A person who fails to comply with *subsection (1), (2)* or *(4)* commits an offence and is liable—

(a) on summary conviction, to a class A fine, or

(b) on conviction on indictment, to a fine not exceeding €100,000.

(6) A person who holds a licence under *subsection (9)* may retail to a person in the State over the internet such veterinary medicinal products as permitted under regulations made by the Minister, if the person is permitted under the licence to retail the product.

(7) A person shall not retail over the internet to a person in the State a veterinary medicinal product unless the person holds a licence under *subsection (9)* to retail the product.

(8) A person who fails to comply with *subsection (7)* commits an offence and is liable—

(a) on summary conviction, to a class A fine, or

(b) on conviction on indictment, to a fine not exceeding €100,000.

(9) The Minister may grant a licence to—

(a) the holder of a retailer's licence,

(b) pharmacist, or

(c) a veterinarian supplying his or her own clients,

in accordance with any regulations made under *subsection (6)* specifying the categories of veterinary medicinal products that may be retailed over the internet to a person in the State under the licence.

(10) A person who holds a licence under *subsection (9)* and retails over the internet other than in accordance with the licence commits an offence and is liable—

(a) on summary conviction, to a class A fine, or

(b) on conviction on indictment, to a fine not exceeding €50,000.

(11) The holder of a licence granted under Regulation 36(3)(a) of the Regulations of 2007 which was in force on 27 January 2022 is deemed to have continued in force after that day and, if in force on the passing of this Act, to be the holder of a licence under this section and has effect accordingly.

Licencing of import of veterinary medicinal products in relation to their use under Articles 110 to 114 or 116 of VMP Regulation

26. (1) The Minister may, on application, authorise in accordance with Article 106(3) of the VMP Regulation by licence, to be known as a special import licence, or notification to be known as a special import notification, the import, possession, retail or use of a veterinary medicinal product for the purposes of Article 110, 111, 112, 113, 114 or 116 of the VMP Regulation by –

(a) a veterinarian,

(b) the holder of a wholesale distribution authorisation, or

(c) the holder of a marketing authorisation.

(2) A person who imports, possesses, retails or uses a veterinary medicinal product—

(a) for the purposes of Article 110 or 116 of the VMP Regulation, or

(b) that has not been granted a marketing authorisation by the competent authority or the European Commission, for the purposes of Article , 112, 113 or 114 of the VMP Regulation,

without holding a special import licence or notification commits an offence and is liable—

(i) on summary conviction, to a class A fine, or

(ii) on conviction on indictment, to a fine not exceeding €300,000.

(3) The Minister may make regulations as permitted by Article 106(3) of the VMP Regulation on procedures required for the implementation of Articles 110 to 114 and 116.

Regulations – rules on retail

27. (1) The Minister may make regulations in relation to the retail, importation or exportation of veterinary medicinal products, ingredients for such or medicated feed, generally or by such class of persons as specified in the regulations, including—

(a) prohibiting or restricting the retail, importation or exportation of a veterinary medicinal product or an ingredient thereof or medicated feed or a category of such,

(b) prohibiting or restricting the retail, importation or exportation of an animal or carcase of an animal to which a specified a veterinary medicinal product or an ingredient thereof has been administered or a specified medicated feed has been fed, or

(c) imposing prohibitions, restrictions or conditions on their retail, importation or exportation or possession justified on grounds of protection of public and animal health or of the environment.

(2) A person who contravenes or fails to comply with a provision of any regulations made under *subsection (1)* which is stated in the regulations to be a penal provision—

(a) to which this paragraph applies, commits an offence and is liable on summary conviction to a class A fine, or

(b) to which this paragraph applies, commits an offence and is liable—

(i) on summary conviction, to a class A fine, or

(ii) on conviction on indictment, to a fine not exceeding €100,000.

Chapter 4

Control of possession and administration of veterinary medicinal products or medicated feed

Prohibition on possession of veterinary medicinal products or medicated feed

28. (1) The Minister may by regulations prohibit or restrict the possession or control of specified veterinary medicinal products or ingredients thereof or medicated feed, generally or by such persons specified in the regulations.

(2) A person who has in his or her possession or under his or her control a veterinary medicinal product or an ingredient thereof or medicated feed which is prohibited or restricted under regulations made under *subsection (1)* commits an offence.

(3) A person who sells or supplies to another person a veterinary medicinal product or an ingredient thereof or medicated feed which the other person is prohibited from possessing or having control of under regulations made under *subsection (1)* commits an offence. It is a defence for a person accused of contravening this subsection to show he or she was unaware that the other person was so prohibited or restricted and being so unaware was reasonable in the circumstances.

(4) A person who has in his or her possession or under his or her control—

(a) a veterinary medicinal product or an ingredient thereof or medicated feed for the purpose of selling or otherwise supplying or exporting it to another person, or

(b) an animal or the carcase of an animal knowing, or in the circumstances ought to know, it to be an animal or carcase to which a veterinary medicinal product or an ingredient has been administered or medicated feed has been fed for the purpose of—

(i) selling or otherwise supplying or exporting the animal or any produce for human consumption which is derived in whole or in part from the animal or carcase to another person, or

(ii) slaughtering the animal for human consumption,

where such sale or supply or exportation would be in contravention of regulations under *section 27(1)(a) or (b) or (c)* commits an offence.

(5) A person who commits an offence under this section is liable—

(a) on summary conviction, to a class A fine, or to imprisonment for a term not exceeding 6 months, or to both, or

(b) on conviction on indictment, to a fine not exceeding €300,000, or to imprisonment for a term not exceeding 2 years, or to both.

(6) In this section "human consumption" includes intended for incorporation in, or manufacture into, a food intended for human consumption.

Administration of veterinary medicinal products or medicated feed

29. (1) The Minister may by regulations prohibit or restrict a person, other than a veterinarian, to administer to an animal a specified veterinary medicinal product or an ingredient thereof.

(2) A person who contravenes regulations made under *subsection (1),* or directs another to so contravene, commits an offence and is liable—

(a) on summary conviction, to a class A fine, or to imprisonment for a term not exceeding 6 months, or to both, or

(b) on conviction on indictment, to a fine not exceeding €300,000, or to imprisonment for a term not exceeding 2 years, or to both.

(3) The Minister may make regulations governing the administration or use of veterinary medicinal products or medicated feed generally or by a specified class of persons.

(4) A person who contravenes regulations made under *subsection (3)* commits an offence and is liable on summary conviction to a class A fine.

Chapter 5

Storage, advertising and licensing certain veterinary medicinal products, etc

Regulations – secure storage, etc. of veterinary medicinal products

30. (1) The Minister may make regulations—

(a) specifying precautions to be taken for the purpose of ensuring the secure storage of veterinary medicinal products,

(b) in relation to the storage or handling of veterinary medicinal products, or

(c) requiring that stored veterinary medicinal products which, because of their condition, the period within which they may be used has expired or for any other reason, are not intended to be used shall be destroyed or disposed of in a specified manner.

(2) A person who fails to comply with a provision of any regulations made under this section commits an offence and is liable on summary conviction to a class A fine.

(3) The Minister may approve or establish training courses in respect of the proper and safe handling and secure storage of veterinary medicinal products.

Advertising of veterinary medicinal products or medicated feed

31. (1) The Minister may make regulations for the advertising or promoting of veterinary medicinal products or medicated feed, including imposing prohibitions, restrictions or conditions on providing such.

(2) Regulations under this section may in particular provide for:

(a) as permitted under Article 119(1), deciding to allow the advertisement of veterinary medicinal products not authorised or registered in the State in accordance with specified conditions,

(b) permitting the advertising of veterinary medicinal products that are subject to veterinary prescription referred to in Article 120(2) to professional keepers of animals, by way of derogation under paragraph (2) from paragraph (1) of Article 120, or

(c) as permitted under Article 122, establishing procedures the Minister considers necessary for the implementation of Articles 119, 120 and 121,

of the VMP Regulation.

(2) A person who fails to comply with a provision of any regulations made under this section which is stated in the regulations to be a penal provision to which this subsection applies commits an offence and is liable on summary conviction to a class A fine.

Licences required for certain activities

32. (1) The Minister, upon application to him or her, may permit by licence—

(a) the manufacture, import or export of autogenous vaccines;

(b) the collection storage and supply of blood, or the storage and supply of blood constituents obtained by the physical separation of donor blood into different fractions within a closed-bag system, from an animal to be used in, or administered to non-food-producing animals, with a view to restoring, correcting or modifying physiological functions by exerting a metabolic action or immunological action under the supervision or direction of the veterinarian named in the licence, or

(c) the import of medicated feed or intermediate products.

(2) A person who carries out an activity referred to in *subsection (1)* without holding a licence granted under this section to carry out the activity commits an offence and is liable—

(a) on summary conviction, to a class A fine, or

(b) on conviction on indictment, to a fine not exceeding €300,000.

Chapter 6

Matters under national law mentioned in VMP Regulation or Medicated Feed Regulation

Regulations – additional to VMP Regulation and Medicated Feed Regulation

33. (1) The Minister may make regulations in relation to matters mentioned in the VMP Regulation that are to be determined by national law or to be put in place by national procedures or that the State is permitted to do, including:

(a) requiring the availability of a packaging leaflet in such a format as permitted under Article 14(3);

(b) imposing specific requirements on veterinarians or other health professionals in respect of the reporting of suspected adverse events as permitted under Article 79(2);

(c) imposing conditions on the role of responsible person as permitted under Article 100(2)(a);

(d) the supply by a wholesale distributor of veterinary medicinal products for the purposes of Article 101(2);

(e) as permitted under Article 107(7), making further restrictions or prohibitions on the use of antimicrobials in animals;

(f) as permitted under Article 108(4), making additional requirements for record-keeping by owners and keepers of food-producing animals;

(g) as permitted under and in accordance with Article 110(1), prohibiting the manufacture, import, distribution, possession, sale, supply or use of immunological veterinary medicinal products;

(h) for the purpose of Article 117, providing that appropriate systems are in place for the collection and disposal of waste veterinary medicinal products,

of the VMP Regulation.

(2) The Minister may make regulations—

(a) establishing maximum levels of cross contamination for active substances in non-target feed as permitted under Article 7(5),

(b) laying down procedures for the approval of establishments under Article 13, including a licencing system,

(c) for the purpose of Article 13(5), to ensure that relevant information regarding the activities of retailers of medicated feed for pets is available to Minister including requiring a registration or licencing system, or

(d) for the purpose of Article 18, providing that appropriate collection and discard systems are in place for medicated feed and intermediate products that are expired or in case an animal keeper has received a larger quantity of medicated feed than is actually used for the treatment referred to in the veterinary prescription for medicated feed,

of the Medicated Feed Regulation.

(3) A person who contravenes or fails to comply with a provision of any regulations made under this section which is stated in the regulations to be a penal provision—

(a) to which this paragraph applies, commits an offence and is liable on summary conviction to a class A fine, or

(b) to which this paragraph applies, commits an offence and is liable—

(i) on summary conviction, to a class A fine, or

(ii) on conviction on indictment, to a fine not exceeding €100,000.

Chapter 7

Administrative – Regulations and licences

Regulations – Part 2

34. (1) Every regulation made under this Part shall be laid before each House of the Oireachtas as soon as may be after it is made and, if a resolution annulling the regulation is passed by either such House within the next 21 days on which that House has sat after the regulation has been laid before it, the regulation shall be annulled accordingly, but without prejudice to the validity of anything previously done thereunder.

(2) Regulations under this Part may contain such matters which are incidental, supplementary and consequential as the Minister considers necessary.

(3) Regulations under this Part are in addition to and not in substitution for the VMP Regulation or the Medicated Feed Regulation.

Licences generally (Part 2)

35. (1) A licence shall contain such terms and conditions as the Minister decides. The licence may be suspended or revoked if any of the terms or conditions attached to it are not complied with by the holder of the licence.

(2) An application for a licence or alterations to a licence shall be—

(a) made in such form and manner as the Minister decides, and

(b) accompanied by such fee (if any) as the Minister specifies in regulations. Fees to accompany applications for licences or alterations are not refundable.

(3) A person who, when applying for a licence furnishes information to the Minister knowing it to be false or misleading in any material respect commits an offence and shall be liable on summary conviction to a class A fine.

(4) The Minister may vary the terms or conditions of a licence.

(5) The Minister may withdraw a licence where he or she considers the holder is not complying with the licence or any terms or conditions attached to it.

(6) (a) Where the Minister proposes to refuse to grant a licence or to withdraw or vary a licence , the Minister shall notify the applicant or holder of the proposal. The applicant or holder may within such period as the Minister allows in the notification, being not less than 14 days, make representations in writing to the Minister in relation to the proposal. The Minister, having considered any representations so made, may grant or refuse to grant the licence or withdraw or vary the licence and notify the applicant or holder of the decision.

(b) If the decision is to refuse the grant of the licence or to withdraw or to vary the licence, the person may within 14 days of being notified of the decision, appeal to a judge of the District Court in whose district he or she carries on the business of the retail of veterinary medicinal products. On hearing the appeal, the judge may confirm the decision of the Minister or allow the appeal. The decision of the court is final save that an appeal on a point of law lies to the High Court.

(c) A decision of the Minister to withdraw or vary a licence takes effect on the notification of the decision to the holder. The holder, if making an appeal under *paragraph (b),* may apply to the court where the appeal is lodged to have the decision suspended until the appeal is determined or withdrawn.

(7) In this section "licence" means a licence granted under this Part.

Part 3

Enforcement

Authorised officers

36. (1) The Minister may for the purpose of enforcing *Part 2* or regulations made thereunder appoint in writing such persons or class of persons, as he or she considers appropriate, to be authorised officers for the exercise of the functions conferred on an authorised officer under this Part.

(2) A person appointed as an authorised officer under section 10 of the Animal Remedies Act 1993 is deemed to be appointed as an authorised officer to exercise the functions conferred on an authorised officer under this Part.

(3) An authorised officer appointed under this section shall be furnished with a warrant of his or her appointment and, when exercising a function conferred on him or her as an authorised officer, the officer shall, if requested by a person affected, produce the warrant, or other evidence (including an identity document relating to the officer under *section 57*) that he or she is such an officer, for inspection.

(4) For the purposes of enforcing *Part 2* or regulations made thereunder where an authorised officer or a member of the Garda Síochána or an officer of customs has reasonable grounds for believing that—

(a) the manufacture, placing on the market, importation, preparation, handling, storage, transport, exportation, distribution, sale, supply, marketing, advertising or use of a veterinary medicinal product or any ingredient for a veterinary medicinal product or medicated feed or intermediate products or pharmacovigilance activities 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 *Part 2* in, on, under or from any land, premises or in, on or from any vehicle,

(c) any land, vehicle or premises is used for or in connection with the breeding, rearing, feeding, keeping, training, exhibiting, selling or transporting of animals,

(d) any land or premises is a slaughterhouse 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 a veterinary medicinal product 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 veterinary medicinal product or any ingredients for veterinary medicinal products or medicated feed or intermediate products or any machinery (including any telephonic or other computerised information management system), instrument,

equipment, container, record or other thing used in the manufacture, preparation, handling, storage, transport, placing on the market, exportation, distribution, sale, supply or use of veterinary medicinal products or ingredients for veterinary medicinal products or medicated feed or intermediate products,

the authorised officer, member of the Garda Síochána or officer of customs (in this section referred to as the "relevant person") may, stop, subject to *subsection (5),* 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 other authorised officers, members of the Garda Síochána and officers of customs (if any) as the relevant person considers appropriate—

(i) search for and examine, inspect or test any animals, food derived from animals or carcases of animals or anything believed to be a veterinary medicinal product or an ingredient for a veterinary medicinal product, medicated feed or intermediate products or anything to which *paragraph (f)* relates,

(ii) take such specimens (including blood, urine, faeces, tissue, hair or remains of implants) from any animals, food derived from animals or carcases 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 carcases,

(iii) take, without payment, samples of, or from, any substances, or of or from a thing which may be considered appropriate for the purposes of *Part 2* or regulations made thereunder as he or she may reasonably require and may carry out or cause to be carried out on the sample such tests, analyses, examination or inspections as he or she considers necessary or expedient and mark or otherwise identify it.

(iv) seize and detain anything to which *paragraph (f)* relates or anything which is believed to be or to contain a veterinary medicinal product or an ingredient for a veterinary medicinal product or medicated feed or intermediate products kept, used or intended to be used in contravention of *Part 2* or regulations made thereunder, as the case may be,

(v) search for and examine any record and take extracts from and copies of any such record,

(vi) seize and detain an animal in respect of which it is, with reasonable grounds, believed by the relevant person that a prohibited veterinary medicinal product or ingredient for a veterinary medicinal product has been administered to it in contravention of *Part 2* or regulations made thereunder,

(vii) require any person who is suspected to be, or to have been engaged in the importation, 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 veterinary medicinal product, ingredient for a veterinary medicinal product, animal, food derived from animals, carcases of animals or medicated feed or intermediate products or anything to which *paragraph (f)* relates, or any person who is suspected to be, or to have been, engaged in the breeding, rearing, feeding, keeping, training, 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 veterinary medicinal product, ingredient, animal, food, carcase or thing or medicated feed or intermediate products, to produce them to the relevant person or any authorised officer, member of the Garda Síochána or officer of customs,

(II) in the case of any information (including passwords) in relation to such document, veterinary medicinal product, animal, food, carcase, telephonic system, information management system, or thing or medicated feed or intermediate products which may be required (including the source of that document, product, 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,

(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)*.

(5) An authorised officer may only stop a vehicle for the purposes of *subsection (4)* in a public place (within the meaning of the Road Traffic Act 1961) if accompanied by a member of the Garda Síochána and the officer requests the member to stop the vehicle.

(6) The functions of a relevant person under this section 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 *section 37*, anything to which *subsection (4)* relates—

(a) is being destroyed or disposed of, or

(b) is likely to be destroyed or disposed of.

(7) An authorised officer, a member of the Garda Síochána or an officer of customs accompanying the relevant person may exercise all the functions conferred on the relevant person by virtue of this section.

(8) An authorised officer when exercising a power under this section may be accompanied by any other person, and may take with him or her, or that person may take with them, any equipment or material to assist the officer in the exercise of the power.

(9) An authorised officer may use reasonable force, if necessary, to enter land or premises to exercise his or her powers under this section.

(10) Where in the course of exercising a power under this section, an authorised officer finds or comes into possession of anything that the officer has reasonable grounds for believing to be evidence of an offence or suspected offence under *Part 2*, the officer may seize and retain it for use as evidence in proceedings for an offence under *Part 2*.

(11) For the purposes of enforcing *Part 2* or regulations made thereunder, an authorised officer may require a person to give information or produce for inspection any record regarding the

importation, manufacture, preparation, handling, storage, transport, exportation, advertising, distribution, sale, supply, issuing or dispensing of prescriptions for veterinary medicinal products or medicated feed or use of any veterinary medicinal product, ingredient for a veterinary medicinal product, animal, food derived from animals, carcases of animals or medicated feed or intermediate products as is in the person's knowledge or procurement.

(12) A person is not required on examination or inquiry under this section to give any answer or information tending to incriminate the person.

Search warrant

37. (1) Where a judge of the District Court is satisfied by information on oath of an authorised officer, a member of the Garda Síochána or an officer of customs that there is reasonable cause for suspecting that—

(a) evidence of or relating to the commission or intended commission of an offence under *Part 2* 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,

(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 veterinary medicinal product or ingredient for a veterinary medicinal product in relation to which a contravention of *Part 2* or regulations made thereunder, 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 *Part 2*, 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 section.

(2) A search warrant issued under this section shall be expressed and operate to authorise a named authorised officer, named member of the Garda Síochána or named officer of customs, accompanied by such authorised officers, members of the Garda Síochána and officers of customs or other persons 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 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 *section 36*.

Search of suspects and stopping of vehicles

38. (1) Where a member of the Garda Síochána or an officer of customs has reasonable grounds for believing that a person is in possession, in contravention of *Part 2*, of a veterinary medicinal product or an ingredient for a veterinary medicinal product or medicated feed or intermediate products, 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 product or feed 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 Regulation which any such member or officer reasonably suspects to be something which might be required as evidence in proceedings for an offence under this *Part 2*.

(2) Where a member of the Garda Síochána or an officer of customs 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. If the person refuses the member may arrest the person without warrant.

(3) A member of the Garda Síochána or an officer of customs may stop a vehicle, vessel or aircraft for the purposes of this Part and may require it to be moved for inspection to such place as the member directs.

(4) A person who, without reasonable excuse, fails to comply with a request of a member of the Garda Síochána or an officer of customs under *subsection (2)* or *(3)* commits an offence and is liable on summary conviction to a class A fine.

(5) Nothing in this Part operates to prejudice any power to search or to stop, or to seize or detain property, which may, apart from this Part, be exercised by a member of the Garda Síochána or an officer of customs.

Power of arrest

39. Where with reasonable cause a member of the Garda Síochána—

(a) suspects that an offence under *Part 2* or *section 38 (4)* or *41* has been committed or attempted, and

(b) suspects a person of having committed the offence or having made the attempt,

the member 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,

(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.

Saving for certain power

40. Nothing in this Part shall operate to prejudice any power to search, or to seize or detain property, which may, apart from this Part, be exercised by a member of the Garda Síochána or an officer of customs.

Obstruction

41. A person who —

(a) obstructs or impedes an authorised officer, member of the Garda Síochána or officer of customs or any person who accompanies such officer or member, in the exercise of any of the functions conferred on or exercisable by the officer or member under *section 36*,

(b) fails, without reasonable excuse, to comply with a requirement of an authorised officer, member of the Garda Síochána or officer of customs under *section 36*,

(c) purporting to give information to an authorised officer under *section 36* for the exercise of the officer's or member's functions under that section—

(i) makes a statement that he or she knows to be false or misleading in a material particular or recklessly makes a statement which is false or misleading in a material particular, or

(ii) intentionally fails to disclose a material particular,

commits an offence and is liable on summary conviction to a class A fine.

Compliance notice

42. (1) Where an authorised officer is of the opinion that a person is not complying, or has not complied with *Part 2* or regulations made thereunder the officer may serve on the person a notice ("compliance notice") stating that opinion on the person.

(2) A compliance notice shall—

(a) require the person on whom it is served to take such action as specified in the notice,

(b) inform the person on whom it is served that he or she may appeal the notice to the District court under *section 43*, and

(c) state that if the person on whom the notice is served fails to comply with the notice, he or she commits an offence and is liable to the penalty set out in *subsection (7).*

(3) A person on whom a compliance notice is served shall—

(a) comply with the notice until it expires or is annulled under *section 43*, and

(b) not cause or permit another person to contravene the terms of the notice.

(4) A compliance notice may specify a time limit within which the action specified in the notice is to be complied with.

(5) A compliance notice may be modified or withdrawn by a further notice and the earlier notice has effect subject to the modification or withdrawal.

(6) A compliance notice shall include an address for the service of an appeal under *section 43*.

(7) A person on whom a compliance notice is served who fails to comply with, or causes another person to contravene, the notice commits an offence and is liable—

(a) on summary conviction, to a class A fine, or

(b) on conviction on indictment, to a fine not exceeding €50,000.

Appeal against compliance notice

43. (1) A person on whom a compliance notice is served may, not later than 10 days from the date of the service of the notice, appeal the notice to the judge of the District Court having jurisdiction in the District Court district—

(a) where the veterinary medicinal product or animal feed to which the notices relates is situated, or

(b) where the person bringing the appeal ordinarily resides or carries on business.

(2) Notice of an appeal shall contain a statement of the grounds upon which it is alleged that the compliance notice is unreasonable having regard to this Act and shall be served on the Minister at the address included on the notice in accordance with *section 42*(6) not later than 2 days prior to the appeal.

(3) A copy of a notice of an appeal shall be lodged with the District Court clerk not later than 2 days prior to the hearing of the appeal.

(4) A compliance notice in respect of which an appeal is brought under this section has effect pending the making of an order under *subsection (5).*

(5) On the hearing of an appeal the judge may confirm, modify or annul the compliance notice concerned.

(6) A person, including a person on whom a compliance notice has been served, shall not—

(a) pending the determination of the appeal, deal with any veterinary medicinal product or animal feed to which the notice relates, other than in accordance with the terms of the compliance notice, or

(b) if the notice is confirmed or modified on appeal, deal with any veterinary medicinal product or animal feed to which the notices relates other than in accordance with the terms of the compliance notice as confirmed or modified.

(7) A person who fails to comply with *subsection (6*) commits an offence and is liable—

(a) on summary conviction, to a class A fine, or

(b) on conviction on indictment, to a fine not exceeding €50,000.

(8) In this section "appeal" means an appeal under *subsection (1).*

Seizure and detention for non-compliance with compliance notice

44. (1) Subject to an appeal under *section 43,* where —

(a) the owner, occupier or person in charge of land or premises, or the owner or person in possession or control of a veterinary medicinal product or any ingredient for a veterinary medicinal product or medicated feed or intermediate product fails to comply with a compliance notice within the time specified in the notice,

(b) an authorised officer has reasonable grounds for believing that a compliance notice, whether or not modified under *section 42*(5), will not be complied with, or

(c) a compliance notice has been confirmed with or without modification under *section 42*(5) and the notice has not been complied with,

then the authorised officer may seize and detain the product or feed and any means of transport or other thing used in connection with such.

(2) Where a veterinary medicinal product or any ingredient for a veterinary medicinal product or medicated feed or intermediate product, means of transport or other thing is seized and detained under *subsection (1),* an authorised officer may—

(a) sell, destroy or dispose of the product, feed or other thing or cause it to be sold, destroyed or disposed of, or

(b) take such other measures in relation to the product, feed, means of transport or other thing as the authorised officer considers appropriate, in the circumstances.

(3) Before exercising any power under *subsection (2)* an authorised officer shall by notice inform the person concerned of his or her intention and afford the person an opportunity to make representations to the officer within 10 days of service of the notice. The officer shall consider the representations and by notice inform the person of his or her decision. If the person is aggrieved by the decision, he or she may, within 10 days of the service of the decision, appeal to the judge of the District Court within whose district the person resides or carries on business. On the hearing of the appeal the judge may confirm, modify or annul the notice.

(4) The profits, if any, arising out of the sale, destruction or disposal of a veterinary medicinal product or any ingredient for a veterinary medicinal product or medicated feed or intermediate product, means of transport or other thing seized and detained under *subsection (1*) shall be paid to the owner of the product, feed, means of transport or other thing less any expenses (including ancillary expenses) incurred in connection with the seizure, detention, sale, destruction or disposal.

(5) The costs (including ancillary costs) of a measure taken under this section may be recovered by the Minister—

(a) as a simple contract debt in a court of competent jurisdiction from the person who was the owner of the veterinary medicinal product or any ingredient for a veterinary medicinal product or medicated feed or intermediate or means of transport or other thing at the time the measure was carried out, or

(b) by deducting the costs from any moneys due, or becoming due, and payable by the Minister to the person on whom the compliance notice concerned was served.

(6) Where the Minister proposes to recover the costs of anything done under this section the Minister shall—

(a) inform by notice the person concerned of the costs (including, but not limited to, salaries, subsistence, hiring of vehicles, machinery or equipment, feeding and veterinary fees) the reason for the costs and that he or she may make representations in relation to the proposal not later than 14 days from the date of the notice,

(b) consider any representations duly made, and

(c) make a decision and inform by notice the person concerned, stating the decision and the reasons for the decision.

Impersonation of an authorised officer, etc. and possession of certain identity documents

45. (1) A person who, with the intention to deceive—

(a) purports to be, or

(b) acts in a manner that would lead another person to believe that he or she is,

a person duly appointed as an authorised officer or other officer of the Minister either generally or for the purposes of this Part commits an offence and is liable on summary conviction to a class A fine or to imprisonment for a term not exceeding 6 months, or to both.

(2) A person who, without lawful excuse, has 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 or other officer of, the Minister either generally or for the purposes of this Part commits an offence and is liable on summary conviction to a class A fine or to imprisonment for a term not exceeding 6 months, or to both.

Evidence of class of veterinary medicinal product to which a contravention relates

46. In any proceedings for an offence under *Part 2* in which it is alleged that a contravention of *Part 2* has occurred in relation to a class of veterinary medicinal product or a class of ingredient for a veterinary medicinal product or a class of medicated feed or intermediate products, it shall not be necessary to show that the contravention relates to a particular veterinary medicinal product or ingredient for a veterinary medicinal product or a particular medicated feed or intermediate product where it can be shown that it relates to a thing which is a member of such a class of veterinary medicinal product or class of ingredient for a veterinary medicinal product or medicated feed or intermediate product.

Disposal of things seized

47. If, in the course of exercising a power under this Part, a person, being an authorised officer, a member of the Garda Síochána or an officer of customs, finds or comes into possession of any thing which such a person believes to be evidence of any offence or suspected offence under *Part 2*, it may be seized and retained for use in evidence in any criminal proceedings, for such period from the date of seizure as is reasonable or, if proceedings are commenced in which the thing so seized is required for use in evidence, until the conclusion of the proceedings, and thereafter it shall be returned to its owner, unless—

(a) returning it would cause the owner to be in possession of the seized item contrary to law,

(b) the expiry date of a seized medicine has expired,

(c) the person from whom it was seized cannot be found within in a period of 30 days, or

(d) an order from the court has been obtained to otherwise dispose of it,

and an authorised officer may, other than where *paragraph (d)* applies, approve the disposal, without payment or compensation of the thing following the issuing of a disposal notice to the owner giving him or her 10 days to appeal the decision to the Minister to dispose.

Evidence on certificate, etc.

48. (1) In proceedings for an offence under *Part 2*, a certificate purporting to be signed by a person employed at a laboratory named in the certificate stating the capacity in which that person is so employed and stating one or more of the following, namely—

(a) that the person received a sample submitted to the laboratory,

(b) that, for a period as is specified in the certificate, the person had in his or her custody a sample so submitted,

(c) that the person gave to such other person as is specified in the certificate a sample so submitted,

(d) that the person carried out a laboratory examination for the purpose of detecting the presence, in a sample so submitted, of a substance, ingredient for a veterinary medicinal product or medicated feed or intermediate product or a veterinary medicinal product or medicated feed or intermediate product, or

(e) that a particular substance, ingredient for a veterinary medicinal product or medicated feed or intermediate product or a veterinary medicinal product or medicated feed or intermediate product was present in the sample,

is, unless the contrary is shown, evidence of the matters stated in the certificate.

(2) A certificate purporting to be signed by an officer of the Minister and to certify that on a specific day or days or during the whole of a specified period-

(a) a particular person did not hold a licence granted under regulations made under *Part 2*,

(b) such a licence is suspended or has been revoked, or

(c) that a particular such licence, was subject to a particular condition or conditions,

is, without proof of the signature of the person purporting to sign the certificate or that he or she is an officer of the Minister, evidence, unless the contrary is shown, of the matters stated in the certificate.

(3) In proceedings for an offence under this *Part 2* the court may, if it considers that the interests of justice so require, direct that oral evidence of any matter stated in a certificate under *subsection* (*1) or (2)* be given, and the court may for the purpose of receiving oral evidence adjourn the matter.

Offences by bodies corporate, etc.

49. (1) Where an offence under *Part 2* 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 willful 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, shall be guilty of an

offence and shall be liable to be proceeded against and punished as if guilty of the first-mentioned offence.

(2) Where the affairs of a body corporate are managed by its members, *subsection (1)* shall apply in relation to the acts and defaults of a member in connection with the functions of management as if such a member were a director or manager of the body corporate.

Service of notices and notifications

50. (1) Subject to *subsection (2),* any notification, notice or document required or authorised by virtue of *Part 2* to be given to any person by the Minister or required to be given under *Part 2* shall be addressed to the person concerned by name and may be given –

(a) by delivering it to the person,

(b) by leaving it at the address at which the person carries on business or ordinarily resides or, in the case in which an address for service has been furnished, at that address,

(c) by sending it by post in a prepaid registered letter to the address at which the person carries on business or ordinarily resides or, in a case in which an address for service has been furnished, to that address, or

(d) by electronic communication, if the person concerned has agreed to service of notices, notifications or documents by such means, provided that there is a facility for confirming receipt of the electronic communication and that such receipt has been confirmed.

(2) For the purposes of this section, a company (within the meaning of the Companies Act 2014) shall be deemed to be ordinarily resident at its registered office, and every other body corporate and every unincorporated body shall be deemed to be ordinarily resident at its principal office or place of business.

Disqualification from keeping animals, veterinary medicinal products, or medicated feed, etc.

51. (1) A person who is convicted on indictment of an offence under *Part 2* may, in addition to the penalty imposed thereunder—

(a) be disqualified from keeping, dealing in or having charge or control, directly or indirectly, of either or both—

(i) any animal or class or classes of animal, and

(ii) any veterinary medicinal product or medicated feed or class or classes of a veterinary medicinal product or medicated feed or any ingredient thereof,

or

(b) be disqualified from working in or having charge or control of any one or more of the following, that is to say, the manufacture, importation, preparation, handling, storage, transport, exportation, distribution, sale or supply of either or both food intended for human consumption and food intended for animal consumption or of any class or classes of either or both such foods,

for such period, including where appropriate for the life of the person, as the court thinks fit.

(2) In this section "control" includes, in relation to a body corporate, the power of the person concerned to secure, by means of holding shares or the possession of voting power in or in relation to that or any other body corporate, or by virtue of powers conferred by articles of association or other document regulating that or any other body corporate, that the affairs of the first-mentioned body corporate are conducted in accordance with the wishes of that person.

Forfeiture of animal, veterinary medicinal product, etc.

52. (1) Where—

(a) a veterinary medicinal product,

(b) an ingredient for a veterinary medicinal product,

(c) an animal to which a veterinary medicinal product has been administered,

(d) any thing used in connection with an unauthorised veterinary medicinal product or any thing directly used in connection with any other veterinary medicinal product, or

(e) any thing used in connection with an animal to which a prohibited a veterinary medicinal product has been administered or any thing directly used in connection with an animal to which any other veterinary medicinal product has been administered,

has come into the possession of an authorised officer in respect of which an offence is with reasonable cause suspected by the officer of having been committed under *Part 2*, or where an offence has been committed or is alleged to have been committed under *Part 2* in respect of any of the matters referred to in *paragraph (a), (b), (c), (d)* or *(e),* and on the application before a court of—

(i) the Minister, or

(ii) where criminal proceedings have been instituted, the person who instituted those proceedings,

the appropriate court may, at its discretion and where it is satisfied that an offence has been committed (whether or not any person has been convicted of the offence) order the forfeiture of any such animal, veterinary medicinal product, ingredient for a veterinary medicinal product, or other thing, as the case may be.

(2) Any thing ordered by the appropriate court to be forfeited under this section shall be disposed of as the Minister thinks fit, and any moneys arising from such disposal shall, without prejudice to it being taken into account (where appropriate) for the purposes of *section 53*, be paid into or disposed of for the benefit of the Exchequer in such manner as the Minister for Public Expenditure and Reform directs.

(3) (a) In this section—

"appropriate court" means—

(i) in case the estimated value of the animal, veterinary medicinal product, ingredient for a veterinary medicinal product or other thing to be forfeited does not exceed €15,000, the District Court,

(ii) in case the estimated value aforesaid does not exceed €75,000, the Circuit Court,

(iii) in any case, the High Court;

"estimated value", in relation to the thing sought to be forfeited, means the estimated amount of money which, in the opinion of the court, a willing purchaser would pay to a willing seller when such a thing could be sold legally and after deduction for—

(i) the estimated costs incidental to such a sale, and

(ii) the estimated amount of any tax or duty owing to the State in respect of that thing,

and when it cannot be sold legally then such estimated value, if any, as the court considers appropriate.

(b) (i) If, in relation to an application under this section to the District Court, that court becomes of the opinion during the hearing of the application that—

(I) the estimated value aforesaid will exceed €15,000, or

(II) that for any reason it should decline jurisdiction,

it may, if it so thinks fit, transfer the application to the Circuit Court or the High Court, whichever it considers appropriate having regard to the estimated value aforesaid or to such other matters that it considers appropriate.

(ii) If, in relation to an application under this section to the Circuit Court, that court becomes of opinion during the hearing of the application that—

(I) the estimated value aforesaid will exceed €75,000, or

(II) that for any reason it should decline jurisdiction,

it may, if it so thinks fit, by order transfer the application to the High Court.

(c) An application under this section shall be brought in a summary manner.

(4) (a) An order shall not be made by a court under this section unless the court is satisfied that in the circumstances all practicable steps have been taken to notify any person of the proceedings relating to the application for the order and who, in the opinion of the court, should be given the opportunity of being heard by it on that application.

(b) The court concerned may make such order as to the costs of the parties to or heard by the court in proceedings relating to an application for an order under this section as it considers appropriate.

Recoupment of costs of certain disposals

53. Where any thing which is seized from or forfeited by a person under this Part is duly disposed of by or on behalf of the State, the costs of such disposal, less any moneys arising from such disposal, shall (except where such costs have been waived in writing) be recoverable from such person as a simple contract debt in any court of competent jurisdiction.

Forgery

54. (1) A person shall not forge a document purporting to be—

(a) a veterinary prescription,

(b) a licence under *Part 2*, or

(c) a record required to be kept, or any other document issued or maintained, under regulations made under *Part 2*,

(which is, in this section, referred to as a "forged document").

(2) A person shall not forge an endorsement or other entry purporting to be for any purpose of this Act on any document whatsoever required to be kept for the purposes of *Part 2* (which document with such entry in this section is referred to as a "falsely endorsed document").

(3) A person shall not, with intent to deceive, create or alter—

(a) a veterinary prescription,

(b) a licence under *Part 2*, or

(c) a record required to be kept or any other document issued or maintained under regulations made under *Part 2*,

(which document if so altered is, in this section, referred to as an "altered document").

(4) A person shall not utter a forged document, a falsely endorsed document or an altered document.

(5) A person shall not have in his or her possession or under his or her control, a forged document, a falsely endorsed document or an altered document.

(6) *Subsection (5)* does not apply to—

(a) an authorised officer or a member of the Garda Síochána or an officer of customs, when acting in the course of his or her duty, or

(b) a person who has taken into his or her possession a document for the purpose of—

(i) preventing another from committing or continuing to commit an offence, or

(ii) delivering it into the custody of a person specified in *paragraph (a)*.

(7) A person who contravenes this section commits an offence and is liable—

(a) on summary conviction, to a class A fine, or to imprisonment for a term not exceeding 6 months, or to both,

(b) on conviction on indictment, to a fine not exceeding €50,000, or to imprisonment for a term not exceeding 2 years, or to both.

Summary proceedings

55. (1) Proceedings for an offence under *Part 2* may be brought and prosecuted summarily by the Minister.

(2) Notwithstanding section 10(4) of the Petty Sessions (Ireland) Act 1851, summary proceedings for an offence under this Act may be instituted within 2 years from the date of the offence.

Fixed payment notice

56. (1) Where an authorised officer has reasonable grounds for believing that a person is committing or has committed an offence under *Part 2* which may only be prosecuted summarily, he or she may serve on the person a notice in writing (in this section referred to as a "fixed payment notice") stating that—

(a) the person is alleged to have committed the offence,

(b) the person may during the period of 28 days beginning on the date of the notice make to the Minister, at the address specified in the notice, a payment of €500 accompanied by the notice,

(c) the person is not obliged to make the payment, and

(d) a prosecution in respect of the alleged offence will not be instituted during the period specified in the notice and, if the payment specified in the notice is made during that period, no prosecution in respect of the alleged offence will be instituted.

(3) Where a fixed payment notice is served under *subsection (1*)—

(a) the person to whom the notice applies may, during the period specified in the notice, make to the Minister at the address specified in the notice the payment specified in the notice accompanied by the notice,

(b) the Minister may receive the payment, issue a receipt for it and retain the money so paid, and any payment so received shall not be recoverable in any circumstances by the person who made it, and

(c) a prosecution in respect of the alleged offence shall not be instituted in the period specified in the notice, and if the payment so specified is made during that period, no prosecution in respect of the alleged offence shall be instituted.

(2) In proceedings for an offence under this Act the onus of proving that a payment in accordance with a fixed payment notice has been made lies on the person on whom the fixed payment notice was served.

(3) In proceedings for an offence referred to in *subsection (1)* it is a defence for the accused to show that he or she has made a payment in accordance with this section pursuant to a fixed payment notice issued in respect of that offence.

Composite identity cards.

57.— (1) The Minister may issue or cause to be issued to a person an identity document in respect of one or more than one function conferred on that person by the Minister under this Act or any other enactment or regulations under the European Communities Act 1972 (whether or not with the approval, consent or otherwise of another Minister of the Government) and each such document shall indicate—

(a) that it is an identity document by reference to it being an identity card, warrant card, authorisation card or such other cognate expression as the Minister considers appropriate;

(b) the name of the person to whom it is issued;

(c) that it is issued pursuant to *section 57* of the *Veterinary Medicinal Products, Medicated Feed and Fertilisers Regulation Act 202*2;

(d) a reference to the provisions of every enactment or regulations in respect of which functions have been conferred by the Minister together with any designatory title (if any) for each of those functions;

and shall include a photograph of the person to whom it is issued and, either generally in respect of all such documents or in respect of a class or classes of such documents, such other matters as the Minister considers appropriate.

(2) A relevant statutory requirement shall be satisfied if, in lieu of the document to which that requirement relates being produced by the person authorised or otherwise appointed, there is produced by the person so authorised or otherwise appointed an identity document issued pursuant to *subsection (1),* and the relevant statutory requirement shall be construed accordingly.

(3) In this section—

"conferred", in relation to a function, means any form of assignment of the function to a person whether by means of a warrant of appointment or otherwise;

"photograph" means a full-face photograph of the person concerned and includes any other full-face image of the person concerned which is in the nature of a photograph, whether produced electronically or otherwise;

"relevant statutory requirement" means a requirement, however expressed, in any provision of an enactment that a person authorised or otherwise appointed under the enactment regulations made under the European Communities Act 1972 to exercise any function shall, when exercising that function, produce if requested by any person affected a specific document to that person.

(4) An identity card issued under section 17 of the Animal Remedies Act 1993 which is in force on the passing of this Act is deemed to have been issued under this section.

Part 4

Amendment of Fertilisers Feeding Stuffs and Mineral Mixtures Act 1955

Definition (Part 4)

58. In this Part, "Act of 1955" means the Fertilisers Feeding Stuffs and Mineral Mixtures Act 1955.

Amendment of definitions in Act of 1955

59. Section 1 of the Act of 1955 is amended—

(a) by substituting for the definition of "fertiliser" the following:

"'fertiliser' means (subject to any exemptions which may be prescribed) any article (including, in particular, lime and ground limestone) manufactured for use as a fertiliser of the soil and includes any substance, mixture, micro- organism or any other material, applied or intended to be applied on plants or their rhizosphere or on mushrooms or their mycosphere, or intended to constitute the rhizosphere or mycosphere, either on its own or mixed with another material, for the purpose of providing the plants or mushrooms with nutrient or improving their nutrition efficiency;

'fertiliser economic operator' means a manufacturer, authorised representative, importer or distributor (whether wholesale or retail) of a fertilising product;

'import' means import into the State from another Member State or a third country;",

(b) by substituting for the definition of "the Minister" the following

"'Minister' means Minister for Agriculture, Food and the Marine;

'premises' includes a building, a dwelling or other structure (whether temporary or permanent) on or under land or in water;",

(c) by inserting after the definition of "prescribed" the following:

"'professional fertiliser end user' means any person who uses fertiliser products in the course of his or her professional activities, including as an operator, technician, employer or self-employed person, whether in the farming or other sectors, but excludes private domestic use;",

(d) in the definition of "the Assistant State Chemist", by substituting " State Laboratory;" for " State Laboratory.", and

(e) by inserting after the definition of "the Assistant State Chemist" the following:

"'use' means all operations carried out with a fertiliser product, including storage, handling, mixing and application, including application by third parties.".

Fertiliser and compound feeding stuff exceptions

60. The following section is inserted after section 1 of the Act of 1955:

"1A. The Minister may prescribe an article or substance deemed not to be a fertiliser or compound feeding stuff for the purpose of this Act.".

Licences under section 5 of Act of 1955

61. Section 5 of the Act of 1955 is amended—

(a) in subsection (3)(c) by deleting "by post", and

(b) by inserting after subsection (3) the following:

"(3A) An application for a licence under regulations made under this section shall be made in such form and manner as the Minister decides and accompanied by such fee (if any) as the Minister decides. Fees to accompany applications for licences or alterations are not refundable.

(3B) A person who, when applying for a licence under regulations made under this section, furnishes information to the Minister knowing it to be false or misleading in any material respect commits an offence and shall be liable on summary conviction to a class A fine.

(3C) (a) Where the Minister proposes to refuse to grant a licence under regulations made under this section or to revoke or vary a condition of such a licence, the Minister shall notify the applicant or holder of the proposal. The applicant or holder may within such period as the Minister allows in the notification, being not less than 14 days, make representations in writing to the Minister in relation to the proposal. The Minister, having considered any representations so made, may grant or refuse to

grant the licence or revoke or vary the licence and notify the applicant or holder of the decision.

(b) If the decision is to refuse the grant of the licence or to suspend or revoke or to vary the licence, the person may within 14 days of being notified of the decision, appeal to a judge of the District Court in whose district he or she carries on the business concerned. On hearing the appeal the judge may confirm the decision of the Minister or allow the appeal. The decision of the court is final save that an appeal on a point of law lies to the High Court.

(c) A decision of the Minister to revoke or vary a licence takes effect on the notification of the decision to the holder. The holder, if making an appeal under paragraph (b), may apply to the court where the appeal is lodged to have the decision suspended until the appeal is determined or withdrawn.".

Fertiliser registers and sales data

62. The following sections are inserted after section 7 of the Act of 1955:

"*Fertiliser Economic Operators' Register*

7A. (1) The Minister shall establish and maintain, in such form (including in electronic form) as he or she considers appropriate, a register of persons who manufacture, import, place on the market or make available on the market (whether wholesale or retail) a fertiliser product, to be known as the Fertiliser Economic Operators' Register (in this section referred to as the 'Register').

(2) An application for entry in the Register shall be made in such form and manner as the Minister may specify.

(3) A person who, when applying for registration in the Register, furnishes information to the Minister knowing it to be false or misleading in any material respect commits an offence and is liable on summary conviction to a class A fine.

(4) A person entered in the Register shall be assigned a unique fertiliser economic operator registration identification number.

(5) The Minister may enter in the Register in respect of a person entered in it the following details:

(a) the person's name;

(b) the name and address of his or her place of business;

(c) the nature of the business operated;

(d) his or her phone number, email address and any other relevant contact details;

(e) his or her unique fertiliser economic operator registration identification number.

(6) The Minister may prescribe additional details to be included on the Register in respect of an entry in it to ensure the effective management of the Register.

(7) The Minister may attach conditions to registration, revoke or vary a condition, attach a new condition, refuse an application or remove a person from the Register.

(8) A person who manufactures, imports, places on the market or makes available on the market (whether wholesale or retail) a fertiliser product without being entered in the Register commits an offence and is liable—

(a) on summary conviction, to a class A fine, or

(b) on conviction on indictment, to a fine not exceeding €100,000.

(9) A certificate purporting to be signed by an officer of the Minister that the person specified in the certificate is, or is not, entered in the Register shall, until the contrary is proved, be evidence of the matters so certified and it shall not be necessary to prove the signature of the officer or that he or she was in fact such an officer or was in fact so authorised.

(11) A person entered in the Register who purchases a fertiliser product shall supply his or her unique fertiliser economic operator registration identification number to the person from whom he or she acquires the fertiliser product.

(12) A person who fails to comply with subsection (11) commits an offence and is liable on summary conviction to a class A fine.

Professional Fertiliser End Users' Register

7B. (1) The Minister shall establish and maintain, in such form (including electronic form) as he or she considers appropriate, a register of professional fertiliser end users, to be known as the Professional Fertiliser End Users' Register (in this section referred to as the 'Register').

(2) An application for entry in the Register shall be made in such form and manner as the Minister may specify.

(3) A person who, when applying for registration in the Register, furnishes information to the Minister knowing it to be false or misleading in any material respect commits an offence and shall be liable on summary conviction to a class A fine.

(4) A person entered in the Register shall be assigned a unique professional fertiliser end user registration identification number.

(5) The Minister may enter in the Register in respect of a person entered in it the following details:

(a) the person's name;

(b) the name and address of his or her place of business;

(c) the nature of the business operated;

(d) his or her phone number, email address and any other relevant contact details;

(e) his or her unique professional fertiliser end user registration identification number.

(6) The Minister may prescribe additional details to be included on the Register in respect of an entry in it to ensure the effective management of the Register.

(7) The Minister may attach conditions to registration, revoke or vary a condition, attach a new condition, refuse an application or remove a person from the Register.

(8) A person who operates as a professional fertiliser end user without being entered in the Register commits an offence and is liable—

(a) on summary conviction, to a class A fine, or

(b) on conviction on indictment, to a fine not exceeding €100,000.

(9) A certificate purporting to be signed by an officer of the Minister that the person specified in the certificate is, or is not, entered in the professional fertiliser end user register shall, until the contrary is proved, be evidence of the matters so certified and it shall not be necessary to prove the signature of the officer or that he or she was in fact such an officer or was in fact so authorised.

(11) A person entered in the Register who purchases a fertiliser product shall supply his or her unique professional fertiliser end user identification registration number to the person from whom he or she acquires the fertiliser product.

(12) A person entered in the Register who fails to comply with subsection (11) commits an offence and is liable on summary conviction to a class A fine.

Fertiliser registers – representation and appeals

7C. (1) The Minister, where he or she considers that an applicant for registration in a Register should not be entered in the Register, may refuse the application, or a person entered in the Register is not complying with this Act or a condition of registration, may remove the person from the Register. The Minister may, if considering refusing an application for registration in, or the removal of a person from, the Register, notify the person of the proposal. The notification shall allow the person to make representations to the Minister against the proposal within such period as the Minister allows in the notification, being not less than 14 days, of the person being notified. The Minister, having considered any representations so made, may enter the person in the Register, refuse the application or remove the person from the Register and notify the person of his or her decision.

(2) If the decision is to refuse an application for registration in, or to remove the person from, the register, the person may within 14 days of being notified appeal to a judge of the District Court in whose district he or she carries on the business concerned. On hearing the appeal the judge may confirm the refusal for registration in, or removal of the person from, the register or allow the appeal. The decision of the court is final save that an appeal on a point of law lies to the High Court.

(3) A decision of the Minister to remove the person from the register takes effect on the date of notification of the decision to the person. The person, if making an appeal under subsection (2), may apply to the court where the appeal is lodged to have the decision suspended until the appeal is determined or withdrawn.

(4) A person who is aggrieved by a condition attached to his or her registration in a Register may within 14 days of the condition being attached make representation to the Minister regarding the condition. The Minister having considered the representation may confirm with or without modification the condition or remove it. If further aggrieved by the decision the person may within 14 days of notification of the decision appeal to a judge of the District Court in whose district he or she carries on the business concerned. On hearing the appeal the judge may confirm the condition or vary it or allow the appeal. The decision of the court is final save that an appeal on a point of law lies to the High Court.

(5) In this section 'Register' means the Fertiliser Economic Operators' Register or the Professional Fertiliser End Users' Register, as the case may be.

National Fertiliser Database

7D. (1) The Minister shall establish and maintain a database containing the information referred to—

(a) in subsection (2) and submitted to him or her by a person entered in the Fertiliser Economic Operators' Register, and

(b) in subsection (6) and submitted to him or her by a person entered in the Professional Fertiliser End Users' Register,

in accordance with this section (to be known as the National Fertiliser Database and in this section referred to as the 'database') for the purposes set out in section 7E.

Details to be uploaded by fertiliser economic operator

(2) A person entered in the Fertiliser Economic Operators' Register shall submit to the Minister, at such time or times prescribed under subsection (11)(a), information of manufacturing, imports, placing on the market, making available on the market or sales (whether wholesale or retail) of fertiliser products undertaken by the person, by entering onto the database the information required to be submitted under subsection (3) and as prescribed under subsection (4) in relation to the product and in the form and manner prescribed under subsection (10) and in accordance with any conditions prescribed under subsection (11)(b)(i).

(3) The following information shall be submitted by a person entered in the Fertiliser Economic Operators' Register to the Minister for the purposes of subsection (2):

(a) in the case of Importers and manufacturers—

(i) their unique fertiliser economic operator registration number,

(ii) the trade name of the fertiliser product imported or manufactured,

(iii) the quantity of the product imported or manufactured (in kilograms or litres),

(iv) the quantity of product sold (in kilograms or litres),

(v) the unique registration identification number of the fertiliser economic operator or professional fertiliser end user, as the case may be, acquiring the product,

(vi) the declared nutrient content of the fertiliser product,

(vii) the inhibitor used, if relevant,

(viii) the manufacturer of the fertiliser product, if relevant,

(ix) if the fertiliser product was repackaged or relabelled, the relevant details,

(x) if the fertiliser product is intended for the domestic market only, export only, or both, and

(xi) the neutralising value, reactivity and grain size for liming materials only;

(b) in the case of wholesalers and retailers—

(i) their unique fertiliser economic operator registration number,

(ii) the trade name of the fertiliser product concern,

(iii) the unique registration identification number of the fertiliser economic operator or professional fertiliser end user, as the case may be, acquiring or returning the product,

(iv) the date of transfer of the fertiliser product, and

(v) the quantity of the product acquired or returned (in kilograms or litres).

(4) The Minister may prescribe additional information required to be submitted to the Minister by a fertiliser economic operator for entry on the database.

(5) A person entered in the Fertiliser Economic Operators' Register who —

(a) fails to comply with subsection (2), or

(b) when submitting under subsection (2) information to the Minister, furnishes information to the Minister knowing it to be false or misleading in any material respect,

commits an offence and is liable on summary conviction to a class A fine.

Details to be uploaded by professional fertiliser end user

(6) A person entered in the Professional Fertiliser End Users' Register shall submit to the Minister, at a time or times prescribed under subsection (11)(a), details of fertiliser products on his or her premises or under his or her control, whether for his or her own use or not, by entering onto the database the information required under subsection (7) and as prescribed under subsection (8) in relation to the product and in the form and manner prescribed under subsection (10) and in accordance with any conditions prescribed under subsection (11)(b)(ii).

(7) The details to be submitted to the Minister by a person entered in the Professional Fertiliser End Users' Register for the purposes of subsection (6) shall include—

(a) his or her unique professional fertiliser end user registration number,

(b) the trade name of the fertiliser product,

(c) the manufacturer of the fertiliser product,

(d) the quantity (in kilograms or litres) of fertiliser product on his or her premises or under his or her control, and

(e) upon request, the quantity of fertiliser product—

(i) on his or her premises or under his or her control that is third party product, or

(ii) used by him or her over a specified period.

(8) The Minister may prescribe additional details to be submitted to the Minister by a professional fertiliser end user for entry on the database.

(9) A person entered in the Professional Fertiliser End User Register—

(a) fails to comply with subsection (6), or

(b) when submitting under subsection (6) information to the Minister, furnishes information to the Minister knowing it to be false or misleading in any material respect,

commits an offence and is liable on summary conviction to a class A fine.

Matters to be prescribed

(10) The Minister may prescribe the form and manner of a submission referred to in subsection (2) or (6) and require that the information be completed and submitted electronically or otherwise and in a form compatible with the database.

(11) The Minister may prescribe—

(a) the periods of time referred to in subsections (2) and (6) and such time periods may specify that returns are to be made—

(i) at regular intervals of time, and

(ii) in real time or within a specified period, or

(b) conditions for the making of statistical returns to the Minister by—

(i) a fertiliser economic operator on the import, export, manufacture, sale and return of fertiliser products, or

(ii) a professional fertiliser end user on the stocks of fertiliser products on his or her premises or under this or her control.

Processing of information

7E. (1) The Minister may process data submitted by a fertiliser economic operator or a professional fertiliser end user for inclusion in the National Fertiliser Database for the following purposes—

(a) to track the sale of fertiliser product from the point of manufacture or import, through the supply chain, to its sale to the professional end user,

(b) to verify the use of fertiliser products at farm level,

(c) to monitor compliance with this Act, legislation of the European Union in relation to nitrates or the common agriculture policy eco- schemes,

(d) to achieve a reduction in the use of inorganic nitrogen fertiliser,

(e) to inform policy and control programmes of the Department in the areas of nitrates, biodiversity, climate change and fertiliser usage, and

(f) to effectively operate schemes of the Department.

(2) The Minister may prescribe additional purposes for which data submitted by a fertiliser economic operator or a professional fertiliser end user for inclusion in the National Fertiliser Database may be processed having regard to environmental factors and the need to produce agricultural products.

(3) The Minister may provide to a fertiliser economic operator, through a secure web portal of the Department, confirmation that a unique registration identification number submitted by a fertiliser economic operator or professional fertiliser end user, as the case may be, acquiring a fertiliser product is a valid number contained on the relevant Register.

(4) The Minister may share with third parties prescribed by the Minister anonymised reports produced from data provided under section 7D to bring about change in fertiliser use.

(5) In this section 'Department' means Department of Agriculture, Food and the Marine.

Service of notices and notifications

7F. (1) Subject to *subsection (2),* any notification, notice or document required under this Act to be given to any person by the Minister shall be addressed to the person concerned by name and may be given –

(a) by delivering it to the person,

(b) by leaving it at the address at which the person carries on business or ordinarily resides or, in the case in which an address for service has been furnished, at that address,

(c) by sending it by post in a prepaid registered letter to the address at which the person carries on business or ordinarily resides or, in a case in which an address for service has been furnished, to that address, or

(d) by electronic communication, if the person concerned has agreed to service of notices, notifications or documents by such means, provided that there is a facility for confirming receipt of the electronic communication and that such receipt has been confirmed.

(2) For the purposes of this section, a company (within the meaning of the Companies Act 2014) shall be deemed to be ordinarily resident at its registered office, and every other body corporate and every unincorporated body shall be deemed to be ordinarily resident at its principal office or place of business.".

Authorised officers – Act of 1955

63. The following sections are substituted for section 8 of the Act of 1955:

"*Authorised officers – inspection and taking samples*

8. (1) The Minister may for the purpose of enforcing this Act appoint in writing such persons or classes of persons as he or she considers appropriate to be authorised officers for the exercise of all or any of the functions conferred on an authorised officer under this Act.

(2) An authorised officer may at all reasonable times enter and inspect any land or premises, railway wagon, vehicle, ship, vessel or aircraft in which he or she has reasonable grounds for believing that any fertiliser, feeding stuff, compound feeding stuff or mineral mixture is manufactured for sale, kept or carried for sale or sold, or a document or record related to a fertiliser, feeding stuff, compound feeding stuff or mineral mixture is kept or any equipment or machinery relating to such, and may—

(a) examine and take samples and stock of any fertilisers, feeding stuffs, compound feeding stuffs or mineral mixtures, or of any materials capable of being used in the manufacture of fertilisers, feeding stuffs, compound feeding stuffs or mineral mixtures, which he or she finds in the course of his inspection,

(b) examine a document or record related to a fertiliser, feeding stuff, compound feeding stuff or mineral mixture, equipment, machinery or other thing used in connection with a fertiliser, feeding stuff, compound feeding stuff or mineral mixture,

(c) require the name and address of the owner, or person in possession or control of a document or record related to a fertiliser, feeding stuff, compound feeding stuff or mineral mixture, equipment, machinery, a vehicle or a vessel used in connection with a fertiliser, feeding stuff, compound feeding stuff or mineral mixture or require details of place of departure, journey or destination,

(d) inspect a vehicle, a vessel, an aircraft, a railway wagon, a container, equipment, machinery, a computerised information management system or other thing used in connection with a document or record related to a fertiliser, feeding stuff, compound feeding stuff or mineral mixture and require the person in charge or control of such to refrain from moving it,

(e) require the owner, person in possession or control of any premises, equipment, machinery, a computerised information management system, a vehicle, a vessel or other thing used in connection with a document or record related to a fertiliser, feeding stuff, compound feeding stuff or mineral mixture, to produce to the officer such records (and in the case of a record stored in non-legible form, produce to him or her a copy in a legible form) that are in the person's possession or procurement, or under the person's control, as the officer may reasonably require,

(f) inspect and take copies of any record (including a legible reproduction of one stored in non-legible form) or extracts from the record that the officer finds or is produced to him or her during an inspection, or

(g) make a record, including by means of writing, sound recording, photograph, video or other means.

(3) An authorised officer may require a person to give information regarding the ownership and identity of a document or record related to a fertiliser, feeding stuff, compound feeding stuff or mineral mixture, equipment, machinery, a vehicle, a vessel or other thing used in connection with a document or record related to a fertiliser, feeding stuff, compound feeding stuff or mineral mixture as is in the person's knowledge or procurement.

(4) Where an authorised officer has reasonable grounds for believing that—

(a) an offence is being or has been committed under this Act, or

(b) evidence of an offence to which paragraph (a) relates may be, is or has been on any land or premises, or in a vehicle, a vessel, an aircraft, a railway wagon, a container, equipment or machinery,

the officer may, in addition to the powers exercisable by him or her under subsection (1):

(i) search the land or premises;

(ii) search the vehicle, vessel, aircraft, railway wagon, container, equipment or machinery (including any computerised information management system);

(iii) require a person in charge or control of the vehicle, vessel, aircraft, railway wagon, container, equipment or machinery to—

(I) refrain from moving it, or move it to a location where it may be searched,

(II) give information regarding its place of departure, journey or destination, and

(III) where the equipment or machinery is part of a computerised information management system, provide assistance (including providing passwords) to enable access to such devices or systems;

(iv) seize and detain a document or record related to a fertiliser, feeding stuff, compound feeding stuff or mineral mixture and mark or otherwise identify it;

(v) detain a vehicle, vessel, aircraft, railway wagon, equipment, machinery (including any computerised information management system) or container for such reasonable period necessary for the purposes of permitting an inspection or a search under this section either at the place where it was first detained or require it to be moved to such other location as the authorised officer requires;

(vi) remove any equipment, machinery (including any computerised information management system), books, documents or records and detain them for such reasonable period necessary for the purpose of his or her functions under this Act;

(vii) give such direction to a person who has a document or record related to a fertiliser, feeding stuff, compound feeding stuff or mineral mixture, or who has equipment, machinery, vehicle or vessel or other thing used in connection with a document or record related to a fertiliser, feeding stuff, compound feeding stuff or mineral mixture in his or her possession or under his or her control or who has information relating to such, as the authorised officer may reasonably consider necessary for the purposes of this Act.

(5) An authorised officer shall not enter, except with the consent of the occupier, a private dwelling unless he or she has obtained a search warrant under section 8A other than where he or she has reasonable grounds for believing that before a search warrant could be sought in relation to the dwelling under section 8A, any evidence of an offence referred to in subsection (4)(a) is being or is likely to be disposed of or destroyed.

(6) An authorised officer, when exercising a function under this Act, may be accompanied by other persons and may take with him or her, or those persons may take with them, any equipment or materials to assist the officer in the exercise of the function.

(7) An authorised officer may use reasonable force, if necessary, to exercise his or her functions under this Act.

(8) Where, in the course of exercising a function under this Act, an authorised officer finds or comes into possession of anything that the officer has reasonable grounds for believing to be evidence of an offence or suspected offence under this Act, the officer may seize and retain it for use in evidence in proceedings for an offence under this Act.

(9) An authorised officer may only stop a vehicle for the purposes of *subsection (4)* in a public place (within the meaning of the Road Traffic Act 1961) if accompanied by a member of the Garda Síochána and the officer requests the member to stop the vehicle.

(10) A member of the Garda Síochána may stop a vehicle or vessel, for the purposes of this Act and may require it to be moved for inspection to such place as he or she directs.

(11) A person who has—

(a) a document or record related to a fertiliser, feeding stuff, compound feeding stuff or mineral mixture, or

(b) equipment, machinery, a vehicle, a vessel or other thing used in connection with a document or record related to a fertiliser, feeding stuff, compound feeding stuff or mineral mixture

in his or her possession or under his or her control, or information or a record relating to any of them, shall give such—

(i) assistance to an authorised officer, or person who accompanies the officer, and

(ii) information to an authorised officer on request being made, in that behalf by the officer, as the officer may reasonably require for the exercise of his or her functions under this Act.

(12) The owner or person in charge of any premises used in connection with a document or record related to a fertiliser, feeding stuff, compound feeding stuff or mineral mixture shall, if required by an authorised officer, where it is practicable and possible, provide suitable equipment or facilities or a suitable part of the plant or establishment for the officer to carry out his or her functions under this Act.

(13) An authorised officer may require a person to give to the officer such information as is in the person's power or procurement as regards any premises specified by the officer including—

(a) whether or not the premises is used, either partly or wholly, for or in connection with a fertiliser, feeding stuff, compound feeding stuff or mineral mixture,

(b) the name of the owner, occupier or person who is in charge of the premises, and

(c) whether or not the premises is let and, if let, the name and address of the person to whom, and the period of time for which, it is let.

(14) Nothing in section 17 of the Industrial and Provident Societies Act 1893 prevents an authorised officer from exercising a function conferred on him or her by this Act.

(15) A person who —

(a) obstructs or interferes with an authorised officer when exercising a power conferred on him or her under this Act,

(b) fails or refuses, without reasonable cause, to comply with a requirement of an authorised officer under this Act,

(c) fails, without reasonable cause, to give assistance or requested information to an authorised officer in accordance with this Act,

(d) in purporting to give information to an authorised officer for the exercise of the officer's functions under this Act—

(i) makes a statement that he or she knows to be false or misleading in a material particular or recklessly makes a statement which is false or misleading in a material particular, or

(ii) intentionally fails to disclose a material particular, or

(e) aids or abets a contravention of this Act and any instrument made under this Act for the time being in force,

commits an offence and is liable on summary conviction to a class A fine.

(16) A sample may be taken under this section in the prescribed manner or in any other manner.

(17) Where—

(a) a sample is taken under this section in the prescribed manner,

(b) the State Chemist or the Assistant State Chemist causes the sample to be analysed in the prescribed manner by any person acting under the direction of the State Chemist or the Assistant State Chemist, and

(c) the State Chemist or the Assistant State Chemist gives a certificate in the prescribed form of the result of the analysis,

evidence of the result of the analysis may be given in any legal proceedings, but save as aforesaid, evidence of the result of an analysis of a sample taken under this section shall not be given in any legal proceedings.

(18) In any legal proceedings the production of a certificate, purporting to be under this section and to be signed by the State Chemist or the Assistant State Chemist, shall be sufficient evidence of the facts stated in the certificate and of the analysis having been duly carried out, unless either party requires the person who made the analysis to be called as a witness.

(19) A statement or admission made by a person pursuant to a requirement under subsection (11)(ii) is not admissible in evidence in proceedings brought against the person for an offence (other than an offence under this section for failing to give information or giving false information) under this Act.

Search warrant

8A. (1) If a judge of the District Court is satisfied by information on oath of an authorised officer that there are reasonable grounds for believing–

(a) evidence of or relating to the commission or intended commission of an offence under this Act is to be found on a premises,

(b) there is or was a document or record related to a fertiliser, feeding stuff, compound feeding stuff or mineral mixture, equipment or other thing made, used or adapted for use (including manufacture and transport) in connection with a document or record related to a fertiliser, feeding stuff, compound feeding stuff or mineral mixture, or

(c) a document or other record related to a thing to which paragraph (a) or (b) refers is or may be on the premises,

the judge may issue a search warrant.

(2) A search warrant under this section shall be expressed and operate to authorise a named authorised officer, accompanied by such authorised officers or other persons as the named authorised officer thinks necessary, at any time, within one month from the date of issue of the warrant, on production if so requested of the warrant, to enter (if necessary by use of reasonable force) the premises, vehicle, vessel or aircraft named in the warrant.

(3) If a premises is entered under a warrant issued under this section, an authorised officer so entering may exercise all or any of the powers conferred on an authorised officer under this Act.".

Prosecution of offences – Act of 1955

64. The following section is substituted for section 12 of the Act of 1955:

"12. (1) Proceedings or an offence under this Act may be brought and prosecuted summarily by the Minister.

(2) Notwithstanding section 10(4) of the Petty Sessions (Ireland) Act 1851, summary proceedings for an offence under this Act may be instituted within 2 years from the date of the offence.".

Penalties – Act of 1955

65. The Act of 1955 is amended by substituting—

(a) in section 2(4), "a class A fine" for "a fine not exceeding twenty-five pounds",

(b) for subsection (3) of section 4 the following:

"(3) A person who contravenes a regulation under this section commits an offence and is liable on summary conviction to a class A fine.",

(c) for subsection (6) of section 5 the following:

"(6) A person who commits an offence under this section is liable on summary conviction to a class A fine.",

(d) in section 6(3), "a class A fine" for "a fine not exceeding twenty-five pounds",

(e) in section 7(2), "a class A fine" for "a fine not exceeding twenty-five pounds", and

(f) in section 9, "a class A fine" for "a fine not exceeding fifty pounds".

SCHEDULE

Part 1

ROUTES OF RETAIL

Options for designation of route of retail in the terms of a marketing authorisation

1. **'Prescription Only'** —a veterinary medicinal product designated "prescription only" may only be retailed by—

(a) a pharmacist from a pharmacy in accordance with a veterinary prescription for the product,

(b) a veterinarian where the animal to which the product is to be administered is under his or her care and he or she has issued a veterinary prescription for the veterinary medicinal product, or

(c) subject to regulations made under *section 12(2),* a retail responsible person from a premises to which a retailer's licence relates, if the person has a veterinary prescription relating to the veterinary medicinal product in his or her possession or it is accessible on the national database.

2. **'Prescription Only Exempt'** —a veterinary medicinal product designated "prescription only exempt" may only be retailed by—

(a) a pharmacist from a pharmacy,

(b) a veterinarian where the animal to which the product is to be administered is under his or her care, or

(c) subject to regulations made under *section 12(2),* a retail responsible person from a premises to which a retailer's licence relates.

3. **'Licensed Retailer'** —a veterinary medicinal product designated "licensed retailer" may only be retailed—

(a) by a pharmacist from a pharmacy,

(b) by a veterinarian where the animal to which the product is to be administered is under his or her care, or

(c) from a premises to which a retailer's licence relates.

4. **'Companion Animal Medicine'** —a veterinary medicinal product designated "companion animal medicine" may only be retailed —

(a) from a pharmacy,

(b) by a veterinarian,

(c) from a premises to which a retailer's licence relates, or

(d) from the premises of a person entered in the Register.

Part 2

SYMBOLS DENOTING ROUTE OF RETAIL

A veterinary medicinal product designated:

(a) '**prescription only'** may be denoted by the following symbol:

POM

(b) **'prescription only exempt'** may be denoted by the following symbol:

POM(E)

(c) **'licensed retailer'** may be denoted by the following symbol:

LM

(d) **'companion animal medicine'** may be denoted by the following symbol:

CAM