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Bill Digest

Veterinary Medicinal Products, Medicated Feeds and Fertilisers Regulation Bill 2023

Bill No. 7 of 2023

Dr Mike Brennan, Senior Researcher (Agriculture and Environmental Science)

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Abstract

The Bill provides for amending the regulatory regime concerning the sale, importation, possession, storage, dispensing and prescription of veterinary medicinal products. It provides for the creation of a national online database to record veterinary prescriptions and dispensing of veterinary medicinal products & feed by registered dispensing outlets. It enables the capture and processing of data on the import, manufacture, sale, supply and use of fertiliser, and the storage of this data in a National Fertiliser Database which will encompass the registration of fertiliser economic operators and end users.

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Summary

The General Scheme of the Veterinary Medicinal Products, Medicated Feeds and Fertilisers Regulation Bill 2022 (the "Bill") was published on 14 July 2022.[1] The Bill was published on 14 December 2022 by the Minister for Agriculture, Food and the Marine.[2] The Bill underwent pre-legislative scrutiny by the Joint Committee on Agriculture, Food and the Marine, with the Committee publishing their Report on the pre-legislative scrutiny of the General Scheme on 17 November 2022.

A Regulatory Impact Analysis (RIA) was published in 2021.

This Bill Digest provides a background to the Bill, its RIA, and comments on the implementation of the recommendations made by the Joint Committee's Pre-legislative scrutiny report. The principal provisions of the Bill are explained, and some of the implications and implementation issues for the Bill are highlighted

What the Bill does:

The Bill is comprised of three parts, which include 64 sections, and two schedules:

- Part 1 (1-3): Preliminary
- Part 2 (4-56): Veterinary medicinal products and medicated feed – prescriptions and dispensing – national database
- Part 3 (57-64): Amendment of Fertilisers Feeding Stuffs and Mineral Mixtures Act 1955

The primary aims of the Bill are:

1. Provide the Minister with powers to make Regulations on areas of the EU Regulations that may be determined by national law.
2. Provide for the introduction of a database on which veterinary prescriptions and dispensing of veterinary prescriptions shall be recorded on Commencement Order.
3. Repeal the *Animal Remedies Act 1993* and modernise veterinary medicine legislation.
4. To amend the *Fertilisers, Feeding Stuffs and Mineral Mixtures Act 1955* by inserting new registration requirements and related provisions into that Act to enable the Minister capture and process information on the manufacture, import, sale, supply and use of fertiliser in the State.
5. To provide for the introduction of a National Fertiliser Database.

Why is primary legislation required?

The Bill seeks to address a number of Ireland's obligations under EU legislation, specifically the EU Regulation on Veterinary Medicinal Products EU 2019/6 (the VMP Regulation) and the Council Directive 91/676/EEC concerning the protection of waters against pollution caused by nitrates from

[1] Department of Agriculture, Food and the Marine, General Scheme of the Veterinary Medicinal Products, Medicated Feeds and Fertilisers Regulation Bill 2022

[2] Department of Agriculture, Food and the Marine, Veterinary Medicinal Products, Medicated Feed and Fertilisers Regulation Bill 2022

agricultural sources (the Nitrates Directive). The **VMP Regulation** was agreed in 2018, came into effect in January 2019 and applies to all Member States since 28 January 2022. The VMP Regulation **seeks to enable the development of fit-for-purpose veterinary legislation** which would no longer be based on the equivalent human medicines authorisation system. On 27 January 2022, the Minister for Agriculture, Food and the Marine signed S.I. No. 36/2022 – 'European Union (Veterinary Medicinal Products and Medicated Feed) Regulations 2022 which gives effect to the VMP Regulation.

The Nitrates Directive has been in place since 1991, and **aims to protect water quality from agricultural pollution and promote good farming practice**. All EU Member States are required to prepare National Nitrates Action Programmes (NAP) that outline rules for the management and application of livestock manures and other fertilisers. Ireland is currently on its 5th NAP, which came into effect on 11th March 2022[3] and will run to 2025.

[3] S.I. European Union (Good Agricultural Practice for Protection of Waters) Regulations 2022 gives effect to the 5th NAP.

Introduction

The Veterinary Medicinal Products, Medicated Feeds and Fertilisers Regulation Bill 2022 (the "Bill") was published on 14 December 2022. The Bill addresses two distinct areas of agricultural importance; veterinary medicines and fertilisers. In relation to veterinary medicines, the Bill seeks to:

- **Amend the regulatory regime** concerning the sale, importation, possession, storage, dispensing and prescription of veterinary medicinal products.
- Provide for the **creation of a national online database to record veterinary prescriptions** made by veterinarians and the dispensing of the veterinary medicinal product/medicated feed by a registered dispensing outlet.

In relation to fertilisers, the Bill seeks to:

- Enable the Minister to **capture and process information on the import, manufacture, sale, supply and use of fertiliser** in the State, and this **information to be stored in a National Fertiliser Database** which will encompass the registration of fertiliser economic operators and end users.

This Bill Briefing proceeds with the following sections:

- Table of Provisions
- Background, Policy and Legislative Context to the Bill
- Summary of the Principal Provisions of the Bill
- Summary of the Pre-legislative scrutiny of the Bill with the L&RS traffic light analysis of the PLS recommendations versus the published bill.

Table of provisions

A summary of the Bill's provisions is included in Table 1 below. This does not provide a complete treatment of the Bill but is intended to provide Members with an overview of what each section encompasses.

Table 1 Table of provisions of the Veterinary Medicinal Products, Medicated Feeds and Fertilisers Regulation Bill 2023

Part	Sections	Title	Effect
1	1-3	Preliminary	Standard sections that provide a short title, collective citation, repeals and dissolutions[4] and expenses of the Minister.

[4] The Bill repeals:

- The Animal Remedies Act 1993
- The provisions of the following Acts are repealed:
  - section 41 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006;
  - section 76 of the Animal Health and Welfare Act 2013; and
  - section 17 of the Horse Racing Ireland Act 2016.
- The Animal Remedies Consultative Committee is dissolved.

Part	Sections	Title	Effect
2	4-56	Regulation of veterinary medicinal products and medicated feed	This Part is broken into 8 Chapters and sets out in detail the new regulatory regime for the importation, sale, possession, storage, prescription and administration of veterinary medicinal products. It also deals with enforcement of the provisions of the Bill. Part 2 deals with: • Chapter 1, Section 4: **Interpretation of the Bill** • Chapter 2, Sections 5 – 8: Details **who can and cannot issue prescriptions and dispense medicated products**, providing for the setup of a **national database recording veterinary prescriptions**, and outlines the **requirements for prescriptions** under Article 105 of Veterinary Medicinal Products Regulation (VMP Regulation) and Article 16 of Medicated Feed Regulation. • Chapter 3, Sections 9 – 26: Outlines the **rules, restrictions, limitations, labelling, type of premises, record keeping, licencing and training requirements for the retail of veterinary medicinal products**. This Chapter also provides for the establishment of **Companion animal**[5] **medicine retailers' register**, i.e. a register of retailers of veterinary medicinal products designated "companion animal medicine". Lastly, this Chapter deals with regulations on **rules on retail**, **retail at distance (postal/delivery transactions)** and **internet retail**, including **who can conduct retail transactions by these methods**. • Chapter 4, Sections 27 – 28: Provides for the making of regulations by the Minister **to prohibit or restrict the possession or control of specified veterinary medicinal products or medicated feed ingredients,** as well as regulations **to govern the administration or use of veterinary medicinal products or medicated feed**

[5] A "companion animal" is a pet or domestic animal.

Part	Sections	Title	Effect
			generally or by a specified class of persons. • Chapter 5, Sections 29 – 31: Provides for the making of regulations by the Minister **concerning the secure storage of veterinary medicinal products**, regulation for **advertising or promoting of veterinary medicinal products or medicated feeds**, and for the issuing of **licences governing the manufacture, import or export** of autogenous vaccines[6], **collection and storage of blood & blood products for medicinal use**, and for the **importation of medicated feed or intermediate products**. • Chapter 6, Section 32: Provides for Matters under **national law mentioned in VMP Regulation or Medicated Feed Regulation**. • Chapter 7, Sections 33 – 34: Concerns administrative matters around making of regulations and granting of licences**.** • Chapter 8, Sections 35 – 56: Deals with the **enforcement of regulations made under this Bill**, including the **appointment of Authorised Officers[7] [8]**, the **powers of Authorised Officers**, the **circumstances for issuing a search warrant**, **defining what constitutes obstruction**, procedures for parties to **appeal compliance notices**, and outlines the **liability of bodies corporate who commit offences under the proposed legislation**.

[6] Autogenous vaccines, also called autologous vaccines, autovaccines, "self" or custom vaccines, are vaccines that are manufactured by isolating and destroying microorganisms from infected individuals and used to stimulate immunity to the same individual.

[7] An Authorised Officer means a person appointed or deemed to be appointed as an authorised officer under section 36.

[8] A person appointed as an Authorised Officer under 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.

Part	Sections	Title	Effect
3	57-64	Amendment of Fertilisers Feeding Stuffs and Mineral Mixtures Act 1955	The final Part provides for several **amendments** to the *Fertilisers Feeding Stuffs and Mineral Mixtures Act 1955*. These amendments include: • Modernising the definition of 'fertiliser' • Defining '**professional fertiliser end user'**[9] • Providing for the creation and maintenance of a **Fertiliser Economic Operators' Register**[10] • Introducing the **requirement** for the person who "*manufactures, imports, places on the market or makes available on the market (whether wholesale or retail) a fertiliser product*" to **be on the Fertiliser Economic Operators' Register, or they will be committing an offence** • Providing for the creation and maintenance of a **Professional Fertiliser End Users' Register** • Introducing the **requirement** for Professional Fertiliser End Users (**including farmers**) to be on the **Professional Fertiliser End Users' Register, or they will be committing an offence** if they purchase and use fertiliser products in the course of their professional activities

Source: Derived from the text of the Veterinary Medicinal Products, Medicated Feed and Fertilisers Regulation Bill 2023

Background, Policy and legislative context

The agri-food sector makes a significant contribution to the Irish economy, including exports, employment as well as its estimated contribution to Gross Value Added and Modified Gross National Income.

Livestock farming is by far the largest component of Irish farming (~85%), with Ireland primarily employing a model of grass fed livestock rearing. Given the Irish farming sector's reliance on

[9] A **professional fertiliser end user** is defined as any person who uses fertiliser products in the course of his or her professional activities, **which includes farmers.**

[10] The **Fertiliser Economic Operators**' Register is a register of persons who manufacture, import, place on the market or make available on the market (whether wholesale or retail) a fertiliser product.

livestock rearing, and its dependence on dependable and rapid grass growth, the Bill's focus on veterinary medicine and use of fertiliser are of significant importance to the sector.

Current government policy

Veterinary Medicines

The primary legislation covering the use of Veterinary Medicines in Ireland is currently the Animal Remedies Act 1993. This 1993 Act defines animal remedies as "*any substance or combination of substances administered to animals for the purpose of treating, preventing or modifying disease, making a medical or surgical diagnosis in animals or correcting or modifying physiological functions in animals*". More detailed provisions for animal remedies are contained in the secondary legislation made under this Act.[11] The 1993 Act sets out a full range of enforcement powers to Authorised Officers of the Department of Agriculture, Food and Marine (DAFM), to the Garda and customs services, including powers to enter and search premises/lands, examine and take samples, detain/seize animals, records, substances etc. Where evidence of the use of hormones or other prohibited substances is found in an animal or its carcass, the carcass will be condemned, and live animals found to be illegally treated will be permanently excluded from the food chain. Included in the possible penalties in the 1993 Act is the provision for the possibility of a person who is convicted on indictment, being disqualified from keeping animals or animal remedies.

Fertilisers

The primary legislation covering the manufacture, sale, import, storage of fertilisers, and the enforcement of this legislation and subsequent regulations is the Fertilisers Feeding Stuffs and Mineral Mixtures Act 1955, while regulations around the application of fertilisers are provided through secondary legislation[12].

EU Legislative context

EU Regulation on Veterinary Medicinal Products EU 2019/6

The EU Regulation on Veterinary Medicinal Products EU 2019/6 (the VMP Regulation) were agreed in 2018, came into effect in January 2019 and **applied to all Member States on 28 January 2022**. On 27 January, the Minister for Agriculture, Food and the Marine signed S.I. No. 36/2022 – 'European Union (Veterinary Medicinal Products and Medicated Feed) Regulations 2022 which gives effect to the VMP Regulation.

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[11] Related SIs include:

- Animal Remedies Act 1993 (Commencement) Order, 1993 (S.I. No. 283 of 1993)
- Animal Remedies Act, 1993 (Section 32(1)(b)) (Commencement) Order, 2001 (S.I. No. 468 of 2001)
- Animal Remedies Act, 1993 (Section 32(1)(b)(i)) (Commencement) Order, 2001 (S.I. No. 513 of 2001)
- European Communities (Animal Remedies)(No.2) Regulations 2007 (S.I. No.786 of 2007)
- Animal Remedies (Poisons Act 1961) Regulations 2007 (S.I. No. 861 of 2007)

[12] S.I. European Union (Good Agricultural Practice for Protection of Waters) Regulations 2022

The VMP Regulation seeks to enable the development of fit-for-purpose veterinary legislation which would no longer be based on the equivalent human medicines authorisation system.

The overarching objectives of the VMP Regulation are to:

- harmonise the internal EU market for veterinary medicinal products,
- reduce the administrative burden on companies and regulatory authorities,
- enhance safety and availability of veterinary medicinal products,
- stimulate innovation of new and existing medicines; and
- **strengthen the EU response to fight antimicrobial resistance**.

Among other things, the VMP Regulation bans the prophylactic[13] use of antimicrobials (AMs) in groups of animals, restricts metaphylactic[14] use in groups of animals, and requires certain AMs to be reserved for humans only. At a broader level, member states are required to collect data on the sale and use of AMs in animals. **These changes are motivated by the urgent need to address Antimicrobial resistance** (AMR). Thus, the VMP Regulation is in line with the **EU Farm to Fork Strategy**, which aims to reduce overall sales of AMs for farmed animals and in aquaculture by 50% by 2030.

What is AMR?

Antimicrobials[15] are substances used to kill microorganisms or to stop them from growing and multiplying. **Antimicrobial resistance (AMR)** is defined as the ability of a microorganism to stop an antimicrobial from working against it. AMR is driven largely by **excessive and inappropriate use of AMs** in human and animal populations. As a consequence, antibiotics and other **AMs can become ineffective** and infections become increasingly difficult or impossible to treat. This significantly increases the risk of disease spread, severe illness and death. Importantly, the **AMR can be transferred between many disease causing microorganisms that infect humans, animals and live in the environment**, and so the consequences of AMR go beyond the inability of an antimicrobial to work in a given individual.

Globally, **AMR is a leading cause of death**[16] with the highest rates in low income and low resource settings. AMR means that previously standard treatments are becoming ineffective, resulting in increased morbidity and mortality, affecting both individuals and wider society. Rising rates of AMR will make infection control and treatment increasingly difficult and expensive. AMR also causes significant disruption to routine hospital services, as operating theatres and other settings need to be decontaminated after treating patients with resistant infections.[17] AMR imposes significant financial burdens on society, as patients infected with drug-resistant microorganisms are more likely to have longer stays in hospital, to have poorer outcomes and to be unable to work.

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[13] The VMP Regulation defines prophylactic use as '*the administration of a medicinal product to an animal or group of animals before clinical signs of a disease, in order to prevent the occurrence of disease or infection*'.

[14] The VMP Regulation defines metaphylactic use as *'the administration of a medicinal product to a group of animals after a diagnosis of clinical disease in part of the group has been established, with the aim of treating the clinically sick animals and controlling the spread of the disease to animals in close contact and at risk and which may already be subclinically infected'.*

[15] For example antibiotics, antivirals and antifungals.

[16] Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis - The Lancet

[17] This is a similar situation to COVID decontamination procedures.

What is the policy response to AMR in Ireland?

Ireland recognises the importance of AMR as a society-wide risk, and responded with the National Action Plan on Antimicrobial Resistance 1 (2017 – 2020) and National Action Plan on Antimicrobial Resistance 2 (2021 – 2025). Both these Action Plans recognise the potential for the transfer of AMR between animal to human systems and list actions to address this issue.

Challenges of reducing AM use

As noted above, the VMP Regulation was transposed into Irish law on 27 January 2022, and the requirements of the VMP Regulation necessitate changes to the use of such products for the Irish farming sector. Importantly, the bans on the prophylactic[18] use of AMs in groups of animals, as well as restrictions on use of metaphylactic[19] AMs use in groups of animals present challenges and opportunities for private veterinary practitioners, particularly those operating in the dairy sector. Prophylactic use of AMs is relatively widespread in the Irish dairy sector, and separately the use of critically important AMs (i.e. those of importance for human medicine) as part of mastitis[20] control treatments has been slowly rising. [21]

The Irish dairy sector saw **sustained improvements in national milk quality up to 2017**, before plateauing. Current estimates suggest approximately two-thirds of Irish herds have optimal mastitis control, **however the remaining one-third presents a problem with regard to correct use of AMs**. In these herds, there are more infected cows, often lower levels of farm hygiene and/or poorer farm management and higher infection rates at all production stages. In these herds, **currently there is a reliance on the use of AMs to resolve infection**, both to treat cows infected at the end of lactation (therapeutic usage) and to prevent new infection during the period between lactations (**prophylactic usage**).[22]

Nitrates Directive and Ireland's 5th Nitrates Action Programme

The Nitrates Directive

In place since 1991, Council Directive 91/676/EEC concerning the protection of waters against pollution caused by nitrates from agricultural sources (the Nitrates Directive) aims to protect water

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[18] The VMP Regulation defines prophylactic use as '*the administration of a medicinal product to an animal or group of animals before clinical signs of a disease, in order to prevent the occurrence of disease or infection*'.

[19] The VMP Regulation defines metaphylactic use as *'the administration of a medicinal product to a group of animals after a diagnosis of clinical disease in part of the group has been established, with the aim of treating the clinically sick animals and controlling the spread of the disease to animals in close contact and at risk and which may already be subclinically infected'.*

[20] Bovine mastitis is **an inflammatory response of the udder tissue in the mammary gland caused due to physical trauma or microorganism infections**. It is considered the most common disease leading to economic loss in dairy industries due to reduced yield and poor quality of milk.

[21] Trends in estimated intramammary antimicrobial usage in the Irish dairy industry from 2003 to 2019 (animalhealthireland.ie)

[22] More, S.J., McAloon, C., Boloña, P.S., O'Grady, L., O'Sullivan, F., McGrath, M., Buckley, W., Downing, K., Kelly, P., Ryan, E.G. and McCoy, F., 2022. Mastitis control and intramammary antimicrobial stewardship in Ireland: challenges and opportunities. Frontiers in veterinary science, p.310.

quality from agricultural pollution and promote good farming practice. All EU Member States are required to prepare National Nitrates Action Programmes (NAP) that outline rules for the management and application of livestock manures and other fertilisers.

Ireland's Nitrates Action Programme (NAP) & the National Fertiliser Database

Ireland's NAP is designed to prevent surface and ground water pollution from agricultural sources and to protect and improve water quality. Local Authorities are responsible for enforcing the Nitrates Regulations, and conduct farm inspections on a sample of farms to ensure compliance with the NAP measures. Ireland is currently on its 5th NAP which came into effect on 11th March 2022[23] and will run to 2025. Compared to the 4th NAP, the 5th NAP contains significantly greater environmental ambition and strengthens a number of existing measures and adds new measures to enhance environmental protection. One of these measures is the development of the **National Fertiliser Database**, which will **provide a more realistic picture of where and how much fertiliser is applied to land**. A number of other measures are **directly dependent on the Database**. These dependent measures include:

- **National Agricultural Inspection Programme**: The EPA will develop and implement this new Programme for Local Authorities. These inspections will be more targeted and risk-based with a stronger focus on compliance and follow-up enforcement. Information from the Database will inform this risk-based approach. Information from the database will increase the evidence base for this risk-based strategy.
- **Chemical Fertiliser Control**: Starting with a 10% reduction of chemical nitrogen applied nationally which may be increased to a 15% reduction nationally after the midterm interim review of the programme. Information from the Database will assist in the monitoring of this reduction.
- **Improved assessment of compliance with Good Agricultural Practices (GAPs)**: Information from the database will allow DAFM to improve assessment of compliance with the requirements under the GAP regulations[24], as well as analysis of farming activities generally.

Why swift and improved action to mitigate Nitrate pollution is needed

Agriculture is the single biggest source of water pollution in Ireland [25], with Nitrate emissions from livestock farming of particular concern. Ireland's previous Nitrate Action Programmes have failed to deliver the required water quality outcomes, with the EPA noting that "*agriculture remains the most significant pressure with excess nutrients impacting on water quality and trends going in the wrong direction"*, that "*evidence shows that water quality problems are not just a concern for the more intensive farms but are relevant to all farmers*" and "*Agricultural and other land management practices are causing significant problems for water quality, air quality, nature and*

[23] S.I. European Union (Good Agricultural Practice for Protection of Waters) Regulations 2022 gives effect to the 5th NAP.

[24] S.I. European Union (Good Agricultural Practice for Protection of Waters) Regulations 2022

[25] Environmental Protection Agency – Ireland's Environment – An Integrated Assessment 2020 (epa.ie)

climate change and risking the reputation of Ireland as a food producing nation with strong environmental credentials". [26]

Regulatory Impact Analysis (RIA)

An RIA on the impact of this Bill[27] was conducted in 2021. The RIA examined **two** scenarios in relation to the Bill:

1. Do nothing
2. Introduce legislation to allow the Minister to:
    a. make regulations concerning matters left to national discretion by the governing EU regulations,
    b. provide for a national database maintained by the Minister establishing a system to record prescriptions of veterinary medicinal products,
    c. provide for rules on the retailing of Veterinary Medicinal Products and Medicated Feeds,
    d. capture and process information on the import, manufacture, sale, and supply and use of fertiliser in the State,
    e. establish a National Fertiliser Database which will encompass the registration of fertiliser economic operators and end users.

Scenario 1 was never a viable option, as significant risks were associated with it such as:

i) inappropriate use of veterinary medicinal products resulting in negative animal health impacts due to increased antimicrobial and antiparasitic resistance,
ii) increased risk of antimicrobial resistance spreading to human diseases from animal sources,
iii) increased administrative burden on farmers, as they will have to complete manual records to verify compliance. These records will then have to physically checked by DAFM, resulting in more delays,
iv) inability of the State to track fertiliser sales and usage which, preventing the effective operation of certain agricultural schemes and delay payments,
v) inability of Ireland to deliver on its commitments to the European Commission arising from the recent review of Ireland's Nitrates Action Programme and the extension of the Nitrates Derogation.

Scenario 2 was the preferred option, as this option allows Ireland to address the risks presenting in Scenario 1, and to attempt to meet our European and national commitments under the VMP Regulation, Nitrates Directive, the EU's Farm to Fork Strategy, the Climate Action Plan 2023 and Food Vision 2030.

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[26] EPA submission on the 4th review of Ireland's Nitrates Action Programme - 2nd consultation - Catchments.ie - Catchments.ie

[27] Regulatory Impact Assessment for VMP Bill.pdf (cloud.gov.ie)

Public consultations

In advance of the VMP Regulation coming into effect in January 2022, DAFM engaged in a public consultation which ran from 16 June 2019 to 22 July 2020.[28] Additionally, the Health Products Regulatory Authority (who are the competent authority for the VMP Regulation) produced regular updates on the application of the Regulation in relation to products on sale in Ireland and guidance on changes to procedures, regulations and ICT requirements for veterinary stakeholders. [29][30]

Pre-legislative scrutiny of the General Scheme of the Bill

The Joint Committee on Agriculture, Food and the Marine agreed to undertake pre-legislative scrutiny of the General Scheme following a request from the Minister. It held hearings with selected stakeholders, commencing with a meeting with stakeholders on 5 October[31] and with a meeting with the Minister of State for Agriculture, Food and Marine on 11 October 2022[32]. The debate concerning the Bill continued on 19 October 2022[33]. The Committee published their Report on the pre-legislative scrutiny of the General Scheme on 17 November 2022, which consisted of nineteen comments/recommendations.

Table 2 Key to traffic light dashboard comparing the Bill as published with Committee PLS recommendations.

L&RS categorisation of the Department's response in the Bill to the Committee's key issue	Traffic light dashboard used in Table 3 to highlight impact of the Committee's PLS conclusion
Key issue has clearly been accepted and is reflected in the Bill.	
The Bill may be described as adopting an approach consistent with the key issue or the impact of the key issue is unclear.	
Key issue has not been accepted or implemented in the Bill.	

[28] DAFM, 2019 Public Consultation on EU Regulation 2019/6 on Veterinary Medicinal Products (www.gov.ie)

[29] HPRA Update on implementation of the new veterinary regulation - July 2022

[30] HPRA Update on implementation of the new veterinary regulation – January 2023

[31] Joint Committee on Agriculture, Food and the Marine debate - Wednesday, 5 Oct 2022 (oireachtas.ie)

[32] Joint Committee on Agriculture, Food and the Marine debate - Tuesday, 11 Oct 2022 (oireachtas.ie)

[33] Joint Committee on Agriculture, Food and the Marine debate - Wednesday, 19 Oct 2022 (oireachtas.ie)

Table 3 Traffic light dashboard comparing the Bill as published with Committee PLS recommendations.

Commentary as per Committee report (emphasis inserted by researcher)	Whether addressed (either in whole or in part) in the Bill	Department Response (emphasis inserted by researcher)
1. The Committee was informed by several stakeholders that since January 2022 there has been a significant decrease of up to 90% in sales of intramammary antimicrobials and veterinary vaccines in co-ops, licensed merchants and pharmacies which dispense veterinary products. It should be noted that Veterinary Ireland subsequently provided data to the Committee which showed that there has been a significant decrease in sales of intramammary antimicrobials, however, the figure of this decrease is substantially lower than 90%. The prescription length for antibiotics has been shortened to 5 days and the Committee heard that this has had a negative impact on a farmer's choice on where to purchase their veterinary medicines. Many farmers will feel obliged to purchase their veterinary medicines from their veterinary practitioners. The Committee is concerned that this has created a monopoly in the sector which will reduce availability of the medicines and have a costly impact on farmers as their choice is limited. Notwithstanding this it would be a detriment to the rural economy and communities if these businesses are no longer in a position to operate. HPRA recommended **an impact assessment be undertaken in advance of implementation of this legislation**, DAFM have committed to this, but it has not been undertaken. The **Committee recommends that this impact assessment is undertaken**.	–	The HPRA Report of the Task Force on the method of supply of antiparasitic veterinary medicinal products that are intended for food-producing species which ultimately recommended the upregulation of antiparasitics for food producing animals to prescription only medicines stated that: "An impact assessment of policy options on resistance control as well as on stakeholders and current product providers would be needed. The options should place the control of resistance as its central aim and consider: What changes in the national legislation are required to ensure that antiparasitic veterinary medicinal products that are designated veterinary prescription control are accessible in a manner which: • Limits the development of resistance, • Fosters sustainability of the drugs used, • Promotes the use of evidence-based scientific tests to underpin the use of the drugs, • Provides for the necessary control and access, and, • Complies with Regulation 2019/6. • Whether there would be any limitations or conditions for veterinary practitioners or other prescribers that would

Commentary as per Committee report (emphasis inserted by researcher)	Whether addressed (either in whole or in part) in the Bill	Department Response (emphasis inserted by researcher)
		restrict their rights or ability to prescribe the products in question. This might include specification of the detailed conditions for issuing a prescription, as well as the operation of any specified animal health and welfare programmes for the farm/animal etc., • What limitations or conditions, if any, should attach to those authorised to dispense veterinary prescriptions for antiparasitic veterinary medicinal products, • Whether a particular provision is necessary for antiparasitic veterinary medicines for bees, poultry, fish and minor species, • Whether any changes to the legislation governing the purchase and possession of the relevant animal remedies and associated record-keeping would be needed, • Whether, or to what extent, existing actors in the provision of antiparasitic diagnostic services to food-producing animals would be actively engaged in discussions on the preceding policy options." On consideration of the above Report and in order for DAFM to evaluate the impacts in a collaborative manner DAFM set up an Antiparasitic Resistance stakeholder Group, chaired by the Chief Veterinary Officer. The

Commentary as per Committee report (emphasis inserted by researcher)	Whether addressed (either in whole or in part) in the Bill	Department Response (emphasis inserted by researcher)
		terms of reference for this group are: 1. To protect the efficacy of antiparastics for the benefit of animal health and welfare, the sustainability of food production and the agri-food sector. 2. To identify, propose and manage the implementation of solutions to allow Ireland comply with Regulation 2019/6, specifically taking account of the recommendations of the HPRA Task Force on the method of supply of antiparasitic veterinary medicinal products that are indicated for food-producing animals, whilst recognising the current expertise of existing actors and benefits of current supply chain infrastructure for stakeholders. 3. To provide a mechanism to guide and co-ordinate actions to address antiparasitic resistance in the animal health sector, and possible impact on human health and the environment. 4. To provide a forum for the sharing of information so that all stakeholders are kept up to date on actions

Commentary as per Committee report (emphasis inserted by researcher)	Whether addressed (either in whole or in part) in the Bill	Department Response (emphasis inserted by researcher)
		being carried out across the sector. 5. To provide a mechanism to identify any new or emerging issues, synergies, research gaps and opportunities, and to develop innovative solutions to address issues that arise. **All of the elements identified in the HPRA recommendations were addressed as part of this process and informed the development of the policy proposals.**
2. Implementation of this Regulation in its proposed format will have a myriad of effects. However, the impact on antiparasitic veterinary medicines will be quite the opposite of that intended as stated in Objective 5 of EU Regulation 2019/6 whereby: '*This Regulation aims to reduce the administrative burden, enhance the internal market, and increase the availability of veterinary medicinal Pre-legislative Scrutiny of the Veterinary Medicinal Products, Medicated Feeds and Fertilisers Regulation Bill 2022 Page 15 of 30 products, whilst guaranteeing the highest level of public and animal health and environmental protection*.	–	Objective 5 of EU Regulation 2019/6 related to the wider veterinary medicinal products market and in this, both at an EU level and also at a national level in Ireland, through the enactment of this Bill, there has been significant progress in meeting this objective. Ensuring the effective regulation of veterinary medicinal products through approving and licensing the use of veterinary medicinal products, supporting intra Member State availability of products whilst guaranteeing the highest level of public and animal health and environmental protection is at the core of both EU and national efforts in implementing this regulation. The significant and positive efforts made in addressing antimicrobial resistance at both EU level and here in Ireland is an example of this.

Commentary as per Committee report (emphasis inserted by researcher)	Whether addressed (either in whole or in part) in the Bill	Department Response (emphasis inserted by researcher)
		The upregulation of antiparasitic veterinary medicinal products to prescription only was as a result of a HPRA task force report recommendation. The HPRA are the competent authority in Ireland to make such a recommendation. **It was found that this category of medicine no longer met the criteria which permitted it be derogated from the prescription requirement**. In implementing this recommendation Ireland is giving full effect to the legal requirements of Article 34 of EU 2019/6. Antiparasitics will now align with all other veterinary medicinal products that are subject to a prescription. **There is no additional administrative burden pertaining to this class of medicine than to any other prescription only medicine.** The Department has and continues to work in conjunction with all stakeholders to ensure Objective 5 of Regulation 2019/6 is met.
3. The Committee heard concerns from stakeholders of the ability to access veterinary medicines if the role of the Responsible Person and Pharmacist is terminated or restricted. The witnesses felt that the level of coverage and support provided by veterinary practitioners was restricted or limited in certain rural areas. The purchase of Irish veterinary practices by multinational corporations who will not provide the same level of service to farmers is a concern. The level of coverage and support is also impacted by		Advice was sought from the office of the Attorney General on the matter and **only a veterinary practitioner is legally entitled to prescribe veterinary medicinal products in Ireland**.

Commentary as per Committee report (emphasis inserted by researcher)	Whether addressed (either in whole or in part) in the Bill	Department Response (emphasis inserted by researcher)
the need for veterinary practitioners to build a relationship with clients which can involve being on site and interacting with the client and their animals. Witnesses felt that the Responsible Person and Pharmacist, because of their presence in the locality, addressed these concerns that in some instances cannot be wholly met by veterinary practitioners who may be otherwise committed to farm calls, TB testing, factory work, etc, thereby putting the practice receptionist in a prescribing and dispensing role. The Responsible Person or Pharmacist must be present in their retail outlet when supplying medicines. The Committee is cognisant of this situation and **recommends that all efforts should be examined and reviewed with the objective of allowing the continued operation of the Responsible Person and Pharmacist role. Their expertise and experience should not be dismissed. <u>The Committee recommends that a Responsible Person is allowed to be able to prescribe as well as dispense antiparasitic drugs</u>.**		
<u>4.</u> The Committee was informed that the retrospective recognition of the prescribing practice of the Responsible Person and Pharmacist as indicated by the legal opinion recently supplied to DAFM would facilitate the derogation provided for in Article 105.4 of EU Regulation 2019/6. *De facto* or counter prescribing by the Responsible Person and Pharmacist must be enshrined in law to avail of the derogation.		Advice was sought from the office of the Attorney General on the matter and **only a veterinary practitioner is legally entitled to prescribe veterinary medicinal products in Ireland**.
<u>5.</u> At a Committee meeting several stakeholders alluded to the risk that by restricting the prescribing of antiparasitic		**DAFM can confirm that a list of antiparasitic veterinary medicinal products is being**

Commentary as per Committee report (emphasis inserted by researcher)	Whether addressed (either in whole or in part) in the Bill	Department Response (emphasis inserted by researcher)
products to veterinary practitioners only could result in various brands of products available for selection being restricted. The Committee heard that this restriction in turn could lead to reduced choice and increased costs to farmers. This would also impact the Veterinary Pharmaceutical manufacturing industry in Ireland which employs a significant number of people and contributes significantly to the Irish economy. It should be noted that other witnesses who gave evidence before the Committee felt that the risk did not exist. The Department stated that they are in the process of producing a list where those who are given the prescription can dispense a comparable bioequivalent product from this list.		**produced** that will ensure that the issues as raised by some stakeholders will not occur. This list of products that can be dispensed in lieu or a prescribed antiparasitic, under conditions, will ensure the farmer has the most choice and can ensure that the most cost-effective product is dispensed. Section 6(1)(d) of the Bill specifically refers.
6. The Committee **believes that separation of prescribing and dispensing of veterinary medicines will eliminate the commercial conflict of interest which may undermine the prescribing of veterinary medicines**. This is practiced in the Scandinavian countries achieving significantly lower levels of resistance to medicines. **The Committee recommends that this should be examined extensively**.		This matter has been considered previously by the Department. **Any attempt to separate the prescribing and dispensing of veterinary medicinal products is a complex matter and the Department has previously advised the Committee that this would be seen as providing state aid to one sector**. Furthermore, such a move may also impact on competition in the supply of veterinary medicines.
7. The Committee **recommends that Head 7(4)(iii) should read '*the Veterinary Council for purposes associated with its regulatory functions*' in line with the wording of 7(4)(i)** as the Committee was informed that the VCI has additional statutory functions for which this information will be required such as its power to investigate (via Authorised Officers) and prosecute		**Bill has been amended**, and text now reads: "*the Veterinary Council of Ireland for purpose of performing their functions under the Act of 2005*"

Commentary as per Committee report (emphasis inserted by researcher)	Whether addressed (either in whole or in part) in the Bill	Department Response (emphasis inserted by researcher)
for various offences under Part 10 of the Veterinary Practice Act 2005. IFA highlighted that many of the proposed penalties for offences are significant and may be excessive particularly when inadvertent errors have been prosecuted in the recent past. **The Committee recommends that these should be reviewed**.		
8. At a meeting stakeholders expressed their **concerns with regards to the sharing of data provided on the National Veterinary Prescription System** (NVPS) and if third parties will have access to this information. It was highlighted to the Committee that in the Bill Bord Bia are listed as one of the bodies where information from the database can be shared with, however, not every farmer is a member of Bord Bia's Quality Assurance scheme. **The Committee recommends that clarity is brought on these concerns by ensuring in the Bill that the use and storage of data provided by users of the NVPS is in line with the General Data Protection Regulation (GDPR) and that safeguards are in place to ensure that data isn't shared with third parties unless it is necessary and appropriate.**		**The provisions in the Bill in relation to data are compliant with the GDPR**.
9. During its series of meetings, the Committee heard from stakeholders that there are **concerns that in its current format the NVPS requires an excessive number of data inputs for a veterinary medicine prescription, and it is not user friendly**. These concerns were raised at the Committee's meeting with the Minister of State and his Departmental Officials. **The Committee**		DAFM is continuing to engage with users of the NVPS.

Commentary as per Committee report (emphasis inserted by researcher)	Whether addressed (either in whole or in part) in the Bill	Department Response (emphasis inserted by researcher)
recommends that the Department continues its engagement with users of the NVPS to ensure that the system is easily accessible and is of an assistance rather than an administrative burden to the user.		
10. The Committee **recommends that the term 'veterinarian' is replaced with the term 'veterinary practitioner' throughout the Bill**. Under Head 10 of the Bill the following definition should be included to be in line with the Bill's provided definition of a 'veterinary nurse': ''*Veterinary practitioner' means a veterinary practitioner registered under Part 4 of the Veterinary Practice Act 2005*.'	✓	DAFM notes the recommendation, the term veterinarian is defined in the Bill as "*a veterinary practitioner registered under Part 4 of the Act of 2005".* The recently introduced EU Regulation 2019/6 uses the term veterinarian throughout and DAFM has implemented this Regulation in S.I. 36 of 2022 defining the term in the same manner as currently drafted in the Bill. For consistency purposes the preferred term to use is veterinarian.
11. The Committee notes a **typographical error** in Head 17(1)(d) where it should read '*under section 109 of the Veterinary Practice Act 2005*' rather than section 19.	✓	DAFM has noted this and it has been corrected
12. Head 20(4) states that '*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.*' The Committee was informed that the term 'certificate of suitability' has specific meaning under the Veterinary Practice Act 2005 as it relates to a premises at or from which a registered veterinary practitioner can practice veterinary medicine. **As the use of this term in Head 20(4) of this Bill may cause confusion the Committee**	✓	DAFM has noted the recommendation and has amended the Bill to remove the term certificate of suitability to avoid any confusion

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recommends that an alternative term is used.		
13. The Committee **believes that alignment of the prescribing and dispensing regimes on both sides of the border is essential**. The All-Ireland Animal Health strategy advocated by DAFM and all farming bodies will otherwise be undermined due to the inevitable, unnecessary and damaging black market for veterinary medicines that will evolve. Differing regimes will threaten our food quality standards. In excess of 50% of Northern Irish milk and meat are processed in the Republic, are labelled as 'Irish', but will be compliant with differing standards. This will not satisfy our major customers, jeopardising employment in this sector.		The advice of the Attorney General is clear that **only a veterinary practitioner is legally entitled to prescribe veterinary medicinal products in Ireland** and therefore it is not legally permissible to provide for a prescribing system for anti-parasitic veterinary medicinal products as currently exists in Northern Ireland.
14. Several stakeholders expressed their **concerns to the Committee on how information submitted by users to the proposed National Fertiliser Database could be used**, in particular, in deciding to carry out inspections undertaken by DAFM with regards to other schemes and the possibility of the provision of this data to third parties. The Committee **recommends that clarity is brought on these concerns by ensuring in the Bill that the use and storage of data provided by users on the National Fertiliser Database is in line with the General Data Protection Regulation (GDPR)**.		**DAFM have amended sections**: • 61 – 7E(1) to introduce language that more clearer defines the conditions for processing data entered into the database. • 61 – 7E(4) to explicitly state that the Minister may share with other Ministers of the Government or bodies established under statute data or reports produced from data from the Database where required for the performance of their functions. DAFM have stated that they have received advice from the

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		Data Protection Commission on this issue. • 61 – 7E(6) to include the criteria for entering into a data sharing agreement with food and feed processors where, in the opinion of the Minister, such sharing may bring about a change in fertiliser use, improve water quality or achieve other environmental and sustainable targets.
15. The Committee heard from several stakeholders of their **concern that the creation of the proposed National Fertiliser Database could increase administrative burden to fertiliser users**. Witnesses stated that some users may not be technologically literate and are already reliant on consultants to fill out applications for other agriculture payments and schemes on agfood.ie. This assistance will likely extend to the National Fertiliser Database as well and increase administrative requirements on these services. To assist in compliance of the Database, **the Committee recommends that the Department ensures that the database's design is accessible and user-friendly and that there is continuous engagement between the Department and users as it is rolled out**.	–	**DAFM have indicated that they believe the system's design is user-friendly and easy to use.** For example, • the system will use DAFM's existing portal (www.agfood.ie) • for farmers, the unique identifier is their herd number • professional fertiliser end users will only need to provide returns once a year
16. The National Fertiliser Database is set to come into effect on 1 January 2023 with 2023 as its first accounting year. Due to global circumstances, **this year there**	–	DAFM has taken **2018 as the baseline.**

Commentary as per Committee report (emphasis inserted by researcher)	Whether addressed (either in whole or in part) in the Bill	Department Response (emphasis inserted by researcher)
has been an unprecedented increase in fertiliser prices and witnesses informed the Committee that there are widespread predictions of more restricted fertiliser use and availability in 2023. Stakeholders expressed their **concern that the data provided for 2023 will be used as baseline to inform future policy decision making**. The **Committee recommends that these conditions are taken into account when the Department are using data from the National Fertiliser Database in future policy decisions**		
17. During the Committee's meetings the **issue of the ability to purchase fertiliser in Northern Ireland and being able to move it unrecorded throughout the Island** was raised as a risk to the completeness and validity of the National Fertiliser Database. It was revealed that the Database will be dependent on fertiliser users in the Republic of Ireland who have purchased fertiliser in Northern Ireland to record the purchase of the product on the Database. The **Committee recommends** that in order to draw assurance and to ensure compliance with the National Fertiliser Database **that the Department consider incorporating onsite inspection of fertiliser stocks as part of its farm inspection of other schemes**. If this isn't possible the **Committee requests the Department outlines what regulatory regime will be in place to ensure compliance with the proposed National Fertiliser Database and the achievement of the Bill's objectives.**		DAFM have stated that **any purchase of fertilisers outside the state will be classed as an import**, and as such will require farmers to register as a Fertiliser Economic Operator and appropriately record these imports on the Database. As Northern Ireland is subject to the Northern Ireland Protocol, those who import fertilisers are not subject to import taxes/duties. In terms of compliance, DAFM has indicated that the **existing system of on farm site inspections will be used to detect nonregistered imported fertilisers**. DAFM have stated that discussions with relevant officials in Northern Ireland have suggested that a similar system may be introduced in that jurisdiction in the future, which is anticipated to be similar to and/or compatible with the Database.

Commentary as per Committee report (emphasis inserted by researcher)	Whether addressed (either in whole or in part) in the Bill	Department Response (emphasis inserted by researcher)
18. The Committee heard that t**hose purchasing fertiliser for commercial use must register with the National Fertiliser Database** and **those purchasing small amounts for non-commercial use**, such as home gardening, **are not required to register** as a user on the Database. In its meeting with Minister Heydon, **it was unclear where entities such as local community sport clubs who maintain grounds fall**. The **Committee requests clarification on whether these clubs are required to register as a professional user in the National Fertiliser Database as they purchase fertiliser to maintain their pitches**.	–	DAFM has clarified that **such clubs will be required to register as professional fertiliser end users**.
19. The **Committee recommends that the Department uses a simplified system for small suppliers of fertiliser and to give a login number that is compatible with all its systems so that additional costs are not incurred by small suppliers of fertilisers.**	–	**DAFM considers that the administrative burden is already low**, requiring only once a year returns, and therefore does not represent a significant barrier to use of the system.

Principal provisions of the Bill

An outline of the Bill has been provided by the Department in the Explanatory Memorandum published on 30 January 2023, which summarises all the provisions of the Bill. This section focuses on the Bill's principal provisions.

Part 2 Regulation of veterinary medicinal products and medicated feed

As highlighted above, the Bill provides for the establishment, maintenance and operation of a database ("national database") on which veterinary prescriptions and dispensing of veterinary prescriptions shall be recorded to ensure a competitive market for the supply of veterinary medicinal products and to comply with certain reporting obligations under the VMP Regulation.

Section 5: only veterinarians can prescribe; This section of the Bill provides for restrictions on those who may issue a veterinary prescription to **ensure only registered veterinary**

practitioners do so and provides that **all veterinary prescriptions shall be issued electronically and dispensed and recorded on or transmitted to the national database**.

Section 7: the National Database; This section of the Bill provides for the establishment, maintenance and operation of **a national database on which veterinary prescriptions and dispensing of veterinary prescriptions shall be recorded** to ensure a competitive market for the supply of veterinary medicinal product and to comply with certain reporting obligations under the VMP Regulation. It provides for persons who the i**nformation held on the database may be accessed by, shared with and the reasons for the processing of the data**. **This section has a commencement order** attached to it.

Section 11: restrictions on who can sell veterinary products; This section provides for the routes of retail of veterinary medicinal products to ensure that veterinary medicinal products are retailed in an appropriate manner. The routes are detailed in the Schedule to this Bill.

Section 17: restrictions on premises used to sell veterinary products; This section provides for **the restriction on use of premises storing a veterinary medicinal product** for the purpose of retail to ensure the safe storage of veterinary medicinal products and for the protection of animal and human health.

Section 18: granting a medicinal product retailer's licence; Provides for the **granting of a licence (on application)**, to be known as a veterinary medicinal product retailer's licence when certain criteria are fulfilled for the purpose of retailing veterinary medicinal products to ensure the safe and appropriate retailing of veterinary medicinal products.

Section 24: retail at a distance (sending, receiving and internet sales of veterinary products); provides for rules on retailing at a distance. In this section "at a distance" means that the service is provided without the parties being simultaneously present as permitted in the VMP Regulations. In other words, this section relates to buying and selling veterinary medicines with persons in another EU Member State or third country. **It is prohibited to buy from, or sell to, another person in another Member State or a third country a veterinary medicinal product subject to a veterinary prescription at a distance.** Some third country purchases are allowed, in accordance with procedures as laid out by the competent authority concerned as permitted by Article 106(3) of VMP Regulation. This section also covers **internet sales**, stating that the Minister may grant a licence to certain persons[34] to conduct internet sales, subject to the conditions of their licence and regulations made by the Minister under this section.

Section 25: defining who can import veterinary medicines; provides for the issuing of a **special import licence**, allowing certain persons[35] to import veterinary medicinal products in relation to their use under Articles 110 to 114 or 116 of VMP Regulation.

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[34] The Minister may grant a licence to:

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

(b) a pharmacist;

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

(d) a person registered in the Companion animal medicine retailers' register

[35] Special import licences can be issued to:

Part 3 Amendment of Fertilisers Feeding Stuffs and Mineral Mixtures Act 1955

Section 61: creating Registers (Fertiliser Economic Operator's Register and a Fertiliser End User register) and the National Fertiliser Database; This section defines the terms **Fertiliser Economic Operator** and **Professional Fertiliser End User** [36], as well as **requiring the Minister to establish a register for each category.** Once the Bill is enacted, **only registered Fertiliser Economic Operators can sell fertiliser**. Furthermore, **only registered Professional Fertiliser End Users can purchase fertiliser** for professional use once the legislation is in force [37]. Once registered both Fertiliser Economic Operators and Professional Fertiliser End Users will be allocated a unique registration number (**for farmers** this will be their **herd number**).

Importantly, farmers who engage in farm-to-farm transfers of fertiliser must register as Fertiliser Economic Operators, as will farmers who import fertiliser from Northern Ireland or elsewhere.

Additionally, this section provides for the creation of the **National Fertiliser Database**. The Database will encompass the registration of Fertiliser Economic Operators and End Users. Information on the manufacturing, import, placing on the market, making available on the market or sales (whether wholesale or retail) of fertiliser products will be included in the Database. The section also provides **extensive procedures for proper data processing, data storage, data sharing, and data deletion.**

(a) a veterinarian,

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

(c) the holder of a marketing authorisation.

[36] The **Fertiliser Economic Operators**' Register is a register of persons who manufacture, import, place on the market or make available on the market (whether wholesale or retail) a fertiliser product.

A **professional fertiliser end user** is defined as any person who uses fertiliser products in the course of his or her professional activities**.**

[37] DAFM, 2022 National Fertiliser Database Information Note Updated

Contact:

Houses of the Oireachtas
Leinster House
Kildare Street
Dublin 2
D02 XR20

www.oireachtas.ie
Tel: +353 (0)1 6183000 or 076 1001700
Twitter: @OireachtasNews

Library & Research Service
Tel: +353 (0)1 6184701
Email: library.and.research@oireachtas.ie