EXPLANATORY MEMORANDUM TO

THE FOOD AND DRINK, VETERINARY MEDICINES AND RESIDUES (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019

2019 No. [XXXX]

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department for Environment, Food and Rural Affairs and is laid before Parliament by Act.

2. Purpose of the instrument

2.1 The majority of this instrument corrects retained EU law on Geographical Indication (GI) schemes. The remainder makes a small number of non-GI provisions on sector standards for wines and spirits and on veterinary medicines.

2.2 GIs are a form of intellectual property protection for the names of agricultural, food and drink products, the qualities or characteristics of which are attributable to the region or locality where they are produced and/or the traditional methods by which they are produced. Examples include Scotch Whisky, Welsh Lamb and Kentish Ale and Lough Neagh Eels.

Explanations

What did any relevant EU law do before exit day?

2.3 The relevant EU law provides Member States, including the UK, with GI schemes for agricultural products and foodstuffs, wine, aromatised wine and spirit drink products; and wine and spirit drink regulations.

2.4 Relevant EU law on GI schemes provides the framework to administer and enforce GI schemes. All products protected by the GI schemes receive legal protection from imitation. These schemes ensure all EU Member States are compliant with the GI elements of the World Trade Organisation (WTO) Trade Related Aspects of Intellectual Property Rights agreement obligations (TRIPS).

2.5 Relevant EU law on wine and spirit drinks provides EU Member States with the legal frameworks to administer and enforce on the definition, description, presentation and labelling of products in these sectors.

2.6 For veterinary medicines the relevant EU law sets out the application and assessment process for Maximum Residue Limits (MRLs) and pan-EU marketing authorisations issued by the European Medicines Agency (EMA).

Why is it being changed?

2.7 This instrument is being laid to address deficiencies in the retained EU legislation arising from the UK's withdrawal from the EU.

2.8 This instrument will enable the administration and enforcement of retained EU Regulations after the UK's withdrawal from the EU, as provided for by the European Union (Withdrawal) Act 2018.

What will it now do?

2.9 This instrument will make domestic law which regulates UK GI schemes and the UK spirit drink and wine sectors, and will amend retained EU law as regards veterinary medicines and MRLs. It will:

- Provide a UK framework to administer and enforce regulations on GI schemes for agricultural products and foodstuffs, wine, aromatised wine and spirit drink products, thus fulfilling World Trade Organisation (WTO) Trade Related Aspects of Intellectual Property Rights agreement (TRIPS) international obligations;
- Ensure the continued UK protection of existing UK GIs[1];
- Enable applications for UK GI protection to be made by producer groups from the UK and third countries;
- Provide a UK framework to administer and enforce regulations in the UK's wine sector;
- Provide a UK framework to administer and enforce regulations in the UK's spirit drink sector;
- Provide a UK framework for the setting of MRLs;
- Convert pan-EU approvals for marketing authorisations in respect of veterinary medicinal products to UK national approvals; and
- Make consequential changes to the Fees Schedule in the Veterinary Medicines Regulations 2013.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.2 The territorial application of this instrument includes Scotland and Northern Ireland.

3.3 The powers under which this instrument is made cover the entire United Kingdom (see section 24 of the European Union (Withdrawal) Act 2018) and the territorial application of this instrument is not limited either by the Act or by the instrument.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is the United Kingdom.

4.2 The territorial application of this instrument is the United Kingdom.

5. European Convention on Human Rights

5.1 The Parliamentary Under-Secretary of State for Food and Animal Welfare, David Rutley MP, has made the following statement regarding Human Rights:

[1] This includes the three cross-border Irish GIs; Irish whiskey, Irish cream and Irish poteen, which can be produced anywhere on the island of Ireland.

"In my view the provisions of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 are compatible with the Convention rights."

6. Legislative Context

6.1 This instrument addresses deficiencies in retained EU law in relation to wine sector regulations, spirit drink sector regulations and regulations on GIs for agricultural products and food stuffs, wine, aromatised wine and spirit drinks. It also amends certain domestic regulations which concern enforcement of those regulations so as to address deficiencies (principally to remove references which are inappropriate after EU exit.

6.2 The amendments made are to ensure this legislation continues to operate as a matter of UK law after the withdrawal of the United Kingdom from the EU.

6.3 This instrument provides for the domestic administration and enforcement of UK GI schemes, which will provide legal protection from imitation for all products recognised by the schemes. This instrument also creates UK operable regulations to administer and enforce the wine and spirit drink sector standards on definition, description, presentation and labelling.

6.4 Additionally this instrument covers a number of Veterinary Medicine provisions that required an affirmative legislative vehicle. This is largely the domestic setting of MRLs for substances used as veterinary medicines in food-producing animals. MRLs are set to protect consumers from residues of medicines in produce. These limits are used to establish withdrawal periods (the period that must elapse after the last administration of the medicine before produce from that animal may enter the food chain).

6.5 It also provides for the conversion of veterinary medicines issued by the European Medicines Agency (EMA) to UK approvals in order for these products to remain on the UK Market. This instrument makes changes to fees set in conjunction with the Veterinary Medicines Regulations 2013. The fee changes reflect the fact that authorisation procedures involving EU Member states will not be relevant to the UK after exit day.

6.6 Section 8(1) of the European Union (Withdrawal) Act 2018 (the 2018 Act) provides that a Minister of the Crown may, by regulations, make such provision as the Minister considers appropriate to prevent, remedy or mitigate any failure of retained EU law to operate effectively or any other deficiency in retained EU law arising from the withdrawal of the United Kingdom from the EU. The instrument is made in exercise of these powers, and the power in paragraph 21 of Schedule 7 to the 2018Act which allows for supplementary provision to be made, including a provision that restates retained EU law in a clearer or more accessible way.

Relationship to other Statutory Instruments.

6.7 There are a number instruments to which this legislation relates, across both Business As Usual (BAU) and EU Exit legislative programmes, which are either laid or planned. These are (SI names as accurate at point of laying this instrument):

Exit legislation - confirmed

6.8 The Veterinary Medicines and Animal Products (Examination of Residues and Maximum Residues Limits) (Amendment etc.) (EU Exit) Regulations 2018. The main Veterinary Medicines (VM) Exit legislation, as relevant to the VM provisions that have been transferred to this instrument. See sections 6.4 and 6.5 of this explanatory memorandum.

6.9 Market Measures (Basic Acts) (CAP) (EU Exit) (Miscellaneous Amendments) 2019. Sets out the legal basis of the GI arrangements for wine, including a definition of what a Designation of Origin and GI of the wine sector includes.

6.10 The Agriculture (Transfer of Functions) (EU Exit) (No 2) Regulations 2019. Sets out whether decisions on the authorities responsible for the verification, and the compliance and protection of protected designations of origin, protected GIs and protected traditional terms are retained or devolved. As relating to the Market Measures regulation at section 6.9 of this explanatory memorandum, which provides the legal basis for the wine GI scheme.

Exit legislation - potential

6.11 At the time of laying this instrument it had not been resolved which of the below potential Statutory Instruments would be applicable. It is not expected that all the SIs referenced in sections 6.12 through to 6.15 of this explanatory memorandum will relate to this instrument, however the SI references in section 6.16 is anticipated.

6.12 The Food and Farming (Miscellaneous Amendments) (EU Exit) Regulations 2019 (aka 'wash-up' SI) to take forward EU Exit amendments to wine and spirits provisions that were not available in time to be captured in this instrument.

6.13 The Environment, Food and Rural Affairs (Miscellaneous Amendments) (EU Exit) Regulations 2019 (aka 'wash-up' SI) to take forward exit amendments to wine and spirits provisions that were not available in time to be captured in this instrument.

6.14 The Food and Drink (Amendment) (EU Exit) Regulations 2019 (provisional). To lay using affirmative procedure, to ensure that essential EU Exit amendments are made that must come into force on exit day, including provisions from recently updated EU wines regulations.

6.15 The Food and Drink (Amendment) (EU Exit) (No. 2) Regulations 2019 (provisional). To lay to make less urgent exit amendments, which can come into force shortly after exit day, including provisions from recently updated EU wines regulations.

6.16 The Quality Schemes for Agricultural Products and Foodstuffs (Symbol) Regulations 2019. Expected to be made soon after EU Exit to bring in the new UK scheme logos.

Non-Exit legislation (Business As Usual):

6.17 The Quality Schemes (Agricultural Products and Foodstuffs) Regulations 2018. Creating a bespoke enforcement and civil sanctions regime for the use of EU Protected Food Names on products produced and/or sold in the UK. Came into force 1 January 2019.

6.18 Amendment to The Wine Regulations 2011. To amend a UK SI enforcing the provisions of EU wines regulations which are being updated in January 2019, to ensure we can continue to enforce and amend the EU wine regulations in the UK.

7. Policy background

What is being done and why?

7.1 The European Union (Withdrawal) Act 2018 provides for the repeal of the European Communities Act 1972 and makes other provisions in connection with the withdrawal of the United Kingdom from the EU.

Geographical Indications (GIs)

7.2 While the UK has been a Member State of the European Union, EU regulations have provided for the registration and protection of GIs in the UK. These cover: i) agricultural products and foodstuffs; ii) wines iii) spirit drinks and iv) aromatised wines. The schemes provide legal protection from imitation for both regional and traditional specialties, whose authenticity and origin can be guaranteed. This gives assurance to consumers that products are genuine and enables producers to better promote and market their products.

7.3 EU regulations have also governed the definition, description, presentation and labelling rules for spirit drinks, as well as the definition, description, presentation, labelling and oenological rules for wines and aromatised wines.

7.4 As a signatory to the WTO TRIPS agreement, the UK is required to have a legal means for interested parties to prevent the public being misled about the geographical origin of a product or the use of a GI in a way that results in unfair competition. For agricultural products and foodstuffs, wines, spirit drinks and aromatised wines, this is currently carried out under the four existing EU GI schemes.

7.5 As the UK leaves the EU, it must put rules in place to continue complying with its WTO TRIPS obligations. Under the European Union (Withdrawal) Act 2018 incorporated EU law will be amended so that it is operable in the UK after EU Exit. This instrument amends those regulations (and existing domestic regulations) on GI schemes and the wine and spirit drink sectors. The amendments made by this instrument will create working UK GI schemes, and domestically enforceable UK regulations for the wine and spirit drink sectors. This will ensure the UK continues to protect the 86 product names from the UK that are registered as GIs under the EU schemes and continues to meet its WTO TRIPS obligations.

7.6 The amendments made by the EU Exit regulations are mostly changes to make sure the rules continue to work in the UK and there is minimal disruption to stakeholders. A key instance is empowering the Secretary of State to grant GI applications instead of the European Commission.

7.7 However, there are a few instances where more substantive amendments are necessary to make the schemes operable under UK law. The main changes include:

1. The GI schemes will be administered as UK schemes, not as EU schemes. All GI applications will go through a single UK scrutiny and opposition process, rather than the two-stage process for applications to the EU schemes (the current Member State and European Commission stages will be combined into a single modified UK scheme process);
2. Appeals provisions are being introduced as a result of the UK assuming new responsibilities and functions, previously belonging to the EU. These allow those with a legitimate interest to appeal to the First-tier Tribunal where they disagree with decisions made in the administration of the scheme; and

3. The creation and use of new UK GI logos, including allowing existing UK agri-food GIs three years to comply with the requirement to use the new UK logo when trading in the UK market.

Veterinary Medicines

7.8 Parts 4 and 5 of this instrument deal with veterinary medicines. Although essential for the treatment of animals and ensuring animal welfare, veterinary medicines also present a range of potential risks to human health and the environment. If misused, they can affect human health directly or may enter the natural environment through production, use or disposal causing long-lasting damage. The existing EU and UK veterinary medicines legislation sets out the requirements for placing veterinary medicines on the market to ensure their safe use and the protection of public health and the environment.

7.9 MRLs, are set to protect consumers from residues of medicines in produce. These limits are used to establish withdrawal periods (the period that must elapse after the last administration of the medicine before produce from that animal may enter the food chain). MRLs also facilitate trade in animals and produce, as compliance with MRLs and food safety regulations provides assurance of the safety of animal-derived produce. Following EU Exit any new MRLs set by the Commission will not apply to the UK. The amendments made by the instrument will ensure that the UK can set appropriate MRLs and ensure that products for food-producing species can be made available on the UK market. Existing MRLs will be carried across to the new UK procedure. As the function of setting MRLs is expected to be exercised frequently, it is considered appropriate for the function to be exercised administratively, with a duty on the appropriate authority to publish and maintain a MRL register that must be available and searchable online.

7.10 Approximately 13% of veterinary medicines available on the UK market are approved by the European Medicines Agency. To ensure these medicines remain on the market and can be subject to the necessary regulatory controls it is necessary to convert these approvals to UK national authorisations. This instrument will provide a mechanism to update these authorisations, for example in light of new manufacturing processes, and will provide sufficient regulatory oversight and assurance of these medicines.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

8.1 This instrument is being made using the power in section 8 of the European Union (Withdrawal) Act 2018 in order to address failures of retained EU law to operate effectively or other deficiencies arising from the withdrawal of the United Kingdom from the European Union. The instrument is also made under the powers in paragraph 1 of Schedule 4 and paragraph 21 of Schedule 7 to the European Union (Withdrawal) Act 2018. In accordance with the requirements of that Act, the Minister has made the relevant statements as detailed in Part 2 of the Annex to this explanatory memorandum.

9. Consolidation

9.1 This instrument is not consolidating any other provisions.

10. Consultation outcome

10.1 The public were consulted between 4 October and 1 November 2018 on the future UK GI schemes logos and appeals processes, as well as being given the opportunity to provide broader comments on the GI schemes and non-GI provisions on sector standards for wines and spirits.

10.2 92 responses came from a number of stakeholder organisations and groups including UK and EU producers, trade associations, third sector organisations and individuals.

10.3 Regarding the logo, respondents were happy with the proposed three year adoption period until logo use became mandatory on food and agricultural products. Views on the logo design varied, but key themes that emerged were that logos should convey provenance, quality and heritage. The Department will introduce another statutory instrument as part of the EU Exit process to implement the new UK logos for use once their development is complete (as referenced at section 6.16 of this explanatory memorandum).

10.4 The majority of those who responded to questions on the appeals process supported our proposals for using General Regulatory Chamber Rules and First-tier Tribunal (part of the UK court system empowered to deal with a number of issues which might form the substance of appeals, and to ensure the cases are dealt with in the interest of justice and minimising parties' costs). This action has been confirmed in the Government's response to the consultation (see 10.6) and appeals procedures are being set out in published scheme guidance to be published by 29 March 2019.

10.5 Respondents also raised a variety of other issues including recognition of UK GIs in the EU, UK recognition of EU GIs and making sure the transition to the new UK schemes is easy, simple and does not have a negative effect on producers.

10.6 The full consultation summary and response was published on 25 January 2019. The response can be found at:

10.7 https://www.gov.uk/government/consultations/geographical-indications-gi-creatinguk-schemes-after-eu-exit

10.8 A public consultation was not carried out in respect to the veterinary medicines provisions in this instrument. However, there has been significant informal engagement with the animal health industry which supports these proposals.

11. Guidance

11.1 The UK will be publishing guidance on the UK GI schemes. This will be publically available on the day that the schemes enter into force; either by 29 March 2019 if there is no withdrawal deal with the EU, or December 2020 if there is (subject to the length of any implementation period agreed with the EU).

11.2 The Veterinary Medicines Directorate publishes guidance on the regulation of the manufacture, distribution and use of veterinary medicines. The required changes to guidance have been made.

12. Impact

12.1 The anticipated impact on business, charities or voluntary bodies is low.

12.2 Of the changes introduced by this instrument, those regarding packaging requirements are the only ones that present significant cost implications to businesses.

12.3 The use of the appropriate UK logo will be mandatory for registered UK agricultural and foodstuff products in the UK market, meaning existing producers will have to change their labels to adopt the new logo. This is in keeping with the rules applied to Member States' use of the EU logos.

12.4 The impact of this change has been minimised by introducing a three year adoption period before the use of the new UK GI logo becomes mandatory (for applicable products). This will allow businesses to incorporate labelling changes within their normal labelling refresh cycles. Economic evidence and stakeholder consultation supports the Government's choice of three years as a suitable period.

12.5 In relation to veterinary medicines, this instrument will require those who wish to market a veterinary medicine for food-producing species to apply for an MRL before applying for a Marketing Authorisation if one does not already exist. There is an accompanying fee for this application. Due to the absence of a cost base for this work (as it is carried out the EMA currently) the existing fee for an EU MRL has been incorporated into this instrument. This fee will be reviewed once a cost base has been established.

12.6 For those veterinary medicine approvals issued by the EMA, the conversion to a UK authorisation will be free in order to minimise the burden on industry. These products will be subject to the same requirements for national authorisation once converted and will be subject to annual fees. The impact for this cannot be calculated as the annual fee is based on turnover of all veterinary medicines by each company, so will be different for each company.

12.7 There is no significant impact on the public sector.

12.8 An Impact Assessment has not been prepared for this instrument because the business impacts of the preferred options were assessed to be below the necessary minimum threshold.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses (employing up to 50 people).

13.2 To minimise the impact on small businesses with regards the new UK GI logos, a three year adoption period is provided before their use becomes mandatory (for applicable products). This period allows relevant businesses to make changes within standard labelling refresh cycles. Economic evidence5 sets out that, compared with requiring immediate change, three years decreases the cost to business by 95%. Stakeholder consultation supported this proposal. To support businesses in preparing for the new logos, we are providing comprehensive scheme guidance (see section 11 of this explanatory memorandum).

13.3 As regards veterinary medicines and residues, the approach taken by the Veterinary Medicines Directorate is to carry out a continual process of informal consultation with stakeholders on proposed legislative developments.

14. Monitoring & review

14.1 As this instrument is made under the European Union (Withdrawal) Act 2018, no review clause is required.

15. Contact

15.1 Anna Bainbridge at the Department for Environment, Food and Rural Affairs Telephone: 02080266573 or email: Anna.Bainbridge@defra.gov.uk can be contacted with any queries regarding this instrument in relation to provisions relating to Geographical Indications and wine and spirit sector standards.

15.2 Lea Reynolds at the Veterinary Medicines Directorate of the Department for Environment, Food and Rural Affairs. Telephone 01932338321 or email l.reynolds@vmd.defra.gsi.gov.uk can be contacted with any queries regarding this instrument in relation to provisions relating to the Veterinary Medicines provisions.

15.3 Ananda Guha, Deputy Director responsible for Geographical Indications, at the Department for Environment, Food and Rural Affairs, can confirm that this Explanatory Memorandum meets the required standard. The Deputy Director responsible for the Veterinary Medicines provisions is Paul Green.

15.4 The Parliamentary Under-Secretary of State for Food and Animal Welfare, David Rutley MP, at the Department for Environment, Food and Rural Affairs can confirm that this Explanatory Memorandum meets the required standard.

Annex

Statements under the European Union (Withdrawal) Act 2018

Part 1

Table of Statements under the 2018 Act

This table sets out the statements that may be required under the 2018 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(3), 3(7) and 17(3) and 17(7) of Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/Sifting Committees
Appropriate-ness	Sub-paragraph (2) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	A statement that the SI does no more than is appropriate.
Good Reasons	Sub-paragraph (3) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain the good reasons for making the instrument and that what is being done is a reasonable course of action.
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain what, if any, amendment, repeals or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them. State that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.
Explanations	Sub-paragraph (6) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2 In addition to the statutory obligation the Government has made a political commitment to include these statements alongside all EUWA SIs	Explain the instrument, identify the relevant law before exit day, explain the instrument's effect on retained EU law and give information about the purpose of the instrument, e.g., whether minor or technical changes only are intended to the EU retained law.
Criminal offences	Sub-paragraphs (3) and (7) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9, and	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.

		23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising sections 10(1), 12 and part 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority by Statutory Instrument.	State why it is appropriate to create such a sub-delegated power.
Urgency	Paragraph 34, Schedule 7	Ministers of the Crown using the urgent procedure in paragraphs 4 or 14, Schedule 7.	Statement of the reasons for the Minister's opinion that the SI is urgent.
Explanations where amending regulations under 2(2) ECA 1972	Paragraph 13, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement explaining the good reasons for modifying the instrument made under s. 2(2) ECA, identifying the relevant law before exit day, and explaining the instrument's effect on retained EU law.
Scrutiny statement where amending regulations under 2(2) ECA 1972	Paragraph 16, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement setting out: a) the steps which the relevant authority has taken to make the draft instrument published in accordance with paragraph 16(2), Schedule 8 available to each House of Parliament, b) containing information about the relevant authority's response to— (i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and (ii) any other representations made to the relevant authority about the published draft instrument, and, c) containing any other information that the relevant authority considers appropriate in relation to the scrutiny of the instrument or draft instrument which is to be laid.

Part 2

Statements required when using enabling powers under the European Union (Withdrawal) 2018 Act

1. Appropriateness statement

1.1 The Parliamentary Under-Secretary of State for Food and Animal Welfare, David Rutley MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 does no more than is appropriate".

1.2 This is the case because: the amendments to domestic legislation are the minimum required to make the legislation operable. See section 6 of the main body of this explanatory memorandum for reference.

2. Good reasons

2.1 The Parliamentary Under-Secretary of State for Food and Animal Welfare, David Rutley MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action".

2.2 These are: Amendments to domestic legislation are the minimum required to make the legislation operable. See section 6 of the main body of this explanatory memorandum for reference.

3. Equalities

3.1 The Parliamentary Under-Secretary of State for Food and Animal Welfare, David Rutley MP, has made the following statement(s):

"The instrument does not amend, repeal or revoke a provision or provisions in the Equality Act 2006 or the Equality Act 2010 or subordinate legislation made under those Acts.

3.2 The Parliamentary Under-Secretary of State for Food and Animal Welfare, David Rutley MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In relation to the instrument, I, Parliamentary Under-Secretary of State for Food and Animal Welfare, David Rutley MP, have had due regard to the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010."

4. Explanations

4.1 The explanations statement has been made in section 2 of the main body of this explanatory memorandum.

5. Legislative sub-delegation

5.1 The Parliamentary Under-Secretary of State for Food and Animal Welfare, David Rutley MP has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view it is appropriate to create a relevant sub-delegated power in The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019."

5.2 There are two elements in this instrument to which this statement relates. One concerns geographical indications relating to agri-food and aromatised wine. The other concerns veterinary medicines. Both involve replacing an existing EU process which is exercised through delegated legislation with a power in UK law which is exercised administratively with decisions published on a publicly accessible register.

5.3 A relevant sub-delegated power concerning geographical indications is appropriate because:

- it is desirable for the Secretary of State to exercise the power to determine applications for geographical indications relating to agri-food and aromatised wine by administrative means rather than by Statutory Instrument given that:
    - there may be a large volume of such decisions depending on the number of applications which are made, and a requirement for all such decisions to be made by Statutory Instrument would require additional resource and could cause delay in ensuring that decisions are made and come into force promptly;
    - scrutiny and awareness of the decisions made by the Secretary of State will be sufficiently provided through the requirement for decisions to be published on a register.

5.4 A relevant sub-delegated power concerning veterinary medicines is appropriate because:

- it is desirable for the appropriate authority (the Secretary of State or the Department of Agriculture, Environment and Rural Affairs) to exercise the power to classify substances and establish minimum residue limits for veterinary medicines by administrative means rather than by SI given that:
    - there may be a large volume of such decisions depending on the number of applications which are made, and a requirement for all such decisions to be made by SI would require additional resource and could cause delay in ensuring that decisions are made and come into force promptly;
    - scrutiny and awareness of the decisions made by the appropriate authority will be sufficiently provided through the requirement for decisions to be published on a register maintained on the Internet.