

Health, Social Care and Sport Committee

28th Meeting, 2022 (Session 6), Tuesday, 4 October 2022

UK statutory instruments - consideration of consent notifications

Introduction

1. This paper supports the Committee's consideration of 'type 1' consent notification sent by the Scottish Government relating to the following UK statutory instruments (SIs) —
 - [SI notification: The Food and Feed \(Miscellaneous Amendments\) Regulations 2022](#)
2. The letter from the Minister for Public Health, Women's Health & Sport, containing the notification can be accessed in **Annexe A**.

Process for parliamentary scrutiny of consent notifications for UK statutory instruments

3. The process for the Scottish Parliament's consideration of consent notifications is set out in a [protocol](#) agreed between the Scottish Government and Scottish Parliament.
4. The protocol provides for the Scottish Parliament to scrutinise the Scottish Government's decisions to consent to certain secondary legislation made by the UK Government. Specifically, this relates to UK Government secondary legislation on matters which are within devolved competence and are in areas formerly governed by EU law.
5. The protocol establishes a proportionate scrutiny approach and categorises SIs into type 1 and type 2.
6. For type 1 SI notifications, the Scottish Parliament's agreement is sought *before* the Scottish Government gives consent to the UK Government making secondary legislation in devolved competence. Except in respect of urgent notifications, the Scottish Parliament will have a minimum of 28 days to consider type 1 notifications.
7. For type 2 SI notifications, however, the Scottish Government will notify the Scottish Parliament within five days *after* giving consent.
8. Type 2 applies where all aspects of the proposed instrument are either clearly technical, do not involve a policy decision or update references in legislation that

are no longer appropriate following EU exit. All other proposals fall into the type 1 category. In line with the proportionate scrutiny approach, each type 1 notification will be considered by the Committee. Committees will be notified of all type 2 notifications which fall within their remit; it is not, however, anticipated that these will normally be considered at a committee meeting. The protocol includes a number of review mechanisms and the categorisation of type 2 notifications will be monitored in this way.

9. **The Committee's role in relation to type 1 notifications is to decide whether it agrees with the Scottish Government's proposal to consent to the UK Government making regulations within devolved competence.**
10. If members are content for consent to be given, the Committee will write to the Scottish Government accordingly. The Committee may wish to note any issues in its response or request that it be kept up to date on any relevant developments.
11. If the Committee is not content with the proposal, however, it may make one of the following three recommendations—
 - (1) that the Scottish Government should not give its consent to the provision being made in a UK SI and that the Scottish Government should instead produce an alternative Scottish legislative solution;
 - (2) that the Scottish Government should not consent to the provision being made in a UK SI laid solely in the UK Parliament and should instead request that the provision be included in a UK SI laid in both Parliaments under the joint procedure (N.B. joint procedure is not available in every case so the option of making this recommendation will not always be available); or
 - (3) that the provision should not be made at all (that is, that the Scottish Government should not consent to the provision being included in a UK SI, nor should the Scottish Government take forward an alternative Scottish legislative solution).

For decision

12. The Committee is invited to consider whether the provisions set out in the notifications should be included in UK SIs.

Clerks to the Committee
29 September 2022

Annexe A

**The Food and Feed (Miscellaneous Amendments) Regulations 2022 EU EXIT
LEGISLATION – PROTOCOL WITH SCOTTISH PARLIAMENT**

On 21 September 2022, the Scottish Government wrote to the Convener of the Health, Social Care and Sport Committee:

I am writing in relation to the protocol on obtaining the approval of the Scottish Parliament to proposals by the Scottish Ministers to consent to the making of GB secondary legislation affecting devolved areas arising from EU Exit.

That protocol, as agreed between the Scottish Government and the Parliament, accompanied the letter from the then Cabinet Secretary for Government Business and Constitutional Relations, Michael Russell MSP, to the Conveners of the Finance & Constitution and Delegated Powers and Law Reform Committees on 4 November 2020 and replaced the previous protocol that was put in place in 2018.

I attach a Type 1 notification which sets out the details of the Statutory Instrument (SI) which the UK Government propose to make and the reasons why I am content that Scottish devolved matters are to be included in this SI. Please note, whilst we have been given sight of a draft SI we are not able to share this with the Parliament as it is not ready to be placed in the public domain at this stage. We will, in accordance with the protocol, advise you when the final SI is laid and advise you as to whether the final SI is in keeping with the terms of this notification.

I am copying this letter to the Convener of the Delegated Powers and Law Reform Committee.

I look forward to hearing from you in due course.

MAREE TODD

NOTIFICATION TO THE SCOTTISH PARLIAMENT**The Food and Feed (Miscellaneous Amendments) Regulations 2022****Is the notification Type 1 or Type 2**

1. Type 1.

Overview of the SI

2. This Type 1 notification concerns provisions made in respect of Great Britain (GB) to amend retained direct European Union (EU) law in various areas of food and feed law, including legislation on novel foods, food additives, enzymes and flavourings, genetically modified food and feed, feed additives, food contact materials (FCM) and the hygiene of foodstuffs.
3. The UK Government has previously made amendments under a Great Britain Statutory Instrument (GBSI), such as 'The Food and Feed Safety (Miscellaneous Amendments and Transitional Provisions) Regulations 2022'. These GBSIs included amendments to retained EU law relating to numerous areas, including general food law, genetically modified (GM) food and feed and feed additives. Following reviews of the Regulations further deficiencies, inoperabilities and inconsistencies have been identified
4. Consequently, this proposed SI makes the further amendments needed to fix the aforementioned issues of deficiency, inoperability and inconsistency, to make the relevant retained EU law appropriate for GB. This proposed instrument, following the affirmative procedure, will be laid in draft on 13 October 2022. We have not been provided with a coming into force date for this instrument.
5. The proposed SI will also cover amendments to domestic law in England relating to FCM, extraction solvents, undesirable substances in feedstuffs and categories of feed materials. Equivalent changes are planned to be made to the analogous domestic food law in Scotland through a Scottish Statutory Instrument (SSI).

Details of the provisions that Scottish Ministers are being asked to consent to.

6. This Statutory Instrument (SI) includes the following GB amendments:
 - Amending retained Regulation (EU) 450/2009 to remove the requirement to include the 'Do Not Eat' pictograph (which is an EU pictograph) and the substitution of cross references to an EU Directive with references to current retained EU law.
 - Amendment to Article 1(4) of retained Regulation (EC) 853/2004 to address an inconsistency between Article 1 of retained Regulation (EU) 852/2004 and Article 1 of 853/2004 with regards to the requirement for national rules for the direct supply of small quantities of primary products,
 - Amendment of Article 10 of 853/2004 to take account of a pre-exit amendment to Regulation (EU) 2019/1243,
 - Various fixes to legislation concerning feed additives, including amendments to retained Regulation (EC) 1831/2003, retained Commission Regulation (EC) 378/2005, retained Commission Regulation (EC) 429/2008,

retained Regulation (EC) 152/2009, including the GB submission of feed additive applications to FSS/FSA and samples to the reference laboratory and labelling requirements across the UK.

- Fixes to retained Regulation (EC) 767/2009 to correct the reference to an Article which has since been renumbered and reinstating the word permitting the use of the term 'pet food',
 - The amendment of Article 35 of retained Regulation (EU) 2015/2283 on novel foods to introduce a GB-specific transitional period for edible insects,
 - An amendment to retained Regulation (EC) 1331/2008 on food additives, enzymes and flavourings regarding previously missed references to the EU term 'Community list' to update this to 'Domestic list'.
 - Reinstating powers in Article 8(6), and Article 20(6) of Regulation (EC) No 1829/2003 which allow for the withdrawal of Genetically Modified Organisms (GMOs) and the provision of limited periods of time for existing stocks of products to be used up and for removal of traces of GMOs from the food and feed chain (tolerance periods). This will confer powers on Scottish Ministers for Scotland (as well as other GB Ministers in relation to England and Wales) to be able to legislate for the further extension of tolerance periods.
7. The extension of these tolerance periods for a further three years until 31 December 2025 and consequential amendments to retained Commission Regulation (EU) 619/2011 and retained Commission Decisions 2007/305/EC, 2007/306/EC, 2007/307/EC to reflect the extension of the tolerance period.

Summary of the proposals

8. The changes are as follows:

Amendment to Novel Food regulations to provide a GB-specific transitional period for edible insects

9. Article 35(2) of retained Regulation (EU) 2015/2283 currently provides for a transitional period for food products and sectors that were brought into scope of the Novel Food regulations for the first time when 2015/2283 was introduced. These transitional arrangements, as retained in Scotland and the rest of GB, apply to a limited number of edible insect products.
10. When EU law was retained following EU exit, the transitional arrangements in Article 35(2) were not adapted to the regulatory and market context in Scotland or the rest of GB. Instead, the current provisions are reliant on applications being submitted to the EU, which has been identified as a deficiency. This SI therefore proposes to amend this provision to introduce a Scotland and GB-specific time-limited transitional period for certain edible insect products and deadlines for submitting applications to GB. This would provide certainty and a clear timeline to industry and enforcing authorities and would adapt the Regulation to operate appropriately in Scotland and in a wider GB context. This proposed SI would also omit paragraphs 1 and 3 from Article 35, which include now defunct references to the previous novel food regulation and to repealed Articles of 2015/2283.

Removal of the requirement to use the 'Do Not Eat' pictograph

11. Article 11 of retained Regulation 450/2009 includes the requirement to include the 'Do Not Eat' pictograph, which this SI proposes to remove for active and intelligent materials placed onto the Scottish and wider GB market. The mandatory requirement to include the words 'DO NOT EAT' will continue to apply. This removal is suggested if the European Commission (EC) confirms that it has ownership of the copyright of the pictograph. Where the EC has copyright of the pictograph it is proposed that the requirement in Scotland and throughout GB to include it should be removed. This amendment does not concern all food contact materials, only those that are active or intelligent e.g. oxygen scavengers and moisture absorbers that are inserted into packs of food. This would apply to GB only.
12. A technical question has been formally submitted to the EC and the response will be indicative of whether action to remove the requirement to use the pictograph on active and intelligent materials in Scotland and in the wider GB market should proceed. This amendment therefore remains provisional depending on the response from the EC. If no response is received by the time this SI is laid, the amendment will proceed.
13. The option of replacing the image with a GB-specific pictograph applying in Scotland was considered to present a potentially significant burden to businesses placing products on to the market in GB and also create regulatory divergence across the UK with Northern Ireland continuing to apply the 'Do Not Eat' pictograph, as per the EU regulations, applicable under the Northern Ireland Protocol (NIP). Therefore the minimal intervention (removing the requirement) was determined to be the most effective and least burdensome approach, whilst retaining a high level of safety for consumers.
14. Cross references in Article 11 to EU Directive 2000/13/EC are also replaced with references to retained Regulation (EU) No. 1169/2011, or Articles of 1169/2011. This is to update 1831/2003 to reference the current relevant retained EU law as opposed to an obsolete EU Directive.

Amendment to common authorisation procedure for food additives, food enzymes and food flavourings

15. Retained Regulation (EU) 1331/2008 established a common authorisation procedure for food additives, food enzymes and food flavourings. Amendments were previously made in 'The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019' to replace references to the 'Community list', which is an EU-specific term, with the term 'domestic list'.
16. However, a reference to 'Community list' within Article 7(4) remains. This deficiency must now be rectified to ensure that 1331/2008 reads consistently.

Corrections to animal feed regulations

17. Retained Regulation (EU) 767/2009 sets out the requirements for the marketing, labelling and composition of animal feeding stuffs and includes provisions intended to safeguard both animal and human health.
18. Amendments were made in 'The Animal Feed (Amendment) (EU Exit) Regulations 2019', which fixed inoperabilities in retained EU legislation on animal feed that arose as a consequence of EU exit. When these changes were made, an incorrect numbering reference was introduced and the expression 'pet food' when designating feed for pets was inadvertently deleted.
19. This SI therefore proposes corrections to 767/2009 to reinstate the wording permitting the use of the term pet food and correcting the reference to an article that has been renumbered.

Amendments to feed additives legislation

20. The Animal Feed (Amendment) (EU Exit) Regulations 2019 amended feed additive legislation to fix deficiencies. This SI proposes amendments to address further deficiencies. This SI amends Article 1, 2 and 3 of retained Regulation (EU) 1831/2003 on additives for use in animal nutrition to remove references to EU Directives. It replaces these references with definitions and references to retained EU law to substitute the function of these references. It also amends Article 4 to remove a reference to a repealed Article of retained Regulation 178/2002.
21. This SI also makes amendments to Articles 7 and 8 of 1831/2003, to provide a legal basis for applications to be submitted to GB, including Scotland, and so Article 10 on existing products functions correctly. Article 16(1), which was previously amended to 'GB' under the EU Exit Regulation, is amended to 'UK' to re-harmonise labelling requirements in GB and NI. Article 13(6), which requires that any modification, suspension or revocation of an authorisation must be in a form prescribed by Ministers is omitted. This requirement is already implicit in 1831/2003, since Ministers are required to make regulations for these changes under Article 13(5), which implies these regulations are in a form agreed by Ministers. Article 13(6) is therefore an unnecessary provision added in a previous EU Exit regulation.^[1] Annex 2 of 1831/2003 is also amended to update references to retained Regulation 2017/625.
22. This SI also proposes minor amendments to clarify the process for analytical sample submission to the GB Reference Laboratory in Retained EU Regulations 1831/2003 (on feed additives), 429/2008 (on preparing applications) and 378/2005 (on reference laboratories). Further minor amendments will be made to the above Regulations and Retained EU Regulation 152/2009 (on analytical methods) to update cross-references to reflect the most recent legislation in force.

Food Hygiene legislation – Requirement to establish rules in national law

23. The General Food Hygiene (EU Exit) Regulations 2019 amended retained Regulation (EC) 852/2004 on the requirements for hygiene of foodstuffs,

omitting Article 1(3). This Article required Member States to establish, under national law, rules governing the direct supply, by producers, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer.

24. The Specific Food Hygiene (Amendment etc.) (EU Exit) Regulations 2019 amended retained Regulation (EC) 853/2004 on specific hygiene rules for food of animal origin. Instead of omitting the same requirement from Article 1(4), it amended it to require that Scottish Ministers (and other GB Ministers for England and Wales), as the appropriate authority, establish rules in law governing the activities and persons relating to direct supply of small quantities of primary products, meat from poultry and lagomorphs and wild game meat to the final consumer or local retail establishments directly supplying the final consumer.
25. Therefore the requirement for national rules was amended differently between 852/2004 and 853/2004, inadvertently creating an inconsistency between the two regulations. This SI therefore proposes to re-establish consistency in food hygiene legislation, by amending 853/2004 to remove the requirement from Article 1(4) for Ministers to establish rules in law.
26. This approach to addressing the inconsistency is not a policy change but rather a technical fix of the retained law. Following EU exit, the provision set out in Article 1(4)(c) of retained Regulation 853/2004 became redundant. It is a statement of requirement but does not confer the power to make Regulations to implement that requirement. Consequently, whilst this SI proposes to address this inconsistency through the removal of a provision, it does not change Regulation making powers of Ministers (and by extension FSS) or the substantive policy objectives of the regulation.

Food Hygiene legislation – Amendment of Articles 10 and 11 of 853/2004

27. Regulation 11(a) of The Specific Food Hygiene (Amendment etc.) (EU Exit) Regulations 2019 (SI 2019/640) amended Article 10(1) of 853/2004, substituting in a new paragraph. Following these changes, further deficiencies in these two articles arose and the legislation now requires a further amendment to ensure the correct provisions are in place.
28. After SI 2019/640 was laid, subsequent EU legislation, Regulation (EU) 2019/1243 further amended Article 10 and 11 of 853/2004. These changes were made whilst the UK was still part of the EU, but since the 2019 Regulations were already laid they were not captured in retained EU law. Through amendments to Regulation 11(a) of the 2019 Regulations, this SI proposes to insert the amendments made in 2019/1243 into Article 10 and Article 11 of the retained version of 853/2004 to correct this.
29. For Article 10, this would include inserting more specific areas and issues which any amendments made to Annexes II and III of 853/2004 (on the specific requirements for food of animal origin) may prescribe (e.g. providing specific hygiene requirements for premises; the rules for transport of meat whilst it is warm). Article 10 will also be amended to list the objectives of 853/2004, to ensure that any derogations from Annexes II and III which are

adopted do not affect the achievement of these objectives. The objectives were not previously listed at this point.

30. Regulation 12 of SI 2019/640 also amended Article 11 of 853/2004, which allows Ministers to prescribe specific implementing measures in relation to Annexes II and III of 853/2004. However, the EU amendments in 2019/1243 removed the reference to Annexes II and III.
31. Therefore, the current retained version of 853/2004 is more specific than the EU law at the end of the implementation period. Whilst the applicability of Article 11 in retained EU law and EU law at the end of the implementation period is the same, it is necessary to amend the retained law to reflect the status of EU law at the end of the implementation period.
32. Since both Article 10 and 11 were amended prior to the end of the implementation period, the current retained version of 853/2004 does not accurately reflect the EU law on the 31st of December 2020. This proposed amendment therefore addresses this deficiency and brings the retained version of 853/2004 in line with the status of EU law at the end of the implementation period.

Genetically Modified (GM) Food and Feed - Reinstatement of powers and extension of transitional period for 3 GMOs

33. The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (SI 2019/705) amended retained Regulation (EC) No 1829/2003 on GM food and feed. Regulation 12 and 24 of SI 2019/705 omitted Article 8(6) and Article 20(6) of Regulation (EC) 1829/2003. These Articles contained powers to set limited time periods for existing stocks of GM food and feed products which have been withdrawn from the market to be used up and for the removal of traces of these GMOs from the food and feed chain. These powers were removed in error.
34. The omission of powers in Articles 8(6) and 20(6) from 1829/2003 has been identified as a deficiency and it is proposed that they should be reinstated. The current transitional periods for three withdrawn genetically modified organisms (GMOs, Ms1×Rf1, Ms1×Rf2 and Topas 19/2 oilseed rape) are set to expire on the 31st of December 2022. Should these transitional periods not be renewed, GM oilseed rape consignments would be required to have an absolute zero detectable presence for the three withdrawn GMOs upon sampling and detection control measures.
35. In addition to the reinstatement of powers in Articles 8(6) and 20(6) of Regulation (EC) 1829/2003, which will give Scottish Ministers (and GB Ministers for England and Wales) powers to set time periods, it is also proposed that the tolerance periods be extended for the three withdrawn GMOs for a further three years until 31 December 2025, in line with the current length of the tolerance period granted by the EU. This SI proposes using powers under the European Union Withdrawal Act to reinstate Articles 8(6) and 20(6) of Regulation (EC) 1829/2003 and extend the tolerance periods for the three withdrawn GMOs so as to align with EU decisions.

36. This SI also proposes to make a consequential minor amendment to the date in Article 2(b) of retained Commission Regulation (EU) No 619/2011. This minor amendment to 619/2011 is to ensure there is alignment with the proposed extension of the tolerance periods, thereby ensuring 619/2011 can operate effectively. Amendments will also be made to retained Commission Decisions 2007/305/EC, 2007/306/EC, 2007/307/EC extending the transitional periods for the three withdrawn GMOs. This is to reflect the extension of the tolerance period to 31 December 2025.

Does the SI relate to a common framework or other scheme?

37. These policy areas are included in the common framework relating to food and feed safety and hygiene. In line with the framework, officials from Food Standards Scotland and the Food Standards Agency have discussed the proposed amendments and agreed the approach to seek consent from Scottish Ministers as appropriate.

Summary of stakeholder engagement/consultation

38. Consultation has been carried out for the GB amendments in this proposed SI. Some of these amendments are covered by previous consultations carried out on EU exit amendments.

39. Consultations were carried out in 2018 and 2020 on the proposed approach to retained EU law for food and feed safety and hygiene and amendments to UK food and feed regulations. The 2018 consultation can be viewed at <https://www.food.gov.uk/news-alerts/consultations/proposed-approach-to-retained-eu-law-for-food-and-feed-safety-and-hygiene> and the 2020 consultation can be viewed at <https://www.food.gov.uk/news-alerts/consultations/amendments-to-retained-eu-law-for-food-and-feed-safety-and-hygiene-for-the-end-of-the-transition-period>

40. The two consultations demonstrated significant support for the proposed approach to amendments to retained EU Law for food and feed safety and hygiene.

41. The following amendments were not covered by previous consultations and therefore separate consultations have been undertaken or are planned:

- The consultation on the GB-specific transitional period for edible insects received 315 responses, however only 64 of these provided substantive comments relevant to the consultation questions. The industry expressed a range of views, with the majority supportive of the provision of a GB specific transitional measure.
- Some stakeholders expressed concerns on safety and clear labelling for consumer choice and potential allergens. These are factors which will be considered as part of the process for considering applications for novel food authorisation which is necessary for these products to remain on the market beyond the transitional period. FSS and FSA have undertaken a rapid risk assessment which considers potential food safety concerns during the transition period. Replies to these specific points are still being prepared.
- The consultation on the removal of the requirement to use the 'Do Not Eat' symbol on active and intelligent materials received 3 responses. 2 responses agreed with the proposed approach to remove the requirement. 1 respondent highlighted that organisations and charities representing

individuals which may need clear pictograms, such as those with Alzheimer's disease, should be consulted. The consultation was sent to organisations representing individuals with visual impairment, Alzheimer's disease and learning difficulties, but no responses were received.

- The consultation on reinstating powers in GM legislation and extending transitional periods for existing stocks of now unauthorised GMOs is due to commence shortly. We can provide an update to the Committee on the outcome as soon as possible following the close of the consultation.

42. FSS highlighted these FSA-led GB wide consultations to Scottish stakeholders. FSS are not currently aware of any planned revisions to the instrument as a result of these responses.

A note of other impact assessments, (if available)

43. The FSA carried out some impact assessments for these amendments:

- The FSA has not identified any significant impact from the amendment to introduce a GB-specific transitional period for edible insects other than in relation to a negligible one-off familiarisation cost to businesses and local authorities.
- The FSA consider the level of impact of the removal of the requirement to include the 'Do Not Eat' symbol on active and intelligent materials to be extremely low. They expect a small one-off familiarisation cost to businesses and local authorities which manufacture these materials and articles.

Summary of reasons for Scottish Ministers' proposing to consent to UK Ministers legislation

44. Since all of the amendments in this proposed SI address deficiencies, inoperabilities and inconsistencies of retained EU law, which applies in Scotland and throughout GB, it is appropriate that these changes be implemented through GB-wide legislation. None of these amendments constitute policy changes, but rather correct retained EU law to operate appropriately in a GB context. Many of these amendments also address issues with how EU law was retained. Since EU law was retained and previous amendments were made through GBSIs, it is considered appropriate to do the same for these amendments. Furthermore, given the time limitations in order to make these amendments prior to the expiry of the powers required to do so under the European Union Withdrawal Act 2018 (EUWA), it is appropriate these amendments be made on a GB basis in a single instrument.

Intended laying date (if known) of instruments likely to arise

45. The SI is due to be laid under the draft affirmative procedure in the Westminster Parliament on 13 October 2022.

If the Scottish Parliament does not have 28 days to scrutinise Scottish Minister's proposal to consent, why not?

N/A

Information about any time dependency associated with the proposal

The SI is being introduced with the aim of laying on the 13th of October 2022, as this is the latest date possible for an affirmative instrument using powers under the EUWA, which expire after the 31st of December 2022.

Are there any broader governance issues in relation to this proposal, and how will these be regulated and monitored post-withdrawal?

N/A

Any significant financial implications?

N/A

SI NOTIFICATION: SUMMARY**Title of Instrument**

The Food and Feed (Miscellaneous Amendments) Regulations 2022

Proposed laying date at Westminster

13 October 2022 (draft affirmative procedure)

Date by which Committee has been asked to respond

7 October 2022 (assuming notification is sent before September 9th, this gives the Scottish Parliament the required 28 days before recess on 8 October 2022)

Power(s) under which SI is to be made

Section 8 and 8C of the European Union (Withdrawal) Act 2018.

Categorisation under SI Protocol

Type 1

Purpose

The 2022 Regulations will make numerous amendments and corrections to retained EU food and feed law in order to fix and address inoperabilities, inconsistencies and deficiencies arising from the UK's exit from the EU and the resulting retained EU law. These amendments relate to legislation on novel foods, food additives, enzymes and flavourings, genetically modified food and feed, feed additives, food contact materials and the hygiene of foodstuffs.

All of these amendments will help ensure the operability of the relevant retained EU law for GB.

Other information**SG Policy contact:**

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^[1] Animal Feed (Amendment) (EU Exit) Regulations 2019/654 Pt 3 reg. 21