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12 April 2024

Dear Finlay,

THE OFFICIAL CONTROLS (MISCELLANEOUS AMENDMENTS) REGULATIONS 2024
DEFRA PH/050/R
EU EXIT LEGISLATION – PROTOCOL WITH SCOTTISH PARLIAMENT

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 UK secondary legislation affecting devolved areas arising from EU Exit.

That protocol, as agreed between the Scottish Government and then 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 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, we are yet to have sight of the final SI and it is not yet available 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 it is in keeping with the terms of this notification.

It is regrettable that on this occasion the Scottish Government has not been able to comply with the agreed Protocol timescales. The UK Government has only recently shared a draft of this instrument and as I stated in my letter to the Committee of 10 April 2024 regarding the Official Controls (Extension of Transitional Periods) (Amendment) Regulations 2024, I can only again express my frustration with the handling of the UK Government's plans on legislation in this area. In a similar vein, whilst the timing of this notification is regrettable, I do believe the instrument is nonetheless necessary.

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

Given the extremely tight and regrettable timing as I have mentioned, I look forward to hearing from you by **Thursday 18 April 2024**.

Yours sincerely,

MAIRI GOUGEON

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NOTIFICATION TO THE SCOTTISH PARLIAMENT

The Official Controls (Miscellaneous Amendments) Regulations 2024– "Defra PH/050/R"

Is the notification Type 1 or Type 2

Type 1

A brief overview of the SI

The purpose of this instrument is to make provisions to implement the second milestone of the Border Target Operating Model (BTOM)**1**, from 30 April 2024, introducing a new global risk-based import regime for goods from both the European Union (EU) (as well as Switzerland, Norway, Iceland, Liechtenstein, Greenland and the Faroe Islands) and the rest of the world (RoW), to protect biosecurity and support trade between Great Britain (GB) and third countries. The changes made by this instrument relate to controls on imports to England, Wales and Scotland for the set of commodities known collectively as sanitary and phytosanitary (SPS) goods.

The instrument will amend assimilated law regulating the movement of animals and SPS goods into Great Britain. In so far as it applies to Scotland it will relate to devolved matters.

This instrument will see the introduction of documentary and risk-based identity and physical checks at the border on medium-risk animal products, plants, plant products and high risk food and feed of non-animal origin from EU and EEA member states (corresponding changes in respect of plant and plant products were made through PH040 which the Committee considered at its meeting on 20 March 2024). Existing inspections of high-risk plants/plant products from the EU will move from place of destination to Border Control Posts, together with the simplification of imports from Rest of the World (RoW) countries. This will include the removal of routine checks at border control posts on low-risk animal products, plants, plant products from RoW countries, and provision to amend the frequency of physical and identity check levels on medium-risk animal products from RoW countries.

This instrument concerns measures regarding SPS controls on goods entering GB directly from outside of the United Kingdom. These measures are necessary due to the UK no longer being an EU member as the UK is required to manage its own regime for imports of sanitary and phytosanitary goods to GB in a non-discriminatory manner based on scientific evidence, assessment of risk and in line with the UK's international obligations. This is done in conjunction with other UK administrations in order to avoid diversion of trade routes. The checks required on products entering GB are proportional to the risk level of those products, in line with the scientific principles we share with the EU. These measures will not create any barriers to re-entry to the European Union.

PH/050/R is made in exercise of powers contained in

- Articles 72(3), 73(2), 76(4) and 105(6) of Regulation (EU) 2016/2031 of the European Parliament and of the Council on protective measures against pests of plants (the Plant Health Regulation (PHR)); and
- Articles 22(2), 48(h), 54(3), 77(1), 90 and 144(6) of, and paragraph 3(2) of Annex 6 to, Regulation (EU) 2017/625 of the European Parliament and of the Council on official controls

1 The Border Target Operating Model: August 2023 - GOV.UK (www.gov.uk)

and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products (the Official Controls Regulation (OCR)).

PH/050/R is to be laid on 22 April 2024, and is to come into force on 30 April 2024.

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

Summary of the proposals:

PH/050/R makes the further necessary changes to SPS controls on imports from all countries into GB from 30 April 2024. It introduces a new global risk-based approach to imports of animal products, plants and plant products , with controls appropriately weighted against the risks posed both by the commodity and the country of origin.

In so far as it extends to Scotland, the SI will make the following provisions:

Amendments to the Transitional Staging Period in the OCR applying to all SPS goods

PH/050/R will amend Annex 6 to the OCR, which modifies the application of the OCR to SPS goods entering GB from EU and EEA member States and certain other countries and territories during a transitional staging period. A separate instrument (PH/055/R) notified on 10 April 2024, will extend the end date of the transitional staging period to 31 January 2025. Currently SPS goods from these countries are not required to enter Great Britain via a Border Control Post (BCP), and completion of a common health entry document (CHED) is not necessary for pre-notification of importation or to record the outcome of official controls by competent authorities. Annex 6 to the OCR is amended:

- to require that SPS goods (other than live animals) must come through a point of entry with a relevant BCP. Exceptions will be made for products arriving from the Republic of Ireland into certain west coast ports in England and Wales, and (in relation to plants and plant products) Scotland. Live animals may continue to enter GB through any point of entry.
- to require pre-notification for the importation of animals and SPS goods to be done by CHED, and to record the outcome official controls by competent authorities to give competent authorities discretion in relation to enforcement for minor and technical regulatory non-compliances which do not pose a risk to human, animal or plant health, or to the environment.

A temporary easement (three months from 30 April 2024) is introduced applicable to SPS goods now required to enter via a point of entry with a relevant BCP to allow a scanned copy of an original Export Health Certificate (EHC) or Phytosanitary Certificate (PC) to be provided in an importer's prenotification. Where a scanned copy is uploaded, the original EHC or PC must be provided to the competent authority of the border control post within 5 or 3 business days respectively of the consignment's arrival in GB.

Plant Health

- The Official Controls and Phytosanitary Conditions (Amendment) Regulations 20212 are amended to move physical and identity checks of EU goods to BCPs and Control

2 S.I. 2021/136

Points (CPs). That means that plant health import checks of EU regulated plants and plant products must be performed at designated BCPs or CPs once the Place of Destination scheme comes to an end. Trade will have to present goods for inspection at the border accordingly before they are able to move their goods to destination.

- The instrument also makes amendments to Regulation (EU) 2019/2072 (the Phytosanitary Conditions Regulation) to re-categorise certain plants and plant products according to the risk they pose to GB biosecurity, on the basis of technical assessments. Consequently, the regulatory status of some goods will be updated. This change will remove import controls on certain goods where they are judged to not be proportionate to the risk, increasing the number of commodities which do not require a phytosanitary certificate, and are not subject to any import checks. Other commodities will be subject to reduced or enhanced import checks. These are outlined in Annex 1 to this notification.

- Parallel changes are made to Annex 8 to the OCR and the Plant Health (Amendment etc.) (EU Exit) Regulations 20203 respectively to alter the list of fruit and vegetables exempt from requiring a phytosanitary certificate and pre-notification when being imported from certain countries, including the EU, Liechtenstein and Switzerland.

Amendments relating to animals products

- A partial exemption from routine official controls at border control posts is made for certain categories of animal products from risk-assessed RoW countries presenting a low or no specific risk subject to certain conditions. These are outlined in Annex 2. The importation of these low risk goods will still require to be pre-notified, and they will be required to enter through a point of entry which has a border control post designated for those goods. Intelligence-based checks on such goods may be carried out.

- Commission Implementing Regulation (EU) 2019/2129 is amended to enable the amendment of uniform frequency rates for identity and physical checks to applied to RoW animals and animal products entering GB. Where a risk assessment has been carried out the frequency rate for identity and physical checks on animal products from a country may be amended by publication of those rates online, and amended from time to time.

- Consequential and incidental amendments are made to the Trade in Animals and Related Product (Scotland) Regulations 2012 (TARP)4(and to equivalent regulations in England5and Wales)6 which provide for the enforcement and implementation of the OCR in relation to the import of animals and animal products. Schedule 5 to TARP provides for transitional modifications applicable during the transitional staging period for imports from EEA member States and certain other countries and territories. Incidental and consequential amendments are made to these provisions to reflect the changes being made to Annex 6 to the OCR. Consequential amendments are also

3 S.I. 2020/1482
4 S.S.I. 2012/177
5 S.I. 2011/1197
6 S.I. 2011/2379 (W.252))

made to TARP to reflect the partial exemption for low risk RoW goods from routine official controls at BCPs.

- Animal products can continue to arrive from Ireland via any point of entry in Wales, and in Scotland and England, either any point of entry with a Border Control Post or a named point of entry without a BCP in England. These points of entry will be listed in the SI and include all ports without a BCP on the west coast of GB through which animal products are known to be imported commercially, of which there are currently none known in Scotland.

Why the need for change
Legislative change is required to deliver the BTOM for both relevant countries and RoW countries, and to make the necessary changes to SPS controls on imports from all countries, including the EU, into GB.
Other information

This SI does not transfer any legislative functions.

The World Trade Organization (WTO) has been notified of these provisions.

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

Provisional Plant Health Framework
Provisional Animal Health and Welfare Framework

Summary of stakeholder engagement/consultation

In accordance with Article 144(7) of the OCR, Defra carried out a short targeted stakeholder engagement, on behalf of all GB administrations, over a 12 day period over March – April 2024, providing a summary of the changes to be made by this instrument and inviting views on the proposed amendments. This engagement was targeted at key stakeholders in the SPS sector, including representative trade and industry organisations, interest groups and Port Health Authorities. Over 300 organisations and individuals from these groups were asked for feedback on the proposed legislative changes.

Eight responses were received in response to this engagement, with two responses relating to the extension of the TSP, which since the engagement period, is being legislated for in a separate instrument (Defra PH/055/R).

Stakeholders' comments were focused on seeking clarity on the implementation of the SI, for example, on how the regime will be enforced from 30 April 2024. We understand that detail on check rates for commodities assessed as medium-risk under the BTOM will be published on gov.uk, and details of the Common User Charge at Sevington, about which information was also requested, have now been published. No objections were raised to the principle of proceeding with this SI, which is integral to protecting GB's biosecurity and delivering the policy design described in the published BTOM.

Separate stakeholder engagement was held for six weeks from January 2024 on the proposal to re-categorise certain plants and plant products according to the risk they pose to GB biosecurity. This engagement was published on the Plant Health Portal and circulated to stakeholders in the Plant Health Advisory Forum. PHAF members include the Fresh Produce Consortium, Horticultural Trades Association (HTA) as well as Scottish Stakeholders, including National Farmers Union for Scotland (NFUS). 4 responses were

received from stakeholders, and a full summary of these responses and the UK Government's response to these will be published on the Plant Health Portal.

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

The SI takes account of devolved competence. Since 1 January 2021, GB has operated its own SPS regime, which is focused on addressing the risks it faces. This regime is the second phase of BTOM that facilitates the processes for the import of live animals, germinal products, animal products, plants and plant products and other relevant goods entering GB from a third country.

Scottish Ministers consider that consenting to PH/050/R is the only effective way to introduce the objectives as set out in BTOM. It provides certainty to Scottish importers that there is to be a GB-wide approach.

A note of other impact assessments, (if available)

Defra has prepared a full Impact Assessment which will be published on the legislation.gov.uk website. The impact on business, charities and voluntary bodies is additional costs on importing SPS goods. All businesses, charities and voluntary bodies importing goods from the EU and certain other countries will now need to comply with certain import requirements which applied to all existing third countries.

The legislation does impact small or micro businesses.

No specific action is proposed to exempt regulatory burdens on small or micro businesses. The basis for this is that amendments apply equally to all businesses importing animal and plant goods. There is no exemption for small or micro businesses, given the importance of protecting biosecurity through the actions of all businesses, regardless of their size.

The impact on the public sector will relate to delivery of SPS controls, i.e., increased or changed activity for local authorities and others with regulatory responsibility for carrying out controls. However, regulatory authorities will deliver the import controls regime under a cost recovery model so the net effect on the public sector is thought to be small.

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

PH/050/R will be made using the negative procedure and it is intended to be made on 22 April 2024 and will come into force on 30 April 2024.

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

As is the case with the parallel instrument PH/055/R the UK Government's original intention was to lay an SI in early April but this has been regrettably delayed due to complexities associated with the SI together with late changes required to the instrument bringing forward the next phase of the published Border Target Operating Model from 30 April 2024. Whilst the Scottish Parliament is unfortunately not being afforded 28 days to scrutinise the instrument it should also be highlighted that with the instrument scheduled to

be laid in the UK Parliament on 22 April 2024, and coming into force on 30 April 2024, the 21 day rule at Westminster will be similarly breached.

Information about any time dependency associated with the proposal.

N/A

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

None.

Any significant financial implications?

As mentioned previously, the impact on business, charities and voluntary bodies is additional costs on importing SPS goods. All businesses, charities and voluntary bodies importing goods from the EU and certain other countries will now need to comply with certain import requirements which applied to all existing third countries.

Annex 1

Outcome of review of Annex 11 goods

- Higher risk goods (e.g., spinach), or goods from a certain region, will move from Part B to Part A of Annex 11 so they are subject to a higher level of checks on import into GB.
- Low-risk goods (e.g., plums, cherries from certain regions) will move from Part A to Part B of Annex 11 meaning that these goods will be subject to a lower level of checks on import into GB, though still require a phytosanitary certificate.
- Goods of negligible risk to GB (e.g., fresh coffee berries, papaya) will move from Part A to Part C of Annex 11; items listed in Part C do not require phytosanitary certificates to enter GB and do not require phytosanitary inspection.

Commodity	**Original Annex 11 categorisation**	**Outcome after evaluation**
Papaya (*Carica papaya*) from all countries	Annex 11A	Annex 11C
Black-, white- or redcurrants and gooseberries (fruit of any *Ribes* species) from all countries (other than North and Central America*)	Annex 11A	Annex 11C
Syzygium fruit from all countries	Annex 11A	Annex 11C
Cherries, apricots, peaches, plums etc. (fruit of any *Prunus* species) from the EU and other mainland European countries**	Annex 11A	Annex 11B
Quinces (*Cydonia*) from all countries (other than North America) ***	Annex 11A	Annex 11B
Cucumbers (*Cucumis sativus*) from mainland European countries (other than Turkey) ****	Annex 11B	Annex 11C
Coffee berries (*Coffea*) from all countries	Annex 11B	Annex 11C
Olives (*Olea europea*) from all countries	Annex 11B	Annex 11C
Hops cones (*Humulus*) from all countries	Annex 11B	Annex 11C

Chicory, above ground parts, (*Cichorium*) from all countries	Annex 11B	Annex 11C
Capers and caper berries (*Capparis spinosa*) from all countries	Annex 11B	Annex 11C
Juniper berries (*Juniperus*) from all countries	Annex 11B	Annex 11C
Globe artichoke (*Cynara cardunculus*) from all countries	Annex 11B	Annex 11C
Fennel (*Foeniculum vulgare*) from all countries	Annex 11B	Annex 11C
All Annex 11 part B plants [1] from the EU, Switzerland and Liechtenstein other than: cherries, apricots, peaches, plums, quinces etc. (fruit of any *Prunus* or *Cydonia* species)	Annex 11B	Annex 11C
Spinach leaves (*Spinacia oleracea*) from all countries	Annex 11B	Annex 11A
Parts of plants (other than fruits and seeds) of *Ipomoea a*nd Solanaceae species from all countries (other than from Americas, Australia and New Zealand*****, and of tomato (*Solanum lycopersicum*) and aubergine (*S. melongena*) from all countries, as these are already medium risk)	Annex 11B	Annex 11A

**Ribes* species from all countries of North and Central America remain Annex 11A
***Prunus* species from non-European countries remain Annex 11A
****Cydonia* from North America remain Annex 11A
***** Cucumis sativus* non-European countries and Turkey remain Annex 11A
****** Ipomoea a*nd Solanaceae species from all countries from Americas, Australia and New Zealand remain Annex 11A

Annex 2

Categories of goods posing a low risk exempted from routine checks at border control posts

Table 1

Animal by-products and derived products

Product	***Intended use of the product in Great Britain***	***Additional conditions and permitted countries***
Apiculture by-products	For use other than in apiculture	Must meet the requirements in entry 10 of Table 2 (apiculture by-products) in Section 1 of Chapter 2 of Annex 14 to Regulation 142/2011.
Collagen	Other than as feed material	The product must— (a) be derived from animals born, continuously reared and slaughtered in permitted countries where the BSE risk is negligible or controlled(**7**); and (b) come from a country which is listed either in the column headed "third countries' lists" in the appropriate row of Table 1 in Chapter 1, section 1 of Annex 14 to Regulation 142/2011, or as referred to in that column.
Dicalcium phosphate	Other than as feed material	The product must— (a) be derived from animals born, continuously reared and slaughtered in permitted countries where the BSE risk is negligible or controlled; and (b) come from a country which is listed either in the column headed "third countries' lists" in the appropriate row of Table 1 in section 1 of Chapter 1 of Annex 14 to Regulation 142/2011, or as referred to in that column.
Fish oil	Other than as feed material	The product must come from a country listed— (a) in the column headed "third countries' lists" in the appropriate row of Table 1 in

(7) In Table 1, the reference to a country's BSE status is to the status of a country determined in accordance with Article 5 of Regulation 999/2001 of the European Parliament and the Council, laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies. Details of each country's BSE status are included in the document entitled "Bovine Spongiform Encephalopathy (BSE) risk status of trading partners", published by the Secretary of State on 10th February 2023 in accordance with Article 5(7B) of that Regulation. This document can be found at. bse.pdf (amazonaws.com).

		Chapter 1, section 1 of Annex 14 to Regulation 142/2011; or (b) under legislation or lists as referred to in that column.
Gelatine, other than photogelatine	Other than as feed material	The product must— (a) be derived from animals born, continuously reared and slaughtered in permitted countries where the BSE risk is negligible or controlled; and (b) come from a country which is listed either in the column headed "third countries' lists" in the appropriate row of Table 1 in Chapter 1, section 1 of Annex 14 to Regulation 142/2011, or as referred to in that column.
Highly processed derived products from animal by-products in a category specified in Chapter 1, section 1, Table 1 or in Chapter 2, section 1, Table 2 of Annex 1 to Regulation 142/2011	For use as laboratory reagents and pharmaceutical use, including in the manufacture of pharmaceuticals and laboratory reagents	The product must— (a) meet the specific import requirements which apply under Annex 14 to Regulation 142/2011 to the category of animal by-product from which the highly processed product was derived; (b) have undergone processing which ensures that it does not carry any risk of transmission of a disease communicable to humans or animals; and (c) cannot be returned to its original structure or composition.
Hydrolysed protein	Other than as feed material	The product must— (a) be derived from animals born, continuously reared and slaughtered in permitted countries where the BSE risk is negligible or controlled; and (b) come from a country which— (i) is listed either in the column headed "third countries' lists" in the appropriate row of Table 1 in Chapter 1, section 1 of Annex 14 to Regulation 142/2011, or as referred to in that column; and (ii) is not South Africa, India or Uruguay.
Intermediate products	Use as specified in paragraph 35 of Annex 1 to Regulation 142/2011	Must have undergone processing which ensures that the product— (a) carries no risk of transmission of a disease communicable to humans or animals; and

		(b) cannot be returned to its original structure or composition. Must come from a third country listed as a member of the World Organisation for Animal Health(**8**). Must meet the requirements of Annex 12 to Regulation 142/2011 other than— (a) paragraph 3 of that Annex, insofar as it relates to the requirement for checking at a border control post; and (b) paragraph 5 of that Annex.
Treated blood products, other than from equidae	Other than as feed material; for in-vitro use only, for the manufacture of derived products for uses outside the feed chain for farmed animals	Must— (a) meet the requirements specified in entry 2 of Table 2, in Section 1 of Chapter 2 of Annex 14 to Regulation 142/2011; and (b) must be derived from animals born, continuously reared and slaughtered in permitted countries where the BSE risk is negligible or controlled. Excludes— (a) blood derived from bovine or ovine animals in South Africa; (b) blood derived from poultry in Canada or the USA; (c) blood derived from mixed species in Brazil, Israel, South Africa, Thailand or the USA; (d) blood derived from aquatic species in Israel, South Africa, South Korea, Uruguay or the USA.
Treated feathers, parts of feathers and down	Other than as feed material	Must meet the requirements in entry 9 of Table 2 (treated feathers) in Section 1 of Chapter 2 of Annex 14 to Regulation 142/2011.
Treated milk and milk-based products and treated blood products	For use only as a stabiliser or carrier for materials specified in note 1	Must meet the requirements specified— (a) for treated milk and milk-based products, in entry 4 of Table 1 in Section 1 of Chapter 1 of Annex 14 to Regulation 142/2011; or (b) for treated blood products— (i) in entry 2 of Table 2 in Section 1 of Chapter 2 of Annex 14 to Regulation 142/2011; or (ii) in entry 3 of Table 2 in Section 1 of Chapter 2 of Annex 14 to Regulation 142/2011 and have been

(**8**) A list of members can be found on the website of the World Organisation for Animal Health at Members - WOAH - World Organisation for Animal Health.

		treated in accordance with the requirements in point 2(b)(ii) of Chapter 4 of Annex 13 to Regulation 142/2011. The animal by-product used as the stabiliser or carrier is at a concentration of either — (a) 3% or less of the entire product, with no limit on the individual unit size; or (b) a percentage greater than 3% but no more than 10% of the entire product, with a maximum individual unit size of 100 ml. The animal by-product used as the carrier or stabiliser is— (a) intended for laboratory or pharmaceutical use only; and (b) not for any subsequent use other than as a carrier or stabiliser. Must come from a country listed for the relevant category of product in the column headed "Third countries' lists"— (a) for treated milk and milk-based products, in entry 4 of Table 1 in Section 1 of Chapter 1 of Annex 14 to Regulation 142/2011; and (b) for treated blood products, in entry 2 of Table 2 in Section 1 of Chapter 2 of Annex 14 to Regulation 142/2011.

(1) Product is intended to be used as a stabiliser or carrier for any of—

(a) monoclonal antibodies, polyclonal antibodies, proteins, enzymes, peptides and polypeptides separated from plasma or serum and purified to the extent that they do not contain any viable pathogenic micro-organisms;

(b) cells which do not contain a pathogen;

(c) cell cultures which are more than one generation removed from tissue harvested from an animal;

(d) stem cells derived from animals born and reared exclusively in a laboratory environment; and

(e) material other than animal by-products or derived products.

Table 2

Low risk products of animal origin from permitted countries

1. Commodity	*2. Conditions for inclusion in low risk category*	*3. Comments*
Apiculture products for human consumption	Low risk for Argentina, Australia, Brazil, Canada, Chile, India, New Zealand, Ukraine, United States, Uruguay and Vietnam.	Must come from a country— (a) listed in the Annex to Decision 2011/163; and (b) specified as approved for inclusion in a document published by the Secretary of State in accordance with Article 17 of Regulation 2019/626.
Bovine meat and meat products	Low risk for chilled or fresh meat and meat products from New Zealand. As regards New Zealand and any other permitted country which has a negligible or controlled BSE status: low risk if shelf stable at ambient temperature and sterilised.	Fresh meat and meat used to make meat products must — (a) meet the requirements for fresh meat in Regulation 206/2010; and (b) come from a country listed in Annex 1 of to Regulation 206/2010 and specified in a document published by the Secretary of State for the purposes of Article 3a of that Regulation. Bovine meat products must— (a) meet the requirements of, Decision 2007/777; (b) come from a country or part of a country listed in Annex 2 to Decision 2007/777 and specified in a document published by the Secretary of State in accordance with the requirements of Article 3(a) and (b) (for imports) or 5(1)(a) (for goods in transit) of that Decision; (c) meet the relevant requirements in Regulation 999/2001; and (d) not include specified risk material.

		Fresh meat and meat products must meet the relevant requirements of Regulation 853/2004.
Composite products, other than those containing bivalve molluscs, echinoderms, tunicates or marine gastropods or their products.	As regards all permitted countries, low risk if shelf stable at ambient temperature and sterilised.	Composite products (other than those otherwise exempted from official controls under Article 6 of Decision 2007/275, or by listing in accordance with Article 3(1)(b) of Decision 2007/275) must— (e) so far as concerns any milk or dairy products they contain, come from a country listed by the Secretary of State in accordance with Article 3 or 4 of Regulation 605/2010(**9**); (f) so far as concerns any bovine meat or meat products they contain, come from a country with negligible or controlled BSE status.
Dairy products and colostrum-based products which are preserved at frozen or chilled temperatures	Low risk for Canada and New Zealand only. Products must only contain milk which has been subject to pasteurisation or an equivalent or higher level of treatment (eg UHT processing).	Products must meet the requirements of Regulations 605/2010 and 853/2004 and of any assimilated direct minor legislation or regulations made under those Regulations.
Dairy products and colostrum-based products (other than those preserved at frozen or chilled temperatures).	Low risk for Canada and New Zealand if shelf-stable at ambient temperature. Low risk for all permitted countries if shelf stable at ambient temperature and sterilised.	Goods in this category must— (a) meet the requirement of Article 4 of Regulation 605/2010 and of Regulation 853/2004 and any assimilated direct legislation or regulations made under those Regulations; and (b) come from a country specified in a document published by the Secretary of State in accordance with the

(**9**) Article 6(2) of Commission Decision 2007/275 refers to the countries listed in Annex 1 of Regulation 605/2010. However, Article 3 of, and Annex 1 to, Regulation 605/2010 were amended by S.I. 2022/735 to require such of those countries or parts of countries listed in Annex 1 from which milk, dairy products, colostrum and colostrum-based products are to be authorised by the appropriate authority for importation to be specified in a document published by the Secretary of State.

		requirements of Article 3 of Regulation 605/2010.
Egg products	Low risk for the USA if shelf-stable at ambient temperature.	Goods in this category must meet the other requirements of Regulation 798/2008, Regulation 853/2004 and any assimilated direct minor legislation or regulations made under those Regulations.
Fishery products, including crustaceans	Low risk for New Zealand, except for species of the families of *Scombridae, Clupeidae, Engraulidae, Corfenidae, Pomatomidae* or *Scombresosidae* ("histamine susceptible species"), except for fishery products from aquaculture. Low risk, with the exception of histamine susceptible species, bivalve molluscs, echinoderms, tunicates or marine gastropods, for all permitted countries if shelf stable at ambient temperature and sterilised	Goods in this category must meet the applicable requirements of Regulations 852/2004, 853/2004 and 1251/2008. Country of origin must be listed in Annex 2 of Regulation 2019/626. Must meet the requirements for fishery products in Regulation 2019/628.
Gelatine and collagen	Low risk for bovine products from permitted countries where the BSE risk is negligible or controlled. Low risk for non-bovine products from all permitted countries.	Must meet the applicable requirements of Regulations 852/2004 and 853/2004. Must meet the requirements of Regulation 2019/628. For gelatine and collagen derived from bovine or ovine animals— (a) must meet the requirements of Regulation 999/2001; and (b) must not include specified risk material.
Highly refined products of animal origin	Low risk for all permitted countries.	Must meet the relevant requirements of Regulation 2019/628 and Regulation 853/2004.
Honey	Low risk for Argentina, Australia, Brazil, Canada, Chile, India, New Zealand, Ukraine, United States, Uruguay and Vietnam.	Must come from a country— (a) listed in the Annex to Decision 2011/163; and

		(b) specified as approved for inclusion in a document published by the Secretary of State in accordance with Article 17 of Regulation 2019/626.
Milk	Low risk for all permitted countries if shelf stable at ambient temperature and sterilised.	Goods in this category must— (a) be authorised by the Secretary of State to be imported into Great Britain, from a third country listed in Annex 1 to Regulation 605/2010, and specified in a document in accordance with the requirements of Article 2 of that Regulation; and (b) meet the other requirements of Regulation 605/2010, Regulation 853/2004 and any assimilated direct minor legislation or regulations made under those Regulations.
Ovine, caprine and camelid meat and meat products	Low for fresh meat and meat products from Australia. Low risk for all permitted countries if shelf stable at ambient temperature and sterilised.	Fresh meat or meat products in this category imported from Australia must meet the requirements applicable to fresh meat in Regulation 206/2010. For meat products which are shelf stable at ambient temperature— (a) must come from a country or part of a country listed in Annex 2 to Decision 2007/777 and specified in a document published by the Secretary of State in accordance with the requirements of Articles 3(a) and (b) (for imports) or 5(1)(a) (for goods in transit) of Decision 2007/777(**10**);

(**10**) Article 5 of Decision 2007/777 was amended by S.I. 2020/1462 and 2022/735.

		(b) for ovine and caprine animals, must meet the requirements of Regulation 999/2001; and (c) must not include specified risk material.
Porcine meat and meat products	Low risk for all permitted countries if shelf stable at ambient temperature and sterilised.	Must meet the requirements of Regulation 853/2004 and Decision 2007/777, and of any applicable assimilated direct minor legislation or regulations made under Regulation 853/2004.
Poultry meat and poultry meat products	Low risk for all permitted countries if shelf stable at ambient temperature and sterilised.	Must— (a) meet the applicable requirements of Regulations 853/2004, Regulation 798/2008 and Decision 2007/777, and of any applicable assimilated direct minor legislation or regulations made under Regulation 853/2004; and (b) come from a country or territory listed in Annex 1 to Regulation 798/2008 and specified in a document published by the Secretary of State in accordance with Article 3 of Regulation 798/2008. Poultry meat products must not originate in China or Thailand.
Rabbit meat, game meat and rabbit and game meat products	Low risk for all permitted countries if shelf stable at ambient temperature and sterilised.	Must meet the requirements of Regulations 853/2004 and Decision 2007/777, and of any applicable assimilated direct minor legislation or regulations made under Regulation 853/2004. Must— (a) come from a country listed in Part 1 of Annex 1 to Regulation 119/2009 and specified in a document published by the Secretary of State for

		the purposes of Article 3 of Regulation 119/2009; and (b) meet the relevant requirements in Regulation 119/2009.
Rendered animal fat and greaves	Low risk for bovine products from permitted countries where the BSE risk is negligible or controlled. Low risk for non-bovine products from all permitted countries.	Must— (a) meet the requirements of Regulations 852/2004 and 853/2004 and of any applicable assimilated direct minor legislation or regulations made under those instruments; and (b) for products derived from bovine, ovine or caprine animals, meet the relevant requirements in Regulation 999/2001; and not include specified risk material.
Soliped meat and meat products	Low risk for all permitted countries if shelf stable at ambient temperature and sterilised	Must— (a) meet the requirements of—Regulation 853/2004 and any instruments made under that Regulation; (b) for meat products, meet the requirements of Decision 2007/777; (c) come from a country or part of a country listed in Annex 2 to Decision 2007/777; and (d) come from a country or part of a country specified in a document published by the Secretary of State in accordance with the requirements of Articles 3(a) and (b) (for imports) or 5(1)(a) (for goods in transit) of Decision 2007/777.

Table 3

Permitted countries

Country or region
Argentina
Australia
Botswana
Brazil
Canada
Chile
China
Ecuador
India
Israel
Japan
Namibia
New Zealand
Nicaragua
Singapore
South Africa
South Korea
Thailand
Turkey
Ukraine
United States
Uruguay
Vietnam

SI NOTIFICATION: SUMMARY

Title:

The Official Controls (Miscellaneous Amendments) Regulations 2024 – "Defra PH/050/R"

Proposed laying date at Westminster:

22 April 2024

Date by which Committee is to respond:

By 18 April 2024 at the latest.

Power(s) under which SI is to be made:

This SI is subject to negative procedure and is made in exercise of powers contained in

- Articles 72(3), 73(2), 76(4) and 105(6) of Regulation (EU) 2016/2031 of the European Parliament and of the Council on protective measures against pests of plants (the Plant Health Regulation (PHR)); and
- Articles 22(2), 48(h), 54(3), 77(1), 90 and 144(6) of, and paragraph 3(2) of Annex 6 to, Regulation (EU) 2017/625 of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products (the Official Controls Regulation (OCR)).

Categorisation under SI Protocol:

Type 1

Purpose:

Defra PH/050/R makes provisions to implement the second milestone of the Border Target Operating Model (BTOM)**11**, from 30 April 2024, introducing a new global risk-based import regime for goods from both the European Union (EU) (as well as Switzerland, Norway, Iceland, Liechtenstein, Greenland and the Faroe Islands) and the rest of the world (RoW), to protect biosecurity and support trade between Great Britain (GB) and third countries. The changes made by this instrument relate to controls on imports to England, Wales and Scotland for the set of commodities known collectively as sanitary and phytosanitary (SPS) goods.

The instrument will amend assimilated law regulating the movement of animals and SPS goods into Great Britain. In so far as it applies to Scotland it will relate to devolved matters.

Other information

The instrument is linked with the Plant Health (Fees) (England) and Official Controls (Frequency of Checks) Amendments Regulations 2024**12** "Defra PH/040", which ensured appropriate checks for medium-risk plants and plant products from the EU, Liechtenstein and Switzerland are taken at the appropriate level. The Rural Affairs and Islands Committee provided formal consent to proceed

11 The Border Target Operating Model: August 2023
12 The Plant Health (Fees) (England) and Official Controls (Frequency of Checks) (Amendment) Regulations 2024

with the UK SI at its meeting on Wednesday 28 February 2024. The Scottish Parliament RAI Committee has provided formal consent to proceed with the UK SI at its meeting on Wednesday, 28 February 2024.

It is also linked with the Official Controls (Extension of Transitional Periods) (Amendment) Regulations 2024 “Defra PH/055” which **extends the transitional staging period from 29 April to 31 January 2025 and are necessary in order to bring in the second phase of BTOM controls. The notification for this instrument was submitted to the Scottish Parliament by the Cabinet Secretary for Rural Affairs, Land Reform and Islands on 10 April 2024.**

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