Ministear airson Slàinte Phoblach is Slàinte Bhoireannach
Jenni Minto BPA

Minister for Public Health and Women's Health
Jenni Minto MSP

T: 0300 244 4000

E: scottish.ministers@gov.scot

Scottish Government
Riaghaltas na h-Alba
gov.scot

Clare Haughey (MSP)
Convener of Health, Social Care and Sport Committee,
Scottish Parliament
Edinburgh
EH99 1SP

hscs.committee@parliament.scot

19 March 2024

Dear Clare,

THE HEALTH CLAIMS (REVOCATION) REGULATIONS 2024

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 the Parliament, accompanied the letter from the 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 2** 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 that while we have had sight of the final draft SI, it is not 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.

Grateful if the Committee could note the notification accompanying this letter.

Yours sincerely,

Jenni Minto MSP

Cc: DPLR.Committee@parliament.scot

ANNEX C

NOTIFICATION TO THE SCOTTISH PARLIAMENT

Name of the SI(s)

The Health Claims (Revocation) Regulations 2024

Is the notification Type 1 or Type 2

This is a **type 2 notification** as no new laws are being proposed, and the proposed revocations are considered to have no impact on Scottish laws.

Brief description

- The UK Government is proposing to revoke 60 obsolete instruments of secondary assimilated law (as defined in section 21(1) of the Retained EU Law (Revocation and Reform) Act 2023 (c.28)) ("the REUL Act") for Great Britain.

- The instruments being revoked by these Regulations, have no ongoing legal purpose, as the health claims which they authorised or rejected have already taken effect in law. The permitted health claims are listed in the Annex to Regulation 432/2012.

- These revocations will have no impact on Scottish Law, nor on the Scotland's robust standards in this regard.

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

- Ministers are being asked for consent to the revocation of this assimilated direct legislation on a GB wide basis, using secondary legislation made under powers in the REUL Act.

Summary of the proposals

- These Regulations revoke 60 instruments of secondary assimilated law (as defined in section 21(1) of the REUL Act for Great Britain. The proposed regulations revoke 60 instruments of direct assimilated legislation extending across Great Britain.

- The instruments revoked by the proposed regulations authorised the use of, or refused authorisation for the use of, health claims in respect of food. They were made by the European Commission prior to the UK's exit from the EU and became part of domestic law by virtue of section 3 of the European Union (Withdrawal) Act 2018 (c.16) ("EUWA").

- Where a health claim was approved by the European Commission, it was added to the list of permitted health claims in the Annex of Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing that list of health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health ("Regulation 432/2012"). Regulation 432/2012 was also incorporated into domestic law by section 3 of EUWA and became known as "assimilated direct legislation".

- The instruments revoked by the proposed regulations, therefore, have no ongoing legal purpose, as the health claims which they authorised are included in list of permitted health claims in the Annex to Regulation 432/2012.

- Department of Health and Social Care officials have shared the draft Statutory Instrument (SI), of which a list of the proposed nutrition legislation to be revoked is attached in the Annex to this notification. FSS officials have reviewed this list and are content that they reflect the discussions between officials of the UK Government, Welsh Government, FSA Northern Ireland, and FSS; and that their revocation would have no impact on Scottish Food Law.

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

- There is no impact on the UK Internal Market Act. However, this subject has been discussed extensively by officials of the 4 UK nations within the provisional common framework of the Nutrition related Labelling Composition and Standards (NLCS) policy group.

- The NLCS provisional common framework sets out arrangements for co-operation between officials in the Department for Health and Social Care (DHSC), Food Standards Scotland (FSS), Welsh Government (WG) and the Food Standards Agency (FSA) with regards to nutrition related labelling, composition, and standards (NLCS) policy. The framework respects: devolution settlements; established constitutional conventions and practices; and the overarching Devolution: Memorandum of Understanding as it stands (currently under review) between the UK Government, the Scottish Ministers, the Welsh Ministers and the Northern Ireland Executive.

- Officials from Northern Ireland Civil Service (NICS), including the FSA have engaged in the common frameworks process where the policy area intersects with the devolved competence of the Northern Ireland Assembly. However, during the absence of the Northern Ireland Executive, officials' input had been limited to analysis and factual responses only. We anticipate that this will change following the restoration of the Northern Ireland (NI) Executive

Government.

Nutrition and Health Claims application and the GB Register

- Nutrition and health claims refer to any claims made on food products that suggest that there could be a nutritional or health benefit to the consumer when they consume such a product. Regulation (EC) No 1924/2006 sets out the legal framework for businesses wanting to make nutrition and/or health claims on their products. This is to ensure that claims made about a product are accurate and consumers are not misled. Nutrition and health claims are required to be based on scientific evidence and may only be used in commercial communications if they have been authorised following scientific assessment of substantiating evidence.

- The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and the Nutrition (Amendment etc.) (EU Exit) Regulations 2020 amended UK legislation relating to nutrition to remedy deficiencies on EU exit and provided the legal basis to transfer responsibilities from EU organisations involved in the risk assessment and risk management processes covered by nutrition legislation to bodies in Great Britain. This means that since 1 January 2021 anyone wishing to make a new health claim on a product in GB that is not already included in the GB Nutrition and Health Claims (NHC) Register (GB Register) must submit an application to the appropriate authorities in the UK for that claim to be assessed and authorised before it can be used here.

- Approved claims are entered into the GB Register within Annex of Commission Regulation (EU) No 432/2012, after going through an application process with the UK Nutrition and Health Claims Committee (UKNHCC), and once confirmed by the relevant authorities (UK Government and Devolved Governments' Ministers). The UKNHCC, a statutory committee of independent experts established in March 2019, operates in a similar way and to similar timescales as the process used in the EU, whilst providing a specific assessment of claims for use on food intended for the GB market.

Summary of stakeholder engagement/consultation

- A 12-week consultation was conducted by the UK government between 09 August 2023 and 31 October 2023, which was developed through engagement with officials in the devolved administrations (DAs) in Scotland, Wales and Northern Ireland, and in line with the agreements set out in the NLCS common framework, to maintain a consistent and co-ordinated policy approach across the UK. This consultation was circulated widely and published on GOV.UK to seek views on the proposed changes. Feedback was sought from any person who or organisation which may be impacted by the reform proposals contained within the consultation. This England only consultation last year proposed to revoke these 60 items of REUL. FSS did not follow suit as the proposal was not considered a policy change and,

therefore, did not engage the general food law requirement to consult those affected by a change in the law.

- Of the 51 responses to this question: 42 (82%) agreed; 3 (6%) disagreed; 6 (12%) did not know. Most respondents agreed that revoking the NLCS legislation from the statute book would make it simpler to navigate for enforcement officers. Details of the consultation and the UK Government's response have been published and are available here.

A note of other impact assessments, (if available)

- A full business and regulatory impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sector is foreseen.

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

- Scottish Ministers propose to give their consent given that the authorisations have already taken effect in law, being retained in Commission Regulation No 432/2012; and their revocation would not affect Scottish Law nor Scotland's robust standards in this regard**.**

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

- June 2024

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

- N/A

UK Frameworks, the Internal Market Act 2020 and EU Alignment policy

- These matters have been considered by officials within the structures for engagement set out in the common framework for Nutrition-related Labelling and Compositional Standards (NLCS). There are no Internal Market or EU alignment issues as the legal standards that apply in this area will continue to apply after the redundant assimilated direct legislation is revoked.

- These matters are part of a GB wide scheme and process for the authorisation of health claims on foods placed on the market as set out in the common framework.

Information about any time dependency associated with the proposal

- DHSC and UK Government colleagues are looking to lay this legislation in Westminster Parliament by June 2024. Given this is a type 2 notification, it

would be helpful if the Scottish Parliament could either provide a view or indicate its intention to note this document at the earliest.

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

- None envisaged, as the proposal only revokes redundant assimilated direct legislation as regards both approved and rejected nutrition and health claims applications.

Any significant financial implications?

- None

SI NOTIFICATION: SUMMARY

Title of Instrument The Health Claims (Revocation) Regulations 2024
Proposed laying date at Westminster June 2024
Date by which Committee has been asked to respond At the earliest
Power(s) under which SI is to be made Section 14(1) of the Retained EU Law (Revocation and Reform) Act 2023.
Categorisation under SI Protocol Type 2
Purpose • Ministers are being asked to give consent to the revocation of 60 pieces of assimilated direct legislation on a GB wide basis, using secondary legislation made under powers in the Retained EU Law (Revocation and Reform) Act 2023 ("REUL Act").
Other information • This subject has been discussed extensively by officials of the 4 UK nations within the provisional common framework of the Nutrition-related Labelling and Composition Standards (NLCS) policy group. • The proposed GB SI revokes the implementing legislation for decisions on 60 nutrition claims. The status of the approved claims is reflected in assimilated law by the fact they are listed in the GB Nutrition and Health Claims Register.
FSS Policy contact: Chika Edeh: chika.edeh@fss.scot

ANNEX- PROPOSED LEGISLATION FOR REVOCATION

SCHEDULE

Enactments revoked

1. Commission Decision of 17 December 2009 authorising a health claim on the effect of water-soluble tomato concentrate on platelet aggregation and granting the protection of proprietary data under Regulation (EC) No. 1924/2006 of the European Parliament and of the Council (2009/980/EU)(a).

2. Commission Regulation (EC) No. 984/2009 of 21 October 2009 refusing to authorise certain health claims made on food, other than those referring to the reduction of disease risk and to children's development and health(b).

3. Commission Regulation (EC) No. 1025/2009 of 29 October 2009 refusing to authorise certain health claims made on food, other than those referring to the reduction of disease risk and to children's development and health(c).

4. Commission Regulation (EC) No. 1167/2009 of 30 November 2009 refusing to authorise certain health claims made on foods and referring to the reduction of disease risk and to children's development and health(d).

5. Commission Regulation (EC) No. 1168/2009 of 30 November 2009 refusing to authorise a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health(e).

6. Commission Regulation (EU) No. 375/2010 of 3 May 2010 refusing to authorise a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health(f).

7. Commission Regulation (EU) No 376/2010 of 3 May 2010 amending Regulation (EC) No 983/2009 on the authorisation and refusal of authorisation of certain health claims made on food and referring to the reduction of disease risk and to children's development and health(g).

8. Commission Regulation (EU) No. 382/2010 of 5 May 2010 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health(h).

9. Commission Regulation (EU) No. 383/2010 of 5 May 2010 refusing to authorise a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health(i).

10. Commission Regulation (EU) No. 958/2010 of 22 October 2010 refusing to authorise a health claim made on foods, other than those referring to the reduction of disease risk and to
to children's development and health(**j**) .

11. Commission Regulation (EU) No. 1161/2010 of 9 December 2010 refusing to authorise a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health(**a**) .

12. Commission Regulation (EU) No. 1162/2010 of 9 December 2010 refusing to authorise certain health claims made on foods and referring to the reduction of disease risk and to children's development and health(**b**) .

13. Commission Decision of 13 December 2010 amending Decision 2009/980/EU as regards the conditions of use of an authorised health claim on the effect of water-soluble tomato concentrate on platelet aggregation (2010/770/EU)(**c**) .

14. Commission Regulation (EU) No. 432/2011 of 4 May 2011 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health(**d**) .

15. Commission Regulation (EU) No. 666/2011 of 11 July 2011 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health(**e**) .

16. Commission Regulation (EU) No. 1170/2011 of 16 November 2011 refusing to authorise certain health claims made on foods and referring to the reduction of disease risk(**f**) .

17. Commission Regulation (EU) No. 1171/2011 of 16 November 2011 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health(**g**) .

18. Commission Regulation (EU) No. 378/2012 of 3 May 2012 refusing to authorise certain health claims made on foods and referring to the reduction of disease risk and to children's development and health(**h**) .

19. Commission Regulation (EU) No. 379/2012 of 3 May 2012 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health(**i**) .

20. Commission Regulation (EU) No 536/2013 of 11 June 2013 amending Regulation (EU) No 432/2012 establishing a list of permitted health claims made on foods other than those referring to the reduction of disease risk and to children's development and health(**j**) .

21. Commission Regulation (EU) No. 851/2013 of 3 September 2013 authorising certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No. 432/2012(**k**) .

22. Commission Regulation (EU) No. 1017/2013 of 23 October 2013 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health(**l**) .

23. Commission Regulation (EU) No 1018/2013 of 23 October 2013 amending Regulation (EU) No 432/2012 establishing a list of permitted health claims made on foods other than those referring to the reduction of disease risk and to children's development and health(**a**) .

24. Commission Regulation (EU) No. 1066/2013 of 30 October 2013 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health(**b**) .

25. Commission Regulation (EU) No. 40/2014 of 17 January 2014 authorising a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No. 432/2012(**c**) .

26. Commission Regulation (EU) No. 155/2014 of 19 February 2014 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health(**d**) .

27. Commission Regulation (EU) No. 175/2014 of 25 February 2014 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health(**e**) .

28. Commission Regulation (EU) No 686/2014 of 20 June 2014 amending Regulations (EC) No 983/2009 and (EU) No 384/2010 as regards the conditions of use of certain health claims related to the lowering effect of plant sterols and plant stanols on blood LDL-cholesterol(**f**) .

29. Commission Regulation (EU) No. 1154/2014 of 29 October 2014 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health(**g**) .

30. Commission Regulation (EU) No. 1229/2014 of 17 November 2014 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health(**h**) .

31. Commission Regulation (EU) 2015/7 of 6 January 2015 authorising a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No. 432/2012(**i**) .

32. Commission Regulation (EU) 2015/8 of 6 January 2015 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health(**j**) .

33. Commission Regulation (EU) 2015/391 of 9 March 2015 refusing to authorise certain health claims made on foods and referring to children's development and health(**k**) .

34. Commission Regulation (EU) 2015/402 of 11 March 2015 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health(**l**) .

35. Commission Regulation (EU) 2015/539 of 31 March 2015 authorising a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No 432/2012(**a**) .

36. Commission Regulation (EU) 2015/1041 of 30 June 2015 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health(**b**) .

37. Commission Regulation (EU) 2015/1052 of 1 July 2015 refusing to authorise certain health claims made on foods and referring to the reduction of disease risk(**c**) .

38. Commission Regulation (EU) 2015/1886 of 20 October 2015 refusing to authorise certain health claims made on foods and referring to children's development and health(**d**) .

39. Commission Regulation (EU) 2015/1898 of 21 October 2015 refusing to authorise a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health(**e**) .

40. Commission Regulation (EU) 2015/2314 of 7 December 2015 authorising a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No. 432/2012(**f**) .

41. Commission Regulation (EU) 2016/371 of 15 March 2016 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health(**g**) .

42. Commission Regulation (EU) 2016/372 of 15 March 2016 refusing to authorise a health claim made on foods and referring to the reduction of disease risk(**h**) .

43. Commission Implementing Regulation (EU) 2016/854 of 30 May 2016 authorising certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No. 432/2012(**i**) .

44. Commission Implementing Regulation (EU) 2016/862 of 31 May 2016 refusing to authorise a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health(**j**) .

45. Commission Regulation (EU) 2016/1379 of 16 August 2016 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health(**k**) .

46. Commission Regulation (EU) 2016/1381 of 16 August 2016 refusing to authorise a health claim made on foods and referring to children's development and health(**l**) .

47. Commission Regulation (EU) 2016/1390 of 17 August 2016 refusing to authorise a health claim made on foods and referring to children's development and health(**m**) .

48. Commission Regulation (EU) 2016/1411 of 24 August 2016 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health(**a**) .

49. Commission Regulation (EU) 2016/1412 of 24 August 2016 refusing to authorise a health claim made on foods and referring to the reduction of disease risk(**b**) .

50. Commission Regulation (EU) 2016/1413 of 24 August 2016 amending Regulation (EU) No 432/2012 establishing a list of permitted health claims made on foods other than those referring to the reduction of disease risk and to children's development and health(**c**) .

51. Commission Regulation (EU) 2017/236 of 10 February 2017 refusing to authorise a health claim made on foods and referring to the reduction of disease risk(**d**) .

52. Commission Implementing Regulation (EU) 2017/672 of 7 April 2017 authorising a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No. 432/2012(**e**) .

53. Commission Implementing Regulation (EU) 2017/676 of 10 April 2017 authorising a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No. 432/2012(**f**) .

54. Commission Regulation (EU) 2017/1200 of 5 July 2017 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health(**g**) .

55. Commission Regulation (EU) 2017/1201 of 5 July 2017 refusing to authorise a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health(**h**) .

56. Commission Regulation (EU) 2017/1202 of 5 July 2017 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health(**i**) .

57. Commission Regulation (EU) 2018/199 of 9 February 2018 refusing to authorise a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health(**j**) .

58. Commission Regulation (EU) 2018/1555 of 17 October 2018 refusing to authorise certain health claims made on foods and referring to the reduction of disease risk(**k**) .

59. Commission Regulation (EU) 2018/1556 of 17 October 2018 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health(**l**) .

60. Commission Regulation (EU) 2019/651 of 24 April 2019 refusing to authorise a health claim made on foods and referring to children's development and health(**a**) .