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Delegated Powers and Law Reform Committee Comataidh Cumhachdan Tiomnaichte is Ath-leasachadh Lagh

Subordinate Legislation Considered by the Delegated Powers and Law Reform Committee on 16 March 2021

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Delegated Powers and Law Reform Committee

The remit of the Delegated Powers and Law Reform Committee is to consider and report on the following (and any additional matter added under Rule 6.1.5A)—

(a) any—

(i) subordinate legislation laid before the Parliament or requiring the consent of the Parliament under section 9 of the Public Bodies Act 2011;

(ii) [deleted]

(iii) pension or grants motion as described in Rule 8.11A.1; and, in particular, to determine whether the attention of the Parliament should be drawn to any of the matters mentioned in Rule 10.3.1;

(b) proposed powers to make subordinate legislation in particular Bills or other proposed legislation;

(c) general questions relating to powers to make subordinate legislation;

(d) whether any proposed delegated powers in particular Bills or other legislation should be expressed as a power to make subordinate legislation;

(e) any failure to lay an instrument in accordance with section 28(2), 30(2) or 31 of the 2010 Act;

(f) proposed changes to the procedure to which subordinate legislation laid before the Parliament is subject;

(g) any Scottish Law Commission Bill as defined in Rule 9.17A.1; and

(h) any draft proposal for a Scottish Law Commission Bill as defined in that Rule.

(i) any Consolidation Bill as defined in Rule 9.18.1 referred to it in accordance with Rule 9.18.3.



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Introduction

1. At its meeting on 16 March 2021, the Committee considered the following instrument under its remit and agreed to draw it to the attention of the lead committee:
 - Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Amendment Regulations 2021 (SSI 2021/123).
2. The Committee's recommendations in relation to this instrument are set out in the next section of this report.
3. The Committee also determined that it did not need to draw the Parliament's attention to the instruments set out at the end of the report.

Scrutiny of instruments under the Committee's remit: instruments drawn to the attention of the lead committee

Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Amendment Regulations 2021 (SSI 2021/123)

4. This instrument lays down the compositional and labelling standards for a specific type of infant formula and follow-on formula which is manufactured from protein hydrolysates. This can be used for infants who have allergies.
5. Section 28(2) of the Interpretation and Legislative Reform (Scotland) Act 2010 requires that negative instruments are laid at least 28 days before they come into force, not counting recess periods of more than 4 days. As this instrument was made on 8 March and comes into force on 26 March 2021, it has breached this rule.
6. The Scottish Government wrote to the Presiding Officer explaining why the 28-day rule has not been complied with.
7. A copy of the correspondence can be found in the **Annex**.
8. **The Committee agrees to draw this instrument to the attention of the Parliament on reporting ground (j) in that it has been laid less than 28 days before coming into force and therefore has breached the laying requirements under section 28(2) of the Interpretation and Legislative Reform (Scotland) Act 2010.**
9. **The Committee is content with the explanation provided by the Scottish Government for failure to comply with the laying requirements.**

No points raised

COVID-19 Committee

Health Protection (Coronavirus) (Restrictions and Requirements) (Miscellaneous Amendments) (Scotland) (No. 2) Regulations 2021 (SSI 2021/117)

Health and Sport Committee

Burial and Cremation (Scotland) Act 2016 (Commencement No. 4) Regulations 2021 (SSI 2021/126 (C.10))

Justice Committee

Act of Adjournal (Criminal Procedure Rules 1996 Amendment) (Electronic Authentication) 2021 (2021/116)

Civil Litigation (Expenses and Group Proceedings) (Scotland) Act 2018 (Commencement No. 4 and Transitional Provision) Regulations 2021 (SSI 2021/125 (C.9))

Local Government and Communities Committee

Local Government Finance (Scotland) Order 2021 (SSI 2021/draft)

Non-Domestic Rates (Scotland) Act 2020 (Commencement No. 2, Transitional and Saving Provisions) Amendment Regulations 2021 (SSI 2021/120 (C.7))

Social Security Committee

Disability Assistance for Children and Young People (Consequential Amendments) (Scotland) Regulations 2021 (SSI 2021/122)

- Please note: while the Committee did not need to draw the Parliament's attention to this instrument, it welcomes the fulfilment of the commitment given by the Scottish Government to the Committee to clarify the meaning of "care home" in subordinate legislation amended by the Disability Assistance for Children and Young People (Consequential Amendment and Transitional Provision) (Scotland) Regulations 2021 (2021/73). This was considered by the Committee at its meeting on 2 March 2021.

Standards, Procedures and Public Appointments Committee

Scottish Elections (Reform) Act 2020 (Commencement No. 2 and Saving Provision) Regulations 2021 (SSI 2021/124 (C.4))

Annex

Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Amendment Regulations 2021 (SSI 2021/123)

8 March 2021, the Scottish Government wrote to the Presiding Officer

The Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) (Amendment) Regulations 2021 was made by the Scottish Ministers under Sections 6(4), 16(1)(a) and (e), 26(1) and (3) and 48 (1) of the Food Safety Act 1990.

It is being laid before the Scottish Parliament today, 8 March 2021 and comes into force on 26 March 2021.

Section 28(2) of the Interpretation and Legislative Reform (Scotland) Act 2010 sets out that a negative SSI must be laid before the Scottish Parliament at least 28 days before the instrument comes into force. On this occasion, this has not been complied with and to meet the requirements of section 31(3) of that Act, this letter explains why.

Commission Delegated Regulation 2016/127 (“the Delegated Regulation”) regulates the production of infant formula and follow-on formula. Most of the Delegated Regulation came into effect on 22 February 2020 but it was not intended to apply to infant formula or follow-on formula made from protein hydrolysates until 22 February 2021. Until that date Directive 2006/141/EC (“the Directive”) (the previous regulatory regime) was intended to apply to infant formula or follow-on formula made from protein hydrolysates.

The Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020 (“the 2020 Regulations”) provides the enforcement of the Delegated Regulation and came into force on 22 February 2020. The 2020 Regulations revoked the Infant Formula and Follow-on Formula (Scotland) Regulations 2007 (“the 2007 Regulations”). The 2007 Regulations implemented the previous regulatory regime under the Directive. However the 2007 Regulations were preserved (saved) as they applied to infant formula and follow-on formula manufactured from protein hydrolysates until 21 February 2021, again in line with the EU law.

The new requirements for infant formula and follow-on formula made from protein hydrolysates contained in the Delegated Regulation were due to apply from 21 February 2021 and the Directive was due to be fully revoked from 22 February 2021.

On the 1 February 2021 Food Standards Scotland became aware of an amendment made by the European Commission to Commission Delegated Regulation (EU) No. 2016/127, as it applies in EU law, regarding the timing of the introduction of the new composition standards for infant formula and follow-on formula made from protein hydrolysates. The amendment had the effect of delaying the application date of Commission Delegated Regulation (EU) No 2016/127 to 22 February 2022 and extending the application of the current EU law contained in Directive 2006/141/EC. This amendment to EU law is directly applicable in Northern Ireland under the Northern Ireland Protocol.

The reason for this amendment is, due to the impacts of Covid-19, the European Food Safety Authority has not been able to complete the pre-assessment work on protein hydrolysates to ensure that there is substantial evidence to demonstrate the products comply with the Regulation, i.e. that they are fit for purpose and that they are able reduce

the risk of allergies as required under EU law.

An amendment has been made to the retained EU law Commission Delegated Regulation (EU) No. 2016/127 for Scotland (as well as England and Wales) by the UK government. This amendment has been introduced via the Nutrition (Amendment) and Food for Specific Groups (Food for Special Medical Purposes for Infants, Infant Formula and Follow-on Formula) (Information and Compositional Requirements) (Amendment) Regulations 2021. This was sought to allow time for GB to work up a robust process for assessing compliance with the new regime, and to avoid an unintended divergence from Northern Ireland and to avoid an imbalance between the rules across the UK. Those Regulations also amended the English enforcement regime in line with amendments to Commission Delegated Regulation (EU) No. 2016/127. This GB Statutory Instrument amends the date in respect of the use of protein hydrolysates in infant formula and follow-on formula to 22 February 2022.

It is therefore necessary to align Scotland's enforcement regime with those across the rest of the UK and provide clarity and consistency for businesses.

In order to rectify this inadvertent divergence and minimise the period of time between the previous law, which was revoked on the 22 February 2021 and this SSI, which will reinstate the expired provisions relating to infant formula and follow-on formula manufactured from protein hydrolysates, this instrument is required to come into force on the 26 March 2021.

Unfortunately as a result of the timing and occurrence of this change by the EC, it has not been possible for us to comply with the 28 day rule. However, to allow as much Parliamentary scrutiny time as possible, the coming into force date of this instrument is 26 March 2021.

Food Standards Scotland and the Scottish Government are aware of the difficulties breaching the 28 day rule poses in terms of Parliamentary scrutiny, and regret that on this occasion, due to the timing of this change and to minimise any imbalance in regulations across the UK, it has been impossible to comply with this requirement.

