Delegated Powers and Law Reform Committee

Subordinate Legislation
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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—

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;

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

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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## Committee Membership

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<td>John Scott&lt;br&gt;Scottish Conservative and Unionist Party</td>
<td>Stuart McMillan&lt;br&gt;Scottish National Party</td>
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Introduction

1. At its meeting on 13 December 2016, the Committee agreed to draw the attention of the Parliament to the following instruments—

   Caseins and Caseinates (Scotland) Regulations 2016 (SSI 2016/383)

   National Health Service (Dietitian Supplementary Prescribers and Therapeutic Radiographer Independent Prescribers) (Miscellaneous Amendments) (Scotland) Regulations 2016 (SSI 2016/393)

2. The Committee’s recommendations in relation to the above instruments are set out below.

3. The Committee determined that it did not need to draw the Parliament’s attention to the instruments that are set out at the end of this report.

4. One of these instruments is the Human Trafficking and Exploitation (Scotland) Act 2015 (Commencement No. 2 and Transitional Provisions) Regulations 2016 (SSI 2016/385), which the Committee makes an observation on in paragraph 40 below.
Points raised: Instruments subject to negative procedure

Caseins and Caseinates (Scotland) Regulations 2016 (SSI 2016/383) (Health and Sport)

5. The main purpose of the Regulations is to transpose Directive (EU) 2015/2203 relating to caseins and caseinates intended for human consumption, and to provide powers to enforce the Regulations to food authorities across Scotland. Caseins and caseinates are proteins and salts present in milk products, used primarily in cheese making, protein supplements, formula milk and additives.

6. Regulation 4 provides for restrictions in use and marketing of edible caseins and caseinates. Regulation 5 provides for labelling requirements.

7. The Regulations revoke the Caseins and Caseinates (Scotland) Regulations 1986, as amended. They therefore consolidate and update the provisions.

8. The Regulations are subject to the negative procedure and come into force on 22 December 2016.

9. In considering the Regulations, the Committee sought an explanation in writing from the Scottish Government regarding a number of apparent drafting errors within the instrument. The correspondence is reproduced at Annexe A.

10. The Regulations contain several drafting errors, which have been acknowledged by the Scottish Government in the correspondence. The various errors identified by the Committee are set out in paragraphs 13 to 21 below. The Scottish Government as a result has undertaken to revoke the Regulations urgently, and to lay a corrective set of Regulations.

11. The Committee considers that the errors set out in paragraphs 13 to 18 below appear to be defective drafting, given that they have a potential to affect the operation of the Regulations. The error explained at paragraph 20 to 21 below is a more minor, patent error.

12. The Committee therefore draws the Regulations to the attention of the Parliament under reporting ground (i), as some provisions appear to be defectively drafted.

13. Firstly, regulation 4 contains restrictions on the marketing and use of caseins and caseinates, breach of which is an offence in accordance with regulation 7. Provisions are drafted inconsistently, as regulation 4(a) provides for alternative restrictions (“edible acid caseins, edible rennet caseins or edible caseinates”) but regulation 4(b) and (c) provides for a
conjunctive restriction (“edible acid caseins, edible rennet caseins and edible caseinates”).

14. It appears that, to specify what actions properly constitute an offence, regulation 4(a) to (c) should have been drafted in a consistent manner.

15. Secondly, regulation 4(c) appears to be defectively drafted. The provision refers to non-compliance with standards set out in points (b) and (c) of schedules 1, 2 or 3. The schedules contain numbered paragraphs and tables, so the applicable standards are not properly referred to.

16. Thirdly, regulation 5(1)(a) and (b)(ii) appear to be defectively drafted. There are similar errors in those sub-paragraphs, as they refer to the cations (processing aids or additives) listed in point (d) of schedule 3.

17. Fourthly, regulation 7 appears to be defectively drafted. Regulation 7 provides that a person is guilty of an offence if they fail to comply with any of the foregoing provisions of the Regulations. The Scottish Government has acknowledged that there is no intention to extend the offence provision in regulation 7 to the obligation of a food authority to enforce the Regulations in terms of regulation 6.

18. Fifthly, there appears to be some defective drafting in schedule 4. The schedule modifies the application of provisions of the Food Safety Act 1990, for the purposes of these Regulations. The modifications of sections 29 and 35(1) of the 1990 Act are incorrect. It appears that the two references to “regulation 9 and the schedule” of these Regulations (to be read within the 1990 Act for the purposes of these Regulations) should be references to regulation 8 and schedule 4.

19. Furthermore, the modification of section 32 is incorrect. It appears that the reference to “regulation 9” of these Regulations should be a reference to regulation 8 and schedule 4.

20. The Committee also draws the Regulations to the attention of the Parliament under the general reporting ground, as there is a more minor and patent error in the Regulations.

21. In schedule 4, in respect of the modification of section 29 of the Food Safety Act 1990, there is an incorrect citation of these Regulations as “the Caseins and Caseinates Groups (Scotland) Regulations 2016”.

22. The Committee welcomes that the Scottish Government has undertaken to revoke these Regulations and will make corrected Regulations, which would also come into force on 22 December 2016.

23. The Committee, however, also expresses its concern that an instrument of such poor quality should have been laid before the Parliament.
National Health Service (Dietitian Supplementary Prescribers and Therapeutic Radiographer Independent Prescribers) (Miscellaneous Amendments) (Scotland) Regulations 2016 (SSI 2016/393) (Health and Sport)

24. The purpose of the Regulations is to amend the National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004 (the “GMS Regulations”), the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004 (the “Section 17C Regulations”) and the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009 (the “2009 Regulations”).

25. The amendments:

- create a new category of “independent prescriber” known as a “therapeutic radiographer independent prescriber”;
- extend the definition of “supplementary prescriber” to include registered dieticians.

26. By virtue of amendments to the GMS Regulations and the Section 17C Regulations, contractors and providers (respectively) are now required to notify the Health Board when a therapeutic radiographer independent prescriber or a registered dietician starts or ceases to operate within the practice.

27. The Regulations also correct some drafting errors in both the Section 17C Regulations and the 2009 Regulations. For example, in the Section 17C Regulations, reference to a provider having arrangements in place to secure that a supplementary administrator will administer prescription-only medicine for “parental administration” is amended to refer to “parenteral administration” (i.e. medicine administered in the body other than via the mouth).

28. The Regulations are subject to the negative procedure and come into force on 31 December 2016.

29. In considering the Regulations, the Committee sought an explanation in writing from the Scottish Government regarding the clarity or otherwise of certain regulations within the instrument. The correspondence is reproduced at Annexe B.

30. Among other things, the Regulations amend the definition of “prescriber” in regulation 2(1) of both the GMS Regulations and the Section 17C Regulations. They do so by inserting a new category of “therapeutic radiographer independent prescriber” at new sub-paragraph (g). The word “and” is inserted at the end of sub-paragraph (f).

31. The Committee asked the Scottish Government to clarify whether the use of the word “and” at the end of the penultimate paragraph (g) in the definition of “prescriber” in both the GMS Regulations and the Section 17C Regulations should be a reference to “or”. This was asked on the basis that it appeared the policy
intention is that a prescriber can be any one of the types listed in sub-paragraphs (a) to (h) in the definition, rather than being required to be all of them, to fall within that definition.

32. The Scottish Government responded that it followed the approach taken already in those Regulations, which contained the word “and” at the end of sub-paragraph (e) of the definition of “prescriber”. It also considered that it would be obvious that the sub-categories in the definition would be intended to be read cumulatively and that there has been no confusion to date.

33. The Committee agrees that the potential for confusion is unlikely. However, it considers that the use of the word “and” could result in more than one possible interpretation of the provision.

34. The Committee notes that the updated definition of “prescriber” in the 2009 Regulations, inserted by regulation 9 of the Regulations, uses the word “or”.

35. The word “or” is also used in regulations 3(a) and 6(a) of the Regulations, which insert a definition of “independent prescriber” into regulation 2 of the GMS Regulations and the Section 17C Regulations, respectively.

36. Furthermore, the existing definition of “additional services” in regulation 2 of both the GMS Regulations and the Section 17C Regulations is described as meaning “one or more of” sub-paragraphs (a) to (g) and sub-paragraph (f) contains the word “and” at the end. The absence of the words “one or more of” in the definition of “prescriber” appears to be anomalous.

37. There are also examples in both the GMS Regulations and the Section 17C Regulations, such as in the definition of “independent nurse prescriber”, where the word “and” is clearly intended to be used cumulatively.

38. The Committee therefore draws the instrument to the attention of the Parliament under reporting ground (h) on the basis that the instrument could be made clearer in the following respects.

(i) In regulation 3(b)(ii), the word “or” could be used instead of “and” at the end of sub-paragraph (f) of the definition of “prescriber” in regulation 2(1) of the National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004. This would put beyond doubt that the subcategories listed in that definition are alternatives and not cumulative.

(ii) On the same basis, in regulation 6(b)(ii), the word “or” could be used instead of “and” at the end of sub-paragraph (f) of the definition of “prescriber” in regulation 2(1) of the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004.
No points raised

39. At its meeting on 13 December 2016, the Committee considered the following instruments. The Committee determined that it did not need to draw the attention of the Parliament to any of the instruments on any grounds within its remit.

**Education and Skills**

Higher Education Governance (Scotland) Act 2016 (Commencement, Transitory, Transitional and Savings Provisions) Regulations 2016 (SSI 2016/382 (C.36))

Education (Scotland) Act 2016 (Commencement No. 2) Regulations 2016 (SSI 2016/386 (C.38))

**Environment, Climate Change and Land Reform**

Tweed Regulation (Salmon Conservation) (No. 2) Order 2016 (SSI 2016/391)

Conservation of Salmon (Scotland) Amendment Regulations 2016 (SSI 2016/392)

Financial Assistance for Environmental Purposes (Scotland) Order 2016 (SSI 2016/406)

Community Empowerment (Scotland) Act 2015 (Commencement No. 5) Order 2016 (SSI 2016/394 (C.39))

**Health and Sport**

Patient Rights (Complaints Procedure and Consequential Provisions) (Scotland) Amendment Regulations 2016 (SSI 2016/401)

**Justice**

Lyon Court and Office Fees (Variation) (Devolved Functions) Order 2016 (SSI 2016/390)

Act of Sederunt (Rules of the Court of Session 1994 and Sheriff Court Rules Amendment) (No. 5) (Miscellaneous) 2016 (SSI 2016/384)

Human Trafficking and Exploitation (Scotland) Act 2015 (Commencement No. 2 and Transitional Provisions) Regulations 2016 (SSI 2016/385 (C.37))

Apologies (Scotland) Act 2016 (Commencement and Transitory Provision) Amendment Regulations 2016 (SSI 2016/395 (C.40))

40. In relation to the Human Trafficking and Exploitation (Scotland) Act 2015 (Commencement No. 2 and Transitional Provisions) Regulations 2016, the Committee welcomes that the Scottish Government provided a detailed Policy Note in response to the Committee’s questions. The Policy Note has assisted the
Committee’s subsequent scrutiny of the Regulations by clarifying the operation of regulation 3.

Local Government and Communities

Community Empowerment (Scotland) Act 2015 (Commencement No. 6) Order 2016 (SSI 2016/410 (C.41))
Annexe A

Caseins and Caseinates (Scotland) Regulations 2016 (SSI 2016/383)

On 25 November 2016, the Scottish Government was asked:

1. The first paragraph of the preamble cites, as one of the enabling powers, paragraph 1A of schedule 2 of the European Communities Act 1972. However the preamble does not add an explanation of any ambulatory reference to an EU instrument contained in the Regulations, nor does it appear that such a reference is made in the instrument.

Is there an omission to make such a reference in the Regulations and an omission in the preamble, or is the citation of paragraph 1A of schedule 2 not appropriate?

2. Regulation 4 contains restrictions on the marketing and use of caseins and caseinates, breach of which is an offence in accordance with regulation 7.

(a) Is there an error as regulation 4(a) provides for alternative restrictions (“edible acid caseins, edible rennet caseins or edible caseinates”) but regulation 4(b) and (c) provides for a conjunctive restriction (“edible acid caseins, edible rennet caseins and edible caseinates”)? Otherwise please explain why the provisions are considered to be appropriate.

(b) Supplemental to that, why does regulation 4 properly implement Articles 2 and 3 of Directive (EU) 2015/2203, given that those Articles require Member States to take the necessary steps to ensure that the caseins and caseinates defined in Article 2 are marketed or used in accordance with the rules in the Directive, and the relevant standards set out in the Annexes to the Directive? Is it agreed that the proper implementation of Articles 2 and 3 requires a consistent drafting approach in regulation 4(a) to (c)?

3. Is it agreed that there is an error in regulation 4(c), given that schedules 1 to 3 which contain the applicable standards do not contain any points (b) and (c)? What provision is intended to be referred to?

4. Is it agreed that there are similar errors in regulation 5(1)(a) and (b)(ii), which refer to the cations listed in point (d) of schedule 3? What provision is intended to be referred to?

5. Regulation 7 provides that a person is guilty of an offence if they fail to comply with any of the foregoing provisions of the Regulations.

(a) Please clarify whether it is intended to exclude from liability for the offence any food authority who fails to enforce the Regulations under regulation 6 (given that a food authority is a legal person)?

(b) Accordingly is there any error caused by extending the offence provision in regulation 7 to regulation 6? (It is noted that a contrary approach is taken in regulation 7 of SI 1986/836 which is revoked by this instrument).
6. (a) Are there errors in schedule 4 (modification of provisions of the Food Safety Act 1990), relative to the modifications of sections 29 and 35(1), as it appears that the 2 references to “regulation 9 and the schedule” of these Regulations (to be read within the 1990 Act for the purposes of these Regulations) should be references to regulation 8 and schedule 4?

(b) Similarly is there an error in schedule 4, relative to the modification of section 32, as it appears that the reference to “regulation 9” of these Regulations should be a reference to regulation 8?

(c) Is there an error in schedule 4, relative to the modification of section 29, which appears to contain an incorrect citation of these Regulations, as “the Caseins and Caseinates Groups (Scotland) Regulations 2016”?

7. Is corrective action proposed in relation to any of the queries above?

**The Scottish Government responded as follows:**

The Scottish Government regrets that there are various errors as identified above. These are the result of an error in version control which was not picked up before signing of the instrument. Steps have been taken to avoid that such an error occurring again. The Government intends to revoke SSI 2016/383 and make corrected Regulations coming into force on 22 December 2016.
Delegated Powers and Law Reform Committee
Subordinate Legislation, 15th Report, 2016 (Session 5)

Annexe B

National Health Service (Dietitian Supplementary Prescribers and Therapeutic Radiographer Independent Prescribers) (Miscellaneous Amendments) (Scotland) Regulations 2016 (SSI 2016/393)

On 1 December 2016, the Scottish Government was asked:

1. Regulation 3(a) of the Regulations inserts a definition of “independent prescriber” into regulation 2(1) of the National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004 (the “GMS Regulations”). The end of paragraph (d) contains the word “or”, on the basis that an independent prescriber can be any one of the types listed in the definition. Likewise, the word “or” is used in the definition of “prescriber” in regulation 2(1) of the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009 (as amended by regulation 9(c) of the Regulations).

By way of contrast, in regulation 3(b) of the Regulations, the word “and” is omitted from paragraph (e) of the definition of “prescriber” in regulation 2(1) the GMS Regulations and inserted at the end of paragraph (f) within that definition.

Is it intended that a “prescriber” must be all the types listed in sub-paragraphs (a) to (g) (as amended)? Alternatively, should regulation 3(b) of the Regulations omit the word “and” and insert the word “or”?

2. Does the same point apply in relation to regulation 6(b) of the Regulations as that amends the definition of “prescriber” in regulation 2 of the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004?

The Scottish Government responded as follows:

1. The Scottish Government followed the approach taken to retain consistency with the instrument being amended: the National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004 (“GMS Regulations”). The definition of “prescriber” in regulation 2(1) of the GMS Regulations, in its existing form, uses the word “and” rather than “or” following the penultimate paragraph. In contrast, the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009 (“2009 Regulations”), in its existing form, used the word “or” following the penultimate paragraph of the same definition.

The Scottish Government is not aware of any confusion arising to date, based on the existing definition of “prescriber” in the GMS Regulations.

In the Scottish Government’s view, it will be clear to those using the GMS Regulations (persons working in primary healthcare) that “prescriber” is not intended to be read cumulatively as it is virtually impossible that a single person would fall within each and every one of the listed categories of professionals.

Therefore, the Scottish Government cannot foresee confusion as to interpretation.
2. The Scottish Government followed the approach taken to retain consistency with the instrument being amended: the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004 ("S17C Regulations"). The definition of “prescriber” in regulation 2(1) of the S17C Regulations, in its existing form, uses the word “and” rather than “or” following the penultimate paragraph. In contrast, the 2009 Regulations, in its existing form, uses the word “or” following the penultimate paragraph of the same definition.

The Scottish Government is not aware of any confusion arising to date, based on the existing definition of “prescriber” in the S17C Regulations.

In the Scottish Government’s view, it will be clear to those using the S17C Regulations (persons working in primary healthcare) that “prescriber” is not intended to be read cumulatively as it is virtually impossible that a single person would fall within each and every one of the listed categories of professionals.

Therefore, the Scottish Government cannot foresee confusion as to interpretation.