The Scottish Parliament
Pàrlamaid na h-Alba

HEALTH AND SPORT COMMITTEE

AGENDA

3rd Meeting, 2019 (Session 5)

Tuesday 29 January 2019

The Committee will meet at 10.00 am in the James Clerk Maxwell Room (CR4).

1. **Subordinate legislation:** The Committee will consider the following negative instrument—

   The Foods for Specific Groups (Medical Foods) (Miscellaneous Amendments) (Scotland) Regulations 2018 (2018/392).

2. **Health and Care (Staffing) (Scotland) Bill:** The Committee will consider the Bill at Stage 2.

3. **Human Tissue (Authorisation) (Scotland) Bill (in private):** The Committee will consider a revised draft Stage 1 report.

4. **Work programme (in private):** The Committee will consider its work programme.

5. **Healthcare (International Arrangements) Bill 2017-19 (UK Parliament legislation) (in private):** The Committee will consider a second report.

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The papers for this meeting are as follows—

Agenda item 1

Note by the clerk	HS/S5/19/3/1

Agenda item 2

Health and Care (Staffing) (Scotland) Bill Marshalled List (to follow)	HS/S5/19/3/2
Health and Care (Staffing) (Scotland) Bill Groupings List (to follow)	HS/S5/19/3/3
Health and Care (Staffing) (Scotland) Bill: Bill page and associated documents	HS/S5/19/3/4

Agenda item 3

PRIVATE PAPER	HS/S5/19/3/5 (P)

Agenda item 4

Note by the clerk	HS/S5/19/3/6

Agenda item 5

PRIVATE PAPER	HS/S5/19/3/7 (P)

Health and Sport Committee

3rd Meeting, 2019 (Session 5)

Tuesday 29 January 2019

Subordinate legislation

Note by the clerk

Overview of instrument

1. There is one negative instrument for consideration at today's meeting:

    - The Foods for Specific Groups (Medical Foods) (Miscellaneous Amendments) (Scotland) Regulations 2018 (SSI 2018/392)

The Foods for Specific Groups (Medical Foods) (Miscellaneous Amendments) (Scotland) Regulations 2018

SSI 2018/392

Background:

2. These Regulations make provision to enforce, in Scotland, Commission Delegated Regulation (EU) 2016/128 supplementing Regulation (EU) 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes.
3. Commission Delegated Regulation (EU) No. 2016/128 is directly applicable in EU Member States. However, to fulfil our obligations to the EU, we need domestic legislation to enable the enforcement of and to provide penalties in the event of non-compliance with the new EU law requirements. Failure to introduce enforcement provisions for Commission Delegated Regulation (EU) No. 2016/128 could result in infraction proceedings against the UK, therefore it is necessary to ensure that the EU law requirements can be enforced in Scotland.
4. Regulation 3 restricts the application of the Foods for Special Medical Purposes (Scotland) Regulations 2000 to food for medical purposes developed to satisfy the needs of infants and, in relation to food that is labelled or placed on the market before 22 February 2019.
5. Regulation 4 amends the Foods for Specific Groups (Scotland) Regulations 2016 which enforce the provisions of Regulation (EU) 609/2013 of the European Parliament and of the Council on the provisions of food intended for infants and young children, food for special medical purposes and total diet replacement for weight control.
6. In addition, regulation 2 amends the Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997, to remove redundant text in respect of labelling requirements.
7. A full business and regulatory impact assessment (BRIA) of the effect these Regulations will have on the costs for the business sector has been prepared and placed in the Scottish Parliament Information Centre. Copies may be

obtained from Food Standards Scotland, Pilgrim House, Old Ford Road, Aberdeen, AB11 5RL. **The Policy Note and BRIA for this instrument is attached at Annex A.**

8. An electronic copy of the instrument is available at:

   http://www.legislation.gov.uk/ssi/2018/392/contents/made

9. There has been no motion to annul this instrument.

10. The Committee needs to report by 18 February 2019.

Delegated Powers and Law Reform Committee consideration

11. The Delegated Powers and Law Reform Committee considered the instrument at its meeting on 22 January 2019. The Committee agreed to draw the regulations to the attention of the Parliament on the general reporting ground, as the preamble to the instrument fails to follow proper drafting practice,

12. Further details on DPLR Committee's consideration of the instrument are contained in its 5th Report 2019 (Session 5) Subordinate Legislation considered by the Delegated Powers and Law Reform Committee on 22 January 2019. The relevant section of which is replicated at Annex B.

Annex A

POLICY NOTE

THE FOODS FOR SPECIFIC GROUPS (MEDICAL FOODS) (MISCELLANEOUS AMENDMENTS) (SCOTLAND) REGULATIONS 2018

SSI 2018/392

1. Description

The Foods for Specific Groups (Medical Foods) (Miscellaneous Amendments) (Scotland) Regulations 2018 ("the Instrument") is made by the Scottish Ministers in exercise of the powers conferred by sections 16(1), 17(1) and (2), 26(1) and (3) and 48(1) of the Food Safety Act 1990 and all other powers enabling them to do so. The Instrument is subject to the negative procedure.

2. Policy Objective

The main purpose of the Instrument is to provide enforcement powers to underpin the directly applicable Commission Delegated Regulation (EU) No. 2016/128 which lays down rules on the specific compositional and information requirements for food for special medical purposes.

3. Policy Background

Regulation (EU) No. 2016/128 is a Delegated Regulation under the Framework Regulation 609/2013 on food for specific groups and comes into force 22 February 2019, repealing and replacing Directive 1999/21/EC. It was approved on 25 September 2015 to adopt specific compositional and information requirements for food for special medical purposes, taking into account the provisions of Directive 1999/21/EC (the existing harmonised legislation on dietary foods for special medical purposes, which is implemented in Scotland by the Foods for Special Medical Purposes (Scotland) Regulations 2000). It is the first of four delegated regulations called for by Regulation (EU) No 609/2013 on foods for specific groups which was introduced to simplify existing rules covering foods for particular nutritional uses.

Commission Delegated Regulation (EU) No. 2016/128 is directly applicable in EU Member States. However, to fulfil our obligations to the EU, we need domestic legislation to enable the enforcement of and to provide penalties in the event of non-compliance with the new EU law requirements. Failure to introduce enforcement provisions for Commission Delegated Regulation (EU) No. 2016/128 could result in infraction proceedings against the UK, therefore it is necessary to ensure that the EU law requirements can be enforced in Scotland.

The Instrument amends the Food for Specific Groups (Scotland) Regulations 2016 to extend the existing enforcement provisions for Regulation (EU) No 609/2013 to include Commission Delegated Regulation (EU) 2016/128.

In addition, the Instrument amends the definition of "dietary food" in the Food for Special Medical Purposes (Scotland) Regulations 2000 to restrict the application of those Regulations to food for medical purposes developed to satisfy the needs of infants. The definition also includes food that has been placed on the market prior to

22 February 2019 and which complies with Directive 1999/21/EC in order to allow for stocks to be used until they are exhausted.

During Parliamentary scrutiny for the Foods for Specific Groups (Scotland) Regulations 2016, it was noted that references to “meal replacement for weight control” in the Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 had not been removed and that this had led to a lack of clarity. The Scottish Government agreed to remove the redundant text at the earliest available opportunity. Accordingly, all references to “meal replacement for weight control” in Regulations 2 and 3 of the Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 are omitted.

4. Consultation
A four week consultation was carried out in Scotland on a draft SSI and the supporting Business and Regulatory Impact Assessment (BRIA) from 26 September to 23 October 2018. Two responses were received from sixty-three stakeholders who received the consultation. These were received from a Local Authority Environmental Health Department and an industry body.

The Local Authority Environmental Health Department stated that there are no known manufacturers in their area that are likely to be affected by the composition and labelling requirements for foods for special medical purposes. Both respondents did not raise any concerns regarding the familiarisation costs and questions in the partial BRIA.

5. Other Administrations
The Instrument applies in relation to Scotland only and corresponding Regulations will be introduced in the other UK countries.

6. Guidance
Guidance notes for the Instrument will be prepared in due course.

7. Impact Assessment
A final BRIA has been prepared following the public consultation and accompanies this note.

8. Regulating small businesses
The Instrument will apply to manufacturers and retailers concerned with foods for special medical purposes.

9. Monitoring
Food Standards Scotland will work with Enforcement Authorities where problems or suspected infringements of the legislation arise. The effectiveness of the Instrument will be monitored via general feedback from industry and Enforcement Authorities.

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Food Standards Scotland
Inbhe Bìdh Alba

FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT

The Foods for Specific Groups (Medical Foods) (Miscellaneous Amendments) (Scotland) Regulations 2018

Date:	December 2018
Stage:	Final
Source of intervention:	EU
Type of measure:	Regulation
Contact for enquiries:	Georgina Finch 01224 288371 Georgina.Finch@fss.scot

1. Title of Proposal

1.1. The Foods for Specific Groups (Medical Foods) (Miscellaneous Amendments) (Scotland) Regulations 2018.

2. Purpose and intended effects

Objectives

2.1. The key purposes of the proposed Foods for Specific Groups (Medical Foods) (Miscellaneous Amendments) (Scotland) Regulations 2018 ("the proposed Regulations") are to:

- Enable the enforcement of and Provide penalties for non-compliance with

  The requirements of Commission Delegated Regulation (EU) No. 2016/128 (hereafter referred to as the FSMP regulation) which lays down rules on the specific compositional and information requirements for food for special medical purposes.

- Amend the Foods for Special Medical Purposes (Scotland) Regulations 2000 to restrict the application to food for medical purposes developed to satisfy the needs of infants and foods placed on the market prior to 22 February 2019.

Background

2.2. The FSMP Regulation is a Delegated Regulation under the Framework Regulation 609/2013 on food for specific groups (FSG). It was approved on 25 September 2015 to adopt specific compositional and information requirements for food for special medical purposes, taking into account the provisions of Directive 1999/21/EC (the existing harmonised legislation on dietary foods for special medical purposes, which is implemented in Scotland by the Foods for Special Medical Purposes (Scotland) Regulations 2000).

2.3. The FSG Regulation applied to all Member States from 20 July 2016 and was introduced to simplify existing rules covering foods for particular nutritional uses. It repealed Directives 2009/39/EC (on foodstuffs intended for particular uses) and 1999/21/EC and is executed and enforced in Scotland by the Foods for Specific Groups (Scotland) Regulations 2016.

2.4. The FSG Regulation defines the categories of foods classed as foods for specific groups and calls on the Commission to introduce four delegated regulations to lay down detailed rules on each of the categories. These categories are as follows:

- Infant formula and follow on formula
- Foods intended for infants and young children
- Foods for special medical purposes
- Total diet replacement for weight control

2.5. The four specific Commission Regulations have lengthy transitional arrangements, with part of FSMP regulation applying from 22 February 2019. The table below details the transitional arrangements:

Category of Food for Specific Groups	**Application date**
Food for Special Medical Purposes	22 February 2019
Food for Special Medical Purposes (for infants)	22 February 2020
Infant Formula and Follow-on Formula	22 February 2020
Infant Formula and Follow-on Formula (manufactured from protein hydrolysates)	22 February 2021
Total diet replacement for weight control	27 October 2022

- **Food for Special Medical Purposes (FSMP)**

2.6. FSMPs are developed in close cooperation with health care professionals to feed patients affected by or malnourished because of a specific diagnosed disease, disorder or medical condition that makes it impossible or very difficult for those patients to satisfy their nutritional needs through the consumption of other foods. The composition of food for special medical purposes may differ substantially depending, among others, on the specific disease, disorder or medical condition for the dietary management of which the product is intended, on the age of the patients and the place in which they receive health care support, and the products intended use. In particular, food for special medical purposes can be classified in different categories as laid out below:

- Nutritionally complete food with a standard nutrient formulation which, used in accordance with the manufacturer's instructions may constitute the sole source of nourishment for the persons for whom it is intended
- Nutritionally complete food with a nutrient-adapted formulation specific for a disease, disorder or medical condition which, used in accordance with manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom it is intended
- Nutritionally incomplete food with a standard formulation or a nutrient-adapted formulation specific for a disease, disorder or medical condition which is not suitable to be used as the sole source of nourishment

Rationale for Government intervention

2.7. The FSMP regulation is directly applicable in EU Member States. However, to fulfil our obligations to the EU, we need domestic legislation to enable the enforcement of and to provide penalties in the event of non-compliance with the new European requirements.

Failure to introduce enforcement provisions for the FSMP Regulation could result in infraction proceedings against the UK, therefore it is necessary to ensure that the EU requirements can be enforced in Scotland. The proposed Foods for Specific Groups (Medical Foods) (Miscellaneous Amendments) (Scotland) Regulations 2018 will enable the local authorities in Scotland to take action in the event of non-compliance with the specific labelling and / or composition standards for the products covered by the FSMP Regulation.

3. Consultation

Within Government

3.1. The consultation package was discussed with Scottish Government (SG) officials from Public Health, Child & Maternal Health and Food Drink & Rural Communities. FSS (and the former Food Standards Agency Scotland) also liaised with SG officials during the development of the framework EU legislation.

Public Consultation

3.2. A four week consultation was carried out in Scotland on the draft national legislation from 26 September 2018 to 23 October 2018. A total of two responses were received from sixty-three stakeholders who received the consultation.

Business

3.3. The consultation was sent to a number of trade organisations and local authorities who would have with a better understanding of the businesses in their area and requested details of any known businesses impacted by the proposed SSI. Three businesses in Scotland were identified as possible manufacturers of FSMP to whom the consultation was also sent to. The response from British Specialist Nutrition Association (BSNA) and the Local Authority Environmental Health Officer did not raise any concerns regarding the familiarisation costs and questions in the partial BRIA.

4. Options

The options considered were:

4.1. **Option 1** – **Do nothing**. This means that the directly applicable European Regulation could not be fully enforced in Scotland.

4.2. **Option 2** – Introduce legislation to provide enforcement provisions in Scotland for Commission Delegated Regulation (EU) 2016/128 which would designate enforcement by local authority enforcement officers on a risk based approach. Option 2 is the preferred approach.

Sectors and groups affected

4.3. While these proposed regulations apply to Scotland only, separate enforcement regulations will be introduced in England, Wales and Northern Ireland.

4.4. Consumers – Non-monetised benefits to consumers from the enforcement, in due course, of clear definitions, composition and labelling of food for special medical purposes.

4.5. Enforcement Authorities – enforcement of the rules on food for special medical purposes is the responsibility of Local Authority Environmental Health departments.

4.6. Businesses – Manufacturers and retailers will be the main groups affected by the Foods for Specific Groups (Medical Foods) (Miscellaneous Amendments) (Scotland) Regulations 2018.

Option Appraisal: Costs and Benefits

4.7. **Option 1** – **Do nothing**. FSMP is binding in its entirety and directly applicable in all Member States. Doing nothing would mean the FSMP Regulation will still apply but we would not have the domestic legislation to enforce it. Under EU law, the UK is obliged to provide for the enforcement of EU legislation. Failure to do so may lead to the UK being liable to infraction proceedings and consequent fines. Option 1 is therefore disregarded as an option, but it is the baseline against which other options are appraised.

4.8. **Option 2 – Make appropriate domestic regulations to provide for the enforcement of the FSMP Regulation.** There will be some familiarisation cost to industry and enforcement in ensuring compliance with the FSMP Regulation as identified below.

4.9. There will be some cost to industry and enforcement in ensuring compliance with the new EU Regulation as identified below.

Option 2 – One-off Costs to Industry

One-off familiarisation cost

4.10. This figure is calculated by firstly taking the 2017 Provisional ASHE (Annual Survey of Hours and Earnings)[1] figure for "Scotland Production managers and directors in manufacturing" £23.14 (median value) and uprating it by 30% to account for overheads, giving an hourly wage rate of £30.08. It is estimated that the reading and understanding of the FSMP Regulation will take approximately 1 hour with a further 30 minutes for dissemination to key staff within each firm (a total of 1 hour 30 minutes) at £45.12.

[1] https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/regionbyoccupation4digitsoc2010ashetable15

4.11. We were unable to source precise data to identify businesses and manufacturers of FSMP, however figures taken from the year 2017 indicate that there are approximately 5 manufacturers of "homogenised food preparations and dietetic food[2]" in Scotland[3]. FSMP is categorised in this group of enterprises which do not solely include FSMP therefore FSS encouraged manufacturers or retailers of FSMP to respond to the consultation. The responses received did not raise any concern for familiarisation costs.

4.12. Therefore, we estimate a one off familiarisation cost of £225.62 to industry.

Option 2 – Benefits to Consumers

4.13. The legislation will benefit those requiring FSMP as there will be enhanced protection by way of defined compositional standards and tighter labelling restrictions as well as the need to comply with Regulation (EU) No 1169/2011 on the provision of food information to consumers (FIC). However, FSMP lays down additions and exceptions to the general rules of FIC where required to enable appropriate use to be made of the product.

4.14. The use of nutrition and health claims to promote food for special medical purposes have been prohibited since consumers of such products are patients under medical supervision and are therefore not part of the general healthy population. Consumers will therefore not be subjected to inappropriate promotion of products via nutrition and health claims.

Option 2 – Costs to Enforcement

One-off familiarisation cost

4.15. The SSI allows for the enforcement of the new requirements which include a prohibition on nutrition and health claims as well as an amended nutrition declaration. Local Authorities would need to become familiar with the new provisions. There are 210 enforcement officers throughout the 32 local authorities in Scotland and it is our estimation that it would take one Environmental Health Officer one hour to read and become familiar with the SSI. The hourly pay rate for Qualified Environmental Health Officers is £15.29[4] – averaging approximately £19.88 per hour once uprated to account for non wage labour costs and overheads, taken as 30%. The total one-off cost is therefore estimated at approximately £4174.80.

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[2] Included in the category of "the manufacture of homogenised food preparations and dietetic food: infant formulae, follow-up milk and other follow-up foods, baby foods, low-energy and energy-reduced foods intended for weight control, dietary foods for special medical purposes, low-sodium foods, including low-sodium or sodium-free dietary salts, gluten-free foods, foods intended to meet the expenditure of intense muscular effort, especially for sportsmen, foods for persons suffering from carbohydrate metabolism disorders (diabetes)

[3] Source: Businesses in Scotland 2017, Scottish Government

[4] https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/regionbyoccupation4digitsoc2010ashetable15

5. Scottish Firms Impact Test

5.1. The consultation was circulated to Local Authority Environmental Health departments and trade bodies with a specific request to help identify manufacturers of foods for special medical purposes within Scotland. They were also requested to consider all questions posed in the partial BRIA and the cost estimates. There were no concerns raised on any aspect of the new regulations.

Competition Assessment

5.2. The proposed legislation will apply to all businesses and individuals involved in the Scottish foods for special medical purposes trade equally, allowing them to trade across EU Member States, if appropriate. It should not limit the number or range of suppliers in Scotland either directly or indirectly or reduce the ability of, or incentives to, suppliers to compete. Therefore, it is not expected to have a significant impact on competition.

Test run of business forms

5.3. No new or additional forms will be introduced by this proposal therefore no test run need be completed.

6. Legal Aid Impact Test

6.1. During the consultation period the Justice Directorate was contacted to ascertain whether the new regulations will have any legal aid implications. The Scottish Legal Aid Board confirmed that these Regulations will have no impact on the legal aid fund.

7. Enforcement, sanctions and monitoring

Enforcement

7.1. Enforcement of the regulations will be the responsibility of Local Authority Environmental Health departments. Enforcement should be risk based and proportionate, in line with the approach taken with the current Scottish legislation on medical foods. Enforcement officers would not be expected to initiate separate inspections in relation to the enforcement of these new provisions, but instead to include these as part of their existing regimes.

Sanctions

7.2. Regulation 4 of the Foods for Specific Groups (Scotland) Regulations 2016 lays down that the penalty on summary conviction for an offence under the regulations is a fine not exceeding level 5 on the standard scale.

7.3. No changes are being proposed to the criminal sanctions or civil penalties contained in existing legislation.

Monitoring

7.4. The effectiveness and impact of the regulations will be monitored via feedback from stakeholders, including Enforcement Agencies, as part of the ongoing

policy process. Food Standard Scotland's mechanisms for monitoring and review include; open fora, stakeholder meetings, surveys and general enquiries.

8. Implementation and Delivery Plan

8.1. The publication of the Foods for Specific Groups (Medical Foods) (Miscellaneous Amendments) (Scotland) Regulations 2018 will be communicated to stakeholders by means of an Interested Parties' letter. This will be done shortly after the SSI has been published on the legislation.gov.uk website.

9. Post Implementation Review

9.1. A review to establish the actual costs and benefits and the achievement of the desired effects will take place 10 years from the date the Foods for Specific Groups (Medical Foods) (Miscellaneous Amendments) (Scotland) Regulations 2018 come into force.

10. Summary and Recommendation – Summary Costs and Benefits Table Declaration

Option	Total benefit per annum: economic, environmental, social	Total cost per annum: economic, environmental, social policy and administrative
1	Do nothing therefore no cost	Possible infraction fines
2	**Industry:** Working to a consistent legal standard throughout the EU. **Consumers:** Enhanced protection by way of defined compositional standards and tighter labelling restrictions. No infraction fines due to introducing the new Scottish Statutory Instrument for the execution and enforcement of the FSMP Regulation	**Industry:** One-off familiarisation cost: £225.62 **Enforcement:** One-off familiarisation cost: £4174.80

Option 2 is considered to be the preferred option. It ensures that Scottish Ministers will meet their obligation to implement agreed EU legislation.

11. Declaration and publication

I have read the impact assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs. I am satisfied that business impact has been assessed with the support of businesses in Scotland.

Minister's signature ……JOE FITZPATRICK

Minister's title ……MINISTER FOR PUBLIC HEALTH, SPORT AND WELLBEING

Date ……

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Annex B

5TH REPORT 2019 (SESSION 5) SUBORDINATE LEGISLATION CONSIDERED BY THE DELEGATED POWERS AND LAW REFORM COMMITTEE ON 22 JANUARY 2019

THE FOODS FOR SPECIFIC GROUPS (MEDICAL FOODS) (MISCELLANEOUS AMENDMENTS) (SCOTLAND) REGULATIONS 2018

SSI 2018/392

Purpose

16. The main purpose of these Regulations is to make some technical provisions for enforcement powers, to underpin the directly applicable Commission Delegated Regulation (EU) No. 2016/128. That Regulation lays down rules on the specific compositional and information requirements for food for special medical purposes.

17. Regulation (EU) No. 2016/128 comes into force on 22 February 2019. It is the first delegated Regulation called for by Regulation (EU) 609/2013 on foods for specific groups, which was introduced to simplify existing rules covering foods for particular nutritional uses.

18. Regulation (EU) No. 2016/128 is directly applicable in EU Member States. To fulfil obligations to the EU domestic legislation is required to enable the enforcement of, and to provide penalties in the event of non-compliance with, the new EU law requirements.

19. The Regulations are subject to the negative procedure, and come into force on 22 February 2019.

Committee consideration

20. The Committee noted that the instrument fails to follow proper drafting practice as follows:

    1. The first paragraph of the preamble should have also cited the powers in section 2(2) and paragraph 1A of schedule 2 of the European Communities Act 1972, which are relied upon in part to make the instrument.

    2. A paragraph is also omitted, to explain that an ambulatory reference is made within the instrument to specified provisions of Commission Delegated Regulation (EU) 2016/128, and that it appears to the Scottish Ministers that it is expedient for the reference to those provisions to be construed as a reference to the provisions as amended from time to time.

21. These issues were raised with the Scottish Government and the correspondence is reproduced at Annex B. The omissions were acknowledged by the Scottish Government.

Recommendation

22. **The Committee draws the Regulations to the attention of the Parliament on the general reporting ground, as the preamble to the instrument fails to follow proper drafting practice.**