



## FINAL REGULATORY IMPACT ASSESSMENT

### The Caseins and Caseinates (Scotland) Regulations 2016

**Date:** 18 November 2016  
**Stage:** Final  
**Source of intervention:** EU  
**Type of measure:** Regulation  
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## 1. Title of Proposal

The Caseins and Caseinates (Scotland) Regulations 2016

## 2. Purpose and intended effect

### • Objectives

Directive (EU) 2015/2203 makes very minor adjustment to the substance of Directive 83/417/EEC which is considered to have provided effective controls for some time. It deals mainly with inter-institutional issues and brings clarity and simplification.

The changes are mostly in line with streamlining the regulatory landscape and will have very limited impact on business generally.

The purpose of the draft Scottish Statutory Instrument is to:

- (a) Transpose and
- (b) Provide penalties for non-compliance with

the requirements of Directive (EU) 2015/2203 (hereafter referred to as the CC Directive) which repeals and replaces Council Directive 83/417/EEC, which provides for the approximation of the laws of the Member States relating to certain lactoproteins (caseins and caseinates) intended for human consumption.

This is in order to:

- Take account of other legislation adopted in the meantime, notably with regard to food law;
- Align the compositional requirements of the products concerned to the relevant international standard issued by the Codex Alimentarius: and
- Update the approach used in Directive 83/417/EEC which conferred powers on the European Commission in order to implement some of its provisions.

### • Background

The CC Directive makes very minor adjustment to the substance of Directive 83/417/EEC (which it revokes) which is considered to have provided effective controls for some time.

This was necessary to take into account developments in food law, remove unnecessary provisions and update various terms and references to take into account those used in other EU legislation. It also aligns composition requirements with the international standard set by the Codex Alimentarius for the sake of consistency and to avoid trade distortions.

To fulfil our obligations to the EU, we need domestic legislation to transpose the CC Directive and to provide penalties in the event of non-compliance with the new European requirements.

Given the age of the current domestic legislation and the fact that it pre-dates devolution our preference is to revoke The Caseins and Caseinates (Scotland) Regulations 1986 and replace it with a new Scottish Statutory Instrument (SSI).

## 3. Rationale for Government intervention

Failure to transpose the CC Directive could result in infraction proceedings against the UK; therefore it is necessary to ensure that the EU requirements are implemented and can be enforced in Scotland. The proposed Caseins and Caseinates (Scotland) Regulations 2016 will implement the EU legislation and enable the local authorities in Scotland to take action in the event of non-compliance with the specific labelling and / or composition standards by manufacturers of the products covered by the Regulations.

As the draft Caseins and Caseinates (Scotland) Regulations 2016 focus on the general compositional and information requirements of caseins and caseinates, FSS proposes that the enforcement should be risk based and proportionate, in line with the current approach. 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.

#### 4. Consultation

- **Within Government**

The consultation package was discussed with Scottish Government (SG) officials from Public Health and Food Drink & Rural Communities.

- **Public Consultation**

A shortened 4 week consultation has been carried out in Scotland on the draft national legislation from 23 September 2016 to 23 October 2016

- **Business**

There are very few businesses involved in caseins and caseinates in the UK and our initial contact with industry bodies has not identified any directly affected companies in Scotland. Following a request to the Minister for Public Health, we were granted an exemption from the business impact part of the Impact Assessment process.

Nonetheless, our consultation requested details of any known businesses impacted by the proposed Scottish Statutory Instrument. It was circulated to 136 stakeholders which included industry bodies, retailers and enforcement officers. We received no responses.

#### 5. Options

**Option 1** – Do nothing. This involves the risk of infraction proceedings. As an EU Member State, the UK is obliged to provide for the enforcement of EU legislation. It is also expected that Member States transpose the provisions of the CC Directive into their domestic law. Failure to do so may lead to the UK being liable to infraction proceedings and consequent fines. Scotland would be required to pay a percentage of any UK fine if the infraction relates to a devolved matter.

**Option 2** – Transpose the CC Directive into domestic law. This would update requirements for relevant food businesses and maintain the status quo regarding the enforcement of European legislation in this area.

#### 6. Sectors and groups affected

While these proposed regulations apply to Scotland only, separate but similar regulations will be introduced in England, Wales and Northern Ireland; as such the impact on the UK as a whole has been assessed.

Consumers – As this regulates business to business sales of caseins and caseinates there is limited, if any, impact on consumers.

Enforcement Authorities – Enforcement of The Caseins and Caseinates (Scotland) Regulations 2016 is the responsibility of Local Authority Environmental Health Departments.

## 7. **BENEFITS**

### **Option 1**

Do Nothing. There are no incremental benefits. This is the baseline against which other options are appraised.

#### Consumers

There are no consumer benefits with this option.

#### Enforcement Authorities

Enforcement Authorities would not have to spend time familiarising themselves with new legislation.

### **Option 2**

Transpose the CC Directive into domestic law.

#### Consumers

As this regulates business to business sales of caseins and caseinates, it will enable specific information about these products and their use in food to be passed along the supply chain to those businesses supplying the final consumer. E.g. Allergen information must be provided for products made with milk proteins.

#### Enforcement Authorities

Updated Legislation will be clearer for enforcement authorities to understand.

## 8. **COSTS**

### **Option 1**

Do Nothing. The main cost for this option would be to the Government arising from possible infraction proceedings and consequent fines due to non-enforcement of the EU Regulation. The minimum infraction fine that can be imposed on the UK is 9.938 million Euros.

#### Consumers

There are no costs to consumers with this option.

#### Enforcement Authorities

There would be no familiarisation costs for Enforcement Authorities since there would be no new legislation.

## Option 2

### Transpose the CC Directive into domestic law

#### Consumers

There should be no direct costs to consumers with this option. However, if manufacturers do have to re-label their products these costs may ultimately be passed on to the consumer.

#### Enforcement Authorities

Although this would maintain the status quo regarding the enforcement of European regulation in this area, Local Authorities would need to become familiar with the new SSI. It is estimated 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 £19.15<sup>1</sup> – averaging approximately £24.90 per hour once uprated to account for non wage labour costs and overheads, taken as 30%. The total one-off cost to the 32 local authorities is therefore estimated at approximately £796.80.

Ongoing workloads for Environmental Health Departments are not expected to increase as a result of this SSI, as enforcement work for the products affected is already required.

## 9. Competition Assessment

The proposed legislation will apply to all businesses and individuals involved in the UK Caseins and Caseinates 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. Using the Competition and Markets Authority competition assessment framework<sup>2</sup> developed by the former Office of Fair Trading, it has been established that the preferred policy option (Option 2) is unlikely to have any material negative impact on competition. We assert that this policy will not limit the number or range of suppliers directly or indirectly nor will it limit the ability or reduce incentives of suppliers to compete vigorously.

## 10. Test run of business forms

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

## 11. Legal Aid Impact Test

The Justice Directorate have confirmed that the new regulations will not have any legal aid implications.

## 12. Enforcement, sanctions and monitoring

- **Enforcement**

Enforcement of the regulations will be the responsibility of Local Authorities. In Scotland, Enforcement Officers from Local Authority Environmental Health

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<sup>1</sup> Wage rate obtained from Annual Survey of Hours and Earnings 2015 Provisional

<http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcn%3A77-400803>

Median hourly wage rate of an “environmental health professional” was used, £19.15, plus 30% overheads, totalling £24.77.

<sup>2</sup> [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/284451/OFT1113.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/284451/OFT1113.pdf) The Competition and Markets Authority is now responsible for this area of work.

Departments will need to familiarise themselves with the new requirements and ensure they are adhered to. 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**

Regulation 7 of the draft Caseins and Caseinates (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. No changes are being proposed to the criminal sanctions or civil penalties contained in existing legislation.

- **Monitoring**

The effectiveness and impact of the regulations will be monitored via feedback from stakeholders, including Enforcement Agencies, as part of the ongoing policy process. Agency mechanisms for monitoring and review include; open fora, stakeholder meetings, surveys and general enquiries.

### **13. Implementation and delivery plan**

The requirements of Directive (EC) 2015/2203 regarding caseins and caseinates intended for human consumption come into force on 22 December 2016. These requirements will be enforced by The Casein and Caseinates (Scotland) Regulations 2016 which will come into force on 22 December 2016.

The publication of the Scottish Regulations will be communicated to stakeholders by means of an Interested Parties letter. This will be issued shortly after the Scottish Statutory Instrument has been published on the [legislation.gov.uk](http://legislation.gov.uk) website.

### **14. Post-implementation review**

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 Casein and Caseinates (Scotland) Regulations 2016 come into force.

### **15. Summary and recommendation**

Option 2 – This is the preferred option. It ensures that Scottish Ministers meet their obligation to implement agreed EU legislation. It also ensures that Scottish industry can compete on the same legal basis with its EU counterparts.

## 16. Summary costs and benefits table

| Option | Total benefit per annum:<br>economic, environmental, social   | Total cost per annum:<br>economic, environmental,<br>social policy and<br>administrative                       |
|--------|---|--|
| 1      | No cost to Government as a result of the introduction of The Casein and Caseinates (Scotland) Regulations 2016              | Possible infraction fines.<br>Possible loss of international trade if products do not comply with EU standard. |
| 2      | No infraction fines.<br>High level of consumer protection.<br>Industry working to a consistent legal standard throughout EU | Familiarisation costs for local authorities.   |

Option 2 is considered to be the preferred option

## 17. 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.

Ministers signature .....AILEEN CAMPBELL

Ministers title .....MINISTER FOR PUBLIC HEALTH AND SPORT

Date .....

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