



Department
for Environment
Food & Rural Affairs

Post implementation review of the Caseins and Caseinates (England) Regulations 2017

Date: 22nd November 2023

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We work closely with our 33 agencies and arm's length bodies on our ambition to make our air purer, our water cleaner, our land greener and our food more sustainable. Our mission is to restore and enhance the environment for the next generation, and to leave the environment in a better state than we found it.



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Introduction

The Caseins and Caseinates (England) Regulations 2017 transposed the provisions of the Directive (EU) 2015/2203 and revoked and replaced the Caseins and Caseinates Regulations 1985 and the Caseins and Caseinates (Amendment) Regulations 1989. Casein is the principal protein constituent of milk, washed and dried, insoluble in water and obtained from skimmed milk. Caseinates are obtained by drying casein treated with neutralising agents. Edible casein products can be used in a variety of products such as protein supplements, cheese and meat. Caseins also have industrial uses such as paper coating, fish bait and as a natural hardener for paint.

The Caseins and Caseinates (England) Regulations 2017 set out technical standards for edible caseins and caseinates to be used in food products and make additional provisions for their labelling. The legislation defines and lays out compositional and marketing standards for ““edible acid casein,” “edible caseinate”, and “edible rennet casein” which are sold from business to business for the preparation of food products. The legislation also prohibits the use of a casein or caseinate in the preparation of food that does not comply with the contaminants and impurities criteria laid out.

Specific labelling conditions are set out for casein products not sold as food to ensure that they are marketed in a way that is not misleading as to the product's nature, quality or intended use. These specific rules are designed to ensure that food business operators who use these products in the manufacturing of foods for the final consumer have sufficient information for the labelling of the final product, and to avoid those products being confused with similar products not meant or not suitable for human consumption. This report sets out the findings of Defra's review of The Caseins and Caseinates (England) Regulations 2017 thus fulfilling the statutory obligations to do so.

The primary purpose of the legislation is to provide a level playing field and facilitate the trade of caseins and caseinates intended for human consumption while providing a high-level of protection of human health. The Caseins and Caseinates (England) Regulations 2017 brought in technical changes which took into account legislative developments in wider food law and also aligned compositional requirements with recently amended Codex Alimentarius international standards.¹To this end the review of the regulations has set out to establish whether the legislation: is still necessary to safeguard public health; provides a level playing field for business and; promotes trade based on a set of common standards. Within this, the review has looked at whether the legislation remains up to date with international standards, industry practice and is consistent with wider food law. This review has also assessed whether

¹ The Codex Alimentarius is one of the World Trade Organization “3 sisters” whose key aims are to protect health and facilitate international trade in food. Codex standards are an important reference point for the WTO dispute settlement mechanism and the standards developed by Codex often serve as a basis for national law in many cases.

assumptions around the limited regulatory impacts to business remain accurate, including looking at whether the legislation has led to any unintended consequences.

The analysis detailed in this report will show that The Caseins and Caseinates (England) Regulations 2017 remain necessary in helping to facilitate trade while protecting consumers and continuing to support a level playing field for industry. In doing so the report demonstrates that the legislation remains largely up to date and consistent with food law and international standards with only a minor correction in transposition needed. The analysis in this report supports the initial assumptions regarding the regulatory impacts to business with the report setting out that no measures are needed to mitigate costs.

Policy Objectives

The overarching objective of the legislation is to safeguard public health, provide a level playing field for business and promote trade based on a set of common standards.

The Caseins and Caseinates (England) Regulations 2017 revoked and replaced the Caseins and Caseinates Regulations 1985 and the Caseins and Caseinates (Amendment) Regulations 1989. At that time changes were made 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 adopted 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.

Evidence gathered for the review

Post Implementation Reviews (PIRs) can take different forms, ranging from a light touch approach for low impact and non-controversial regulations, to a detailed approach for high impact and controversial regulations.

As explained in the [Explanatory Memorandum](#) to The Caseins and Caseinates (England) Regulations 2017 no impact assessment was prepared for this legislation. This is because no significant impact on business, charities or voluntary bodies was foreseen. Considering this, the Better Regulation Unit (BRU) team in Defra advised a light-touch review providing a qualitative assessment based on existing data available would be appropriate.

Since the available information in this sector was limited, we also ran an informal targeted stakeholder survey. The survey was sent out via email to a group of 16 contacts which covered a range of stakeholders including food businesses, trading standards, and trade associations who were encouraged to circulate to their wider membership. We targeted stakeholders from the dairy, sports nutrition, and food supplements market, as well as those who represent the food and drink sector more broadly. The survey was not circulated to consumer groups since The Caseins and Caseinates (England) Regulations cover technical standards for products

intended to be sold business to business rather than directly to the consumer. The survey sought insight on:

- Whether the regulations are still consistent with other food standards legislation and international standards.
- Any unexpected impacts or challenges with compliance.
- Whether the reserved descriptions for “edible acid casein,” “edible caseinate” and “edible rennet casein” and the corresponding compositional and labelling requirements are still necessary and up to date with developments within the industry.
- Potential impacts of repealing the regulations.
- Whether the introduction of improvement notices (with a criminal offence for failure to comply with these) as an enforcement mechanism remains proportional and appropriate.

The response to the survey was limited to one large business (non-UK). Limited interest can be explained by a lack of England-based producers (according to available information and previous response to past consultation on these regulations).

Analysis

Has the policy successfully achieved its objectives?

The response to the survey and publicly available information indicates that there remain no domestic producers of products covered by the regulations. However, there are a number of UK wholesalers and distributors, approximately 47 operate in England.²

Caseins are used in multiple foods such as protein supplements which is a growing market. Trade figures indicate an increase in imports of caseins since 2017 from an approximate value of £25.6 million to £33.5 million in 2022.³

These figures illustrate that while there is no evidence of domestic producers, the regulations still have a role in protecting consumers from lower quality of products. They also ensure that domestic food business operators who use these products in the manufacturing of foods for the final consumer have sufficient information for the correct labelling of the final product. This lowers the risk that these products may be confused with similar products not meant or not suitable for human consumption, thus protecting human health and consumer interests.

The continued necessity of the regulations to safeguard consumer health and protect against both food products of lower quality and fraud was supported by the response to the stakeholder survey. The response from the large business, whose role in the supply chain is as an importer, also indicated that the regulations remain important in maintaining a level playing field for

² The Casein and Caseinates Regulations Impact Assessment 2013, this information is indicative and should be treated with caution.

³ HM Revenue & Customs – Overseas trade data.

businesses. While the available evidence suggests this does not apply to domestic businesses currently, maintaining the regulations ensures any businesses which may start operating in this area in future would compete on a level playing field both domestically and overseas. Importantly, these rules ensure our high food standards are maintained and that products not meeting our standards cannot be sold on our market.

The survey response and a review of the international codex standard illustrated that the reserved descriptions “edible acid casein,” “edible caseinate” and “edible rennet casein” remain up to date with industry standards and aligned to the international codex standard. The survey response also highlighted that the compositional and labelling requirements are largely sufficient. However, it has been highlighted in feedback received from the survey that rennet casein should have a *minimum* (not *maximum* as currently written in the legislation) ash content of 7.5% by weight to align with the international codex standard. This assists in the identification of the type of casein that is present and the standard of identity of each casein. It has been noted that this is an error in transposition and was previously correct in 1985 Casein Regulations. Defra will take this forward and ensure this correction by way of an amendment to the regulations at its earliest convenience. Further examination of the codex standard for edible caseins confirmed this is the only amendment needed to ensure The Caseins and Caseinates (England) Regulations 2017 remain consistent. While the codex standard includes additional provisions on additives and hygiene these aspects are covered in separate legislation in England.

Enforcement of The Caseins and Caseinates (England) Regulations 2017 is carried out by trading standards officers from local authorities in England. The Food Safety Act 1990 provides for the use of an improvement notice by an authorised officer from a food authority to address non-compliance. The adoption of improvement notices in The Caseins and Caseinates (England) Regulations 2017 was a move away from criminal sanctions to a more proportionate approach for breaches of the regulations. An improvement notice can be served by an authorised officer if an enforcement authority has reasonable grounds for believing that a Food Business Operator is failing to comply with the legislative requirements. The notice outlines the matter which constitutes the failure to comply and specifies measures which, in the officer’s opinion, the proprietor must take in order to secure compliance within a specified time period. Any person who fails to comply with an improvement notice shall be guilty of an offence.

The respondent to the survey felt that the approach to enforcement using improvement notices is reasonable for addressing non-compliance with the regulations. This approach remains in line with other food legislation such as The Food Information Regulations 2014, The Honey (England) Regulations 2015 and the Fruit Juices and Fruit Nectars (England) Regulations 2013. When responding to consultation exercises for similar legislation local authorities have generally been supportive of the move to the use of improvement notices. Improvement notices provide a way to correct non-compliance efficiently while reducing cost and time for businesses in resolving issues more quickly. This approach has also been viewed as a way of reducing potentially excessive costs associated with court time when criminal proceedings are brought. Hence existing enforcement provisions remain fit for purpose.

Were there any unexpected consequences or costs from the regulations?

As highlighted above there is no evidence to suggest that there are domestic businesses manufacturing casein products covered by this regulation. This is in line with original

expectations outlined in the explanatory memorandum accompanying the legislation, suggesting that no significant impacts or unexpected costs related to The Caseins and Caseinates (England) Regulations 2017 have occurred. Feedback from the stakeholder survey raised no concerns around unexpected costs or complications around complying with the requirements set out.

Could we revise the Regulations to reduce cost to business?

Given that no significant costs for business have been identified as having resulted from the legislation we consider that no revisions are needed in order to reduce costs or other burdens. The response to the stakeholder survey suggested that the impact of repealing The Caseins and Caseinates (England) Regulations 2017 would be extremely negative. They ensure our high food standards are maintained and that products not meeting our standards cannot be sold on our market. It was noted that the regulations should remain up to date with international codex standards in order to keep a level playing field, facilitating trade. Since the current provisions remain largely in line with international codex standards, the only required revision concerns the correction to the minimum ash content requirements for rennet caseins.

How do UK Regulations in this area compare with those in the EU

The Caseins and Caseinates (England) Regulations 2017 transposed the provisions of Directive (EU) 2015/2203. The 2015 directive remains applicable across the 27 EU member states. As the legislation was transposed by Member States, as opposed to being directly applicable, there may be minor transposition differences in language, but we are not aware of any significant differences.

Conclusions

To conclude, The Caseins and Caseinates (England) Regulations 2017 continue to play an important role in protecting consumers from lower quality products and safeguarding health while providing a level playing field for businesses and promoting trade. The evidence suggests that there have been no significant impacts or unexpected costs to businesses as a result of these regulations. Hence, The Caseins and Caseinates (England) Regulations 2017 are considered to represent good value for money in protecting consumer interests in England with little to no on-going costs placed on industry. The requirements remain largely aligned with international standards and provide a level playing field for business, facilitating trade. To ensure the regulations remain fit for purpose the essential quality factors for rennet caseins should be amended to ensure the requirements related to the ash content is reflective of the characteristics of this product and up to date with international standards. Hence, it is recommended that we retain the Regulations with a view to limited revision in this regard. The regulations will be reviewed in 2027 in line with regulation 9(3) which requires a subsequent review report to be published at intervals not exceeding 5 years.

Limitations of this review

As stated above, this is a particularly light touch review given the low impact nature of these regulations. Equally, due to the absence of domestic producers, engagement on these regulations with relevant stakeholders has been low. This has also been experienced during this review with a limited response to the stakeholder survey. There is also little publicly available information on these products, and the conclusions presented in this report have been based on analysis of the evidence we have described above.

Annex A

<p>The Caseins and Caseinates (England) Regulations 2017</p> <p>PIR No: N/A</p> <p>Original IA/RPC No: N/A</p> <p>Lead department or agency: Department for Environment, Food and Rural Affairs</p> <p>Other departments or agencies: N/A</p> <p>Contact for enquiries: miles.healy@defra.gov.uk</p>	Post Implementation Review
	Date: 22/11/2023
	Type of regulation: Domestic
	Type of review: Statutory
	Date measure came into force: 26/09/2017
	Recommendation: Amend
RPC Opinion: N/A	

1. What were the policy objectives of the measure? (Maximum 5 lines)

- A) Provide a high level of protection of human health.
- B) Facilitate trade by aligning with international standards.
- C) Provide a level playing field for businesses.

2. What evidence has informed the PIR? (Maximum 5 lines)

Following advice from the Better Regulation team in Defra, this is a light touch review of the Caseins and Caseinates (England) Regulations 2017. An informal targeted stakeholder survey was conducted to test if there had been any unintended consequences and help determine whether the regulations are still necessary and up to date. Other available sources of information were also used to inform the review such as HM Revenue & Customs – Overseas trade data, past consultation documents, and Codex Alimentarius documents.

3. To what extent have the policy objectives been achieved? (Maximum 5 lines)

The available evidence suggests that the regulations continue to fulfil an important role in protecting consumers and safeguarding human health. They maintain our high food standards and provide a level playing field for businesses, without imposing significant burdens. They also help facilitate trade through aligning with international practices. A minor revision to the compositional requirements for rennet caseins is needed to ensure they remain fit-for-purpose and in line with international standards, thus facilitating trade.

Sign-off for Post Implementation Review: Chief economist/Head of Analysis and Minister

I have read the PIR and I am satisfied that it represents a fair and proportionate assessment of the impact of the measure.

Signed: Michael Archer

Date: **23/11/2023**

A handwritten signature in blue ink that reads "M. Spencer". The signature is written in a cursive style with a large, stylized initial "M".

Signed:

Date: **28/11/2023**

Further information sheet

Please provide additional evidence in subsequent sheets, as required.

4. What were the original assumptions? (Maximum 5 lines)

No significant impacts on businesses, charities, voluntary bodies or the public sector were foreseen. For this reason, no impact assessment was prepared to accompany the legislation.

5. Were there any unintended consequences? (Maximum 5 lines)

The findings of the review remain consistent with the assumptions above. There continues to be no evidence of domestic businesses producing products covered by the regulations. No unexpected costs have been identified.

6. Has the evidence identified any opportunities for reducing the burden on business? (Maximum 5 lines)

Given that no significant or unexpected costs for business have been identified as having resulted from the legislation, no revisions are needed in order to reduce costs or other burdens. The response to the stakeholder survey suggested that the impact of repealing The Caseins and Caseinate (England) Regulations 2017 would be extremely negative. They ensure our high food standards are maintained and that inferior products cannot be sold on our market.

7. How does the UK approach compare with the implementation of similar measures internationally, including how EU member states implemented EU requirements that are comparable or now form part of retained EU law, or how other countries have implemented international agreements? (Maximum 5 lines)

The Caseins and Caseinates (England) Regulations 2017 transposed the provisions of Directive (EU) 2015/2203. This directive is applicable across the 27 EU Member States. As the legislation is transposed by Member States, as opposed to being directly applicable, there may be minor transposition differences in language versions, but we are not aware of any significant differences. Measures in the regulations are consistent with the Codex Alimentarius standards, 188 countries are codex members.