

<b>Title:</b> The Casein and Caseinates Regulations  <b>IA No: DEFRA1479</b>  <b>Lead department or agency:</b> DEFRA  <b>Other departments or agencies:</b> Food Standards Agency Scotland, Wales and Northern Ireland	<b>Impact Assessment (IA)</b>				
	<b>Date:</b> 12/11/2012				
	<b>Stage:</b> Consultation				
	<b>Source of intervention:</b> EU				
	<b>Type of measure:</b> Secondary legislation				
<b>Contact for enquiries:</b> <b>Cath Harris 020 7238 2299</b>					
<b>Summary: Intervention and Options</b>					<b>RPC Opinion:</b> RPC Opinion Status

Cost of Preferred (or more likely) Option				
Total Net Present Value	Business Net Present	Net cost to business per year (EANCB on	In scope of One-In, One- YES	Measure qualifies as
-£0.009	-£0.001	0		

**What is the problem under consideration? Why is government intervention necessary?**  
As identified by the Red Tape Challenge Hospitality, Food and Drink theme, the regulatory landscape for food labelling and composition is difficult to navigate, putting unnecessary burdens on business. As part of the Government's solution to improve this, we committed to consolidate The Casein and Caseinates Regulations 1985 (S.I No 2026)<sup>1</sup> and The Casein and Caseinates (Amendment) Regulations 1989 (S.I No.2321)<sup>2</sup> and, as far as possible, to replace the existing criminal sanctions with civil sanctions.

**What are the policy objectives and the intended effects?**  
(i) To provide in domestic law for proportionate, effective and risk- based enforcement, in England, of certain EU obligations contained in Council Directive 83/417/EEC<sup>3</sup>. This Directive concerns lactoproteins (caseins and caseinates) which are intended for human consumption and mixtures thereof.  
(ii) To simplify Regulations by consolidating two SIs making referencing easier for industry and

**What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)**  
**Option 1** - Do nothing – continue with business as usual (the baseline).  
**Option 2** - Consolidate current regulations from 2 statutory instruments to 1 statutory instrument. The current regulations which apply to composition, standards and labelling would remain unchanged, but the criminal sanctions for breaching the regulations would be replaced with civil sanctions (an improvement notice regime consistent with other similar regulations for food). The only exception to this is with regard to regulation 6 of The Casein and Caseinates Regulations 1985 (which requires heat treatment of casein products). It is proposed that this remains a criminal offence as the Food Standards Agency (FSA) considers a breach of this regulation to be a potentially serious risk to human health.  
**Option 2** is our preferred Option.

<b>Will the policy be reviewed? N/A If applicable, set review date:</b>					
Does implementation go beyond minimum EU requirements?				No	
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.		<b>Micro</b> YES	<b>&lt; 20</b> YES	<b>Small</b> YES	<b>Medium</b> YES
What is the CO <sub>2</sub> equivalent change in greenhouse gas emissions? (Million tonnes CO <sub>2</sub> equivalent)				<b>Traded:</b> N/A	<b>Non-traded:</b> N/A

<sup>1</sup> Statutory Instrument 1985 No.2026

<sup>2</sup> Statutory Instrument 1989 No.2321

<sup>3</sup> OJ No.L237,26.08.1983, P.25

***I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading Options.***

Signed by the responsible  
SELECT SIGNATORY:

Date

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Description: Implement the new requirements under one statutory instrument.

**FULL ECONOMIC ASSESSMENT**

Price Base 2Year 2014	PV Base Year 2012	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: -0.009

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	0.009	0.00	0.009

**Description and scale of key monetised costs by ‘main affected groups’**

Industry

One off costs: familiarisation £1,193 (PV) (EAC<sup>1</sup> £139);

Government

One off costs: familiarisation £7,798 (PV) (EAC £906)

**Other key non-monetised costs by ‘main affected groups’**

There are no non-monetised costs associated with this Option.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	0.00	0	0

**Description and scale of key monetised benefits by ‘main affected groups’**

There are no monetised benefits associated with this option.

**Other key non-monetised benefits by ‘main affected groups’**

Industry: A more proportionate enforcement procedure for businesses

Government: Simpler enforcement procedures for enforcement officers

Key assumptions/sensitivities/risks	<b>Discount rate</b>	3.5
<u>Familiarisation costs</u>		
<u>Industry</u> - equivalent of 1 regulatory affairs/production managers per business approximately 1 hour respectively to familiarise.		
<u>Government</u> - equivalent of 1 trading standards officer per local authority approximately 1 hour respectively to familiarise.		

**BUSINESS ASSESSMENT (Option 2)**

<b>Direct impact on business (Equivalent Annual) £m:</b>	<b>In scope of</b>	<b>Measure</b>
<b>Costs: 0</b>	<b>YES</b>	<b>OUT</b>
<b>Benefits: 0</b>		
<b>Net: 0</b>		

<sup>1</sup> EAC = Equivalent Annual Cost

## Evidence Base (for summary sheets)

### References

- The Casein and Caseinates Regulations 1985 (S.I No 2026)
- The Casein and Caseinates (Amendment) Regulations 1989 (S.I No.2321)

### **Problem under consideration**

1. One of the current Government priorities is to remove burdensome or outdated regulations where they are no longer needed. As part of the Red Tape Challenge (RTC) Exercise covering the Hospitality theme, a review of all existing rules covering food labelling and compositional standards was carried out. It was concluded that the landscape was difficult for businesses to navigate. As a result, the Government committed to merging and repealing a number of food labelling and composition regulations to reduce the regulatory burden on businesses by simplifying the regulatory landscape. There are currently two sets of Casein and Caseinates Regulations. The aim is to streamline the regulations so that there is one Statutory Instrument (SI) and, as far as possible, to replace the criminal sanctions with civil sanctions in line with the government's objectives to reduce the burdens on the industry and others such as enforcers.
2. This impact assessment analyses the options on an England only basis because food is a devolved matter.

### **Rationale for intervention**

3. The aim is to streamline the Regulations and to reduce unnecessary bureaucracy and burdens on business. Consolidating the two SIs requires Government intervention as it is a change in secondary legislation.

### **Options Considered**

The following Options have been considered:

4. **Option 1** – Do nothing – continue with business as usual (the baseline).
5. **Option 2** – Consolidate the current regulations from 2 SI to 1 SI. The current regulations which apply to composition, standards and labelling would remain unchanged, but the criminal sanctions for breaching the regulations would be replaced with civil sanctions (an improvement notice approach consistent with other similar regulations for food). For this option it will be the responsibility of Local Government Trading Standards officers to familiarise themselves with the new single SI, and understand the move to an improvement notice system for non-compliance with the Regulation.

### **Background**

6. Casein is the principal protein constituent of milk, washed and dried, insoluble in water and obtained from skimmed milk. Caseinates are a product obtained by drying casein treated with neutralising agents.
7. Caseins are used in protein supplements, but also have industrial uses such as paper coating, fish bait and as a natural hardener for paint. Edible caseins have a wide range of uses (see Table 1 below).

## 8. Table 1: Edible applications of casein products<sup>2</sup>

Bakery	Cheese products
Coffee whiteners and creamers	Confectionery
Cultured milk products, yoghurt <i>etc.</i>	High fat powders, shortenings and spreads
Ice cream and frozen desserts	Infant foods
Instant breakfasts and beverages	Meat products
Nutritional food bars	Pasta
Pharmaceuticals	Soups and gravies
Sports drinks	Whipped toppings

9. In England, the Casein and Caseinates Regulations implement the requirements of Council Directive 83/417/EEC on the approximation of the laws of the Member States relating to certain lactoproteins (caseins and caseinates) intended for human consumption. The Regulations also lay down specifications for use of reserved descriptions, manufacturing specifications and labelling of products so as to ensure their free movement within the Community.

### Current situation

10. Available information on this sector is limited. Informal consultation with industry suggests that there are no UK casein/caseinate manufacturers.

11. However, some evidence suggests that there are several UK wholesalers and distributors of caseins and caseinates. We have identified 49 UK casein and caseinate wholesalers and distributors of which 47 operate in England<sup>3</sup>.

12. Of these 47 English companies, around 68 per cent are micro and small businesses, of which 4% are micro.

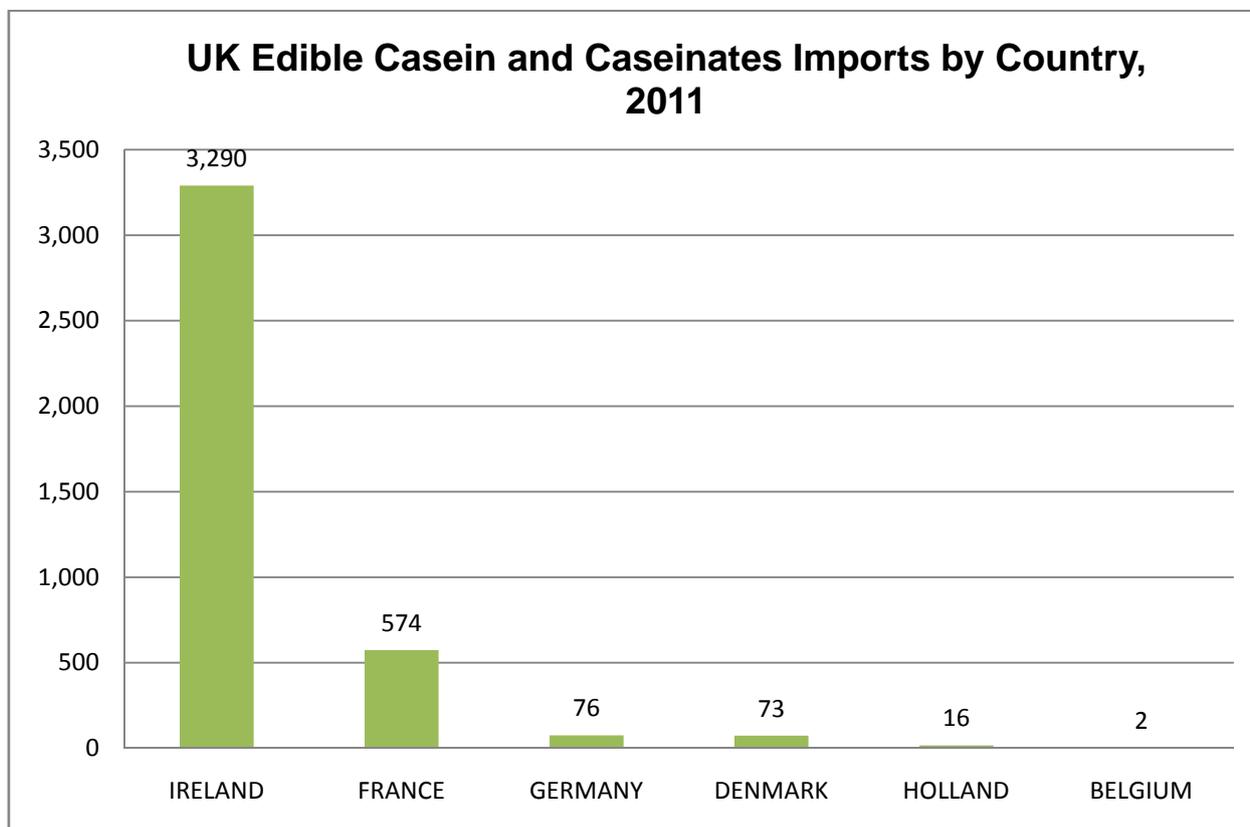
	Micro	Small	Medium	Large	Total
England	2	30	11	4	47
Wales	0	1	0	0	1
Scotland	1				1
NI	0	0	0	0	0
UK	3	31	11	4	49

13. These UK companies import casein and caseinate products from Northern Europe suppliers, predominantly Ireland and France. Indicative figures from industry suggest that in 2011, 4,032 tonnes of edible caseins were imported to the UK. Table 2 provides a breakdown imports by country<sup>4</sup>.

<sup>2</sup> Source: 'Casein Products' – Page 10 – <http://nzic.org.nz/ChemProcesses/dairy/3E.pdf>

<sup>3</sup> Source: Wholesale Pages and Baracel (wholesaler). This information is indicative and should be treated with caution. We are seeking further company information through consultation.

<sup>4</sup> Industry contact.



#### Consultation Question 1

Are there any UK casein/caseinate manufacturers? If available, please provide names of companies which manufacture, supply or wholesale caseins and caseinates.

#### Legislative framework and description of the new requirements

14. The Caseins and Caseinates (England) Regulations 2013 (“the Regulations”) will replace the following two SIs:

- The Casein and Caseinates Regulations 1985 (S.I No 2026) and
- The Casein and Caseinates (Amendment) Regulations 1989 (S.I No.2321)

Both Regulations will be revoked by the proposed Regulations.

#### **Affected Groups**

15. Casein and caseinates **wholesalers and distributors** – Under Option 1, industry will not be affected. However, under Option 2, **casein and caseinates wholesalers and distributors** would be a likely to incur a one-off familiarisation cost but will also benefit from reduced enforcement burden from the consolidation of 2 SIs to 1 SI.

16. **Government** – Under Option 1, Government will not be affected. However, under Option 2, local authorities will also incur a one-off familiarisation cost whilst also benefitting from reduced enforcement burden.

17. **Consumers** – Under both Option 1 and Option 2, there is likely to be no impact on consumers. This is because there is no change to processes or products produced.

### **Consultation Question 2**

Please comment on any businesses in the market, including in the devolved administrations that might be affected by the proposal. Are there any that have been over looked?

## **Option Appraisal**

### **Costs and Benefits**

18. Applying the 'one in one out' (OIOO) methodology to the policy requirements means that the proposed consolidation of The Casein and Caseinates Regulations 1985 (S.I No 2026) and The Casein and Caseinates (Amendment) Regulations 1989 (S.I No.2321) **is subject to OIOO.**
19. It can be classified as '**OUT**' as the cost to both Government and industry are anticipated to be outweighed by the savings and benefits. At this stage, additional information is required to accurately assess the monetised costs and benefits and this will be sought as part of the consultation (we only have the cost side of the information at present). The business assessment figures on the summary pages are shown as zero at this time, until the additional information has been gathered in consultation.

### **Policy Option 1 – Do Nothing (Baseline)**

20. This Option would mean continuing with the current rules and would not deliver the RTC commitments.

### **Costs**

21. There are no incremental costs associated with this Option. This is the baseline to which all other Options are compared.

### **Benefits**

22. There are no incremental benefits associated with this Option. This is the baseline against which all other Options are appraised.

### **Policy Option 2 – Consolidation of 2 SIs to 1 SI**

23. This Option makes for a clearer legislative environment and reduces the burden to industry and local authorities. The standardised approach to enforcement - serving an improvement notice on a trader where an authorised officer has reasonable grounds for believing that the trader has not complied with, or is unlikely to comply with, the Regulations - will be taken in the case of the Casein and Caseinates Regulations 2013 and will be consistent with other similar regulations for food composition, standards and labelling. Having been given an opportunity to put things right and having failed to do so, the draft Regulations provide that a failure to comply with the improvement notice is a criminal offence. There is no requirement for an improvement notice with regard to regulation 6 of the Caseins and Caseinates Regulations 1985: *A person must not use as an ingredient in the preparation of any casein product any casein or caseinate which has not been subjected to heat treatment at least equivalent to pasteurisation unless that*

casein product is itself subjected to such heat treatment during its preparation. This is because a breach of this regulation constitutes a risk to human health, and it is therefore a criminal offence.

24. Enforcement bodies already use the improvement notice approach for a number of other Regulations. Therefore introducing this approach to the new Regulations should not create burdens. In this case it should be seen as a benefit as the sanctions in these Regulations are being brought into line with other existing proposed Regulations. It is anticipated that there will be no additional costs on an ongoing basis.

## **Costs**

### **Industry**

#### **Familiarisation costs (one-off) – This cost has been monetised.**

25. There will be a one-off cost to industry for reading and familiarising themselves with the new Regulations. Time will be spent acquiring, reading and understanding the legislation.. Casein and caseinate wholesalers and distributors would need to become familiar with the new requirements of The Caseins and Caseinates (England) Regulations 2013
26. Familiarisation costs are measured in terms of time costs and are therefore quantified by multiplying the time it takes for a member of staff to read and familiarise him/herself with the Regulation by their wage rate. The wages outlined in this impact assessment represent median gross hourly pay including overtime from the Annual Survey of Household Earnings, 2011, All Employees. The relevant average hourly rate<sup>5</sup> is updated by 30% to take account of non-wage labour costs and overheads, which is in line with standard cost model methodology<sup>6</sup>.
27. It is assumed that **1 hour of 1 regulatory affairs/production manager's time** will be spent for per business. Given these assumptions, the total one off familiarisation costs for industry in England are estimated at around £1,200 (Table 2).
28. In order for one-off costs to be compared to annual costs on an equivalent basis across the time span of the policy, one-off costs are converted into Equivalent Annual Costs (EACs) by dividing the one-off cost by an annuity factor<sup>7</sup>. The total one-off familiarisation cost to businesses in England translates to an equivalent annual cost of £139 over a ten year period.

### **Consultation Question 3**

You are invited to comment on whether the assumptions above are reasonable. Are there likely to be any other costs incurred?

### **Table 2: Total familiarisation costs and Equivalent Annual Cost to Industry by Country**

<sup>5</sup> Wage rates are obtained from ASHE 2011

<sup>6</sup> <http://www.berr.gov.uk/files/file44503.pdf>

<sup>7</sup> The annuity factor is essentially the sum of the discount factors across the time period over which the policy is appraised. The equivalent annual cost formula is as follows:

$$a_{t,r} = \sum_{j=0}^{t-1} \prod_{i=0}^j \left( \frac{1}{1+r_i} \right)$$

	Number of wholesalers and distributors	Total Familiarisation Cost	Equivalised Annual Cost
England	47	£1,193	£139
Wales	1	£25	£3
Scotland	1	£25	£3
Northern Ireland	0	£0	£0
UK	49	£1,244	£145

## Government

Familiarisation costs (one-off) – This cost has been monetised.

29. Local authorities will need to become familiar with the updated Regulations for enforcement purposes. It is estimated that it would take **1 Trading Standards officer, 1 hour** to read and become familiar with the Regulations and disseminate them to key staff. The average hourly pay rate for *Inspectors of standards and regulations*<sup>8</sup> is shown in the table below. This has been up-rated by 30% to account for non-wage labour costs and overheads, in accordance with the standard cost model<sup>9</sup>.

30. Given these assumptions, the total one-off familiarisation cost to businesses in England translates to around £8,000 an equivalent annual cost of £906 over a ten year period (Table 3).

### Consultation Question 4

You are invited to comment on whether the assumptions above are reasonable. Are there likely to be any other costs incurred?

**Table 3: Familiarisation costs for trading standards officers, by Country**

	Number of Local Authorities	Median average hourly wage (uprated by 30%)	Total Familiarisation Cost	Equivalised Annual Cost
England	433	£18.01	£7,798	£906
Wales	22		£396	£46
Scotland	32		£576	£67
Northern Ireland	26		£468	£54
UK	513		£9,239	£1,073

## Benefits

### Industry

A more proportionate enforcement procedure for businesses - This is currently a non-monetised benefit.

31. There would be a benefit to industry in terms of moving from the current criminal sanctions regime to a new regime providing for enforcement by way of an improvement notice, followed up by a criminal offence in those cases where a improvement notice is not complied with. The only exception to this is with regard to regulation 6 (which concerns heat treatment). There is no requirement for a improvement notice with regard to this as a breach of this regulation would be a risk to human health, and therefore a criminal offence. It is anticipated that the gains will originate from reduced costs and the time saved to businesses in resolving the issues more quickly. This will materialise in the fact that the

<sup>8</sup> 2011 Annual survey of Hours and Earnings

<sup>9</sup> <http://www.berr.gov.uk/files/file44503.pdf> [http://www.statistics.gov.uk/downloads/theme\\_labour/ASHE-2009/2009\\_occ4.pdf](http://www.statistics.gov.uk/downloads/theme_labour/ASHE-2009/2009_occ4.pdf)

vast majority of contraventions will be resolved through the issuing of improvement notices.

32. Information provided in the food standards enforcement actions report for 2010/11 shows that there were 69 food standards prosecutions concluded in England<sup>10</sup>. Although it is not possible to give precise figures, the likelihood is that prosecutions resulting from the contravention of The Caseins and Caseinates (England) Regulations 2013 are extremely low or possibly none at all. We would expect the number of cases referred to criminal courts to be reduced. Therefore, this benefit is likely to be small given the number of cases associated with caseins and caseinates is anticipated to be small.

## Government

Simpler enforcement procedures for enforcement officers – *This benefit is currently non-monetised.*

33. There is a potential benefit to Government in terms of moving from the current criminal sanctions regime to the new civil sanctions regime. It is anticipated that the gains will originate from reduced court costs as the number of hearings will be reduced as issues will be resolved through issuing improvement notices, and the time saved to enforcement officers in resolving the issues more quickly instead of preparing for a court case. However, this benefit is likely to be relatively small given the number of cases associated with caseins dealt with by enforcers are anticipated to be small.

### **Consultation Question 5**

In what way would a new improvement notice approach benefit enforcement officers in general? Can you quantify any savings that may be realised?

## **Summary of monetised costs and benefits**

34. Table 4 below provides a summary of the monetised costs and benefits for policy Option 2. This Option is exceptionally low cost. The Net Present Value is around -£9,000 and the Business Net Present Value is -£1,200 over the ten year period. We anticipate that monetising the benefits in this Option through consultation is likely to make this Option an OUT.

<sup>10</sup> <http://www.food.gov.uk/multimedia/pdfs/board/fsa111108.pdf>

Table 4: Summary of costs and benefits

	Year 0	Year 1	Year 2	Year 3	Year 4
<b>COSTS</b>					
<b><i>Industry</i></b>					
Familiarisation (transition)	£1,193	£0	£0	£0	£0
<b>Total Industry Costs</b>	<b>£1,193</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>
<b><i>Government</i></b>					
Familiarisation (transition)	£7,798	£0	£0	£0	£0
<b>Total Government Costs</b>	<b>£7,798</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>
<b>TOTAL COSTS</b>	<b>£8,992</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>
<b>BENEFITS</b>					
<b>TOTAL BENEFITS</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>
<b>NET BENEFIT</b>					
<b>Total Net (Benefit)</b>	<b>-£8,992</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>
Total Net Business (Benefit)	-£1,193	£0	£0	£0	£0

Year 5	Year 6	Year 7	Year 8	Year 9	Total cost/benefit	Annual Cost or Benefits/EA	PV
£0	£0	£0	£0	£0	£1,193	£139	£1,193
<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£1,193</b>	<b>£139</b>	<b>£1,193</b>
£0	£0	£0	£0	£0	£7,798	£906	£7,798
<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£7,798</b>	<b>£906</b>	<b>£7,798</b>
<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£8,992</b>	<b>£1,045</b>	<b>£8,992</b>
<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>
<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>-£8,992</b>	<b>-£1,045</b>	<b>-£8,992</b>
£0	£0	£0	£0	£0	-£1,193	-£139	-£1,193

## SI Consolidation

35. It is anticipated that there will be no gains to industry from SI consolidation. Gains will only be realised if existing businesses refer to the SI over the 10 year time period, or, if new businesses enter the market and save time from reading just one SI rather than two.
36. Indicative data sources<sup>11</sup> suggest that established businesses are unlikely to refer to the SI after familiarising themselves with it unless there is a change to the legislation. Also, there were no new businesses identified in this market.

### Consultation Question 6

Does this assumption that there is no benefit to industry from SI consolidation sound reasonable? Or are there benefits that should be considered?

37. Given that the costs in option 2 arise from familiarisation costs associated with the SI consolidation, whilst the (non-monetised) benefits arise from a change in enforcement regime, a theoretical third option would be to keep two SIs, and just to change the enforcement regime. However, a change to only the sanctions regime would necessitate a change to the two SIs also, which would bring familiarisation costs. Therefore, option 2 is the preferred approach in lessening regulatory burden.
38. Given that a straightforward consolidation of SIs would have minimal impact, no specific group identified in the Statutory Equality Duties Impact Test would be disadvantaged.
39. A Post Implementation Review (PIR) would be disproportionate given that there would be no change in policy beyond the enforcement regime.

## Conclusion

40. **Option 2 is the preferred Option** because it is deregulatory for business. This option allows for a straightforward consolidation of 2 SIs into 1 SI as well as changes to enforcement procedures. The preferred Option is currently exceptionally low cost. The Net Present Value is around -£8,000 and the Business Net Present Value is -£1,200 over the ten year period. However the benefits of the consolidation and change in enforcement regime are not monetised.
41. The costs associated with this option are attributed to familiarisation costs both for industry and to local trading standards officers (one-off transition costs). The benefits are likely to originate from both industry and enforcement bodies of using improvement notices instead of criminal sanctions. With further information from consultation, these benefits, although small, are likely to outweigh the costs of familiarising with a single SI over time.

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<sup>11</sup> Wholesale Pages and Companies House information