

<b>Title: The Animal Feed (Composition, Marketing and Use) (England) (Amendment) Regulations 2019</b> <b>IA No: Food 0151</b> <b>Lead department or agency:</b> Food Standards Agency <b>Other departments or agencies:</b>	<b>Impact Assessment (IA)</b>		
	<b>Date:</b> June 2016		
	<b>Stage:</b> Consultation		
	<b>Source of intervention:</b> EU		
	<b>Type of measure:</b> Secondary legislation		
<b>Contact for enquiries: Nasreen Shah, Tel: 020 7276 8910</b> nasreen.shah@food.gov.uk			

<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 Value	Net cost to business per year (EANCB on 2009 prices)	In scope of One-In, Two-Out?	Measure qualifies as
£0.054m	£0.042m	£0.005m	Yes/No	In/Out/zero net cost

**What is the problem under consideration? Why is government intervention necessary?**  
 Two new European Regulations have been published in the Official Journal (OJ) of the European Union, amending Regulation (EC) No. 1831/2003 of the European Parliament and of the Council as regards requirements for placing on the market and conditions of use of feed additives. Commission Regulation (EU) 2015/327 was published on 3 March 2015 and Commission Regulation (EU) 2015/2294 on 10 December 2015. Government intervention is necessary to provide for the enforcement of the amending provisions to enable enforcement authorities to take appropriate action when necessary.

**What are the policy objectives and the intended effects?**  
 To provide for the execution and enforcement of the amending provisions of Regulation 2015/327 and Regulation 2015/2294 by amending the Animal Feed (Composition, Marketing and Use) (England) Regulations 2015.

**What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)**  
 Option 1. Do Nothing: Do not implement the provisions of EU Regulations 2015/327 and 2015/2294. This will not prevent the two Regulations from being in force in England; they are already legally binding and applicable throughout the European Union (EU) since 22 March 2015 and 29 December 2015 respectively. However, enforcement authorities would not have the necessary powers to enable their enforcement  
 Option 2. Make appropriate domestic Regulations for the proper enforcement of the two EU Regulations and provide for offences for non-compliance. This ensures that the enforcement authorities have necessary powers to fulfil their responsibilities under the Food Safety Act 1990 (as amended), for offences of non-compliance.  
 Option 2 is the preferred option.

<b>Will the policy be reviewed?</b> It will/will not be reviewed. <b>If applicable, set review date:</b> Month/Year						
Does implementation go beyond minimum EU requirements?			Yes / No / N/A			
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	<b>Large</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>		<b>Non-traded:</b>	

***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 Minister

Steve Brine

Date

25<sup>th</sup> March 2019

# Summary: Analysis & Evidence

# Policy Option 1

Description: Do Nothing; do not implement the enforcement provisions of EU Regulation 2015/327 and Regulation 2015/2294

## FULL ECONOMIC ASSESSMENT

Price Base Year 2014	PV Base Year 2015	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)			
			Low: Optional	High: Optional	Best Estimate:	
<b>COSTS (£m)</b>	<b>Total Transition</b> (Constant Price) Years		<b>Average Annual</b> (excl. Transition) (Constant Price)		<b>Total Cost</b> (Present Value)	
Low	Optional		Optional		<b>Optional</b>	
High	Optional		Optional		<b>Optional</b>	
Best Estimate						
<b>Description and scale of key monetised costs by 'main affected groups'</b> This is the baseline against which other options are compared						
<b>Other key non-monetised costs by 'main affected groups'</b>						
<b>BENEFITS (£m)</b>	<b>Total Transition</b> (Constant Price) Years		<b>Average Annual</b> (excl. Transition) (Constant Price)		<b>Total Benefit</b> (Present Value)	
Low	Optional		Optional		<b>Optional</b>	
High	Optional		Optional		<b>Optional</b>	
Best Estimate						
<b>Description and scale of key monetised benefits by 'main affected groups'</b> This is the baseline against which other options are compared.						
<b>Other key non-monetised benefits by 'main affected groups'</b> Maximum of 5 lines						
Key assumptions/sensitivities/risks					Discount rate	3

## BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs:	Benefits:	Net:	Yes/No	IN/OUT/Zero net cost

# Summary: Analysis & Evidence

# Policy Option 2

Description: Option 2: Make appropriate domestic legislation for the execution and enforcement of EU Regulation 2015/327 and Regulation 2015/2294

## FULL ECONOMIC ASSESSMENT

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: -0.054

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	0.054	0.0	0.054

### Description and scale of key monetised costs by 'main affected groups'

There are learning and familiarisation costs to both industry (£575) and enforcement bodies (£12.5k). There are also various labelling costs to industry (41k).

### Other key non-monetised costs by 'main affected groups'

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			

### Description and scale of key monetised benefits by 'main affected groups'

### Other key non-monetised benefits by 'main affected groups'

Key assumptions/sensitivities/risks

Discount rate

3

The information used for the cost-benefit analysis was provided by one stakeholder. There is a risk that this information may not be representative of the potential information industry could provide.

## BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: 0.005	Benefits: 0.000	Net: 0.005	Yes/No	IN/OUT/Zero net cost

# Evidence Base (for summary sheets)

## Problem under consideration

1. Two new European Regulations were published in the Official Journal of the European Union on 3 March 2015 and 10 December 2015 respectively. Commission Regulation (EU) 2015/327 and Commission Regulation (EU) 2015/2294<sup>1</sup> both amend Commission Regulation (EC) No 1831/2003<sup>2</sup> on additives for use in animal feed. The amending provisions provide for the new labelling, placing on the market and conditions of use of additives consisting of preparations and provide for a new functional category in Annex I of the Regulation. These new amending Regulations have been in force throughout the EU since 22 March 2015 and 29 December 2015 respectively.

## Rationale for intervention

2. The new Commission Regulations have been in force since March and December 2015, government intervention is necessary to ensure that enforcement authorities have the powers to enforce their provisions. In the current state however, offenders cannot currently be prosecuted and penalties cannot be imposed on those in breach of the new Commission Regulations.
3. The FSA is amending the Animal Feed (Composition, Marketing and Use) (England) Regulations 2015 to enable the necessary enforcement powers.

## Policy objective

4. The policy objective is to ensure that additives added to animal feed are consistently labelled according to the provisions of Commission Regulation (EU) 2015/327<sup>3</sup> with the aim of bringing clarity and transparency when placing them on the market. It will require operators to provide information about the composition of the preparations which are placed on the market which will enable end users to make an informed choice and allowing appropriate risk assessment and contribute to fairness of transactions. The changes apply to those additives authorised under Regulation 1831/2003 which are 'preparations', i.e. those where the active additive has been mixed with other technological additives or other substances, which are not themselves intended to have a function in the feed - for example, they may assist stability or functionality of the active additive by improving homogeneity or 'flowability'. It will also allow information on certain technological food additives to be provided by means other than on the packaging or label.
5. In addition, as a result of technological and scientific development, some feed additives may improve the hygienic condition of a feed by reducing microbiological contamination and thereby mitigating the possible adverse effects of microorganisms on animal health. With the introduction of Regulation (EU) 2015/2294 a separate functional category is provided for in Annex I of 1831/2003.
6. While the changes introduced by EU Regulation 2015/327 and 2015/2294 have direct application in all EU Member States, it is necessary to amend the 2015 Regulations so the necessary enforcement powers for these Regulations are in place in England. EU Regulation 2015/327 puts in place transitional arrangements for products placed on the market before 23 March 2017 that may continue to be used until existing stocks are exhausted.

## Background

---

<sup>1</sup> OJ L 324, 10.12.2015, pg 3

<sup>2</sup> OJ L 268, 18.10.2003, pg 29, Commission Regulation (EC) No. 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition,

<sup>3</sup> OJ L 58, 3.3.2015, pg. 45

7. Regulation (EC) No. 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition set out a Community procedure for authorising the placing on the market and use of feed additives. The Regulation lays down rules governing the supervision and labelling of feed additives and pre-mixtures in order to provide the basis for the assurance of a high level of protection of human health, animal health and welfare, environment and users' and consumers' interests in relation to feed additives, whilst ensuring the effective functioning of the internal market.
8. EU Regulation 2015/327 was introduced to amend Regulation (EC) No 1831/2003 in particular Annexes III and IV. The amendments concern requirements for the placing on the market and conditions of use of additives consisting of preparations.
9. In addition Regulation 2015/2294 introduces an amendment to Annex I of Regulation (EC) 1831/2003 by introducing a new functional group in the category 'technical additives'. The changes introduced by the new EU Regulations are:

*EU Regulation 2015/327 - Article 1*

- *Amendment to Annex III regarding:*

- *specific labelling requirements for certain additives and for pre-mixtures,*

*and;*

- *Additional labelling and information requirements for certain additives consisting of preparations and premixtures containing such preparations.*

- *Amendment to Annex IV - the following points are added to Annex IV:*

- *Technological additives or other substances or products contained in additives consisting of preparations shall only modify the physico- chemical characteristics of the active substance of the preparation and shall be used in accordance with their conditions of authorisation where such provisions are provided for; and*

- *Physico-chemical and biological compatibility between the components of the preparations shall be ensured in relation to the effects desired.*

*Article 2*

- *Provides a transitional provision allowing additives consisting of preparations and pre-mixtures produced and labelled in accordance with Regulation EC No 1831/2003 before 23 March 2017 may continue to be placed on the market and used until stocks are exhausted.*

*EU Regulation 2015/2294*

- *Adds a new functional group (n) to Annex 1, Point 1 regarding*

- *Hygiene condition enhancers: substances or, when applicable, microorganisms which favourably affect the hygienic characteristics of feed by reducing a specific microbiological contamination.*

## **Sectors and Groups Affected**

10. The proposals will affect animal feed businesses in England; in particular businesses labelling and placing feed products incorporating technological feed additives on the market. In terms of financial impacts, the FSA believes that there will be a one-off cost to businesses in the animal feed sector from reading and familiarising themselves with the new Regulations and in making changes to the labelling templates as required. Impact may be reduced, given the transitional period, allowing changes to be incorporated as part of the other labelling provisions. There are also potential savings where information will no longer be required on labelling products. The FSA believes the impact of the change introduced by amendment 2015/2294 will be minimal – familiarisation only.

11. Enforcement bodies involved in the enforcing of feed law will also be affected by the proposed Regulations, as they are responsible for enforcing the EU Regulation 1831/2003 as amended. In terms of financial costs; the FSA believes that these are likely to be one-off costs for reading and familiarising with the proposed Regulations.

### **Consultation Question 1**

**We invite stakeholders to comment on whether we have adequately captured the UK market or not. If not, please provide us with information on the number of firms affected, their location, and ideally, firm size in terms of number of employees.**

## **Stakeholder engagement**

### ***Additive preparations***

12. The FSA consulted trade association representatives for the animal feed manufacturers for information on possible costs and / or other impacts associated with the proposed changes in the EU Regulation 2015/327. The FSA has been advised that there will be a relatively small impact on producers in terms of costs of labelling for feed additive preparations.
13. The FSA has been advised that the additional mandatory requirement to identify and quantify the technological additives for which maximum permitted level (MPLs) apply would require a change in the label template. It is estimated that an approximate cost of £1000 per company may be incurred to amend the label templates in line with the new requirements. This would be a one-off cost. Furthermore, it is difficult to ascertain the number of producers of additive preparations in England, as many additive preparations are produced by European and / or global manufacturers selling throughout the UK; for whom the cost would be on-off and apply across its market. However, an initial estimate is that there may be 6 companies in England, who would be affected.

### ***Pre-mixtures***

14. For the labelling of premixtures, we anticipate that the majority of the changes will apply only to the more complex multi-component products.
15. In terms of costs, minor changes to the labels may be required to emphasise that technological additives from preparations may be present. Again it is estimated that the cost for facilitating this one-off change could be £1000 per company, with a gradual updating of labels as part of a routine review process.
16. There will also be a need for manufacturers to also identify which of the products they buy and are classified as preparations and the composition of these products. Information will need to be gathered from suppliers or from product data sheets. It is estimated that gathering the necessary information and updating data sheets could be in the region of approximately £6,000 per company. This figure includes £1000 for the necessary labelling changes to be carried out. Producers will be expected to evaluate the information on a case by case basis depending on the needs of the customer.
17. Although in England there is a small number of premixture companies, most if not all will be trading in the UK or throughout Europe, and it is envisaged that the work and costs will be centralised.

## **Options Considered**

**Option 1 – Do nothing – Do not implement the new labelling provisions for additives used in animal nutrition as set out in EU Regulation 2015/327 and Regulation 2015/2294.**

18. Under this option EU Regulation 2015/327 and EU Regulation 2015/2294 will still be applicable in England and the rest of the UK, as they have applied since March 2015 and

December 2015 respectively and are already legally binding within the EU. However enforcement authorities will not have the necessary powers to enable them to enforce the labelling provisions of EU Regulation 2015/327 and EU Regulation 2015/2294.

19. This option would also mean that the UK would fail to meet its Treaty obligations to put in place legislation to provide for the enforcement of EU law and may lead to the UK being liable to infraction proceedings.

### **Option 2 - Make appropriate domestic Regulations for the execution and enforcement of EU Regulation 2015/327 and EU Regulation 2015/2294**

20. Providing for the enforcement of the two EU Regulations would remove the risk of the UK incurring infraction proceedings and ensure that animal feeds and feed ingredients containing added additives and pre-mixtures are labelled consistently throughout the EU.
21. This option also meets the Government's commitment to fulfil its EU obligations and contributes significantly to provide for the means of protecting consumers. European Regulations are binding in their entirety and directly applicable in Member States from the date they take effect. The UK has a legal obligation to ensure that the provisions are in place to provide for the enforcement in full of the two EU Regulations.

### **Option Appraisal**

#### **Costs and Benefits**

#### **Option 1 – Do Nothing – Do not implement the new labelling provisions for additives and pre-mixtures used in animal nutrition as set out in EU Regulation 2015/327 and EU Regulation 2015/2294**

22. There are no costs or benefits associated with this option. This is the baseline against which the policy option is appraised

#### **Option 2 – Make appropriate domestic Regulations for the execution and enforcement of EU Regulation 2015/327 and EU Regulation 2015/2294**

23. There will be some costs to industry in ensuring compliance as identified above.

#### **Costs**

#### **Costs to Industry**

#### **Learning and dissemination (on-costs)**

24. Affected businesses will need to become familiar with the new Regulations. It is estimated that it would take two full time production managers /directors in the manufacturing industry per business, 2 hours in total to learn about the changes and disseminate information to key staff (1 hour for learning and 1 hour familiarisation). The median hourly pay rate for full time production managers/directors is around £26.12<sup>4</sup> based on the Annual Survey of Hours and Earnings (ASHE) inclusive of a 30% uplift to account for overheads, which is in line with the UK Standard Cost Model (SCM) approach<sup>5</sup>. There are an estimated 6 affected FBOs in England. Multiplying the number of affected businesses (6) by the time cost associated with learning and dissemination yields a total one-off cost to businesses in England is £575, which translates to an equivalent annual cost of £67 (2014 prices, 2014 Net Present Value<sup>6</sup>

### **Consultation Question 2**

**2a) We invite industry stakeholders to comment on whether our estimates of familiarisation costs to industry (as outlined in Table X of the IA) seem reasonable; if you agree or disagree**

<sup>4</sup> <http://www.ons.gov.uk/ons/rel/ashe/annual-survey-of-hours-and-earnings/2014-provisional-results/index.html>

<sup>5</sup> <http://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)

<sup>6</sup> Net Present Value is the difference between the Present Value of a stream of costs and a stream of benefits.

**with this assessment, please provide evidence to support your view on the time required per business for familiarisation.**

**2b). It is our assumption that it will take industry to one hour to familiarise themselves and one hour to disseminate (two hours in total) the requirements of the EU Regulations to other members of staff. We invite stakeholders to comment on whether our assumption is a reasonable one. If you agree or disagree with this assumption, please provide evidence to support your views.**

## **Additive Preparations**

### ***Labelling of additive preparations – label template change.***

25. In terms of costs, a minor change to labels may be required to emphasise that technological additives from preparations may be present. Again it is estimated that the costs for facilitating this one-off change could be £1000 per company, with a gradual updating of labels as they go through any routine revision process.

## **Pre-mixtures**

### ***Labelling of Pre-mixtures – label template change***

26. For the labelling of pre-mixtures, the majority of the changes will apply to the complex multi-component products sold to the feed manufacturers by the main premix companies. The labels will have to carry a generic statement saying that technological additives from preparations may be present. This should be a relatively small task to change the label templates which is estimated as a one-off cost of around £1000 and could be implemented during routine review of labels. In England there are 6 updating mixture companies. This leads to an estimated one-off cost of £5,000.

### ***Updated material database information***

27. Of more significance will be the need to identify which products that the pre-mixtures use are classified as preparations and what the composition of these products are. In many cases these products will be purchased from third countries, so businesses will need to check with their suppliers or review their product data sheets to establish the full picture. Once they have the information from their suppliers, they may then want to build the information in to their material database so that they can automatically provide details of the 'secondary' additives and possibly carrier materials, on their pre-mixture data sheets, leading to a total estimated cost per firm of £5,000. Multiplying this by the 6 pre-mixture companies yields a one-off cost of £25,000.

### ***Amended data sheet templates***

28. Firms will then need to generate amended data-sheet templates and, in time, up-date the actual data-sheets, leading to an IT cost of an estimated amount of £1000 per company. This yields a total one-off cost of £5,000 given a total of 5 pre-mixture companies.

29. If this is an automated process the cost will be small on a per label basis. Most companies would have probably 1000-2000 'live' formulations to deal with. It may be that companies will elect not to automatically generate the details for each pre-mixture (hence no cost other than the generic label statements). However, they will then need to evaluate the information on a case by case basis if and when customers require information. This will then be an on-going but 'low level' cost.

### ***Introduction of a new functional group of feed additives***

30. We consider the impact for the introduction of a new functional group of feed additives on industry will be minimal. Any associated costs will be for familiarisation only.



### **Consultation Question 3**

**a) We invite industry stakeholders to comment on whether our estimates of re-labelling costs to industry are an accurate assessment (as outlined in Table X of the IA). If you agree or disagree with these estimates, please provide written evidence to support your views**

**b). We would also welcome industry comments on our assumption that any costs associated with the introduction of a new function category of feed additives is likely to be minimal and at best, will only cover familiarisation costs. If you agree or disagree with this assumption, please provide written evidence to support your views.**

### **Costs to Enforcement Bodies (Local Authorities)**

#### ***Learning and dissemination costs – Familiarisation Costs (One-off costs)***

31. Trading Standards Officers (TSOs) will also need to become familiar with the new Regulations. The FSA estimates that it will take an TSOs approximately two hours to read the Regulations and disseminate information to key staff. It is envisaged that one TSO per local authority will look to assume this role. There are 323 local authorities in England. Familiarisation and dissemination costs can be monetised using the ASHE (Annual Survey of Hours and Earnings) (Provisional 2014) median hourly wage rate of an TSOs of “19.37 inclusive of a 30% uplift to accounts for overheads, which is in line with the UK SCM approach. Multiplying this wage rate by the number of EHOs (323) required for familiarisation; and by the time required (approximately two hours) per officer, yields a total one-off familiarisation cost to enforcement bothies in Northern Ireland of £12.5k, (£2014 prices, 2014 NPV).

### **Consultation Question 4**

**We invite stakeholders to comment on whether our estimates for familiarisation costs (as outlined in Table 1 of the IA) to enforcement bodies are a reasonable assessment. If you agree or disagree with this assessment, please provide evidence to support your view, documenting time required per local authorities for familiarisation.**

## Summary of total costs and benefits under Option 2

32. The costs (present value) under Option 2 are £54k. the total costs to industry are \$41k (present value) – (see table 1)

Table 1

COSTS	Total	PV	Annual Average/ EAC
<b>Enforcement</b>			
<b>Local Authorities</b>			
<b>One-off Costs</b>			
Learning and dissemination	£12,513	£12,513	£1,454
Total one-off cost	£12,513	£12,513	£1,454
<b>On-going costs</b>	£0	£0	£0
<b>Total Cost: Local Authorities</b>	<b>£12,513</b>	<b>£12,513</b>	<b>£1,454</b>
<b>Industry</b>			
<b>One-off Costs</b>			
Learning and dissemination	£575	£575	£67
Labelling of additive preparations - label template change cost	£6,000	£6,000	£697
Labelling of premixtures template	£5,000	£5,000	£581
Updated material date-base	£25,000	£25,000	£2,904
Amended data sheet templates	£5,000	£5,000	£581
Total one-off cost	£0	£0	£0
<b>On-going costs</b>	£0	£0	£0
<b>Total Cost: Industry</b>	<b>£41,575</b>	<b>£41,575</b>	<b>£4,830</b>
<b>Total Cost</b>	<b>£54,088</b>	<b>£54,088</b>	<b>£6,284</b>

33. The net benefit to society from Option 2 is -£54k (present value). The impact on business is a net present value of -£401 which equates to an equivalent annual cost to business of £4.8k (see Table 2)

Table 2

NET IMPACT	Total	PV	Average/ EAC
<b>Net Enforcement</b>	<b>-£12,513</b>	-£12,513	<b>-£1,454</b>
<b>Net Industry</b>	<b>-£41,575</b>	-£41,575	<b>-£4,830</b>
<b>Net Consumer</b>	£0	£0	£0
<b>Net Society</b>	<b>-£54,088</b>	<b>-£54,088</b>	<b>-£6,284</b>

### Consultation Comment 6

We invite stakeholders to comment on whether we have adequately captured all costs and benefits of this proposal in the Impact Assessment (Table 1). If not, please provide us with detailed information and evidence as possible to support your view on any missing costs or benefits, so that we can monetise the introduction of this Regulation more robustly.

### Summary and Preferred Option

34. The total net benefit for society of option 2 is -£54k over ten years in net present value terms. The total equivalent annual cost to business is £4,830.

## **Consultation**

### **Within Government**

35. During the course of negotiations with the Commission, officials of the FSA have kept other government departments informed of its progress. These included; the Department of Health, the Department for Business Innovation and Skills, the Foreign and Commonwealth Office, the Cabinet Office and the Office of Fair Trading. To date no adverse comments have been received from any department.

### **Public Consultation**

#### **Informal**

36. They were asked to provide information on possible costs and / or other impacts, positive/negative associated with the changes to the labelling requirements set out in the new EU Regulation, which would form the basis on the impact(s) on business (please see section on 'appraisal of options above)

#### **Formal Public Consultation**

37. The FSA will conduct a formal public consultation from 25 February 2016 to 1 April 2016 2016. Producers of animal feeds involved in the placing on the market of products with added additives, including importers, distributors, wholesalers and retailers, plus enforcement authorities and consumer organisations will be consulted on the proposed Regulations.

#### **Statutory Review**

38. The FSA is required by the UK Government to carry out a review every five years on the way in which EU legislation is implemented and enforced by the relevant domestic legislation and, to the extent that it is reasonably practicable, to compare that with how the same EU measures are implemented or enforced in other Member States. The FSA will carry out a review in April 2020 or earlier to assess whether the Regulations are achieving their intended objectives.

#### **One In, Two Out Status**

39. The proposed Regulations are out of scope of One-In-Two-Out, as the requirements are of EU origin and the do not introduce any gold plating. Identification of savings equivalent to twice the burden of the estimated costs to business is not therefore required.

### **Wider Impacts**

#### **Small & micro business assessment**

40. The UK feed industry sector is comprised of mainly small and micro businesses (generally greater than 90%<sup>7</sup>) and therefore the greatest impact from new feed measures introduced in the UK will, in the vast majority of cases, be on small and micro businesses. For this reason the FSA assesses the impact on small and micro businesses as standard when undertaking impact assessments.

41. EU legislation generally applies to food/feed businesses regardless of size, as requirements are intended to be risk based to reflect the activities undertaken. Due to the high ratio of small and micro feed businesses in the UK it is often not feasible to exempt smaller businesses from new feed measures as this would fail to achieve the intended effect of reducing risks to consumer health. That said, FSA makes every effort to minimise burdens on small and micro businesses and pays particular attention to impacts on them.

### **Consultation Question 7**

<sup>7</sup> based on data taken from the ONS – Inter-Departmental Business Register (IDBR) - <http://www.ons.gov.uk/ons/rel/bus-register/uk-business/2013/index.html>

**Do you agree with our assumption that there will not be a significant impact on small businesses as a result of this legislation is a correct assumption? If you agree or disagree with this assessment, please provide evidence to support your response.**

### **Race/Gender/Disability Equality Issues**

42. There will be no impacts on existing health, wellbeing or other social inequalities, on human rights, on levels of crime or crime prevention, or on skills and education. There will be no differential impact on rural or urban areas, nor any specific local or regional effects.

### **Consultation Question 8**

**Are you aware of any other impacts under the Specific Impact Tests as a result of the EU Regulations 2015/327 and 2015/2294 and national Regulation? Please provide evidence to support your response.**