CONSULTATION DOCUMENT

THE ANIMAL FEED (COMPOSITION MARKETING AND USE) (ENGLAND) (AMENDMENT) REGULATIONS 2016

CONSULTATION SUMMARY PAGE

Date launched:	25 FEBRUARY 2016	Closing date:	1 APRIL 2016

Who will this consultation be of most interest to?

Manufacturers of animal feed in England, in particular businesses labelling and placing feed products on the market, mixers, farms and businesses involved in the growing, production, storage, transport and import of feed products. Plus enforcement authorities and consumer organisations.

What is the subject of this consultation?

The proposed Animal Feed (Composition, Marketing and Use) (England) (Amendment) Regulations 2016 will amend the Animal Feed (Composition, Marketing and Use) (England) Regulations 2015. This will enable the enforcement in England of Commission Regulation (EU) 2015/327 of 2 March 2015 and Commission Regulation (EU) 2015/2294 both amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards requirements for the placing on the market and conditions of use of additives consisting of preparations.

What is the purpose of this consultation?

To provide interested parties with the opportunity to comment on, and express their opinions on the proposed Animal Feed (Composition, Marketing and Use) (England) (Amendment) Regulations 2016 and the associated Impact Assessment.

Responses to this consultation should be sent to:

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FOOD STANDARDS AGENCY
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Impact Assessment included?	Yes ☒	No ☐ See Annex A for reason.

THE ANIMAL FEED (COMPOSITION MARKETING AND USE) (ENGLAND) (AMENDMENT) REGULATIONS 2016

DETAIL OF CONSULTATION

1. We would welcome your comments on the proposed Animal Feed (Composition, Marketing and Use) (England) (Amendment) Regulations 2016 ("the proposed Regulations") attached at Annex A. The proposed Regulations will amend the Animal Feed (Composition, Marketing and Use) (England) Regulations 2015 to provide for the enforcement and execution of Commission Regulation No. (EU) 2015/327[1] ("Commission Regulation 2015/327) and Commission Regulation No. (EU) 2015/2294 (Commission Regulation 2015/2294").

2. We would particularly welcome comments and supporting evidence in respect of any cost implications that may arise from these proposals as indicated in the draft Impact Assessment (IA) at Annex C.

3. Commission Regulation 2015/327 amending Commission Regulation (EC) No. 1831/2003[2] ("Regulation 1831/2003) was published in the Official Journal (OJ) of the European Union on 3 March 2015. The new Commission Regulation came into force: 20 days after its publication on 23 March 2015, and is applicable throughout the EU.

4. Since the publication of Commission Regulation 2015/327, Regulation 1831/2003 has been amended again by Commission Regulation (EU) 2015/2294[3] , which was published in the OJ on 10 December 2015 and came into force 29 December 2015.

5. Copies of the new Commission Regulations are attached as Annexes D and E and is also available to download free of charge from the EUR-Lex website at:

   http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R0327&from=EN
   http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R2294&from=EN

6. Offices of the Food Standards Agency in Wales and Northern Ireland will each consult on parallel but separate Regulations that will apply in those territories.

Background

7. Regulation (EC) No. 1831/2003 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, environment and users' and consumers' interests in relation to feed additives, whilst ensuring the effective functioning of the internal market.

8. Some additives authorised under Regulation 1831/ 2003 are 'preparations', which means the active additive has been mixed with technological additives or other substances which are not themselves intended to have a function in the feed – for example, they may assist stability for functionality of the active additive by improving homogeneity or flowability.

[1] OJ L 58, 3.3.2015, pg. 45
[2] 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,
[33] OJ L 324, 10.12.2016, pg 3

9. It is considered appropriate to bring more transparency and clarity when placing additive preparations on the market, without affecting intellectual property rights relating to the composition of premixtures containing such additives.

10. In accordance with Commission Regulation 2015/327, a new Annex III is introduced in Commission Regulation (EC) No 1831/2003, which provides for additional labelling requirements for this type of additive and for premixtures containing them. This is intended to allow verification that technological additives used in a preparation are authorised for the intended purpose and that those additives exert a function only on the active substance contained in the preparation.

11. Annex IV of Commission Regulation (EC) No. 1831/2003, on general conditions of use, is also amended, to take into account technological progress and scientific development concerning additives consisting of preparations. Furthermore, in accordance with Commission Regulation 2015/2294, a further point (n) is added in point 1 of Annex I on the additive groups. The changes introduced by the new Commission Regulation are:

Article 1 (Commission Regulation 2015/327)

- *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.*

Article 1 (Commission Regulation 2015/2294)

- *Amendment to point 1 of Annex I – the following point (n) is added*
  - *Hygiene condition enhancers: substances or, when applicable, microorganisms which favourably affect the hygiene characteristics of feed by reducing a specific microbiological contamination.*

12. Although European Regulations are directly applicable in Member States from the date of application specified in them, provisions must be made for their execution and enforcement. The proposed Regulations have been developed for this

purpose. The proposed Regulations will amend the 2015 Regulations, taking into account the provisions of the new Commission Regulations and to ensure that necessary enforcement powers for that Regulation are in place in England.

13. We are therefore conducting this short six week consultation to seek comments from interested parties on the draft SI and its impact

Impact on businesses and Enforcement bodies

14. In terms of impact on businesses and enforcement authorities, there is likely to be a familiarisation cost associated with the proposed Regulations. These include the reading and dissemination of the Regulations to key staff within the organisation. There will also be a cost associated with re-labelling as indicated in the Impact Assessment. The primary business operators involved are animal feed businesses in England, in particular businesses labelling and placing feed products on the market, mixers, farms and businesses involved in the growing, production, storage, transport and import of feed products. Enforcement authorities and consumer organisations will also need to be aware of the proposed changes to the labelling.

15. In terms of costs, the FSA has been advised of estimated costs associated with changes. These indicated that the labelling of additive preparations should only have a small impact on producers of animal feed. The new EU Regulation puts in place transitional arrangements so that products which meet the previous requirements can continue to be placed on the market until 23 March 2017 and may then also continue to be used until existing stocks are exhausted.

16. Familiarisation costs associated with the introduction, of a new functional category of feed additives by Commission Regulation 20145/2294, are expected to be minimal.

Key proposal:

- To amend the Animal Feed (Composition, Marketing and Use) (England) Regulations 2015, in order to provide for the execution and enforcement of a change in labelling requirements introduced by Commission Regulation 2015/357 and the change introduced by Commission Regulation 2015/2294

Purpose of the Consultation

17. The purpose of this six week consultation is to provide interested parties with the opportunity to comment on, and express their opinions on the proposed Regulations 2016 and the associated Impact Assessment.

18. The proposed Regulations will make provisions for the execution and enforcement of the new Commission Regulations. This will provide enforcement authorities with the necessary powers to take appropriate enforcement action where foodstuffs are found to be non-compliant with the new requirements.

Consultation Process / Impact

Within Government

19. 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, the Department of Food and Rural Affairs and the Office of Fair Trading. To date, no adverse comments have been received from any department

Informal Consultation

20. In June 2015, the FSA wrote to a trade association representing animal feed manufacturers for information on costs associated with Commission Regulation 2015/327. The trade association informed that in terms of costs on labelling for additive preparations, this will be a relatively small impact on the producers, as they understand that many producers already provide the required information in the form of data sheets.

21. In addition, the FSA has been advised that Commission Regulation 2015/2294 will cause minimal impact – likely to be familiarisation costs only.

22. Interested parties are invited to respond to the following questions;

Questions asked in this consultation:

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.

2a). We invite industry stakeholders to comment on whether our estimates of familiarisation costs to industry (as outlined in Table 1 of the IA) seem reasonable; if you agree or disagree 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 new Commission 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.

3a). We invite industry stakeholders to comment on whether our estimates of re-labelling costs to industry are an accurate assessment (as outlined in Table 1 of the IA). If you agree or disagree with these estimates, please provide written evidence to support your views,

3b). We would also welcome industry comments on our assumption that any costs associated with the introduction of a new function category of feed additives are 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.

4). We invite enforcement bodies 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.

5). 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.

6). 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.

7). Are you aware of any other impacts under the Specific Impact Tests as a result of the new Commission Regulations and the national Regulation? Please provide evidence to support your response.

Other Comments

23. Any comments that interested parties are able to provide in relation to the proposed Regulations would be gratefully received. We are particularly keen to hear from Small and Medium Enterprises on a likely impact and would encourage them to comment on all aspects of this proposal.

24. Following the consultation, we will review the responses received and consider whether any changes are required to the proposed legislation. A summary of all comments received and the FSA's response to each will be published on the FSA's website within 3 months following the end of the consultation period.

Other relevant documents

25. Commission Regulation (EU) No. 2015/327 as regards requirements for the placing on the market and conditions of use of additives consisting of preparations is available from the EUR-Lex website at:

    http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R0327&from=EN

26. Commission Regulation (EU) No. 2015/2294 as regards the establishment of a new functional group of feed additives is available from the EUR-Lex website at:

    http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R2294&from=EN

27. The Animal Feed (Composition, Marketing and Use) (England) Regulations 2015 are available on the 'legislation.gov.uk' website at:
    http://www.legislation.gov.uk/uksi/2015/255/contents/made

Responding to the Consultation

28. Responses are required by close of business 1st April 2016. Please state, in your response whether you are responding as a private individual or on behalf of an organisation / company (including details of any stakeholders your organisation represents.

29. Thank you on behalf of the Food Standards Agency for participating in this public consultation.

Yours faithfully,

Nasreen Shah
Regulatory Officer
Directorate Support Unit

Enclosed

Annex A – the *Draft* Animal Feed (Composition, Marketing and Use) (England) (Amendment) Regulations 2016

Annex B: Standard Consultation Information

Annex C: *Draft* Impact Assessment

Annex D Commission Regulation (EU) 2015/327

Annex E: Commission Regulation (EU) 2015/2249

Annex F: List of interested parties

Publication of personal data and confidentiality of responses

1. In accordance with the FSA principle of openness we shall keep a copy of the completed consultation and responses, to be made available to the public on receipt of a request to the FSA Consultation Coordinator (020 7276 8308). The FSA will publish a summary of responses, which may include your full name. Disclosure of any other personal data would be made only upon request for the full consultation responses. If you do not want this information to be released, please complete and return the Publication of Personal Data form, which is on the website at **http://www.food.gov.uk/multimedia/worddocs/dataprotection.doc** Return of this form does not mean that we will treat your response to the consultation as confidential, just your personal data.

3. In accordance with the provisions of Freedom of Information Act 2000/Environmental Information Regulations 2004, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with the FSA. However, we will take into account your views when making this decision.

4. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

Further information

5. A list of interested parties to whom this letter is being sent appears in Annex **F.** Please feel free to pass this document to any other interested parties, or send us their full contact details and we will arrange for a copy to be sent to them direct.
6. TBC: A Welsh version of the consultation package can be found at www.food.gov.uk

7. Please contact us if you require this consultation in an alternative format such as Braille or large print.

8. This consultation has been prepared in accordance with HM Government consultation principles[4].

[4] http://www.bis.gov.uk/policies/bre/consultation-guidance

Title: The Animal Feed (Composition, Marketing and Use) (England) (Amendment) Regulations 2016 **IA No: Food 0151** **Lead department or agency:** Food Standards Agency **Other departments or agencies:**	**Impact Assessment (IA)** **Date:** February 2016 **Stage:** Consultation **Source of intervention:** EU **Type of measure:** Secondary legislation **Contact for enquiries:** Nasreen Shah, Tel: 020 7276 8538 nasreen.shah@foodstandards.gsi.gov.uk

Summary: Intervention and Options

RPC Opinion: 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.

Will the policy be reviewed? It will/will not be reviewed. **If applicable, set review date:** 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.	**Micro** Yes	**< 20** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:**	**Non-traded:**	

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 .....

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:**

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				

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

This is the baseline against which other options are compared

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'

This is the baseline against which other options are compared.

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

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[1] both amend Commission Regulation (EC) No 1831/2003[2] 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[3] 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

[1] OJ L 324, 10.12.2015, pg 3

[2] 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,

[3] 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 t 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[4] 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[5]. 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[6]

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 with this

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

[5] http://berr.gov.uk/files/file44503.pdf_http://www.statistics .gov.uk/downloads/theme_labour/ASHE-2009/2009_occ4.pdf

[6] Net Present Value is the difference between the Present Value of a stream of costs and a stream of benefits.

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
Enforcement			
Local Authorities			
One-off Costs			
Learning and dissemination	£12,513	£12,513	£1,454
Total one-off cost	£12,513	£12,513	£1,454
On-going costs	£0	£0	**£0**
Total Cost: Local Authorities	**£12,513**	**£12,513**	**£1,454**
Industry			
One-off Costs			
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
On-going costs	£0	£0	**£0**
Total Cost: Industry	**£41,575**	**£41,575**	**£4,830**
Total Cost	£54,088	£54,088	£6,284

33. The net benefit to society from Option 2 is -£54k (present value). The impact on business is a net present value of -£40l which equates to an equivalent annual cost to business of £4.8k (see Table 2)

Table 2

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

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%[7]) 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

[7] 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.

S T A T U T O R Y I N S T R U M E N T S

2016 No.

AGRICULTURE, ENGLAND

The Animal Feed (Composition, Marketing and Use) (England) (Amendment) Regulations 2016

Made - - - -	***
Laid before Parliament	***
Coming into force - -	***

The Secretary of State makes the following Regulations in exercise of the powers conferred on him by sections 66(1), 68(1), 74A(1) and 84 of the Agriculture Act 1970(**a**), as read with regulation 14 of the Food Standards Act 1999 (Transitional and Consequential Provisions and Savings) (England and Wales) Regulations 2000(**b**).

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Secretary of State that it is expedient for references to the Annexes to Regulation (EC) No. 1831/2003 be construed as references to those Annexes as they may be amended from time to time.

There has been open and transparent public consultation during the preparation of these Regulations in accordance with the requirements of Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (**c**) or, in the case of provisions relating to feed for non food-producing animals, of section 84(1) of the Agriculture Act 1970.

(**a**) 1970 c.40. Section 66(1) contains definitions of the expressions "the Ministers", "prescribed" and "regulations". The definition of "the Ministers" was amended by the Transfer of Functions (Wales) (No.1) Order 1978 (S.I. 1978/272), Schedule 5, paragraph 1. Functions of "the Ministers", so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672 and subsequently transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32). Those functions, so far as exercisable in relation to Scotland were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c.46). By virtue of S.I. 1999/3141, functions of the Secretaries of State for Wales and Scotland previously exercisable in relation to England ceased to be so exercisable and were transferred to the Minister of Agriculture, Fisheries and Food. Functions of the Minister of Agriculture were transferred to the Secretary of State by the Ministry of Agriculture, Fisheries and Food (Dissolution) Order 2002 (S.I. 2002/794). Section 74A was inserted by the European Communities Act 1972 (1972 c.68), Schedule 4, paragraph 6. Sections 66(1) and 84 were amended by S.I. 2004/3254. Section 66(1) was also amended by S.I. 2010/2280.

(**b**) S.I.2000/656.

(**c**) OJ No. L31, 1.2.2002, p.1, as last amended by Regulation (EU) No. 652/2014 of the European Parliament and of the Council (OJ No. L189, 27.6.2014, p.1).

Title and commencement

1.These Regulations may be cited as the Animal Feed (Composition, Marketing and Use) (England) (Amendment) Regulations 2016 and come into force on 27 May 2016.

Amendments to the Animal Feed (Composition, Marketing and Use) (England) Regulations 2015

2.—(1) The Animal Feed (Composition, Marketing and Use) (England) Regulations 2015(**a**) are amended in accordance with paragraphs (2) and (3).

(2) In regulation 2 (interpretation and scope)—

(a) paragraph (1) for the definition of "Regulation 1831/2003" substitute the following definition—

"Regulation 1831/2003" means Regulation (EC) No. 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition (**b**) as last amended by Commission Regulation (EU) 2015/2294 amending Regulation (EC) No. 1831/2003 of the European Parliament and of the Council as regards the establishment of a new functional group of feed additives (**c**)"

(b) In paragraph (3), after "Directive 2008/38" insert ", Regulation 1831/2003".

(3) In regulation 10 (offence of failing to comply with a specified provision of Regulation 1831/2003) for paragraph (1) substitute the following —

"(1) A person commits an offence if that person contravenes or fails to comply with a provision specified in paragraph (2) as read, in the case of subparagraph (a) or (e) with Article 2 (transitional provision) of Commission Regulation (EU) 2015/327 amending Regulation (EC) No. 1831/2003 of the European Parliament and of the Council as regards requirements for the placing on the market and conditions of use of additives consisting of preparations.".

Review

3.—(1) The Food Standards Agency must from time to time —

(a) carry out a review of the operation and effect of regulation 2; and

(b) publish a report setting out the conclusions of the review

(2) In carrying out the review the Food Standards Agency must have regard to how Commission Regulation (EU) 2015/327 amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards requirements for the placing on the market and conditions is implemented in other Member States.

(3) The report must, in particular—

(a) set out the objectives intended to be achieved by regulation 2,

(b) assess the extent to which those objectives are achieved,

(c) assess whether those objectives remain appropriate, and

(d) if those objectives remain appropriate, assess the extent to which they could be achieved in another way which involves less onerous regulatory provision.

(4) The first report under this regulation must be published before the end of the period of 5 years beginning with the day on which these Regulations come into force.

(5) Subsequent reports must be published at intervals not exceeding 5 years.

(**a**) S.I. 2015/255.
(**b**) OJ No. L268, 18.10.2003, p.29.
(**c**) OJ No. L.324 10.12.2015, p.3

Signed by authority of the Secretary State of Health

Jane Ellison
Parliamentary Under Secretary of State
Department of Health

Date

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations provide for the execution and enforcement of Commission Regulation (EU) 2015/327 amending Regulation (EC) No. 1831/2003 of the European Parliament and of the Council as regards requirements for the placing on the market and conditions of use of additives consisting of preparations (OJ No. L58, 3.3.2015, p.46).

2. These Regulations amend the Animal Feed (Composition, Marketing and Use) (England) Regulations 2015 (S.I. 2015 No.255) by —

(a) re-stating the definition of Regulation (EC) No 1831/2003 so it includes the amendments made by Commission Regulation (EU) 2015/327 (*regulation 2(2)(a)*);

(b) providing that any reference in S.I. 2015/255 to an Annex to Regulation (EC) No 1831/2003 is to be construed as a reference to that Annex as it may be amended from time to time (*regulation 2(2)(b)*); and

(c) Providing that certain potential offences of contravening Regulation (EC) No 1831/2003 are subject to transitional arrangements set out in Article 2 of Commission Regulation (EU) 2015/327.

3.A full impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector is available from the Animal Feed, TSEs and Animal By-products Branch of the Food Standards Agency, Aviation House, 125 Kingsway, London, WC2B 6NH and is annexed to the Explanatory Memorandum which is available alongside the instrument on the OPSI website.

COMMISSION REGULATION (EU) 2015/327

of 2 March 2015

amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards requirements for the placing on the market and conditions of use of additives consisting of preparations

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([1]), and in particular Articles 3(5) and 16(6) thereof,

Whereas:

(1) In some preparations, authorised as additives in accordance with Regulation (EC) No 1831/2003, technological additives and other substances or products are incorporated to exert a function on the active substance contained in the preparation, such as stabilising or standardising it, facilitating its handling or its incorporation into feed. For example, those technological additives or other substances or products may increase flowability or homogeneity or reduce the dusting potential of the active substance. The specific composition of authorised additives consisting of preparations will therefore vary according to the rationale for the use of those preparations. The technological additives or other substances or products added to maintain the integrity of an active substance are however not intended to perform a function in the feed in which the preparation is to be incorporated.

(2) Taking into account that technological progress contributes to the development of new preparations, it is appropriate to better consider the specificities of additives consisting of preparations and to bring more transparency and clarity when placing them on the market, without affecting intellectual property rights relating to the composition of premixtures containing such additives.

(3) In particular, it is appropriate to introduce into Annex III to Regulation (EC) No 1831/2003 additional labelling requirements for this type of additives and for premixtures containing them, so as to allow a verification that technological additives used in a preparation are authorised for the intended purpose and that those additives exert a function only on the active substance contained in the preparation.

(4) While the most relevant information should be kept on the packaging or container of the additive or the premixture, technological progress also allows providing information about the composition of the preparations in a more flexible and less costly way via other written means. This is in compliance with the definition of labelling provided for in Regulation (EC) No 767/2009 of the European Parliament and of the Council ([2]).

(5) Operators should be able to provide information about the composition of the preparations which are placed on the market since such information enables the end-user or the purchaser to make an informed choice, allows appropriate risk assessment and contributes to fairness of transactions.

(6) Those additional labelling and information requirements should apply only to additives belonging to the categories referred to in Article 6(1)(a), (b) and (c) of Regulation (EC) No 1831/2003. Where such additives are authorised as preparations, only the active substance is indeed the subject of the authorisation, and not the other components of the preparations, which may vary.

(7) In order to prevent any undesirable effects on human health, animal health or the environment, operators should ensure that there is physico-chemical and biological compatibility between the components of the preparation which is placed on the market and used.

([1]) OJ L 268, 18.10.2003, p. 29.

([2]) Regulation (EC) No 767/2009 of 13 July 2009 of the European Parliament and of the Council on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC (OJ L 229, 1.9.2009, p. 1).

(8) Annex III to Regulation (EC) No 1831/2003, on specific labelling requirements for certain additives and for premixtures, and Annex IV thereto, on general conditions of use, should therefore be amended in order to take into account technological progress and scientific development concerning additives consisting of preparations.

(9) A transitional period is needed to avoid disruptions in the placing on the market and use of existing additives consisting of preparations, and of feed containing them, so that they may be used until stocks are exhausted.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Amendment to Annexes III and IV

Annexes III and IV to Regulation (EC) No 1831/2003 are amended in accordance with the Annex to this Regulation.

Article 2

Transitional provision

Additives consisting of preparations and premixtures containing such additives, which are produced and labelled before 23 March 2017 in accordance with Regulation (EC) No 1831/2003 as it stood before 23 March 2015 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 3

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 2 March 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Annexes III and IV to Regulation (EC) No 1831/2003 are amended as follows:

(1) Annex III is replaced by the following text:

'ANNEX III

1. SPECIFIC LABELLING REQUIREMENTS FOR CERTAIN ADDITIVES AND FOR PREMIXTURES.

(a) Zootechnical additives, coccidiostats and histomonostats:

— the expiry date of the guarantee or the storage life from the date of manufacture,

— the directions for use, and

— the concentration.

(b) Enzymes, in addition to the abovementioned indications:

— the specific name of the active component or components in accordance with their enzyme activities, in conformity with the authorisation given,

— the International Union of Biochemistry identification number, and

— instead of concentration: units of activity (units of activity per gram or units of activity per millilitre).

(c) Micro-organisms:

— the expiry date of the guarantee or the storage life from the date of manufacture,

— the directions for use,

— the strain identification number, and

— the number of colony-forming units per gram.

(d) Nutritional additives:

— the active-substance level, and

— the expiry date of the guarantee of that level or storage life from the date of manufacture.

(e) Technological and sensory additives with the exception of flavouring compounds:

— the active substance level.

(f) Flavouring compounds:

— the incorporation rate in premixtures.

2. ADDITIONAL LABELLING AND INFORMATION REQUIREMENTS FOR CERTAIN ADDITIVES CONSISTING OF PREPARATIONS AND PREMIXTURES CONTAINING SUCH PREPARATIONS.

(a) Additives belonging to the categories referred to in Article 6(1)(a), (b) and (c) and consisting of preparations:

(i) the indication on the packaging or container of the specific name, the identification number and the level of any technological additive contained in the preparation for which maximum levels are set in the corresponding authorisation;

(ii) the following information via any written medium or accompanying the preparation:

— the specific name and the identification number of any technological additive contained in the preparation, and

— the name of any other substance or product contained in the preparation, indicated in descending order by weight.

(b) Premixtures containing additives belonging to the categories referred to in Article 6(1)(a), (b) and (c) and consisting of preparations:

(i) if appropriate, the indication on the packaging or container that the premixture contains technological additives included in additive preparations, for which maximum levels are set in the corresponding authorisation;

(ii) upon request from the purchaser or the user, information on the specific name, the identification number and an indication of the level of technological additives referred to in point (i) of this paragraph included in the additive preparations.';

(2) in Annex IV, the following point 5 is added:

'5. 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.

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

COMMISSION REGULATION (EU) 2015/2294

of 9 December 2015

amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the establishment of a new functional group of feed additives

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([1]), and in particular Article 6(3) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the allocation of feed additives to categories and further to functional groups within those categories according to their functions and properties.

(2) As a result of technological and scientific development, some feed additives may improve the hygienic condition of a feed, in particular by reducing a specific microbiological contamination and thereby mitigating the possible adverse effects of microorganisms on animal health.

(3) In addition to the implementation of the hygienic requirements and good practices along the feed chain, operators may need in specific cases to use hygienic condition enhancers in order to improve the quality of feed for animal nutrition providing additional guarantees for the protection of animal and public health. Since such feed additives cannot be allocated to any of the functional groups provided for in Regulation (EC) No 1831/2003, it is necessary to add a new functional group in the category 'technological additives'.

(4) Regulation (EC) No 1831/2003 should therefore be amended accordingly.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

In point 1 of Annex I to Regulation (EC) No 1831/2003, the following point (n) is added:

'(n) hygiene condition enhancers: substances or, when applicable, microorganisms which favourably affect the hygienic characteristics of feed by reducing a specific microbiological contamination.'

Article 2

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

([1]) OJ L 268 18.10.2003, p. 29.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 9 December 2015.

For the Commission
The President
Jean-Claude JUNCKER

Interested Parties

Contact	Organisation
David Clarke	Red Tractor Assured Food Standards
Catherine Lehane	Red Tractor Assured Food Standards
George Perrott	Agricultural Industries Confederation
Simon Williams	Agricultural Industries Confederation
Inge Verwoerd	Agricultural Industries Confederation
Claire Williams	British Equestrian Trade Association
Geoff Brown	British Association of Feed Supplement and Additive Manufacturers
Ruth Evans	Brewing, Food & Beverage Industry Association
Andrew Large	British Poultry Council
Richard Warren	Dairy UK
Ruth Graham	Diageo
Keneth Chinyama	Food and Drink Federation
Monika Prenner	Purina Nestle
Karen Percival	Nestle UK
Ian Beck	UK Fats and Oils Association
Jaine Chisholm Caunt	Grain and Feed Trade Association
June Arnold	Grain and Feed Trade Association
Julie Benson	Cornwall
Jennifer Donn	National Association of Agricultural Contractors
Martin Savage	National Association of British and Irish Millers
Tim Brigstocke	Royal Association of British Dairy Farmers
Helen Ferrier	NFU
Lorraine Chambers	Kiwa PAI
Marcus Wood	SAI Global
Michael Bellingham	Pet Food Manufacturers Association
Lana Oliver	Pet Food Manufacturers Association
Liz Colebrook	Mars Petcare
Angela Bowden	The Seed Crushers and Oil Processors Association
Paul Featherstone	Sugarich
Robert Brocklesby	Adams and Green
Elizabeth Andoh-Kesson	British Retailer Consortium
David Mackley	AC Shropshire
Robin Crawshaw	RC Feed
Angela Booth	AB Agri
Kevin Wardle	Public Analyst Services

Government Officials

Lee Grist	VMD
Clare Wild	APHA
Carmen Marco	APHA
Adrian Charlton	FERA