

Consultation on proposed changes to national (England only) law in relation to EU Directives on animal feed, food contact materials and extraction solvents.

Launch date: [13 July 2022]

Respond by: [10 August 2022]

This consultation will be of most interest to

- Food, food packaging and feed manufacturers, importers/exports and retailers
- Trade bodies representing stakeholders for animal feed, food contact materials and extraction solvents
- Organisations representing consumer interests in the feed and food-chains
- Enforcement authorities

A list of interested parties is included in Annex A

Consultation subject

This consultation is to seek stakeholders' views, comments, and feedback on the proposals to correct deficiencies in national (England only) legislation relating to animal feed, food contact materials and extraction solvents, separately, to ensure the legislation operates effectively following the UK's exit from the European Union.

Currently, the relevant national legislation for animal feed, food contact materials and extraction solvents contain inoperabilities that need to be resolved following the UK's exit

from the EU. In particular, the legislation cross-refers to Annexes and specific articles of their associated EU Directives. These inoperabilities need to be addressed using European Union (Withdrawal) Act 2018 (EUWA) powers. Following the referendum vote held on the 23rd June 2016, and the subsequent majority vote to leave the European Union, the EUWA was passed on the 26th of June 2018. The EUWA provides that, on exit from the EU, certain directly applicable EU legislation will be converted into UK law. The EUWA also provides ministers with powers to make corrections to retained EU law so that it operates effectively as UK law. Necessary corrections have been made by way of a number of statutory instruments across Government departments, including the FSA. As these powers will no longer be available after 31 December 2022, the revised national legislation must be established before the powers expire. Additionally, in order to ensure clean and operable legislation, miscellaneous references to the Directives and associated Annexes must be removed from national legislation covering animal feed, food contact material and extraction solvents respectively.

This consultation covers changes to the Statutory Instruments in England only. Similar changes are being made to Welsh and Scottish national legislation.

Purpose of the consultation

To seek stakeholders' views, comments, and feedback in relation to the proposals to incorporate requirements in EU Directives into national law on animal feed, food contact materials and extractions solvents. We ask stakeholders to consider if any relevant requirements have been missed, or if they are content with the proposed changes.

Engagement and consultation process

A four-week public consultation is being launched across the UK to provide interested parties with an opportunity to comment on the policy proposals for the incorporation of requirements in EU Directives into national law on animal feed, food contact materials and extraction solvents.

This consultation period is relatively short in comparison to the optimal length of twelve weeks. This shorter consultation is due to the need for the FSA to conclude the process with sufficient time to allow for the use of European Union (Withdrawal) Act 2018

('EUWA') powers, which expire at the end of 2022. These powers would be used to implement the legislation in the event the consultation responses are supportive.

Any responses to this consultation will be given careful consideration and a summary of responses received will be published on the FSA website within three months of the consultation closing.

How to respond

Responses to this consultation should be sent to:

Animal Feed: Taranjit Dhansay <u>Taranjit.Dhansay@food.gov.uk</u>

Food Contact Materials: Tim Chandler tim.chandler@food.gov.uk

Extraction Solvents: Danielle.gazi@food.gov.uk

Details of consultation

Separate sections are set out for the changes to the animal feed, food contact materials and extraction solvent legislation.

Animal feed

Food contact materials

Extraction solvents

Animal Feed

Introduction

 Animal feed legislation in England makes cross references to the lists in Directive 2002/32/EC and Directive 82/475/EEC, the lists within these Directives remain as they were on implementation day (31 December 2020 23:00), amendments to these versions cannot be made.

Directive 2002/32/EC on undesirable substances in animal feed

2. Products intended for animal feed may contain undesirable substances which can endanger animal health or, because of their presence in livestock products, human health or the environment. It is impossible to eliminate fully the presence

of undesirable substances but it is important that their content in products intended for animal feed should be reduced in order to prevent undesirable and harmful effects.

3. Undesirable substances may be present in products intended for animal feed only in accordance with the conditions laid down in the Animal Feed (Composition, Marketing and Use) (England) Regulations 2015 (SI 2015/255), by cross-reference to Directive 2002/32/EC; and these substances may not be used in any other way for the purposes of animal feed. Products intended for animal feed must be sound, genuine and of merchantable quality and therefore when correctly used must not represent any danger to human health, animal health or to the environment or adversely affect livestock production. Using or putting into circulation products intended for animal feed which contain levels of undesirable substances that exceed the maximum levels laid down in the Annex of this Directive must therefore be prohibited.

Directive 82/475/EEC, categories of feed materials which may be used for the purposes of labelling compound feeding stuffs for pet animals

4. The Animal Feed (Composition, Marketing and Use) (England) Regulations 2015 make provision for the enforcement of retained Regulation (EC) No 767/2009 on the placing on the market and use of feed sets out the requirements for the marketing, labelling and composition of animal feeding stuffs and includes provisions intended to safeguard both animal and human health. Mandatory labelling requirements for compound feed set out in this regulation require feed materials of which the feed is composed to be listed on the label. In the case of compound feed intended for non-food producing animals, the indication of the specific name of the feed material may be replaced by the name of the category to which the feed materials belong. Under the Animal Feed (Composition, Marketing and Use) (England) Regulations 2015, only the categories listed in the Annex to Directive 82/475/EEC may be indicated for the purposes of Regulation (EC) No 767/2009.

Main Proposals:

- To allow amendments to the lists of undesirable substances prescribed in
 Directive 2002/32/EC, and to adapt them to scientific and technical
 developments, we propose incorporating these lists into the Animal Feed
 (Composition, Marketing and Use) (England) Regulations 2015, the retaining of
 controls set out in the Directive, and the adjustment of cross references from
 this legislation to the Directive. As part of this we will consider converting
 powers conferred by the Directive into domestic powers.
- To allow the future modification of the category list in Directive 82/475/EEC we propose incorporating the list into the Animal Feed (Composition, Marketing and Use) (England) Regulations 2015 and the adjustment of cross-references from this legislation to the Directive.

Food Contact Materials

Introduction

Regenerated cellulose film (RCF) is thin sheet material obtained from a refined cellulose derived from unrecycled wood or cotton. RCF may be coated on one or both sides. There are specific requirements that need to be adhered when manufacturing RCF that is intended to be brought into contact with foodstuffs. European Council Directive 2007/42/EC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs sets out these requirements. These requirements were previously transposed under national legislation, the Materials and Articles in Contact with Food (England) Regulations 2012 (SI 2012/2619). Following the UK's exit from the European Union, it has been observed that the full list of authorised substances currently prescribed under Annex II (list of substances authorised in the manufacture of regenerated cellulose film) of Council Directive 2007/42/EC should be fully set out within Materials and Articles in Contact with Food (England) Regulations 2012 for ease of reference.

Under the Materials and Articles in Contact with Food (England) Regulations 2012 (as amended), it is proposed to incorporate the full list of authorised substances currently prescribed under Annex II (list of substances authorised in the manufacture of regenerated cellulose film) of Council Directive 2007/42/EC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs. The proposed location will be to list these within a schedule in the Materials and Articles in Contact with Food (England) Regulations 2012. This includes the first part for uncoated regenerated cellulose film, which concerns permitted additives under the headings of softeners and other additives (consisting of first class, second class, third class - anchoring agent and fourth class). The second part for coated regenerated cellulose film consists of permitted additives and coatings (consisting of polymers, resins, plasticisers, other additives and solvents). This will provide clarity to business operators that these substances are permitted for use in coated or uncoated regenerated cellulose film intended to come into contact with foodstuffs, subject to any specific individual restrictions. Including this list of authorised substances within the national regulations will also enable additions to the retained list given that we will assess new substances for authorisation under the Regulated Product Approvals Procedure. It will also be possible

to assess existing authorised substances should new evidence relating to their safety be brought to our/the FSA and FSS's attention.

Main proposals:

- To incorporate the lists in Annex II of Council Directive 2007/42/EC, as it stood on leaving the EU into a new Schedule in the Materials and Articles in Contact with Food (England) Regulations 2012.
- To remove cross-references to Council Directive 2007/42/EC, including to its Annexes, within the Materials and Articles in Contact with Food (England) Regulations 2012.

Changes not being considered

We consider that Ministers have sufficient existing powers under the Food Safety Act 1990 to ensure consumer protection and food safety are maintained in relation to the authorisation and use of substances in RCF. The exercise of these powers will be subject to Parliamentary scrutiny, and any future legislation will be laid before Parliament for its due consideration.

Extraction Solvents

Introduction

Extraction solvents are solvents used in the processing of raw materials or food ingredients to either extract desirable components (for example, flavouring compounds from plants) or to remove or reduce the level of certain substances in food (for example, decaffeination of coffee or removal of fats from soya products). Whilst extractions solvents are removed during the production process, technically unavoidable residues of the solvent may remain in the food. To ensure that the amount of extraction solvent in the food or food ingredient is as low as possible, maximum residue limits (MRLs) are set. If the extraction solvent is a food itself, for example, ethanol, then no numerical limits are set but their use must be in line with Good Manufacturing Practice. In general, extraction solvents are not sold direct to the final consumer but are traded between businesses.

At present, controls on the use of extraction solvents are covered by the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013 (SI 2013/2210) (hereby referred to as the 2013 Regulations) which cross-refer to Directive

2009/32/EC on extraction solvents used in the production of foodstuffs and food ingredients (hereby referred to as the Directive). The 2013 Regulations ensure compliance with certain requirements, such as labelling, and prevent anyone from using or placing on the market an unpermitted extraction solvent. They set out the enforcement provisions and penalties for businesses not complying with the legal requirements. The Directive includes an Annex (Annex I) where permitted extraction solvents, their usage levels and maximum residue levels are set. It also includes an Article, Article 3(c), which serves as a place holder to allow future amendments to be made to purity criteria. The 2013 Regulations were contain cross-references to the Annex and to Article 3(c) (which referred to future work on specific purity criteria for solvents). Annex I to the Directive lists the authorised extraction solvents and associated maximum residue limits.- and Article 3(c) of the Directive cross-references Article 4(d) on establishing specific purity criteria for permitted extraction solvents. This meant that the 2013 Regulations always referred to the most current version of Annex I. This removed the need to update the 2013 Regulations when changes were made to Annex I. Whilst these cross-references provided a practical work around whilst we were a Member State, we must now ensure that these cross-references are removed, and the 2013 Regulation is fully operational as a stand-alone piece of national legislation.

Main proposals:

- To set out the list of permitted extraction solvents in its entirety in the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013, removing the cross-references to Annex I to the Directive.
- To remove other cross-references in the 2013 Regulations to the Directive which are no longer appropriate or which contain inoperabilities as a result of EU exit, for example the reference to Article 3(c) of, the Directive.

Similar proposals are being considered in Wales and Scotland. Food Standards Scotland (FSS) and the FSA in Wales will be carrying out their own separate consultation on this subject.

Changes not being considered

We are not setting out a process in legislation for businesses to apply for the approval of new extraction solvents or modifications to conditions of use for existing extraction solvents. Information is already available on the FSA website on how to apply for extraction solvent approvals- Regulated products: Extraction solvents guidance.

In addition, we consider that Ministers have sufficient existing powers under the Food Safety Act 1990 to ensure consumer protection and food safety are maintained in relation to the authorisation and use of extraction solvents. The exercise of these powers will be subject to Parliamentary scrutiny, and any future legislation will be laid before Parliament for its due consideration.

Impacts

As these are technical changes that do not affect the substance of the current requirements under legislation, we expect no major impacts on businesses. However, as the legislation is changing, there will be familiarisation costs for enforcement authorities and businesses.

A formal regulatory impact assessment has not, therefore, been produced for these minor regulatory amendments. If, however, the consultation should bring to light any impact on enforcement bodies or industry which has not been anticipated, we will reassess the need for a regulatory impact assessment.

Groups affected

The proposals are designed to ensure existing legislation is fit for purpose now we have left the EU. This consultation aims to identify if this approach would help to provide greater clarity for stakeholders, without causing unnecessary disruption.

Animal Feed

The main affected stakeholders are English feed business operators and feed authorities.

Food Contact materials

The main affected stakeholders are English businesses who either sell substances for the production of food contact regenerated cellulose films to other businesses or use them in the manufacture of such food contact materials. English Local Authorities responsible for food standards will also be affected, although the impact on them will be minimal as local authorities do not play a role in the authorisation process itself.

Extraction Solvents

The main affected stakeholders are English businesses who either sell extraction solvents to other businesses or use them in the manufacture of food products. English Local Authorities responsible for food standards will also be affected, although the impact on them will be minimal as local authorities do not play a role in the authorisation process itself.

Costs and benefits

The FSA has not identified any significant impact from the proposals other than in relation to a negligible one-off familiarisation cost once the legislative changes to The Animal Feed (Composition, Marketing and Use) (England) Regulations 2015, Materials and Articles in Contact with Food (England) Regulations 2012, and The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013 No.2210 respectfully are made, outlined below.

The FSA estimates a total one-off familiarisation cost of £325,000 to businesses and Local Authorities in England¹.

- a. We envisage a familiarisation cost for the following businesses depending on the legislation being incorporated. Using the ONS Inter Departmental Business Register (IDBR), we estimate that 12,325 English food businesses could be involved with extraction solvents in England. Using an internal register of Feed businesses, we estimate a total of 1308 feed businesses in England would need to understand the incorporated animal feed legislation, whilst an estimate of 75 Cellulose Films producers and packaging firms would need to familiarise themselves with the Cellulose film legislation.
- b. We estimate that it will take one manager per business one hour to read and understand the legislative changes and then disseminate the information to key staff within their firms. Applying the 2021 median hourly

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¹ Figures are based on 2021 prices.

- pay figures for managers and accounting for overheads, a total cost to businesses in England of £318,000 is calculated²
- c. ³. This translates to an Equivalent Annual Net Direct Cost to Business (EANDCB) of £37,000.
- d. The same methodology outlined above is used to calculate the familiarisation costs for Local Authorities. Using the Annual report on Local Authority food law enforcement, we assume that 266 people across 152 Local authorities in England familiarise themselves with the legislative changes and that this takes one hour across all three of the regulations being incorporated. The FSA estimates a £6,900 one-off familiarisation cost to Local Authorities responsible for food standards in England.

Engagement and Consultation Process

This consultation is to provide interested parties with the opportunity to give their comments and opinions on the proposals explained above. In particular, whether the relevant annexes for each regime should be included into their own, separate, national law.

All responses received will help to inform the approach that may be taken to facilitate the regulation of animal feed, food contact materials and extraction solvents, in England.

We particularly welcome responses and general feedback to the following questions. For each question, please explain your response and provide evidence (where possible) to support your views.

² Wage rates taken from the ONS' 2021 Annual Survey of Hours and Earnings (ASHE), table 14.6a.

³ Wage rates taken from the ONS' 2019 Annual Survey of Hours and Earnings (ASHE), table 14.6a.

Questions asked in this consultation:

Animal Feed

- 1. Do you agree that incorporating the Annex of Directive 82/475/EEC into national legislation would provide ease of reference for enforcement authorities, industry and the public? If not, please explain why.
- 2. Do you agree that incorporating the Annexes of Directive 2002/32/EC into national legislation would provide ease of reference for enforcement authorities, industry and the public? If not, please explain why.
- 3. Are you aware of any impacts of the proposed measures that have not been identified in this consultation?
- 4. Do you agree with the familiarisation cost that has been identified? If not, please explain why.
- 5. Are there any other changes that would help to provide greater clarity on regulating the presence of undesirable substances in animal feed? If yes, please explain what these are, and what benefits they might provide.
- 6. Are there any other changes that would help to provide greater clarity on regulating the use of category labelling on pet food? If yes, please explain what these are, and what benefits they might provide.

Food Contact Materials

- 1. Do you agree that a full incorporation of Annex II of Council Directive 2007/42/EC into national legislation would provide ease of reference for enforcement authorities, industry and the public? If not, please explain why.
- 2. Are you aware with the familiarisation cost that has been identified? If not, please explain why.
- 3. Do you agree with the familiarisation cost that has been identified? If not, please explain why.
- 4. Are there any other changes that would help to provide greater clarity on regulating the use of substances for the production of food contact regenerated cellulose films? If yes, please explain what these are, and what benefits they might provide.

Extraction Solvents

- 1. Do you agree that a full incorporation of Annex I of Directive 2009/32/EC into national legislation would provide ease of reference for enforcement authorities, industry and the public? If not, please explain why.
- 2. Are you aware of any impacts of the proposed measures that have not been identified in this consultation?
- 3. Do you agree with the familiarisation cost that has been identified? If not, please explain why.
- 4. Are there any other changes that would help to provide greater clarity on regulating the use of extraction solvents? If yes, please explain what these are, and what benefits they might provide.

Responses

Responses are required by close 10 August 2022. 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).

Please send response to:

Animal Feed: Taranjit Dhansay <u>Taranjit.Dhansay@food.gov.uk</u>

Food Contact Materials: Tim Chandler tim.chandler@food.gov.uk

Extraction Solvents: Danielle.gazi@food.gov.uk

For information on how the FSA handles your personal data, please refer to the Consultation privacy notice.

Further information

If you require a more accessible format of this document please send details to the named contact for responses to this consultation and your request will be considered.

This consultation has been prepared in accordance with <u>HM Government consultation</u> <u>principles</u>. An Impact Assessment has not been provided as there are no changes to the requirements for animal feed, food contact materials and extraction solvents.

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

Yours,

Animal Feed: Taranjit Dhansay, Animal Feed Branch, Food Policy Division

Food Contact Materials: Tim Chandler, Food Additives, Flavourings and Contact

Materials Branch, Food Policy Division

Extraction Solvents: Food Additives, Flavourings and Contact Materials Branch, Food

Policy Division

Annex A: List of interested parties

Animal Feed

- Agricultural Industries Confederation (AIC)
- Association of Public Analysts
- Assured Food Standards (Red Tractor)
- British Association of Feed Supplement and Additive Manufacturers (BAFSAM)
- British Equestrian Trade Association (BETA)
- National Farmers Union (NFU)
- National Office of Animal Health (NOAH)
- National Trading Standards (NTS)
- Pet Food Manufacturers Association (PFMA)
- Seed Crushers and Oil Processors Association (SCOPA)
- The Grain and Feed Trade Association (GAFTA)
- UK Flour Millers
- UK Former Food Processors Association (UKFFPA)

Food Contact Materials

- Local Authorities and Enforcement Officers
- British Plastics Federation

Extraction Solvents

- Food and Drink Federation
- Food Additives and Ingredients Association (FAIA)
- UK Flavour Association (UKFA)
- British Soft drinks Association (BSDA)
- UK Flour Millers and Association of Bakery Ingredients (ABIM)
- UK Tea and Infusions Society
- British Coffee Association
- Seed Crushers and Oil Producers Association (SCOPA)
- The Snack, Nut and Crisp Manufacturers Association (SNACMA)
- Local Authorities and Enforcement Officers
- British Retail Consortium
- Which?