THE FOOD AND FEED IMPORTS (EU EXIT) REGULATIONS 2018

THE MATERIALS AND ARTICLES IN CONTACT WITH FOOD (EU EXIT) REGULATIONS 2018

THE SPROUTS AND SEEDS (EU EXIT) REGULATIONS 2018

THE ANIMAL FEED (EU EXIT) REGULATIONS 2018

THE FOOD ADDITIVES, FLAVOURINGS, ENZYMES AND EXTRACTION SOLVENTS (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2018.

EU EXIT LEGISLATION – PROTOCOL WITH SCOTTISH PARLIAMENT

I am writing in relation to the protocol on obtaining the approval of the Scottish Parliament to the exercise of powers by UK Ministers under the European Union (Withdrawal) Act 2018 in relation to proposals within the legislative competence of the Scottish Parliament.

As you know, the Cabinet Secretary for Government Business and Constitutional Relations, Michael Russell MSP, wrote to the Conveners of the Finance & Constitution and Delegated Powers and Legislative Reform Committees on 11 September setting out the Scottish Government’s views on EU withdrawal. That letter also said that we must respond to the UK Government’s preparations for a No-Deal scenario as best we can, despite the inevitable widespread damage and
disruption that would cause. It is our unwelcome responsibility to ensure that
devolved law continues to function on and after EU withdrawal.

I attach the notifications which set out the details of the above SIs which the UK
Government propose to make and the reasons why I am content that Scottish
devolved matters are to be included in these SIs.

Please note, we are yet to have sight of the final SIs and they are not available in the
public domain at this stage. We will, in accordance with the protocol, advise you
when the final SIs are laid and advise you as to whether the final SIs are in keeping
with the terms of these notifications.

The policy rationale for the proposed changes that the above SIs will make is to
ensure the continuation of important consumer protection elements of the current EU
food and feed regulatory regime. This includes making the necessary corrections to
an important area of the current body of EU food law dealing with food contact
materials and food additives to ensure that there is a functioning statute book which
will continue to underpin the UK’s regulatory system for food and feed once it
becomes retained EU law.

The proposed Regulations make amendments to what will become retained direct
EU law in a number of specific areas, including law which sets down the certain
import requirements for food and feed of non-animal origin and certain higher risk
food contact materials. In addition the proposed Regulations make amendments to
a significant tranche of feed law, which in part mirrors requirements for food (which
have been subject to separate notification processes to the Parliament). This
includes feed hygiene and labelling, contaminants and technical matters concerning
sampling and analysis of animal feed. In addition, specific rules in relation to the
production and import of sprouts and sprouted seeds for human consumption are
also amended by these Regulations. Where the law contains provisions for the
approval or authorisation of certain products (such as food and feed additives), these
‘regulated products’ are currently the subject of risk assessments carried out by the
European Food Safety Authority and authorisation decisions made by the European
Commission. The amendments in this tranche of SIs are necessary to make legally
workable arrangements, and which reflect devolved responsibilities in future. This
will maintain the high standards of food and feed safety and hygiene that we
currently benefit from as an EU Member State, and I am pleased to note the
assurances provided by the UK Government that these changes will not result in any
material changes to existing levels of public and animal health protection with
respect to domestic and imported food and feed.

It is important to note that these fixing instruments do not modify the key rules on
safety and technical standards associated with this food safety law. These key
elements will be retained at the point of exit. However these Regulations make the
necessary modifications to the existing EU law to delete obsolete references to EU
institutions, replicate, within the UK, certain functions carried out by the EU institutions and transfer powers to allow future amendment to parts of the EU law, where such modifications were previously permissible through standing committee procedures within the EU. This is necessary in preparing the UK statute book for a No-Deal scenario.

The nature of the UK’s future relationship to EU agencies and bodies such as the European Food Safety Authority (EFSA) is subject to ongoing UK-EU negotiations, and the Scottish Government has made clear its position that we would wish to continue to benefit from participation in such agencies. However, in the event of a No-Deal it would not be possible to ensure a legal basis for the continued access to these functions and the instruments therefore reflects the reality of that situation.

The Food Standards Agency (FSA) is the lead UK department for these SIs which are due to be laid in the UK Parliament between 11 and 13 December.

I am copying this letter to the Convener of the Delegated Powers and Law Reform Committee.

I look forward to hearing from you in due course.

JOE FITZPATRICK
NOTIFICATION TO THE SCOTTISH PARLIAMENT

Name of the SI(s) (if known) or a title describing the policy area

The Food and Feed Imports (Amendment) (EU Exit) Regulations 2018

A brief explanation of law that the proposals amend

These Regulations make amendments to, what will become, retained direct EU law which sets down import conditions for high risk food of non-animal origin (FNAO).

Summary of the proposals and how these correct deficiencies

These Regulations make the necessary amendments to the following EU Regulation to ensure it continues to function effectively following the UK’s exit from the EU.


Regulation (EC) No. 669/2009 provides for an increased level of controls for a range of food and feed products from specified third countries, subject to a known or emerging risk to public health. This may be due to the presence of contaminants/undesirable substances such as pathogens, aflatoxins, sudan dyes, or pesticide residues.

The EU Regulation require Food Business Operators (FBO) to pre-notify the relevant competent authorities (CA) of the arrival of specified products from certain third countries at a designated point of entry (DPE), in order that the necessary official controls can be undertaken. The EU regulation also specifies the nature of the controls which apply. The import of products listed in the regulation are permitted entry only through a DPE that has appropriate control facilities for different types of feed and food.

In future the UK will have to determine any revocations or amendments to the controls based on available intelligence and information sharing. FSS is also working with FSA on developing a future framework on food safety and import controls for ministers to consider, in line with the JMC (EN) agreement.

The EU Regulation prescribe specific import controls on products from non-EU 3rd countries which existed at the time the implementing regulation was adopted and these controls will remain unchanged at the point of exit. On that basis, the immediate impact in Scotland should be minimal. However should the risk profile of certain products from EU countries change in future those products and countries, if listed, would be subject to the requirements outlined in this regulation.
As detailed in the notification for The Official Controls For Feed, Food And Animal Health (Amendment) (EU Exit) Regulations 2018, the tertiary legislative powers currently exercised by the European Commission to prescribe the list of imported high risk foods of non-animal origin subject to increased controls are provided for in Regulation (EC) No 882/2004.

In addition to the requirements set out in the EU regulation 669/2009, several other EU regulations, listed below, also set out similar requirements for the import of specific products. The UK fixing SI ensures that these continue to apply and make the necessary minor and technical changes.

**Commission Implementing Decision 2011/884 of 22 December 2011 on emergency measures regarding unauthorised genetically modified rice in rice products originating from China;**

**Commission Implementing Decision 2014/88/EU of 13 February 2014 suspending temporarily imports from Bangladesh of foodstuffs containing or consisting of betel leaves (‘Piper betle’);**

**Commission Regulation (EU) No 284/2011 of 22 March 2011 laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People’s Republic of China and Hong Kong Special Administrative Region, China;**

**Commission Implementing Regulation (EU) No 884/2014 of 13 August 2014 imposing special conditions governing the import of certain feed and food from certain third countries due to contamination risk by aflatoxins;**

**Commission Implementing Regulation (EU) No 885/2014 of 13 August 2014 laying down specific conditions applicable to the import of okra and curry leaves from India;**

**Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins;**

**Commission Implementing Regulation (EU) 2015/943 of 18 June 2015 on emergency measures suspending imports of dried beans from Nigeria;**

**Commission Implementing Regulation (EU) 2015/949 of 19 June 2015 approving the pre-export checks carried out on certain food by certain third countries as regards the presence of certain mycotoxins;**

**Commission Implementing Regulation (EU) 2017/186 of 2 February 2017 laying down specific conditions applicable to the introduction into the Union of consignments from certain third countries due to microbiological contamination.**
It should be noted that some of the instruments above are time bound and the EU regulations extending the period over which they are intended to apply do not require to be fixed through this instrument.

**An explanation of why the change is considered necessary**

The fixes in the UK SI modify the above Regulations to make technical changes to apply the provisions in the context of their application to the UK in the circumstances of a no deal exit from the EU. The amendments reflect domestic arrangements which are already in place for the purposes of imports checks, and repatriate the administrative arrangements for reporting on the outcome of official controls.

**Scottish Government categorisation of significance of proposals**

This instrument has been classed as Category A on the basis that we consider that the changes are technical in nature to maintain operability of existing import controls on high risk FNAO considered necessary to protect public health.

**Impact on devolved areas**

Food and feed safety is a fully devolved area. This includes public health controls in relation to imports. The draft UK SI transfers powers from EU institutions to the Scottish Ministers or FSS in so far as they are within devolved competence.

The Food Standards Agency and Food Standards Scotland are currently discussing the development of a UK-wide framework for food and feed safety and hygiene, with a view to agreeing new working arrangements and enhanced capacity for risk assessment and import controls, currently carried out by EU governance arrangements and systems.

**Summary of stakeholder engagement/consultation**

The FSA carried out a full public consultation across the UK from 4 September until 14 October on the proposed approach to retained EU law for food and feed safety and hygiene. The consultation received 47 responses (including 5 from Scottish stakeholders) of which 81% supported or did not disagree with the proposed approach being outlined, with 17% of replies containing mixed comments. The main concerns raised related to the communication of change and ensuring sufficient lead in time is given. One respondent raised concerns about the timeframe for delivering the legislation needed for day one readiness. FSS highlighted the UK consultation to its stakeholders in Scotland but has not directly engaged with them on the UK Government’s approach.

**A note of other impact assessments, (if available)**

N/A

**Summary of reasons for Scottish Ministers’ proposing to consent to UK Ministers legislation**
The Scottish Ministers believe that the changes proposed in these Regulations are necessary so far as falling within devolved competence to secure continuation of a legally functional regime for import control of high risk FNAO in the event of a no-deal exit from the EU. In the current circumstances where there is existing harmonised EU law in this area and the need to prepare for a No-Deal exit from the EU, the Scottish Ministers consider that it is appropriate therefore for the fixing legislation be made on a UK-wide basis by the UK Government.

**Intended laying date (if known) of instruments likely to arise**

11 December 2018

If the Scottish Parliament does not have 28 days to scrutinise Scottish Minister's proposal to consent, why not?

N/A

Information about any time dependency associated with the proposal

N/A

Are there any broader governance issues in relation to this proposal, and how will these be regulated and monitored post-withdrawal?

The Food Standards Agency and Food Standards Scotland are currently working to develop of a proposed UK-wide framework for food and feed safety and hygiene, of which includes matters of future governance.

**Any significant financial implications?**

There may be financial implications for food safety authorities and possibly Local Authorities, but it is not possible at this stage to assess how significant they may be.
NOTIFICATION TO THE SCOTTISH PARLIAMENT

Name of the SI(s) (if known) or a title describing the policy area

The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2018

A brief explanation of law that the proposals amend

The UK fixing SI makes amendments to, what will become, retained direct EU law relating to materials and articles that intend to come into contact with food. The SI does not introduce any new policy provisions or modify the current EU technical standards in this area which will apply on exit day as they currently do. The existing EU provisions covered by the SI are already fully harmonised and directly applicable in all Member States. The purpose of the SI is to ensure continuity of these EU provisions from exit day.

This also includes provisions for the future amendment of the retained EU law. The power to amend these Regulations in future will be exercisable by Scottish Ministers in so far as they are within devolved competence and exercisable in Scotland.

The relevant EU provisions are:

Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food, Regulation (EC) No. 450/2009 on active and intelligent materials and articles intended to come into contact with food, Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food and Regulation (EC) No. 282/2008 on recycled plastic materials and articles intended to come into contact with food.

Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food sets out the general requirements for all materials and articles expected or likely to be in contact with food. It also provides for specific measures to be adopted for particular groups of materials and substances along with provision for the testing of vinyl chloride monomer.

Regulation (EC) No 450/2009 on active and intelligent materials and articles intended to come into contact with food lays down what can be used in active and intelligent material and specifies that a ‘Declaration of Compliance’ is required. Active materials increase the shelf life or maintain or improve the condition of packaged food whereas intelligent materials monitor the condition of packaged food or the environment surrounding the food.

Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food. These regulations contain a list of permitted monomers and approved additives that can be used and also sets out migration limits for plastic materials and articles that come into contact with food and also details the
requirement for a certificate of conformity.

Regulation (EC) No. 282/2008 on recycled plastic materials and articles intended to come into contact with food establishes the specific rules for food contact recycled plastic materials. These recycled plastics can only be placed on the market if they are manufactured from plastic, obtained from an authorised recycling process.

**Summary of the proposals and how these correct deficiencies**

This SI provides for the ongoing operability of the above EU Regulations to ensure they continue to function effectively after exit day. This includes, for example, replacing EU references and terminology that will not be appropriate when the UK is no longer an EU Member State.

Further, the SI transfers the Commission’s functions and obligations to UK Authorities and defines the “appropriate authority” to mean the Ministers in each of the four administrations and also “Food Safety Authority” to mean the Food Standards Agency and Food Standards Scotland as appropriate.

The SI also makes amendments to related subordinate legislation in England. The equivalent necessary amendments to Scottish domestic legislation will be done by a Scottish Statutory Instrument in due course.

**An explanation of why the change is considered necessary**

The change modifies the above EU provisions by limiting their scope to the UK, and the transfer of administrative functions to the UK Food Safety Authorities and transfer of functions to Ministers to make future regulatory decisions on the basis of risk assessment advice. The practical arrangements by which these functions will be delivered are part of ongoing discussions between FSS and FSA on a future food safety framework.

**Scottish Government categorisation of significance of proposals**

This instrument has been categorised as Category A.

The main purpose of the Regulations is to ensure continuity of law in this area with no policy divergence or modification to the principles to be applied before authorisation. With respect to transfer of powers from the EU institutions, it is anticipated that this will be consistent with the devolution settlement. In particular, the proposed areas of transfer are considered to fall entirely within areas of devolved competence, as currently delineated within the Scotland Act 1998 and the transfer will provide that Scottish Ministers assume those functions of amending EU law, insofar as those amendments are to be applied in Scotland. There are no proposals to sub delegate new powers to legislate to public bodies in this instrument, no new fees being provided for, or new financial implications for businesses or the creation of new fines or penalties. On that basis FSS considers that these changes are principally involved in ensuring continuity of law and the transfer of functions provisions are consistent with the devolution settlement.
Impact on devolved areas

The subject matter is a fully devolved area. The proposed fixes relate to retained direct EU law relating to materials and articles which are intended to come into contact with food. It is intended that the instrument will respect and protect the Scottish Ministers powers to make subordinate legislation instead of the EU institutions in those areas specified in these Regulations. The change in terms of powers and competence highlights that additional capacity may be required in Scotland and the rest of the UK to provide to support the repatriation of powers in this area to UK authorities.

FSA and FSS are currently discussing the development of a UK-wide framework for food and feed safety and hygiene, with a view to agreeing new working arrangements and enhanced capacity for incident handling and risk assessment, currently carried out by EU governance arrangements and systems. Where new arrangements require a legislative underpinning, such as transfer of functions, the legislation will be subject to the protocol which has been established to ensure that parliamentary scrutiny of the instrument and consent is given as required.

The proposed legislation maintains the basis of the existing EU legislative provisions designed to ensure maintenance of the high level of public health protection that food businesses in Scotland and the rest of the UK already operate within. It is therefore important that the necessary functioning statute covering this policy area is in place before exit day.

Summary of stakeholder engagement/consultation

FSA carried out a full public consultation across the UK from 4 September until 14 October on the proposed approach to retained EU law for food and feed safety and hygiene. The consultation received 47 responses (including 5 from Scottish stakeholders) of which 81% supported or did not disagree with the proposed approach being outlined, with 17% of replies containing mixed comments. The main concerns raised related to the communication of change and ensuring sufficient lead in time is given. One respondent raised concerns about the timeframe for delivering the legislation needed for day one readiness. However, none of the comments affected the proposed legislation. FSS highlighted the UK consultation to its stakeholders in Scotland but has not directly engaged with them on the UK Government’s approach.

A note of other impact assessments, (if available)

N/A
Summary of reasons for Scottish Ministers’ proposing to consent to UK Ministers legislation

The Scottish Ministers believe that the changes proposed in the SI are necessary so far as falling within devolved competence to secure continuation of an effective materials and articles in contact with food regulatory regime, and to provide continuity for business immediately from exit day. In the current circumstances where there is existing harmonised EU law in this area and the need to prepare for a No-Deal exit from the EU, the Scottish Ministers consider that it is appropriate for the fixing legislation be made on a UK-wide basis by the UK Government. This is on the basis that there is an appropriate transfer of powers to the Scottish Ministers and Scottish Parliament in the Regulations.

Intended laying date (if known) of instruments likely to arise

11th December 2018

If the Scottish Parliament does not have 28 days to scrutinise Scottish Minister’s proposal to consent, why not?

N/A

Information about any time dependency associated with the proposal

N/A

Are there any broader governance issues in relation to this proposal, and how will these be regulated and monitored post-withdrawal?

FSA and FSS are currently working to develop of a proposed UK-wide framework for food and feed safety and hygiene, of which includes matters of future governance.

Any significant financial implications?

The Regulations are not expected to have any financial implications for business stakeholders in Scotland. There are likely to be financial implications for food safety authorities and for bodies providing them with scientific advice, but it is not possible at this stage to assess how significant they may be.
NOTIFICATION TO THE SCOTTISH PARLIAMENT

Name of the SI(s) (if known) or a title describing the policy area
The Sprouts and Seeds (EU Exit) regulations 2018

A brief explanation of law that the proposals amend
This EU Exit SI makes amendments to, what will become, retained direct EU law which sets down requirements in relation to the both the import and domestic production of sprouts and sprouted seeds.

Summary of the proposals and how these correct deficiencies
This SI makes the necessary amendments to the following EU Regulations to ensure they continue to function effectively following the UK’s exit from the EU.

Commission Implementing regulation (EU) No. 208/2013 on traceability requirements for sprouts and seeds intended for the production of sprouts. The fixes to this regulation are minor and delete obsolete references in relation to the EU. However the fixing SI also maintains an obligation to apply certification requirements for imports of sprouts from 3rd countries which will mean as a consequence that these requirements will apply to sprouts produced in the EU and imported into the UK in the event of a no deal.

Commission Regulation (EU) No 210/2013 on the approval of establishments producing sprouts pursuant to Regulation (EC) No 852/2004 of the European Parliament and of the Council. There is a minor EU reference which will be obsolete and is deleted in this fixing instrument. The requirements in relation to the approval of establishments will continue to apply in the UK after exit.

Commission Regulation (EU) No 211/2013 on certification requirements for imports into the Union of sprouts and seeds intended for the production of sprouts. This regulation applies to consignments imported into the EU and will be amended to set out requirements for import into the UK in future.

An explanation of why the change is considered necessary
The change modifies the above Regulations to make technical changes to apply the provisions in the context of their application to the UK in the circumstances of a no deal exit from the EU.

Scottish Government categorisation of significance of proposals
This instrument has been classed as Category A in so far as these amendments are largely technical in nature.
Impact on devolved areas

Food safety is a fully devolved area. The Food Standards Agency and Food Standards Scotland are currently discussing the development of a UK-wide framework for food and feed safety and hygiene, with a view to agreeing new working arrangements and enhanced capacity for risk assessment, currently carried out by EU governance arrangements and systems.

Summary of stakeholder engagement/consultation

The FSA carried out a full public consultation across the UK from 4 September until 14 October on the proposed approach to retained EU law for food and feed safety and hygiene. The consultation received 47 responses (including 5 from Scottish stakeholders) of which 81% supported or did not disagree with the proposed approach being outlined, with 17% of replies containing mixed comments. The main concerns raised related to the communication of change and ensuring sufficient lead in time is given. One respondent raised concerns about the timeframe for delivering the legislation needed for day one readiness. FSS highlighted the UK consultation to its stakeholders in Scotland but has not directly engaged with them on the UK Government’s approach.

A note of other impact assessments, (if available)

N/A

Summary of reasons for Scottish Ministers’ proposing to consent to UK Ministers legislation

The Scottish Ministers believe that the changes proposed in these Regulations are necessary so far as falling within devolved competence to secure continuation of a legally functional statute book in relation to food and feed in the event of a no-deal exit from the EU. In the current circumstances where there is existing harmonised EU law in this area and the need to prepare for a No-Deal exit from the EU, the Scottish Ministers consider that it is appropriate therefore for the fixing legislation be made on a UK-wide basis by the UK Government.

Intended laying date (if known) of instruments likely to arise

12th December 2018

If the Scottish Parliament does not have 28 days to scrutinise Scottish Minister’s proposal to consent, why not?

N/A

Information about any time dependency associated with the proposal

N/A

Are there any broader governance issues in relation to this proposal, and how will these be regulated and monitored post-withdrawal?
The Food Standards Agency and Food Standards Scotland are currently working to develop of a proposed UK-wide framework for food and feed safety and hygiene, of which includes matters of future governance.

Any significant financial implications? There may be financial implications for food safety authorities and possibly Local Authorities, but it is not possible at this stage to assess how significant they may be.
NOTIFICATION TO THE SCOTTISH PARLIAMENT

Name of the SI(s) (if known) or a title describing the policy area

The Animal Feed (Amendment) (EU Exit) Regulations 2018 (the Regulations).

A brief explanation of law that the proposals amend

The Regulations provides for fixes to, what will become, retained direct EU law which sets down the technical requirements for the placing on the market of animal feed; including requirements in relation to authorisations of new feed additives and sampling and analysis requirements.

Summary of the proposals and how these correct deficiencies

The Regulations make the necessary amendments to the following EU Regulations to ensure they continue to function effectively following the UK’s exit from the EU.

Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. This EU Regulation, as amended on exit, will establish legal procedures in the UK for authorising the placing on the market and use of feed additives. The changes will in effect mean that appropriate authorities as defined (ie Scottish Ministers; or the Secretary of State for the UK as a whole) may authorise new feed additives, following assessment by the Food Safety Authority (ie Food Standards Scotland, or Food Standards Agency for the rest of the UK) and prescribe their conditions of use. The EU Regulation will require that the Food Safety Authority keep a register of authorised additives (which is currently maintained by the Commission); and provides powers for appropriate authorities to amend labelling requirements for various additive categories. The regulations make no changes to the current requirements for the handling of such applications including time frames for assessment.

Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene. This EU Regulation, as amended on exit, will ensure the continued application of the general rules on feed hygiene; the conditions and arrangements ensuring traceability of feed, implementation of a feed safety management system based on (HACCP) principles and the approval of feed establishments. In part these provisions largely mirror for feed, the food hygiene requirements which apply to feed and food businesses. As for food, appropriate authorities (defined as the Scottish Ministers as regards Scotland) may provide for more detailed rules on the application of the requirements in the regulation, for example for the purposes of facilitating the application of the regulations for small businesses in relation to HACCP based systems. The EU Regulation maintains the existing arrangements for the registration and approval of feed businesses (which is administered by
competent authorities in Scotland). The EU Regulations will also require that appropriate authorities consult food safety authorities on any matters falling within the scope of the regulation of significance to public health.

Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives. This regulation sets out the role and responsibility of the community reference laboratory in relation to feed additive authorisations. It is proposed that a UK reference laboratory will undertake relevant functions on exit in the event of no deal.

Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. This EU Regulation sets out the obligations for applicants on the presentation of dossiers to support feed additive applications. The amendments include a requirement for a prescribed application form for applicants to ensure appropriate references in a UK context, and will maintain the detailed requirements that must be met as set out in annexes.

Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed. These are technical rules regarding sampling and methodology of analysis to be applied for official control purposes as regards the determination of constituents, additives and undesirable substances. It includes requires for the calculation and presentation of results and the changes required for exit purposes are very minor. e.g. references to “Union legislation” will be amended to refer to “retained EU law” etc.

Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed. This EU Regulation sets down the conditions for placing on the market and the use of feed to ensure high levels of feed safety and protection of public health. It provides for the Catalogue of feed materials and codes of good labelling to ensure that feed is sound, genuine, unadulterated, fit for its purpose and of merchantable quality; and provides legal requirements for the labelling, packaging and presentation of feed materials.

In addition to minor drafting amendments to ensure correct references in a UK context, the Regulations make amendments including provision to make changes, by appropriate authorities (defined as the Scottish Ministers as regards Scotland), to the more detailed technical requirements, where such provisions can currently be amended through EU comitology procedures.

Commission Regulation (EU) No 619/2011 of 24 June 2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation
The proposed fixes under the Regulations include detailed requirements for sampling and analysis for GM material in feed and where the regulations refer to the views of the European Food Safety Authority (EFSA) in relation to any risk assessments carried out, these are replaced with reference to food safety authorities (Food Standards Scotland as regards Scotland). Other technical changes required for EU exit in legal terms are minor. The Regulations also recognise that emergency measures may be adopted, which in effect mean that existing arrangements in the UK for such measures are simply maintained.

Commission Regulation (EU) 2015/786 of 19 May 2015 defining acceptability criteria for detoxification processes applied to products intended for animal feed. The amendments in the Regulations will result in scientific assessments of a detoxification process that may be permitted on products intended for animal feed being carried out by UK food safety authorities rather than EFSA in future in order to ensure that products meet certain acceptability criteria.

An explanation of why the change is considered necessary

The proposals in the draft instrument modifies the above EU Regulations to make technical changes to apply the provisions in the context of their application to the UK in the circumstances of a no deal exit from the EU. Certain functions in relation to, for example feed additives authorisations, are at present wholly dealt with by EU institutions and therefore this SI repatriates those requirements in a UK context, as well as correcting other technical inoperabilities. It also provides the mechanism though which the retained EU law may be amended in future through the equivalent of tertiary legislation.

Scottish Government categorisation of significance of proposals

This instrument has been classed as Category A in so far as these amendments are largely technical in nature. However, it should be noted that as a consequence of the UK leaving the EU without a deal in place significant additional resource requirements could be placed on UK food safety authorities, particularly in relation to the processing and authorisation of feed additives. In addition it is a policy area where in transferring functions from EU institutions to Scottish and UK Ministers, discussions are ongoing in relation to how decisions in relation to feed additive authorisations which are generally marketed across the UK should be applied.

Impact on devolved areas

Feed safety is a fully devolved area. The Food Standards Agency and Food Standards Scotland are currently discussing the development of a UK-wide framework for food and feed safety and hygiene, with a view to agreeing new working arrangements and enhanced capacity for risk assessment, currently carried out by EU governance arrangements and systems. As part of EU exit contingency planning, additional resources have been secured by the Food Standards Agency (the food safety authority for the rest of the UK) and it is anticipated as part of the development of a UK framework on food and feed safety, these resources will be available in relation to Scotland.
Summary of stakeholder engagement/consultation

The Food Standards Agency carried out a full public consultation across the UK from 4 September until 14 October on the proposed approach to retained EU law for food and feed safety and hygiene. The consultation received 47 responses (including 5 from Scottish stakeholders) of which 81% supported or did not disagree with the proposed approach being outlined, with 17% of replies containing mixed comments. The main concerns raised related to the communication of change and ensuring sufficient lead in time is given. One respondent raised concerns about the timeframe for delivering the legislation needed for day one readiness. Food Standards Scotland highlighted the UK consultation to its stakeholders in Scotland but has not directly engaged with them on the UK Government’s approach.

A note of other impact assessments, (if available)

N/A

Summary of reasons for Scottish Ministers’ proposing to consent to UK Ministers legislation

The Scottish Ministers believe that the changes proposed in the Regulations are necessary so far as falling within devolved competence to secure continuation of a legally functional statute book in relation to feed in the event of a no-deal exit from the EU. In the current circumstances where there is existing harmonised EU law in this area and the need to prepare for a No-Deal exit from the EU, the Scottish Ministers consider that it is appropriate therefore for the fixing legislation be made on a UK-wide basis by the UK Government. This is on the basis that there is an appropriate transfer of powers to the Scottish Ministers to make or review the requirements set out in the Regulations.

Intended laying date (if known) of instruments likely to arise

13th December 2018

If the Scottish Parliament does not have 28 days to scrutinise Scottish Minister’s proposal to consent, why not?

N/A

Information about any time dependency associated with the proposal

N/A

Are there any broader governance issues in relation to this proposal, and how will these be regulated and monitored post-withdrawal?

The Food Standards Agency and Food Standards Scotland are currently working to develop of a proposed UK-wide framework for food and feed safety and hygiene, of which includes matters of future governance.
Any significant financial implications?
Whilst there should be no significant impact on businesses, the totality of the repatriation of functions in relation to feed may have significant financial implications for feed and food safety authorities and certain scientific bodies. However, it is not possible at this stage to quantify the significance of the impact.
NOTIFICATION TO THE SCOTTISH PARLIAMENT

Name of the SI(s) (if known) or a title describing the policy area

The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment) (EU Exit) Regulations 2018

A brief explanation of law that the proposals amend

The UK fixing SI makes amendments to, what will become, retained direct EU law relating to the approval and subsequent control of use of food additives, flavourings, enzymes and extraction solvents. The Regulations do not introduce any new policy provisions or modify the current EU technical standards in this area which will apply on exit day as they currently do. The existing EU provisions covered by the instrument are already fully harmonised and directly applicable in all Member States. The purpose of the Regulations is to ensure continuity of these EU provisions from exit day.

This also includes provisions for the future amendment of the retained EU law. The power to amend these regulations in future will be exercisable by Scottish Ministers in so far as they are within devolved competence and exercisable in Scotland.

The relevant EU provisions are:

Regulation (EC) No. 2065/2003 of the European Parliament and of the Council on smoke flavourings used or intended for use in or on foods. It sets out conditions of production for smoke flavouring ‘primary products’; provide for the establishment of a list of approved primary products and set out now expired transitional measures. This list of approved primary products is now in Regulation 1321/2013.


Regulation 1332/2008 also covers food enzymes used as ingredients (i.e. enzymes which are currently classed as food additives) and those used as processing aids. It does not cover enzymes that are not added to food to perform a technological function, but are intended for human consumption, such as enzymes for nutritional or digestive purposes.


- Community lists of approved food additives which are set out in Annex II and III of the Regulation;
- Conditions of use for food additives used in foods, including in food additives, food enzymes as covered by Regulation (EC) No. 1332/2008, food flavourings as covered by Regulation (EC) No.1334/2008 and nutrients;
- rules on the labelling on food additives sold as such;
- specific rules on the “carry-over” principle - “Carry-over” provisions apply to most foods permitted to contain food additives, but not to those specially prepared for infants and young children. These provisions permit the presence of a permitted food additive in a compound food, to the extent that the food additive is allowed by the provisions of Annex II of Regulation 1333/2008 in one of the ingredients of the compound food.
- rules on the labelling of colours.
- specifications (purity criteria) to be established for permitted food additives.


Regulation 1334/2008 lays down rules in the use of food flavourings and certain food ingredients with flavouring properties (e.g. herbs and spices); provide for the establishment of a list of approved flavourings and source material. The Regulation also set out rules for the labelling of flavouring sold as such.


Commission Regulation (EU) No. 873/2012 on transitional measures concerning the Union list of flavourings and source materials set out in Annex 1 to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council. This legislation sets out the date of application of the positives lists (parts A-F) and sets transitional periods some of which have passed.

Commission Implementing Regulation (EU) No. 1321/2013 establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings. It establishes the positive list of smoke flavourings as referred to in Regulation 2065/2003.

A glossary is attached to provide definitions of food additives, flavourings, enzymes and extraction solvents.

**Summary of the proposals and how these correct deficiencies**

The UK SI makes the necessary amendments to the above EU Regulations to ensure they continue to function effectively in the event of a No Deal exit from the EU. These include, replacing EU references and terminology that will not be appropriate where the UK is no longer an EU Member State. The SI will ensure the continued applicability of retained EU law to ensure the necessary transfer of functions and powers from EU institutions to the appropriate bodies in the UK.

The proposed Regulations also revoke Commission Regulation (EU) No. 257/2010 which set up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No. 1333/2008 of the European Parliament and of the Council on food additives. This is being revoked because the process will become redundant when the UK leaves the EU. However, while the European Safety Authority re-evaluation work is nearing completion, FSS and the FSA will keep up to date with future scientific developments in food safety matters.

**An explanation of why the change is considered necessary**

The change (a) modifies the above EU provisions by limiting their scope to the UK, (b) and transfers administrative functions to the UK Food Safety Authorities and (c) transfers functions to Ministers to make future regulatory decisions on the basis of risk assessment advice. The practical arrangements by which these functions will be
delivered are part of ongoing discussions between Food Standards Scotland (FSS) and the Food Standards Agency (FSA on a future food safety framework.

Scottish Government categorisation of significance of proposals

The Regulations have been categorised as Category A. The main purpose of the Regulations is to ensure continuity of law in this area with no policy divergence or modification to the principles to be applied before authorisation of food additives, flavourings etc. might be granted. With respect to transfer of powers from the EU institutions, it is anticipated that this will be consistent with the devolution settlement. In particular, the proposed areas of transfer are considered to fall entirely within areas of devolved competence, as currently delineated within the Scotland Act 1998 and the transfer will provide that Scottish Ministers assume those functions of amending EU law, insofar as those amendments are to be applied in Scotland. There are no proposals to sub delegate new powers to legislate to public bodies in this instrument, no new fees being provided for, or new financial implications for businesses or the creation of new fines or penalties. On that basis FSS considers that these changes are principally involved in ensuring continuity of law and the transfer of functions provisions are consistent with the devolution settlement.

Impact on devolved areas

The subject matter is a fully devolved area. The proposed SI relates to technical changes to and future modification of retained direct EU law relating to the authorisation and control of use of food additives, flavourings, enzymes and extraction solvents and will therefore affect Scotland. The changes in terms of powers and competence highlights that additional capacity may be required in Scotland and the rest of the UK to support the repatriation of powers in this area to UK authorities.

FSA and FSS are currently discussing the development of a UK-wide framework for food and feed safety and hygiene, with a view to agreeing new working arrangements and enhanced capacity for the administration of future applications and modifications of the law in this area.

The Regulations maintain the basis of the existing EU legislative provisions which are designed to ensure that a high level of public health protection is maintained, and those food businesses in Scotland and the rest of the UK continue to operate safely. It is therefore important that the necessary functioning statute covering this policy area is in place before exit day.

Summary of stakeholder engagement/consultation

FSA carried out a full public consultation across the UK from 4 September until 14 October on the proposed approach to retained EU law for food and feed safety and hygiene. The consultation received 47 responses (including 5 from Scottish stakeholders) of which 81% supported or did not disagree with the proposed approach being outlined, with 17% of replies containing mixed comments. The main concerns raised related to the communication of change and ensuring sufficient lead in time is given. One respondent raised concerns about the timeframe for delivering
the legislation needed for day one readiness. None of the stakeholder comments received impacted on the proposed legislation. FSS highlighted the UK consultation to its stakeholders in Scotland but has not directly engaged with them on the UK Government’s approach.

A note of other impact assessments, (if available)
N/A

Summary of reasons for Scottish Ministers’ proposing to consent to UK Ministers legislation

The Scottish Ministers believe that the changes proposed in the Regulations are necessary so far as falling within devolved competence to secure continuation of an effective regulatory regime for food additives, flavourings, enzymes and extraction solvents, and to provide continuity and food businesses as from exit day. In the current circumstances where there is existing harmonised EU law in this area and the need to prepare for a No-Deal exit from the EU, the Scottish Ministers consider that it is appropriate therefore for the fixing legislation be made on a UK-wide basis by the UK Government. This is on the basis that there is an appropriate transfer of powers to the Scottish Ministers in the Regulations.

Intended laying date (if known) of instruments likely to arise

13th December 2018

If the Scottish Parliament does not have 28 days to scrutinise Scottish Minister’s proposal to consent, why not?

N/A

Information about any time dependency associated with the proposal
N/A

Are there any broader governance issues in relation to this proposal and how will these be regulated and monitored post-withdrawal?

FSA and FSS are currently working to develop a proposed UK-wide framework for food and feed safety and hygiene, of which includes matters of future governance.

Any significant financial implications?

The Regulations are not expected to have any financial implications for business stakeholders in Scotland. There are likely to be financial implications for food safety authorities and for bodies providing them with scientific advice, but it is not possible at this stage to assess how significant they may be.
Glossary

Food additives - Regulation 1333/2008

‘food additive’ shall mean any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods.

Food flavourings - Regulation 1334/2008

(a)‘flavourings’ shall mean products:

(i)not intended to be consumed as such, which are added to food in order to impart or modify odour and/or taste;

(ii)made or consisting of the following categories: flavouring substances, flavouring preparations, thermal process flavourings, smoke flavourings, flavour precursors or other flavourings or mixtures thereof;

(b)‘flavouring substance’ shall mean a defined chemical substance with flavouring properties;

(c)‘natural flavouring substance’ shall mean a flavouring substance obtained by appropriate physical, enzymatic or microbiological processes from material of vegetable, animal or microbiological origin either in the raw state or after processing for human consumption by one or more of the traditional food preparation processes listed in Annex II of Regulation 1334/2008. Natural flavouring substances correspond to substances that are naturally present and have been identified in nature;

(d)‘flavouring preparation’ shall mean a product, other than a flavouring substance, obtained from:

(i)food by appropriate physical, enzymatic or microbiological processes either in the raw state of the material or after processing for human consumption by one or more of the traditional food preparation processes listed in Annex II of Regulation 1334/2008;

and/or

(ii)material of vegetable, animal or microbiological origin, other than food, by appropriate physical, enzymatic or microbiological processes, the material being taken as such or prepared by one or more of the traditional food preparation processes listed in Annex II of Regulation 1334/2008;
(e) 'thermal process flavouring' shall mean a product obtained after heat treatment from a mixture of ingredients not necessarily having flavouring properties themselves, of which at least one contains nitrogen (amino) and another is a reducing sugar; the ingredients for the production of thermal process flavourings may be:

Food and/or source material other than food;

(f) 'smoke flavouring' shall mean a product obtained by fractionation and purification of a condensed smoke yielding primary smoke condensates, primary tar fractions and/or derived smoke flavourings as defined in points (1), (2) and (4) of Article 3 of Regulation (EC) No 2065/2003;

(g) 'flavour precursor' shall mean a product, not necessarily having flavouring properties itself, intentionally added to food for the sole purpose of producing flavour by breaking down or reacting with other components during food processing; it may be obtained from:

food; and/or source material other than food.

(h) 'other flavouring' shall mean a flavouring added or intended to be added to food in order to impart odour and/or taste and which does not fall under definitions (b) to (g);

Smoke flavourings - Regulation (EC) No 2065/2003

1. 'primary smoke condensate' shall refer to the purified waterbased part of condensed smoke and shall fall within the definition of 'smoke flavourings';

2. 'primary tar fraction' shall refer to the purified fraction of the water-insoluble high-density tar phase of condensed smoke and shall fall within the definition of 'smoke flavourings';

3. 'primary products' shall refer to primary smoke condensates and primary tar fractions;

4. 'derived smoke flavourings' shall refer to flavourings produced as a result of the further processing of primary products and which are used or intended to be used in or on foods in order to impart smoke flavour to those foods

Food enzymes - Regulation 1332/2008

(a) 'food enzyme' means a product obtained from plants, animals or micro-organisms or products thereof including a product obtained by a fermentation process using
micro-organisms:

(i) containing one or more enzymes capable of catalyzing a specific biochemical reaction; and

(ii) added to food for a technological purpose at any stage of the manufacturing, processing, preparation, treatment, packaging, transport or storage of foods;

(b) ‘food enzyme preparation’ means a formulation consisting of one or more food enzymes in which substances such as food additives and/or other food ingredients are incorporated to facilitate their storage, sale, standardisation, dilution or dissolution.

**Extraction solvents - Directive 2009/32**

(a) 'solvent' means any substance for dissolving a foodstuff or any component thereof, including any contaminant present in or on that foodstuff;

(b) 'extraction solvent' means a solvent which is used in an extraction procedure during the processing of raw materials, of foodstuffs, or of components or ingredients of these products and which is removed but which may result in the unintentional, but technically unavoidable, presence of residues or derivatives in the foodstuff or food ingredient.