Dear Convenor,

THE FOOD AND FEED (MAXIMUM PERMITTED LEVELS OF RADIOACTIVE CONTAMINATION) (EU EXIT) REGULATIONS 2018
THE GENETICALLY MODIFIED FOOD AND FEED (EU EXIT) REGULATIONS 2018
THE OFFICIAL FEED AND FEED CONTROLS (EU EXIT) REGULATIONS 2018
THE FOOD AND FEED (CHERNOBYL AND FUKUSHIMA RESTRICTIONS) (AMENDMENT) (EU EXIT) REGULATIONS 2018
THE NOVEL FOOD (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, Mike Russell 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. This is the second in a series of such notifications which deal with EU food law that I will be sending to the Health and Sport Committee over the coming weeks.

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, and official control and verification, 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 official controls for food and animal feed, and animal health and welfare, 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.

This tranche of SIs also includes proposed amendments to the monitoring requirements on products subject to restrictions following radioactive contamination and incidents, and also the risk assessment and authorisation processes for novel food and genetically modified food and feed. 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 29th November and 6th 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.

Yours sincerely,

[Signature]

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 (Maximum Permitted Levels of Radioactive Contamination) (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 maximum permitted levels of radioactive contamination in food and feed in the event of an emergency.

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.

Council Regulation (Euratom) 2016/52 lays down maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency.

The specific amendment required is to change references to EU institutions in the EU legislation to appropriate arrangements in the UK. The Regulations do not change the basis of the safety controls themselves which will continue to apply with the same maximum levels set at the point of EU Exit.

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. It requires that specific emergency measures are undertaken in relation to food and feed in the event of a nuclear accident. These obligations specify in a UK context, the relevant authorities, which mirrors in part those provisions and competences that are already set out in the Food and Environment Protection Act 1985 (FEPA 1985).

Scottish Government categorisation of significance of proposals

This instrument has been classed as Category A on the basis that it makes the required amendments to the above EU Regulations which are technical in nature and uncontentious. Whilst there are no powers to make changes to the legislation in this instrument, the Regulations place an obligation on designating authorities (as defined in FEPA 1985) to put in place emergency orders specifying the maximum permitted levels of potentially contaminated food or feed that could be placed on the market. It should also be noted that arrangements for co-operation
between experts drawn from member states are removed from this instrument as this is an inoperability for the fixing purposes in the event of no deal. Matters of international liaison on nuclear co-operation are reserved to the UK Government and are being led by the Department for Business, Energy & Industrial Strategy (BEIS).

**Impact on devolved areas**

Food and 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 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. Although there are no specific transfer of functions provisions in this instrument, it maintains the obligation of Member States to act in certain circumstances to introduce controls to protect the food chain. These obligations are being maintained through reference to existing UK statute, and therefore replicate what currently happens.

The UK’s future relationship with European Institutions and systems remains subject to ongoing UK/EU negotiations.

**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 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 an effective regime for setting maximum permitted levels of radioactive contamination in food and feed following a nuclear accident or other radiological
event and to provide continuity for business on day one 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 emergency orders in the Regulations.

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

29 November 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?

N/A
NOTIFICATION TO THE SCOTTISH PARLIAMENT

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

The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2018 ("the Regulations").

A brief explanation of law that the proposals amend

The Regulations make amendments to, what will become, retained direct EU law relating to genetically modified food and feed. The Regulations do not introduce any new policy provisions or modify the current EU technical standards in this area which will apply as they currently do on exit day. 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.

The relevant EU provisions are:

Regulation (EC) No 1829/2003 on genetically modified food and feed. It contains requirements including the authorisation and labelling of genetically modified food and feed, single applications for food and feed, and requirements of community reference laboratory.

Commission Regulation (EC) No 641/2004 on detailed rules regarding the application procedure for authorisation of new genetically modified food and feed, notification of existing products and the adventitious or technically unavoidable presence of genetically modified material which has benefitted from a favourable risk evaluation.

Commission Implementing Regulation (EU) 503/2013 on applications for authorisation of genetically modified food and feed.


Summary of the proposals and how these correct deficiencies

The Regulations make the necessary amendments to the above EU Regulations to ensure they continue to function effectively following the UK’s exit from the EU. This includes, for example, replacing EU references and terminology that will not be appropriate where the UK is no longer an EU Member State.

Regulation (EC) 1829/2003 sets out the application and authorisation process for genetically modified food and feed as well as labelling requirements. The detailed
rules for these are then set out in Commission Regulation (EC) 641/2004 and Commission Implementing Regulation (EU) 503/2013. The Regulations will ensure the continued application of the various provisions and provides [for arrangements to ensure] the necessary transfer of functions and powers from EU institutions to the appropriate authorities in the UK.

The Regulations revoke Commission Regulation (EC) No 1981/2006 which is mainly concerned with the contribution of costs from food businesses when a Community reference laboratory is used.

An explanation of why the change is considered necessary

The change modifies the above EU provisions by limiting their scope to the UK, and include a limited transfer of functions. For example, references to the ‘European Commission’ are replaced with reference to the “appropriate authority” which for the purposes of Scotland is the Scottish Ministers. The relevant repatriated powers respect the devolution settlement providing an appropriate mechanism for Scottish Ministers to make certain amendments currently within the scope of the EU institutions. Likewise where certain functions are carried out by the European Food Safety Authority (EFSA), these are intended to be repatriated by transfer to the Food Standards Agency and Food Standards Scotland as appropriate in line with the current type of statutory functions undertaken by those organisations.

Scottish Government categorisation of significance of proposals

The Regulations have been categorised as Category A. Whilst the subject matter of the Regulations contains potentially contentious issues, (genetically modified food and feed can be emotive and sensitive issues), 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 GM food or feed might be granted. With respect to transfer of powers from the EU institutions, it is anticipated that this will be limited and 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 amendments relate to retained direct EU law relating to the authorisation of genetically modified food and feed and will therefore affect Scotland. It is intended that the Regulations will
respect and protect the Scottish Ministers’ powers to make subordinate legislation instead of the EU institutions in those areas specified in the 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 support the repatriation of powers in this area to UK authorities.

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 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 UK’s future relationship with European Institutions and systems remains subject to ongoing UK/EU negotiations. FSS is seeking to maintain a good relationship with EFSA, though the details of how this will be achieved are not expected to be clear until the negotiations are finalised.

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 that 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

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 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 the Regulations are necessary so far as falling within devolved competence to secure continuation of
an effective genetically modified food and feed regulatory regime, and to provide continuity for feed 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**

3rd 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 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 stakeholders in Scotland.
NOTIFICATION TO THE SCOTTISH PARLIAMENT

ANNEX D

THE OFFICIAL CONTROLS FOR FEED, FOOD AND ANIMAL HEALTH (AMENDMENT) (EU EXIT) REGULATIONS 2018

A brief explanation of law that the proposals amend

The Official Controls for Feed, Food and Animal Health (Amendment) (EU Exit) Regulations 2018 ("the Regulations") make amendments to, what will become, retained direct EU law relating to official controls for food and animal feed, and animal health and welfare, for the whole of the United Kingdom.

This includes amendments of Regulation (EC) No. 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. This is the horizontal EU framework legislation establishing a harmonised approach to the implementation of these official controls across EU Member States. It is broad in scope, providing the legislative basis for:

- General obligations on Member States with regard to official controls, i.e. that they are carried out regularly, on a risk basis and with appropriate frequency.
- Basic requirements related to the designation of competent authorities and official laboratories, official control staff training and qualifications, control and verification procedures and activities, and methods of sampling and analysis.
- Official controls applied to food and feed imported into the EU from third countries, and any required action in the case of identified non-compliance. This includes veterinary checks applied to products of animal origin under Directive 97/78/EC which can only enter the EU through a Border Inspection Post (BIP), and public health controls applied to food and feed of non-animal origin, including high risks foods that can only enter the EU through Designated Points of Entry (DPEs).
- Charging feed and food businesses to cover the costs occasioned by official controls, including mandatory charging rates for controls in specific sectors, i.e. meat hygiene controls and controls on fishery products at the first point of marketing.
- The network of European and national reference laboratories involved in the coordination of analytical and reference methods used for official control purposes, and the activity of official laboratories.
- Administrative Assistance and Cooperation (AAC) arrangements between Member States in the areas of food and feed, where the outcome of official controls requires action in more than one Member State.
- Requirement for Member States to prepare a single integrated Multi-Annual National Control Plan (MANCP) and Annual Report.
- Community controls in Member States, i.e. audits of Member State official control systems carried out by DG Health and Food Safety of the European Commission.
- Overarching principles applicable to national enforcement measures and sanctions, and the legal basis for the European Commission to implement
emergency safeguard measures in the event of a serious failure of Member States’ control systems.

Whilst the EU Regulations on official controls contain important rules in relation to ensuring the effective administration of the delivery and coordination of official controls required to ensure the legislation is in place, it is important to recognise that most of the key provisions and underpinning principles identified above will automatically apply at the point of EU exit. The Regulations are concerned with ensuring the continued functioning of these provisions in a UK context post exit day, replicating and replacing where necessary the functions carried out by the EU institutions and providing the basis for future modification of certain parts of those rules (currently delegated to the EU Commission and its standing committees) on and after exit day.

Summary of the proposals and how these correct deficiencies

The Regulations make the necessary legal corrections to a number of interlinked EU Regulations and Commission Decisions that together provide the legislative underpinning for official controls on food and feed, and animal health and welfare, to ensure they continue to function effectively following the UK’s exit from the EU.

The proposed corrections to Regulation (EC) No 882/2004 will transfer tertiary legislative and decision making functions currently exercised by the European Commission to appropriate authorities in the UK. These functions will transfer to Scottish Ministers in so far as they are within devolved competence and exercisable in Scotland. This includes functions related to controls on food and feed imported from third countries, for example, decision making functions related to prescribing the list of high risk foods of non-animal origin imported from third countries that are subject to increased levels of official controls, and responsibility for designating Designated Points of Entry (DPEs).

It is proposed that references to obligations on Member State with respect to official control functions and responsibilities will also be corrected so that these obligations are placed upon the appropriate authorities in the UK. This includes those obligations related to the designation of competent authorities and official laboratories. However, these are already provided for in domestic legislation across the four UK countries. The proposal is that these obligations will transfer to Scottish Ministers, or where appropriate Food Standards Scotland, in so far as they are within devolved competence and exercisable in Scotland. This is in line with current arrangements in place for designating such competence, within domestic law in Scotland. It is proposed, for example, that the requirement to prepare and implement a Multi Annual National Control Plan (MANCP) and associated Annual Report will be maintained, with responsibility resting with the appropriate authority. It is anticipated these proposed corrections will provide sufficient legislative flexibility to allow administrative functions currently exercised at a UK level to continue on that basis, with appropriate input form the devolved administrations.

Similar technical changes are proposed to the official control charging provisions, including the application of a euro to sterling exchange rate conversion for the
purposes of calculating the minimum official control charge rates set out in the existing EU law. The UKG has applied this conversion using methodology set out in guidance issued by the Department for Exiting the European Union on changing references in legislation from euro to sterling on no-deal exit SIs. This is based on an exchange rate of £1 = €1.1413 which represents the average exchange rate over 2017.

The corrections will also provide for certain Member State audit functions, currently exercised by DG Health and Food Safety (formerly the Food and Veterinary Office) of the European Commission, to be retained and applied within a UK context. Discussions on this are ongoing to ensure that appropriate accountability to Ministers in all four countries is provided for, to give assurance of the effectiveness of the delivery of these controls. This instrument does not specify who any auditing body would be in future, which is the subject of ongoing discussions across the UK.

The Regulations propose to revoke the AAC provisions for cooperation between Member States to deal with issues of food and feed non-compliance that affects more than one Member State. This is an unavoidable consequence of EU exit, as these will become redundant under a no-deal scenario as the UK will no longer participate in this cooperation network as a Member State. The UK’s future relationship with both the AAC network remains subject to ongoing UK/EU negotiations.

The Regulations will also revoke provisions related to Commission assistance during third country controls carried out in Member States as these will become redundant under a no-deal scenario.

The Regulations will also correct other deficiencies in Regulation (EC) No 882/2004 related to EU references and terminology that will not be appropriate when the UK is no longer an EU Member State. These are technical in nature and non-contentious.

The Regulations amend **Commission Decision 2006/677** which sets out guidelines for the conduct of audits that are carried out under Regulation (EC) No. 882/2004. This is to correct deficiencies related to EU references and terminology that will not be appropriate when the UK is no longer an EU Member State.

The Regulations also amend **Commission Decision 2008/654** laying down guidelines for Member States in preparing the Annual Report on implementation of the single integrated Multi-Annual National Control Plan (MANCP) provided for in Regulation (EC) No. 882/2004. This is to correct deficiencies related to EU references and terminology that will not be appropriate when the UK is no longer an EU Member State. Details of the most recent 2017 UK Annual Report can be found on the FSS website at the following link, should Committee members wish to refer to it.

The Regulations further makes the required amendments and revocations to those provisions within Regulation (EU) No 2017/625 (the latest Official Control Regulation (OCR)). The majority of these provisions will not come into force until after 29th March next year, however those related to European reference laboratories (EURLs) and national reference laboratories (NRLs), have applied from 1 April 2018. Under a no-deal scenario the UK will no longer formally participate in the EURL network as a Member State, and only the relevant NRL provisions will therefore need to be retained and modified as required which is reflected in the proposed Regulations. This includes the provision of new enabling powers to allow the appropriate authority to make subordinate legislation, i.e. to prescribe additional tasks and responsibilities of NRLs.

The Regulations also revoke Commission Regulation (EU) No. 451/2013 which lays down additional responsibilities and tasks for the EURLs for rabies, bovine tuberculosis and bee health, as matters related to EURLs will no longer be relevant in a no-deal scenario. This revocation does not affect Scotland’s TB-free status which will be sought under OIE rules once the UK has left the EU.

The Regulations also make amendments to related subordinate legislation in England that do not affect Scotland. A corresponding Scottish statutory instrument will be made later in the year.

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

The proposed changes are necessary to ensure the UK maintains a functioning statute book relating to official controls for food and animal feed, and animal health and welfare, as provided for by the above EU Regulations and Decisions once this legislation becomes retained direct EU law.

This will ensure the UK continues to have the necessary legislative basis for a robust official control system for domestically produced and imported food and feed to verify business compliance with food and feed law, and the maintenance of high levels of public and animal health and welfare protection. It will also ensure the UK and Scotland can continue to provide the necessary regulatory assurances with respect to UK control systems that is required for both domestic and international trade purposes.

**Scottish Government categorisation of significance of proposals**

Category A – With respect to transfer of powers from the EU institutions, it is anticipated that this will be limited and 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 and the transfer will provide that Scottish Ministers assume those functions of amending the 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 we consider that these changes are principally involved in ensuring continuity of
law and the transfer of functions provisions are consistent with the devolution settlement. It is acknowledged that there is still uncertainty about the nature of any audit body which might be introduced to replicate existing EC audit functions.

Impact on devolved areas

Official controls on food and feed, and animal health and welfare, is a fully devolved area. The proposed amendments to the above retained direct EU law will therefore impact in Scotland. Officials in Food Standards Scotland and the Scottish Government have worked closely with those in the Food Standards Agency and Defra to ensure the instrument as drafted respects and protects devolved competence and Scottish Ministers ability to make subordinate legislation in those areas specified in the Regulations where legislative decision making functions will be repatriated from the EU to the UK.

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 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)

The Food Standards Agency has not carried out an impact assessment in relation to these Regulations as they are aimed at preserving the effect of the current regulatory regime.

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 official control regulatory regime, and to provide continuity for competent and enforcement authorities, as well as businesses, on day one 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 this instrument, as currently drafted, provides adequate safeguards for the appropriate transfer of decision making powers and associated administrative functions to the Scottish Ministers and Scottish Parliament as required, fully respecting devolved competence.
Intended laying date (if known) of instruments likely to arise

The current proposed laying date is 4 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 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 stakeholders in Scotland. No material changes are proposed to the existing mandatory charging regime that applies to official controls performed on specified products of animal origin detailed above.
NOTIFICATION TO THE SCOTTISH PARLIAMENT

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

The Food and Feed (Chernobyl and Fukushima Restrictions) (Amendment) (EU Exit) Regulations 2018

**A brief explanation of law that the proposals amend**

These EU Exit Regulations make amendments to, what will become, retained EU law which sets out specific import control measures in relation to products affected by specific nuclear incidents; namely controls arising in relation to the Chernobyl and Fukushima incidents in 1986 and 2011 respectively.

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

These 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. The Regulations concern public health controls in relation to food following the accidents at the Chernobyl power station on 26 April 1986 and at the Fukushima nuclear power station on 11 March 2011.


Council Regulation (EC) No 733/2008 sets out the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station. Commission Implementing Regulation (EU) 2016/6 imposes special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station and repeals Implementing Regulation (EU) No 322/2014.

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

The EU Exit Regulations will modify the above regulations to apply the provisions in the context of their application to the UK in the circumstances of a no deal with the EU and to ensure that appropriate authorities in the UK, which includes Scottish Ministers, have powers to protect public health. In effect the changes mean that the specific requirements currently placed on Member States to ensure appropriate import controls are placed on certain products from affected countries/areas will be described in a UK context. Competence for enforcement of these Regulations are already ascribed in domestic statute and will not be affected by these changes. The proposed Regulations do not introduce any new
policy provisions or alter the current levels of protection afforded by these specific provisions.

**Scottish Government categorisation of significance of proposals**

This instrument has been classed as Category A on the basis that it makes the required amendments to the above EU Regulations which are technical in nature and uncontentious. Whilst there are powers to make future amendments to import conditions within this fixing SI, the nature of any changes are subject to the international liaison arrangements which will be required in the event of a nuclear incident. We are unaware of any affected products being imported into the UK via Scotland.

With respect to transfer of powers from the EU institutions, it is anticipated that this will be limited and 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 and the transfer will provide that Scottish Ministers assume those functions of amending the 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. The specific subject matter currently has limited material effect at Scottish ports due to the nature of current supply routes from the affected countries.

Whilst there are proposals to transfer limited non-legislative functions currently exercised by EU institutions to Food Standards Scotland, the functions in question are well aligned to the specific functions ascribed to Food Standards Scotland in the Food Scotland Act 2015, e.g. advice on food safety risks and monitoring such risks within the food supply chain. It is therefore considered there was only one obvious policy option as to which body would provide an opinion to Scottish Ministers and the Scottish Parliament in these areas. On that basis we consider 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**

Food and feed safety in relation to imports is a fully devolved area. The proposed amendments reflect devolved competence in full.

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 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 UK’s future relationship with European Institutions and systems remains subject to ongoing UK/EU negotiations. FSS is seeking to maintain a good relationship with EFSA, though the details of how this will be achieved are not expected to be clear until the negotiations are finalised.

The proposed legislation maintains the basis of the existing EU legislative provisions which are designed to maintain 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**

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 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 controls on imports of food and feed affected by the Chernobyl and Fukushima nuclear incidents, and to provide continuity for business on day one 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 and Scottish Parliament in the Regulations and that the responsibilities for undertaking the control measures within the UK have been clarified.

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

5 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 a proposed UK-wide framework for food and feed safety and hygiene, of which includes matters of future governance.

Any significant financial implications?

N/A
NOTIFICATION TO THE SCOTTISH PARLIAMENT

Name of the SI(s) (if known) or a title describing the policy area
The Novel Food (Amendment) (EU Exit) Regulations 2018

A brief explanation of law that the proposals amend

Novel foods are foods which have not been widely consumed by people in the EU before May 1997. The absence of a ‘history of consumption’ means that there is a need to determine the safety and suitability of new foods, including those traditionally consumed in non-EU countries and food produced through new processes. Foods produced for technological purposes and genetically modified food are not covered by the novel food requirements.

Examples of novel foods include:

- New foods, for example, phytosterols and phytostanols used in cholesterol reducing spreads
- Traditional foods eaten elsewhere in the world, for example, chia seeds and baobab
- Foods produced from new processes, for example, bread treated with ultraviolet light to increase the level of vitamin D present

The above Regulations make amendments to, what will become, retained direct EU law relating to novel foods. The proposed Regulations do not introduce any new policy provisions or change the basis of the current rules applying to these types of foods which will be maintained at the point of EU Exit. The existing EU provisions covered by the instrument are already fully harmonised and directly applicable in all member states. The proposed UK SI is intended to ensure continuity of this EU Law at the point of the UK’s exit from the EU making necessary changes to reflect the fact that references to and functions of the EU institutions will change after EU exit.

The instrument relates to the following EU provisions:

Regulation (EU) 2015/2283 on novel foods contains requirements including: procedure for determination of novel food status, requirements for placing novel food on the market, authorisation procedures for novel food, specific rules for traditional food from third countries, and confidentiality and data protection rules.

Commission Implementing Regulation (EU) 2017/2468 laying down administrative and scientific requirements concerning traditional foods from third countries.

Commission Implementing Regulation (EU) 2017/2469 laying down administrative and scientific requirements for applications (for authorisation).
Commission Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods.


These Regulations also make amendments to related subordinate legislation in England. The equivalent necessary amendments to Scottish domestic legislation will be done via a Scottish Statutory Instrument intended to be laid in January.

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

These Regulations make the necessary amendments to the above EU Regulations to ensure they continue to function effectively following the UK’s exit from the EU. This includes, for example, replacing EU references and terminology that will not be appropriate when the UK is no longer an EU Member State.

Regulation (EU) 2015/2283 on novel food provides a definition of novel food, procedure for determination of novel food status, requirements for placing novel food on the market and authorisation procedures for a novel food. It also sets specific rules for traditional food from third countries and data protection. The detailed rules for these are then set out in the four Commission Implementing Regulations detailed above. The EU exit Regulations will ensure the continued applicability of the various provisions and provide for arrangements to ensure the necessary transfer of functions and powers from EU institutions to the appropriate bodies in the UK.

Of particular note is the retention of the definition of novel food. This is “any food that was not used for human consumption to a significant degree within the EU or UK before 15 May 1997...”. The intention is to allow products where history of consumption has been considered in an EU context to remain on the market. If this were to be changed to a history of consumption in UK only then a great number of products that have been safely consumed for many years in the UK would not be compliant with the law.

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

The change modifies the above Regulations by limiting their scope to the UK, and include a limited transfer of functions, for example, by replacing “European Commission” with a form of wording to enable each of the four administrations in the UK to provide for minor amendments in limited parts of the legislation in future. The relevant repatriated powers respect the devolution settlement providing an appropriate mechanism for Scottish Ministers and the Scottish Parliament to make certain amendments currently within the scope of the EU institutions. Likewise where certain administrative functions are carried out by the Commission or EFSA, these are intended to be repatriated by transfer to FSA and FSS as appropriate, since these are the statutory bodies within the UK who currently carry out these type of functions within the UK.

**Scottish Government categorisation of significance of proposals**
This instrument has been categorised as Category A. It covers general and specific technical requirements in relation to obligations with which food business operators must comply currently, tailored to a UK context on EU exit. The main purpose of the instrument is to ensure continuity of law in this area with no significant policy divergence. With respect to transfer of powers from the EU institutions, it is anticipated that this will be limited here and 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. The transfer will provide that Scottish Ministers assume those functions of amending the 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, there are no new fees provided for, no new financial implications for businesses and no creation of new fines or penalties. On that basis we consider 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 amendments relate to retained direct EU law relating to the authorisation of novel food and will therefore affect Scotland. 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 support the repatriation of powers in this area to UK authorities.

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 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 UK’s future relationship with European Institutions and systems remains subject to ongoing UK/EU negotiations. FSS are is seeking to maintain a good relationship with EFSA, though the details of how this will be achieved are not expected to be clear until the negotiations are finalised.

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**
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 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 Governments 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 an effective novel food regulatory regime, and to provide continuity for business on day one 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 and Scottish Parliament in the Regulations.

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

6th 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 a proposed UK-wide framework for food and feed safety and hygiene, of which includes matters of future governance.
Any significant financial implications?

These Regulations are not expected to have any financial implications for stakeholders in Scotland.