12 November 2018

Dear Lewis

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

Thank you for your letter of 8 November, setting out the Committee’s questions in relation to the notifications on the above EU Exit fixing SIs that I notified to the Committee on 30 October. I have addressed the Committee’s questions below, and I hope that this further information provides helpful clarification.

General

I should clarify that should the UK leave the EU without a deal, this will not require the repatriation of the European Food Safety Authority (EFSA) to FSS and FSA, but it will require that certain functions that are currently carried out by EFSA on behalf of the EU will, in the event of a no deal, be required to be carried out in the UK. Principally, this relates to the function of scientific risk assessment, which is required to be undertaken in certain circumstances as part of existing EU procedures. Both FSS and FSA already have dedicated scientific support staff for the purposes of providing and assisting development of risk assessments and there is an existing network of Scientific Advisory Committees which already advise Ministers across the UK on these matters. The new working arrangements will be designed to bolster this base to ensure that there is sufficient scientific resource to undertake current risk assessment functions such as incidents handling, as well as the additional capability
and capacity needed to support the functions that will be repatriated to the UK from EU institutions. As risk assessment is already a function that FSS carries out within its current remit, there will be no requirement to amend the legislation that established FSS.

FSS and FSA already work together closely on risk assessment, and this is covered in a Memorandum of Understanding (MoU) between the two organisations that was agreed between them when FSS was created in 2015. The changes that EU Exit will bring will require that FSS and FSA continue to work collaboratively in future, and in recognition of this, the MoU will be reviewed and updated as appropriate. No legislative changes are foreseen in this regard.

On financial implications, whilst the Scottish Government has already made clear that leaving the EU with no deal would have major financial implications for Scottish businesses, and there will be financial implications for governments across the UK, there should be no new financial implications for food businesses as a consequence of these SIs. This is because the fixing Regulations are designed to repatriate the EU law as it exists on exit day, so businesses will have clarity and continuity of law. The work to create a UK framework in future is about agreeing the practical and administrative arrangements necessary for the four administrations to work cooperatively across the UK in future, and should not create new financial implications for businesses.

Significant progress has been made in developing the framework and the arrangements are designed to respect the devolution settlement ensuring risk assessment and related activities are sensitive enough to support Scottish specific solutions where necessary.

**The Food and Feed (Maximum Permitted Levels of Radioactive Contamination) (Amendment) (EU Exit) Regulations 2018**

The main purpose of this fixing SI is to ensure that action continues to be able to be taken in the event of a radiological incident and that the maximum permitted levels of radioactive contamination of food and feed do not exceed the levels prescribed in what will become retained EU law. The Food and Environment Protection Act 1985 allows Scottish Ministers and Food Standards Scotland to make emergency orders where there are or may be circumstances which are likely to create a hazard to human health, and to set conditions as appropriate. That is, the 1985 Act provides more general protections domestically, which are specified explicitly by EU regulation in this area. There are live orders in place for Scotland at the moment such as The Food Protection (Emergency Prohibitions) (Dalgety Bay) (Scotland) Order 2012. It is expected that the existing protocols and scrutiny processes for such orders, and existing devolved competence to make such orders in relation to Scotland will be maintained through powers available under the 1985 Act.
Designating authorities are defined in the 1985 Act; and will be drawn down in the fixing SI from that definition. For Scotland, that means the Scottish Ministers.

With regard to arrangements for co-operation between Member State experts, whilst the inoperabilities are removed from this instrument, it is recognised that in order to discharge these functions in future, Scotland and the UK as a whole, needs to be able to continue to be able to co-operate with international experts.

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

The proposed amendments to references and terminology in the EU Regulation (EC) No 1829/2003 include ‘Community’ being amended for the UK to reflect the geographic scope of retained EU law. ‘Risk assessor’ in Scotland will be FSS, and ‘Community reference laboratory’ is amended to ‘Reference laboratory’.

On categorisation of the notification, the detailed arrangements of how the functions will be carried out in future is part of the work between FSS and FSA on future frameworks. While there are fees chargeable to applicants in respect of reference laboratories – assessing that applicants’ test methods for detecting and identifying GMO are effective – there are no changes proposed to the level of fees through the fixing SI. Therefore the costs of a new system fall on government rather than on business stakeholders. However, it is not possible at this stage to assess how significant they may be.

The Novel Food (Amendment) (EU Exit) Regulations 2018

The proposed fixes to Regulation (EU) 2015/2283 enable each of the four administrations to provide for amendments to the legislation in future. These include that the appropriate authority (Scottish Ministers in Scotland) may prescribe: that a particular food falls within the definition of novel food; rules for implementation of paragraphs around confidential treatment of information and: changes to the definition of engineered nanomaterials to reflect technical and scientific progress or definitions agreed at international level. There are also administrative functions which are to be repatriated to FSS. These include the safety assessment of novel foods, providing opinions on updates to the list of novel foods and requesting additional information from applicants who wish to market novel foods. In addition, Scottish Ministers will have powers to issue authorisations and update lists of authorised novel food.

As with genetically modified food and feed, the precise nature of the execution of the functions that would fall to FSS and Scottish Ministers is part of the discussions ongoing with the FSA with regard to a future framework for the UK. In terms of ability
for policy divergence, there is scope for Scottish Ministers to initiate an application for novel food in addition to commercial applicants, which may help encourage innovation in new areas.

As with the other fixing SIs, the intention is to ensure a functioning statute book on exit, and to provide clarity and continuity for businesses, by repatriating EU law as it exists on exit. As such, it is likely that the costs of a new system falls on government rather than on business stakeholders, but it is not possible at this stage to assess how significant they may be.

The Official Controls for Feed, Food and Animal Health (Amendment) (EU Exit) Regulations 2018

As the Committee has acknowledged, this is a complex area of policy and legislation.

Regulation (EC) No. 882/2004 is a key piece of European food and feed law establishing the harmonised framework for food and feed, and animal health and welfare official controls. It covers a range of different control activities to verify business compliance with relevant EU law, including competent authority functions, inspections and enforcement, audits, sampling, analysis, and charging for official controls. It provides the legislative framework for controls applied in Member States to food and feed products that are produced in the EU, as well as those that are imported from third countries. The UK fixing SI is intended to ensure this key element of food law continues to function effectively after the UK leaves the EU in a no-deal scenario.

The EU has recently updated Regulation (EC) No. 882/2004 which will be revoked and replaced by Regulation (EC) No. 2017/625. This new Official Control Regulation (OCR) forms part of the Smarter Rules for Safer Food package of three EU Regulations, which also includes the new Animal Health Regulation and Plant Health Regulation.

The OCR is due to come into force in December 2019, although certain aspects, including those related to EU Reference Laboratories (EURLs) and National Reference Laboratories (NRLs) have applied from April 2018. The deficiencies which the fixing SI corrects with regard to NRLs are therefore the relevant provisions in Regulation (EC) No. 2017/625.

On the functions related to auditing delivery of official controls and the future auditing body, the notification recognised there is continued uncertainty about the nature of any future audit body which might be introduced in the UK to replicate existing European Commission functions related to the audit of Member State official control systems. The primary purpose of these audits is to verify that official controls take
place in accordance with the multi-annual national control plan (MANCP) referred to in Article 41 of Regulation (EC) No. 882/2004.

The Department for Environment, Food and Rural Affairs (Defra) is leading the UK Government’s policy consideration of any future domestic official control audit arrangements that may be required after EU exit, and how this will support the UK’s future trade assurance needs. This work is still underway, and officials from the Scottish Government and FSS are participating in these discussions to ensure the interests of Scotland are respected.

The Food Standards Agency (FSA) is leading on the drafting of these Regulations that will amend the existing audit provisions set out in Article 45 of Regulation (EC) No. 882/2004, which is intended to accommodate any future agreed UK Government policy in this area. FSS and Scottish Government officials have been working closely with FSA to ensure the retained legislative basis for any future audit body in what will become retained EU law fully respects devolved competence and accountability in Scotland.

On categorisation of this instrument, insofar as the transfer of these EU audit and reporting functions engage with the protocol characteristics noted above, it may be appropriate to re-classify this instrument as Category B.

The Committee also sought clarification on 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. Article 101 of Regulation (EU) 2017/625, which entered into force on 29 April 2018, provides the EU basis for establishing the responsibilities and tasks of Member State national reference laboratories (NRLs). Article 101(2) empowers the European Commission to adopt tertiary delegated acts, via comitology procedures, to supplement the responsibilities and tasks of NRLs listed in Article 101(1).

The fixing SI proposes to transfer these legislative functions to appropriate authorities in the UK by establishing new enabling powers to make subordinate legislation for this purpose. These powers will be exercisable by Scottish Ministers in Scotland, fully respecting devolved competence.

The Committee also asked for more detail on the wording of the fixes. The deficiencies the Regulations propose to correct, on a no deal basis, with regard to references and terminology, including use of the term “Member State” – to be replaced with the term “United Kingdom”, “appropriate authority”, or “Food Safety Authority” depending on context within the EU law, and use of the term “Community” – to be omitted or replaced with “retained EU law”, “United Kingdom”, “relevant competent authority in the United Kingdom”, or “Food Safety Authority” depending on context within the EU law.
Competence in relation to import controls for food are set out in The Official Feed and Food Controls (Scotland) Regulations 2009 and the Trade in Animals and Related Products (Scotland) Regulations.

In terms of future amendments to import controls themselves, as for all imports, risk assessment of the associated hazards change over time. For example, Commission Implementing Regulation (EU) 2016 has been amended by Commission Implementing Regulation (EU) 2017/2058, further to the results of analysis undertaken indicating a reduction in risk associated with certain products, resulting in changes to the relevant import requirements for certain Japanese products.

Whilst the specific subject matter currently has limited material effect at Scottish ports due to the nature of current supply routes from the affected countries, FSS is in the process of commissioning work to look at any potential changes in future.

In terms of the transfer of non-legislative functions from EU institutions to FSS, the objectives of FSS, as set out in the Food (Scotland) Act 2015 are —

(a) to protect the public from risks to health which may arise in connection with the consumption of food,
(b) to improve the extent to which members of the public have diets which are conducive to good health,
(c) to protect the other interests of consumers in relation to food.

The 2015 Act also describes the general functions of Food Standards Scotland which are—

(a) to develop (and assist the Scottish Ministers and public bodies and office-holders to develop) policies in relation to food matters and animal feeding stuffs matters,
(b) to advise, inform and assist the Scottish Ministers and public bodies and officeholders and other persons in relation to food matters and animal feeding stuffs matters,
(c) to keep the public adequately informed about and advised in relation to matters which significantly affect their capacity to make informed decisions about food matters,
(d) to keep users of animal feeding stuffs adequately informed about and advised in relation to matters which significantly affect their capacity to make informed decisions about animal feeding stuffs matters, and
(e) to monitor the performance of, and promote best practice by, enforcement authorities in enforcing food legislation.

Co-ordinating activity for EU imports, including surveillance and risk assessment is currently undertaken by the Commission, and this function will require to be repatriated in a UK context. Given the statutory role of FSS in food matters it is therefore considered that there is only one obvious policy option as to which body would provide an opinion to Scottish Ministers and the Scottish Parliament in these areas.
I appreciate that there is a lot of technical detail in the answers to the Committee’s questions, but I hope that this is helpful for the Committee in considering the notifications relating to these fixing SIs, and will assist in securing consent to these instruments, to ensure that there is a functioning statute book for food law, in the event of there being a no deal exit from the EU.

JOE FITZPATRICK