14th December 2018

Dear Lewis

Nutrition (Amendment) (EU Exit) Regulations 2019

Thank you for your letter of 12th December 2018.

As requested please find responses in the attached annex A to the questions you raised in the annex to your letter.

I hope this additional information now affords the Committee the ability to reach a decision with respect to consent to this instrument.

Yours sincerely,

[Signature]

JOE FITZPATRICK
Response to Committee Questions

1. The notification indicates on pages 2 and 3 that EU law pertaining to foods for specific groups is currently in a transitional phase. Any new provisions that do not come into force before exit day will not become retained EU law. As a result, different regulatory regimes will apply to different specific groups of foods.

   a. What practical differences would arise as a result of the distinct regulatory regimes that would apply, on the one hand, to foods for special medical purposes (other than that designed to meet the nutritional needs of infants) and, on the other hand, the other specific food groups? Will the Scottish Ministers (or, where relevant, the Secretary of State) have a different suite of regulatory powers in relation to these distinct regimes?

The Foods for Specific Groups Regulation (EU) No 609/2013 sets out the overarching approach for these products with fewer categories of foods than was the case with the foods for Particular Nutritional Uses arrangements. For example the rules on claims about the level of gluten in food, are now within the general food labelling requirements under Regulation (EU) No 1169/2011 on the provision of food information to consumers. The main effect of the transition arrangements is that businesses and enforcers must refer to legislation made under both the Foods for Specific Groups rules and those for foods for Particular Nutritional Uses to be certain of which requirements apply to the products in question, which makes for a more complex landscape. However, this is an unfortunate consequence of timing should we leave the EU with no deal on 29 March which this Instrument is preparing for. There are also some technical differences between the current and future requirements, for example The Infant Formula and Follow-on Formula (Scotland) Regulations 2007 transpose Directive 2006/141/EC. This allows limited nutrition and health claims to be made on infant formula. Commission Delegated Regulation (EU) 2016/127 on the specific compositional and information requirements for infant formula and follow-on formula, does not apply until 22 February 2020 at the earliest and prohibits nutrition and health claims on infant formula. The fixing Instrument provides a mechanism by which equivalent provisions can be made in future.

   b. When is it envisaged the SSI will be made fixing the domestic legislation in relation to food for specific groups?

It is the intention that SSIs to make corrections to domestic legislation early in 2019 following the stakeholder consultation on proposed consequential technical fixes to existing SSIs.

2. Page 3 of the notification indicates that EU law requires the relevant competent authority within the market to be notified when a food for a specific nutritional use is first placed on the market. How will the Scottish Ministers / Foods Standards Scotland become aware of such new foods first being placed on the market in a no-deal scenario?
It is currently the case that businesses must notify FSS when relevant products are first placed on the market in Scotland, and this requirement will be maintained.

3. **Page 4 of the notification indicates that a new committee would be established to conduct the scientific advisory functions currently undertaken by the European Food Standards Agency. It appears that the instrument will confer power to designate the new committee on the Scottish Ministers and, alternatively, on the Secretary of State with the consent of the Scottish Ministers.**

   a. **How is this new committee to be established, given that the power to deal with deficiencies arising from withdrawal in section 8 of the European Union (Withdrawal) Act 2018 does not permit regulations made under that section to establish a public authority?**

   The fixing SI sets out that scientific advice is required for nutrition and health claims and enables Ministers to designate a committee for that purpose but does not establish the committee itself. The designation process is not provided for in the Instrument. The proposed UK-wide framework that is being developed to support joint working in this area will set out how this process will work. Discussions on this framework continue at the official level and remain without prejudice to the views of Scottish Ministers.

   b. **In what circumstances would the Scottish Ministers decide to designate the new committee rather than the Secretary of State? Would this be done by SSI and what Parliamentary scrutiny procedure would apply?**

   It is considered unlikely that such a situation will arise, since it is anticipated that agreement will be reached on a UK-wide committee. However, the fixing SI provides for alternative arrangements in Scotland if agreement cannot be reached. A SSI would not be required to establish the committee. The UK-wide framework agreement that is being developed for this area will establish new working arrangements that will support joint working and maintaining commonality of approach across the UK where this is appropriate.

   c. **Will an instrument through which the designation is made by the Secretary of State with the consent of the Scottish Ministers be laid before the Scottish Parliament? What Parliamentary scrutiny procedure would apply?**

   An Instrument will not be required to establish a committee for this purpose, see comment above.

   d. **How would this new committee be supported, and how would it be paid for?**
Annex A

It is proposed that the new committee will be funded in the first year by the UK Government with money secured from the EU exit budget. Thereafter, it is expected that it will be necessary to bid for funding through the usual spending route, and proportionate contributions may be required from devolved administrations.

e. Would this new arrangement have any financial implications for businesses in the UK?

There are currently no plans to charge for applications for new health claims so there will be no new financial implications for businesses.

f. The notification states that “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”. How have these conversations moved on since the committee previously heard that this was the case during previous SI notifications?

Negotiations on future relationships is a UK Government lead and we are unaware of any further developments.

4. More generally, the notification indicates on page 4 onwards that there are various powers conferred on the Scottish Ministers so far as they are within devolved competence and exercisable in Scotland. There is also provision for the Secretary of State to legislate “where it is expedient to do so” but only with the consent of the devolved administrations.

For example, under the heading “Food supplements” on page 5, it is envisaged that one list will be held for the UK but that each of the devolved administrations will be able to make amendments for their own areas and the Secretary of State will be able to make amendments for the whole of the UK with the consent of each of the devolved administrations.

a. Would the powers exercisable by the Scottish Ministers be made by regulations? What Parliamentary scrutiny procedure would apply?

The powers exercised by the Scottish Ministers would be by SSI, and it is anticipated that the negative resolution procedure will apply. This will be made clear in the final instrument.

b. In the cases where the current instrument would confer legislative powers on the Secretary of State with the consent of the Scottish Ministers in devolved areas, how will the use of the powers be scrutinised by the Scottish Parliament? Has it been considered whether joint procedure at Westminster and the Scottish Parliament would apply to those powers?

At the moment, where Scottish Ministers consent via s57(1) of the Scotland Act 1998 to UK regulations implementing EU obligations, we inform the
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relevant Parliamentary Committee in writing. We are considering the process for scrutinising UK regulations made under provisions amended by EU Exit SIs or SSIs.

c. Is the test that would apply in all cases where the Secretary of State would make such provision with the consent of the Scottish Ministers be “where it is expedient to do so”, as the notification appears to indicate?

In terms of the test that would be applied in the event that the Secretary of State would make legislation on a with consent basis, there are likely to be circumstances where matters require a swift response to an emerging issue that has a cross border impact. This might include emergency measures where a common coming into force date would be essential to ensure protection of both consumers and businesses across the whole of the UK. It might also be the most efficient way of dealing with authorising the placing on the market of new products or dealing with technical amendments which are of a routine and technical nature, and where there is consensus across the UK.

d. How is it to be defined when “it is expedient to do so”?

As outlined above, in defining 'expedient', this could be situations where an imminent risk to health has been identified, for example which requires the speedy removal of a substance which may be added to food supplements or a new product needs to be controlled which is not already covered by other food law. In such circumstances it might be important to expedite this through a UK-wide instrument where the necessary controls have been agreed and it is important to act quickly.

e. Would there be benefit to making the current instrument under joint procedure in terms of paragraph 2 of schedule 7 of the European Union (Withdrawal) Act 2018 to allow the Scottish Parliament to consider the scrutiny procedure that would be proposed for any regulations (or other form of instrument) to be made by the Scottish Ministers under the current instrument?

At the moment, where Scottish Ministers consent via s57(1) of the Scotland Act 1998 to UK regulations implementing EU obligations, we inform the relevant Parliamentary Committee in writing. We are considering the process for scrutinising UK regulations made under provisions amended by EU Exit SIs or SSIs. Scrutiny of further regulations made under provisions amended by EU Exit SIs or SSIs is a matter still to be determined by the UK Government and the Scottish Government. The necessary processes will be developed in consultation with the Parliamentary authorities.

5. The notification states on page 7 that Food Standards Scotland will provide further information on responses to the UK-wide public consultation on the instrument to the Health and Sport Committee if it
The Committee would be grateful to receive this further information as part of its consideration of the notification.

So far 13 responses have been received (none from Scottish stakeholders). Industry stakeholders have so far indicated that they are satisfied with the proposals. However, they would like further clarification on application processes and how relevant scientific assessments will be conducted. They are also keen to understand what levels of harmonisation will be both within the UK market and with the EU in the future. Six of the responses have been from members of the public who have indicated they are satisfied with the proposals and requesting that current regulatory standards are maintained. It is likely that there will be further responses as the consultation runs until the 14 December, a further update can be provided if that would be helpful.

6. The notification states “there are likely to be financial implications for nutrition related authorities and for bodies providing them with scientific advice, but it is not possible at this stage to assess how significant they may be”. What is meant by “nutrition related authorities” and when will such a financial assessment be able to be made?

The ‘nutrition related authorities’ referred to are the Department of Health and Social Care, Food Standards Scotland, Food Standards Agency Northern Ireland and the Welsh Government. Bodies providing scientific advice include Public Health England and the Food Standards Agency and associated UK-wide scientific advisory committees and expert groups such as the Committee on Toxicology (COT) and the Scientific Advisory Committee on Nutrition (SACN).

While we know scientific capability will be required, we do not yet know the likely volume of work. The majority of any new requirement will come from applications for the authorisation of new health claims, therefore it is being proposed that a new expert committee is established for that purpose. Requirements for scientific advice for the other areas of the nutrition related legislation covered by this Instrument is anticipated to be minimal with less than one instance a year.