

Health, Social Care and Sport Committee

20th Meeting, 2022 (Session 6), Tuesday 31 May 2022

Subordinate legislation

Note by the clerk

Purpose

1. This paper invites the Committee to consider the following negative instrument:

[The Food and Feed Safety \(Fukushima Restrictions\) \(Scotland\) Revocation Regulations 2022](#)

Procedure for negative instruments

2. Negative instruments are instruments that are “subject to annulment” by resolution of the Parliament for a period of 40 days after they are laid. This means they become law unless they are annulled by the Parliament. All negative instruments are considered by the Delegated Powers and Law Reform Committee (on various technical grounds) and by the relevant lead committee (on policy grounds).
3. Under Rule 10.4, any member (whether or not a member of the lead committee) may, within the 40-day period, lodge a motion for consideration by the lead committee recommending annulment of the instrument.
4. If the motion is agreed to by the lead committee, the Parliamentary Bureau must then lodge a motion to annul the instrument to be considered by the Parliament as a whole. If that motion is also agreed to, the Scottish Ministers must revoke the instrument.
5. If the Parliament resolves to annul an SSI then what has been done under authority of the instrument remains valid but it can have no further legal effect. Following a resolution to annul an SSI the Scottish Ministers (or other responsible authority) must revoke the SSI (make another SSI which removes the original SSI from the statute book.) Ministers are not prevented from making another instrument in the same terms and seeking to persuade the Parliament that the second instrument should not be annulled.
6. Each negative instrument appears on the Health, Social Care and Sport Committee’s agenda at the first opportunity after the Delegated Powers and Law

Reform Committee has reported on it. This means that, if questions are asked or concerns raised, consideration of the instrument can usually be continued to a later meeting to allow the Committee to gather more information or to invite a Minister to give evidence on the instrument. Members should however note that, for scheduling reasons, it is not *always* possible to continue an instrument to the following week. For this reason, if any Member has significant concerns about a negative instrument, they are encouraged to make this known to the clerks in advance of the meeting.

7. In many cases, the Committee may be content simply to note the instrument and agree to make no recommendations on it.

Guidance on subordinate legislation

8. Further guidance on subordinate legislation is available on the Delegated Powers and Law Reform Committee's web page at:
<http://www.scottish.parliament.uk/parliamentarybusiness/CurrentCommittees/delegated-powers-committee.aspx>

Recommendation

9. The Committee is invited to consider any issues which it wishes to raise in relation to this instrument.

Clerks to the Committee

12 May 2022

SSI 2022/166

Title of Instrument: The Food and Feed Safety (Fukushima Restrictions) (Scotland) Revocation Regulations 2022

Type of Instrument: Negative

Laid Date: 16 May 2022

Meeting Date: 31 May 2022

Minister to attend meeting: No

Motion for annulment lodged: No

Drawn to the Parliament's attention by the Delegated Powers and Law Reform Committee? No.

Reporting deadline: 20 June 2022

Purpose

10. The instrument will revoke retained Commission Implementing Regulation (EU) 2016/6 imposing special conditions governing the import of feed and food originating or consigned from Japan following the accident at the Fukushima nuclear power station.

11. These Regulations also revoke Declaration OFFC 2019/S/003 which was made in terms of regulation 35 of the Official Feed and Food Controls (Scotland) Regulations 2009 and which also imposed controls on the import of certain food and feed from Japan as a result of the Fukushima nuclear accident.

12. A copy of the Scottish Government's Policy Note is included in **Annexe A**.

13. The Minister for Public Health, Women's Health and Sport wrote to the Committee on 13 May 2022 setting out her opinion that the enhanced import controls are no longer required to ensure food is safe, stating that the requirements of general food law will suffice. This correspondence is included in **Annexe B**.

De-regulatory EU non-alignment

14. The [business and regulatory impact assessment](#) (BRIA) notes that removal of the remaining enhanced controls in Scotland will create divergence from the EU position. The EU has also reviewed and amended its regulations and has retained enhanced controls on any food where there is a single instance of exceeding the maximum level of 100 becquerels per kilogram.

15. However, the effect of the Internal Market Act 2020 has also been considered in the Scottish Government's recommendation. If enhanced controls are removed in England but not in Scotland, a product legally placed on the market in England can be placed on the market in the rest of GB without having to comply with rules set out in the countries receiving the goods. The BRIA goes on to state that the FSS and FSA risk assessment indicates that removing these controls would represent a negligible risk to the UK consumer and therefore it is inappropriate to retain existing controls or "ban" foods on safety grounds under the Internal Market Act given there is a high certainty of a negligible risk.

Delegated Powers and Law Reform Committee Consideration

16. The Delegated Powers and Law Reform Committee considered this at their meeting on [24 May 2022](#), and made no recommendations in relation to this instrument.

Annexe A**POLICY NOTE****The Food and Feed Safety (Fukushima Restrictions) (Scotland) Revocation Regulations 2022****SSI 2022/166**

The above instrument was made in exercise of the powers conferred by section Articles 53 and 57(a) of retained Regulation (EC) No. 178/2002 of the European Parliament and the Council on laying down the general principles and requirements of food law and laying down procedures in matters of food safety. The instrument is subject to negative procedure.

Summary Box

The Food and Feed Safety (Fukushima Restrictions) (Scotland) Revocation Regulations 2022 will revoke retained Commission Implementing Regulation (EU) 2016/6 imposing special conditions governing the import of feed and food originating or consigned from Japan following the accident at the Fukushima nuclear power station. These Regulations also revoke Declaration OFFC 2019/S/003 which was made in terms of regulation 35 of the Official Feed and Food Controls (Scotland) Regulations 2009 and which also imposed controls on the import of certain food and feed from Japan as a result of the Fukushima nuclear accident.

Policy Objectives

The instrument is required to give legislative effect to the Minister's decision with respect to the outcome of a review of retained Regulation (EU) 2016/6 which imposes special conditions governing the import of food and feed from Japan following the 2011 nuclear accident.

The Regulation includes the requirement to review the controls to ensure they remain proportionate to protect public health. Following the UK's exit from the EU, this Regulation was retained in Great Britain (GB) along with the requirement for the appropriate authority to review these controls. The appropriate authority are Ministers in Scotland. Food Standards Scotland (FSS) has undertaken the review under its function of developing policy and providing advice relating to matters connected with food safety as provided in Section 3 of The Food (Scotland) Act 2015. The review has followed the risk analysis process established by FSS and the Food Standards Agency (FSA), including an assessment of the risk to public health from consuming Japanese food imported into the UK, if the maximum levels on radiocaesium for food imported from Japan are removed. The conclusion of the risk assessment is that the removal of the maximum levels on radiocaesium for imported food and feed from Japan would result in a negligible increase in dose and a high certainty that the associated risk to consumers is negligible.

The decision of the future of the controls in Scotland rests entirely with the Scottish Ministers and the outcome of that decision is the focus of this Scottish Statutory Instrument (SSI). This SSI will revoke Regulation 2016/6, removing the existing enhanced controls on food and feed which specifically apply to contamination as a result of the Fukushima nuclear accident. This instrument will apply to Scotland only. Not progressing this SSI would mean that the Minister's decision would have no legal effect.

In addition, this SSI will revoke declaration OFFC 2019/S/003. This declaration was made under Regulation 35 of the Official Food and Feed Controls (Scotland) Regulations 2009 (OFFC). Regulation 35 was revoked by regulation 3(2) of the Food and Feed (EU) Exit (Scotland) (Amendments) Regulations 2020, with a savings provision made under regulation 3(4). This states that notwithstanding the revocation of regulation 35, any declaration made under regulation 35 that applies immediately before the revocation comes into force, continues to have effect as if it were made under Article 53 of Regulation 178/2002. Therefore it is appropriate that revocation of the declaration be by way of Scottish Statutory Instrument.

Consultation

To comply with the requirements of Article 9 of retained Regulation (EC) 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law and laying down procedures in matters of food safety, there has been open and transparent public consultation during the preparation and evaluation of this SSI.

A nine-week public consultation was launched on 10 December 2021 and closed on 11 February 2022. We asked for comments from industry, enforcement authorities, consumers and other interested stakeholders on our risk management options. The FSS preferred option was the removal of the existing enhanced controls in line with the outcome of the risk assessment which indicates that this would represent a negligible increase in dose and high certainty that the associated risk to UK consumers is negligible.

FSS received one response from a Scottish local authority supporting the removal of the controls based on the risk assessment showing a negligible risk to consumers. While this is a small number of responses, this reflects the very small size of the market represented by the foods under these controls. The response did not alter the FSS view. The FSA launched a separate, parallel consultation for England and Wales and received a total of 8 responses. Responses received by FSA did not provide evidence that contradict or challenge the conclusions of our risk assessment concerning the impact on risk to GB consumers if these enhanced controls are removed. Discussions were held on a four-nation basis, in line with the provisional Food and Feed Safety and Hygiene Common Framework, to address any devolved concerns and ensure alignment. The views of FSS and the FSA in England and Wales were agreed on.

A list of those FSS consulted, with the exception of private individuals, and who agreed to the release of this information is attached to the consultation page published on [Citizen Space](#).

Impact Assessment

FSS and FSA risk assessors have produced [a risk assessment](#). The conclusion of the risk assessment is that the removal of the 100 Bq/kg maximum level on radiocaesium for imported Japanese food would result in a negligible increase in dose and a high certainty that the associated risk to UK consumers is negligible. The risk assessment has been independently reviewed by the Committee on Medical Aspects of Radiation in the Environment (COMARE), a scientific advisory committee of the Department of Health and Social Care. COMARE agreed with the findings of the risk assessment.

Financial Effects

A UK-wide Business and Regulatory Impact Assessment (BRIA) has been completed and is attached. The Net Benefit (Present Value) of removing controls is estimated to be £0.018m (low estimate £0.002m, high estimate £0.034m). Other key non-monetised benefits include perishability savings (a reduction in products spoiling at port while official controls take place) and trade facilitation. During the public consultation, no evidence was presented to alter this impact assessment.

Food Standards Scotland
6 May 2022

Annexe B

Dear Convener,

The Food and Feed Safety (Fukushima Restrictions) (Scotland) Revocation Regulations 2022

I write to inform the Committee of my decision to remove the remaining enhanced controls in Scotland of certain food imported from Japan following the 2011 Fukushima nuclear accident.

Retained EU Regulation 2016/6 imposed enhanced controls on the import of food and feed from Japan as a result of the Fukushima nuclear accident in 2011, as an emergency measure, to protect consumers from imported food which may have become contaminated with radioactive material released following the nuclear accident.

The European Commission have regularly reviewed these controls and following the UK's exit from the EU, this Regulation was retained in GB along with the requirement for Scottish Ministers, as the appropriate authority in Scotland, to review these controls. Food Standards Scotland (FSS) has undertaken the review of the Regulation under its function of developing policy and providing independent advice relating to matters connected with food safety or other interests of consumers in relation to food and animal feed as provided in Section 3 of The Food (Scotland) Act 2015.

The review of the Regulation has been delivered by FSS, alongside the Food Standards Agency (FSA) for the rest of GB, through an enhanced risk analysis process that is science and evidence based. It consists of three separate but interconnected components: risk assessment, risk management and risk communication. This is an internationally accepted, structured approach to managing food and feed safety risks based on long established guidelines issued by the Food and Agriculture Organisation of the United Nations and the World Health Organisation. This also forms the basis for the EU's approach to food and feed safety risk analysis.

This is the first substantive issue progressed through the risk analysis process. A scientific risk assessment has been produced to assess the risk to public health from consuming Japanese food imported into the UK if the current maximum levels on radiocaesium for food imported from Japan are removed. The risk assessment is available here [Post Fukushima Nuclear Power Station Accident: UK Import Radiological Assessment \(foodstandards.gov.scot\)](https://www.foodstandards.gov.scot/post-fukushima-nuclear-power-station-accident-uk-import-radiological-assessment)

I am satisfied with the conclusion of the risk assessment that the removal of the maximum level on radiocaesium for imported Japanese food will result in a negligible increase in dose and a high certainty that the associated risk to UK consumers is negligible.

Risk assessors used the qualitative categorical scales by the Advisory Committee on the Microbiological Safety of Food¹ to communicate the levels of uncertainty in the risk assessment. The assessment indicates the level of uncertainty in this assessment is low. Low uncertainty is defined by the categorical scales as “there are solid and complete data available, strong evidence is provided in multiple references, authors report similar conclusions”. Negligible is defined as “so rare it does not merit to be considered”.

Low levels of radioactivity can be present in all our food from both natural and artificial sources. In general the health effects of ionising radiation are dependent on the dose received². The potential harm from radioactivity is measured in terms of the dose, measured in millisieverts (mSv). The dose is a combination of the level of radioactivity in the food (measured in becquerels per kilogram), the amount of the food consumed and a factor which depends on the radionuclide present (for example caesium-137). A higher dose represents an increased lifetime risk to health.

The International Commission on Radiological Protection (ICRP) recommends that members of the public should receive no more than the lower end of 1 to 20 mSv per year in an existing exposure situation. The FSS and FSA risk assessment indicates the dose to consumers would be no more than 0.016 mSv per year as a result of consuming food from Japan. For comparison, the average radiation dose to members of the public in the UK is 2.7 mSv from all natural and artificial sources³.

The risk assessment has also been reviewed by the independent Committee on Medical Aspects of Radiation in the Environment (COMARE), a scientific advisory committee of the Department of Health and Social Care. COMARE agreed with the findings of the risk assessment.

With my agreement, FSS launched a nine-week public consultation in December 2021 on the options for the future of these enhanced controls. These options included retaining the current controls, partial removal of controls and a preferred option of removing all the enhanced controls. The preferred option was in line with the outcome of the risk assessment which indicates that removing these controls would represent a negligible increase in dose and any associated risk to consumers. Responses to the consultation were considered by FSS in developing its final risk management advice. On 16 March 2022, the FSS Board discussed this issue at their open meeting and agreed the recommendation to revoke retained Regulation 2016/6 and thereby remove the enhanced controls.

I have given careful consideration to the recommendation, particularly in relation to the Scottish Government’s policy on alignment with the EU. My decision to remove the remaining enhanced controls in Scotland will create divergence from the EU position. The EU has also reviewed its regulation but has reached a different risk management decision to the one recommended to me by FSS. The EU has retained enhanced controls on any food where there is a single instance of exceeding the maximum level of 100 becquerels per kilogram. This maximum level was set to maintain consistency with the action level applied

within Japan which was lowered, nationally, to provide reassurance to Japanese consumers. It is more restrictive by a factor of 12 than the maximum level which would apply in the event of a nuclear accident in the EU and in Scotland. In reaching its decision, the EU did not commission a new risk assessment to consider typical consumption rates of the foods subject to enhanced controls.

Furthermore, I do not anticipate any EU market access issues for Scottish businesses arising from the divergence as there is no evidence that the limited range of foods subject to the EU controls imported into GB are subsequently traded with the EU.

Taking these factors into account it is my view that the recommendation not to align with the EU on this particular issue is appropriate. It is a recommendation based entirely on science and evidence, delivered through an internationally accepted, structured approach to managing food and feed safety risks.

In conclusion, I have considered the recommendation from FSS and it is my opinion that, based on the outcome of the FSS risk analysis, the enhanced import controls are no longer required to ensure food is safe as the requirements of general food law will suffice. I have therefore agreed to FSS proceeding with a Scottish Statutory Instrument being laid on 16 May 2022 to revoke retained Regulation 2016/6. I would be most grateful if you could respond to this letter should you have any concerns.

Yours sincerely,
Maree Todd MSP

¹ [Advisory Committee on the Microbiological Safety of Food](#)

² <https://www.gov.uk/government/publications/ionising-radiation-dose-comparisons/ionising-radiation-dose-comparisons>

³ <https://www.ukhsa-protectionservices.org.uk/radiationandyou/>