

# Review of retained Regulation 2016/6 on importing food from Japan following the Fukushima nuclear accident

## 1 Purpose of the paper.

- 1.1 For Decision
- 1.2 Commission Implementing Regulation (EU) 2016/6 was retained in Great Britain (GB) law following the UK's exit from the European Union (EU) and applies enhanced controls on certain food imported from Japan as a result of the Fukushima nuclear accident in March 2011. This was an emergency measure introduced to protect consumers from imported food which may have become contaminated with radioactive material released as a result of the accident.
- 1.3 The regulation includes the requirement to regularly review the controls to ensure they remain proportionate to protect public health. Following each review, the regulation has been amended or replaced as appropriate. This is the first scheduled review since the UK exited the EU and has followed the FSS and Food Standards Agency (FSA) risk analysis process.
- 1.4 Subject to agreement of the FSS and FSA Boards, GB ministers will be advised that these enhanced import controls can now be removed. Again, subject to subsequent Ministerial decision, Statutory Instruments will be drafted to revoke retained Regulation 2016/6 and if approved by GB Ministers, laid before their respective parliaments under the negative resolution procedure before coming into force.
- 1.5 The Board is asked to:
  - agree that FSS should advise the Minister in Scotland that, based on the outcome of the FSS and FSA's risk analysis, the enhanced sampling and import controls are no longer required to ensure food is safe as the requirements of general food law will suffice.
  - note that FSS officials will continue to work closely with the FSA to ensure actions to remove these controls are co-ordinated.

## 2 Strategic aims

- 2.1 This work supports FSS Strategic Outcome 1 - Food is Safe and Authentic; and Outcome 5 - FSS is trusted and influential.

## 3 Background

- 3.1 In March 2011, an earthquake struck off the east coast of Japan resulting in a tsunami. This caused damage to the Fukushima Daiichi nuclear power station which resulted in radioactive contamination affecting areas of Japan and the food and animal feed grown in these areas.

- 3.2 The European Commission (EC) put in place emergency legislation on the import of food and animal feed from Japan as a result of this accident. Since the accident, the EC has regularly reviewed these controls. At each review, data on the contamination of food and feed in Japan have been considered and the controls amended. In recent reviews, the range of food and feed covered by the controls and the Prefectures (regions within Japan) where enhanced checks are required prior to export have reduced as monitoring has shown that fewer foods are contaminated.
- 3.3 The most recent review was in 2019 and a new review date was set in the legislation for 30 June 2021. This deadline was not met as we could not start our review until FSS and the FSA assumed responsibility after the end of the EU Exit transition period. This meant that there was insufficient time to complete the risk assessment, including external quality assurance.

## 4 Discussion

- 4.1 Retained Regulation 2016/6 applies maximum levels of radioactive caesium on food and feed from Japan. For the majority of foods, a maximum level of 100 becquerels per kilogram (Bq/kg)<sup>1</sup> applies. This level was set by the Japanese authorities in 2012 to provide reassurance to Japanese consumers. It was adopted by the EU to maintain consistency with the action levels applied within Japan. The levels are more restrictive by a factor of 12 than the maximum levels which would apply in the event of a nuclear accident in the UK as set in retained Regulation (Euratom) 2016/52. As a result, FSS and FSA have maintained a long-standing position that the controls are not proportionate to the risk.
- 4.2 The majority of foods from Japan can already be imported into the UK without any enhanced controls as levels of radioactivity are very low and well below the maximum levels in retained Regulation 2016/6. The enhanced controls only apply to a limited number of foods including certain species of fish, wild mushrooms and foraged Japanese vegetables. These products are only imported into the UK in small quantities.
- 4.3 Following the UK's exit from the EU, this Regulation was retained in GB along with the requirement for the appropriate authority to review these controls. The appropriate authority are Ministers in Scotland and Wales and the Secretary of State in England. FSS has undertaken a review under its function of developing policy and providing 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.
- 4.4 These controls are an emergency measure following the Fukushima nuclear accident. As an emergency measure, intervention was intended to be temporary and only apply so far as required to protect public health. The intervention places a cost on importing food from Japan from testing prior to export, obtaining the correct import

<sup>1</sup> A becquerel is a unit of radioactivity defined as one atom in a material undergoing radioactive decay per second and releasing energy and energetic particles in the form of radiation

certification, and Official Controls carried out on import into the UK. The regulations were reviewed as a result of an obligation in the legislation and on the basis of maintaining controls only in so far as they are needed to protect public health.

- 4.5 Over time, levels of contamination in food have reduced due to a combination of radioactive decay, weathering processes and remedial actions by the government and agricultural industry in Japan. Review dates were included in the legislation so the appropriate level of intervention can be considered.
- 4.6 As a former Member State of the EU, the UK participated in the previous EC reviews and consideration of risk management options. This current review is the latest in this process and the first undertaken since the UK left the EU. It has followed the risk analysis process established by FSS and the 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.

### **Data and Risk Assessment**

- 4.7 Since the nuclear accident in 2011, the authorities in Japan have undertaken widespread monitoring of food and animal feed, with over 2.5 million samples reported. These results, which are published on the [Japanese Ministry of Health and Welfare website](#), report only a small number of foods above the 100 Bq/kg maximum level which are almost exclusively wild foods (wild mushrooms, foraged vegetables, fish and game meat) rather than agricultural products.
- 4.8 Japan continues to work closely with International Atomic Energy Agency (IAEA) and other international bodies in the recovery efforts and monitoring following the accident.
- 4.9 FSS and FSA risk assessors have produced [a risk assessment](#). The assessment was based on a model which estimated the committed effective dose (CED)<sup>2</sup> to different age groups, in millisieverts<sup>3</sup> per year (mSv/year), assuming imported food is ingested at reported UK consumption rates. The assessment also estimated the probability that a commodity exceeding the current 100 Bq/kg level would be imported into the UK if no import controls were in place. The assessment also compared the deterministic CED with and without controls in place which showed no significant difference if controls were lifted.
- 4.10 Radiocaesium activity concentrations extracted from Japanese monitoring data were used for the modelling throughout the risk assessment.

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<sup>2</sup> The committed dose in radiological protection is a measure of the stochastic health risk due to an intake of radioactive material into the human body. Stochastic in this context is defined as the probability of cancer induction and genetic damage, due to low levels of radiation. The CED is the sum of the products of the committed organ or tissue equivalent doses and the appropriate tissue weighting factors (Wt), where it is the integration time in years following the intake. The committed period is taken to be 50 years for adults, and to age 70 years for children.

<sup>3</sup> A millisievert is a unit measuring the radiation dose received.

- 4.11 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.
- 4.12 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 risk assessment estimates the dose to UK consumers would be no more than 0.016 mSv per year as a result of consuming food from Japan which is less than 2% of the lower end of this range.
- 4.13 For comparison, the average radiation dose to members of the public in the UK is 2.7 mSv from all natural and artificial sources, according to [UKHSA Radiation and You](#)
- 4.14 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.
- 4.15 In the 11 years that these controls have been in place, there have been no instances where checks have found levels above 100 Bq/kg on products imported into the UK. Across the EU as a whole, there was only one recorded instance, and this was within the first year following the accident.

### Economic Impacts

- 4.16 A [draft UK-wide Impact Assessment](#) has been produced. The Net Benefit (Present Value) for the preferred option 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 the impact assessment.

## 5 Options appraisal

- 5.1 FSS and the FSA launched separate parallel public consultations. The nine-week consultations were 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 consultation included three options:
  - Option 1 – Do nothing and retain the current controls
  - Option 2 – Remove the existing controls (Preferred Option)
  - Option 3 – Retain the existing maximum levels of radiocaesium on imports of food and feed from Japan but adjust the list of foods and prefectures covered by the enhanced controls

- 5.2 Option 2 was the preferred option in line with the outcome of our risk assessment which indicates that removing these controls would represent a negligible increase in dose and any associated risk to the UK consumer.
- 5.3 A total of 9 responses from across the UK to the consultation were received and have been considered in finalising our recommendations. Details of the options considered in the consultation and an overview of the consultation responses received are provided in Annex B.

## **6 Identification of risks and issues**

### **International and trade considerations**

- 6.1 The regulations were reviewed as a result of an obligation in the legislation and on the basis of maintaining controls only in so far as they are needed to protect public health. We have followed our risk analysis process taking into consideration the evidence on public health risk and other legitimate factors. Potential impacts on trade, while not the primary driver, should also be considered as part of looking at other legitimate factors on the basis of assessing whether current restrictions are a proportionate approach to restrictions on trade and commensurate to the protection of public health.
- 6.2 The existing controls apply enhanced requirements on products from Japan which do not apply to domestic goods or similar products imported from other countries. Under the World Trade Organisation (WTO) Sanitary and Phytosanitary (SPS) Agreement, import controls should be based on science and be applied only to the extent necessary to protect human, animal or plant life health following a risk analysis process.
- 6.3 Out of 54 countries and regions that initially applied import controls on food from Japan following the Fukushima nuclear accident, 41 have since lifted them.

### **EU Alignment**

- 6.4 The preferred option to remove the remaining enhanced controls in Scotland will create divergence from the EU position who have had the same requirement to review this regulation. In September 2021, Commission Implementing Regulation (EU) 2021/1533 replaced Regulation 2016/6 in the EU. This new regulation applied similar, but not identical, changes to those proposed in Option 3 of our consultation. The conclusion of the EU's review was to retain enhanced controls on any food where there is a single instance of exceeding the maximum level of 100 Bq/kg. As a result, some controls will remain in place for food imported into the EU. The list of foods covered by the enhanced controls in the EU regulations is now very limited, including wild mushrooms, foraged foods and some species of fish.
- 6.5 In reaching their decision, the EU did not commission a risk assessment to consider typical consumption rates of the affected foods and the significant reduction in levels of contamination in Japanese foods as a whole since the accident. The FSS and FSA risk assessment has done so. The risk assessment which is science and evidence

based, concludes that there is negligible risk to health when taking these factors into account. It is this outcome that is informing our preferred option to remove existing controls.

6.6 We have no evidence that the foods from Japan currently subject to enhanced controls are being imported into GB with the intention to re-export to the EU. This is because of the limited range of foods which remain subject to these controls that are unlikely to be imported for further processing; they are most likely to be imported directly by Japanese restaurants or specialist retailers of Japanese foods. Therefore, it is unlikely that where these foods are imported into Scotland and the rest of GB they will subsequently be traded with the EU, and we do not therefore anticipate any EU market access issues for affected Scottish businesses arising from divergence.

#### Four-country approach

6.7 FSS is working closely with the FSA on this issue in line with our commitments under the provisional common framework for food and feed safety and hygiene. We anticipate that consistent risk management recommendations will be made by the FSS in Scotland and FSA in England and Wales.

6.8 Under the current terms of the Northern Ireland Protocol, Northern Ireland will continue to apply the EU Regulations. We have no evidence that the foods from Japan subject to the EU's enhanced controls are being imported into GB with an onward destination in Northern Ireland. This is because of the limited range of foods which remain subject to these controls that are unlikely to be imported for further processing; they are most likely to be imported directly by Japanese restaurants or specialist retailers of Japanese foods. If food businesses place food from Japan on the market in Northern Ireland, EU requirements would need to be followed.

6.9 The effect of the Internal Market Act 2020 has also been considered. If enhanced controls are removed in England but not in Scotland (for example), 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. Given that the Japanese food imports arrive in English ports before redistribution to the rest of GB, were Scotland to require any additional checks on import it would have little effect on account of the automatic operation of the market access principles in the Act. This means that any imports into GB from Japan would only have to comply with English law, unless exemptions on food safety grounds could be demonstrated. However, as noted, 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.

## 7 Equality Impact Assessment and Fairer Scotland Duty

7.1 Equality Impact Assessment (EQIA) and Fairer Scotland Duty have not been produced for this paper as outlined in Annex A.

## 8 Conclusion/Recommendations

### 8.1 The Board is invited to:

- agree that the Board should advise the Minister in Scotland that, based on the outcome of the risk analysis, the enhanced sampling and import controls are no longer required to ensure food is safe as the requirements of general food law will suffice.
- note that FSS Officials will continue to work closely with FSA to ensure actions to remove these controls are co-ordinated.

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## Annex A

### Equality Impact Assessment and Fairer Scotland Duty

- 1.1 Equality Impact and Fairer Scotland Duty assessments are not considered necessary for this paper. The purpose of the paper is to agree proposed advice to Minister that current import controls are no longer required. This is based on the outcome of our risk assessment which indicates that removing these controls would represent a negligible increase in risk to human health through consumption.

## Annex B

### Options considered in the consultation

#### 1.1 Option 1 – Do nothing and retain the current controls

- In this option, the current controls would remain in place in GB. Food business operators (FBOs) importing food from Japan would continue to incur the costs of official controls on import into GB.
- No legislation would be required for these controls to continue, but an amendment may be required to set a new review date. As these controls were put in place as emergency measures, it is appropriate to regularly review the situation. It is proposed this would be 30 June 2023, following the previous pattern of reviewing every two years.

#### 1.2 Option 2 – Remove the existing controls on food and feed imported into GB which specifically apply to contamination as a result of the Fukushima nuclear accident (Preferred Option)

- This is the preferred option. In this option, domestic legislation would be brought forward in England, Wales and Scotland to revoke retained Regulation 2016/6. There would no longer be a requirement for declarations in relation to the levels of radioactive contamination for imported food from Japan with a destination in GB. There would also be no requirement to test for levels of radiocaesium prior to export for foods destined for GB and no enhanced official controls on arrival. Some of the foods imported from Japan would still require declarations and undergo official controls for other food safety reasons where they are classified as high-risk foods (for example fish under the hygiene requirements for products of animal origin).
- There would be reduced costs to FBOs as a result of removing the costs associated with complying with the enhanced controls.
- This would follow the outcome of our risk assessment, which indicates that removing these controls would represent a negligible increase in risk to the UK consumer. Without specific import controls, the emphasis would fall on FBOs to ensure food is safe under General Food Law (retained Regulation (EC) 178/2002). However, we do not consider that FBOs would need to take any precautions beyond their normal due diligence and so there should be no additional costs transferred to FBOs.

#### 1.3 Option 3 – Retain the existing maximum levels of radiocaesium on imports of food and feed from Japan but adjust the list of foods and prefectures covered by the enhanced controls

- In this option, the controls would remain in place but domestic legislation would be brought forward in Scotland, England and Wales to adjust the scope of the controls in line with previous reviews conducted by the EC. The requirement for pre-export testing would be removed on a prefecture-by prefecture basis where the monitoring in Japan shows no instances of a food from that prefecture being above 100 Bq/kg in the last calendar year, or the last two calendar years in respect of Fukushima prefecture.
- Applying these criteria would remove all fish except landlocked-freshwater salmon and char, as well as Aralia sprout, bamboo shoots and persimmon from the requirement for declarations. No marine species of fish showed levels above 100 Bq/kg in 2019 and 2020, although one sample of a marine fish (black rockfish) did exceed this level in 2021.
- Freshwater salmon and char would continue to require declarations from the whole of Japan with pre-export testing if they originate in Fukushima and Gunma prefectures. Declarations would still be required for mushrooms and certain wild vegetables (including koshiabura<sup>4</sup>, ferns and bracken) from the whole of Japan, with pre-export testing in Fukushima, Miyagi, Ibaraki, Gunma, Iwate, Yamagata, Niigata, Yamanashi, Nagano and Shizuoka prefectures. The prefectures of Tochigi and Chiba would be removed from the specified prefectures where pre-export testing of the remaining listed foods is required.
- FBOs importing food from Japan would continue to incur costs passed on by Japanese exporters for the laboratory analysis and obtaining the correct declarations and the costs of official controls on import into GB. However, this would still be a saving compared to Option 1 as a reduced number of foods would require these measures.
- This option would require secondary legislation to amend the list of foods and prefectures covered by the enhanced controls and to set a new review date. As these controls were put in place as emergency measures, it is appropriate to regularly review the situation. It is proposed this would be 30 June 2023 following the previous pattern of reviewing every two years.
- In September 2021, the EU published EU Regulation 2021/1533 which replaced EU Regulation 2016/6 in the EU. This new regulation applied similar, but not identical, changes to those proposed in this option. The main difference is that the EU have not amended the list of fish species in Annex II which means a larger number of fish species remain subject to controls in the EU than is proposed in this option. It is not clear on what basis the EU have retained controls on a wider number of fish species as the extensive monitoring results published by the Japanese authorities show

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<sup>4</sup> Koshiabura is a Japanese delicacy of the young buds foraged in spring from branches of certain trees

low levels of contamination in all other fish species monitored.

- This option is not considered to be a preferred option as it does not take into account the outcome of our risk assessment. It would continue to apply maximum levels lower than those levels which would apply in the event of a nuclear accident in the UK or EU and is not proportionate to the risk.

## **Overview of consultation responses**

- 1.4 A total of nine responses from across the UK were received and have been considered in finalising our recommendation.
- 1.5 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.
- 1.6 FSA received eight responses. These included three food business, one port health authority and four members of the public (three resident in the UK and one resident in Japan).
- 1.7 The food businesses supported the proposed removal of controls. The port health authority also supported the removal of controls based on the information provided showing little or no risk.
- 1.8 The members of the public generally expressed a lack of trust in the Japanese authorities and that food businesses may be driven more by price than considerations of food safety. However, responses from members of the public did not provide evidence that would contradict or challenge the conclusions of our risk assessment concerning the impact on risk to GB consumers if these enhanced controls are removed.
- 1.9 One member of the public also expressed concerns about lifting import controls while remediation work continued, including proposals to release water currently stored on the Fukushima site. Should this activity proceed the IAEA will work closely with Japan. It is not anticipated that this release of treated water would significantly increase levels of radiocaesium in the environment. Should the situation change, the devolved authorities in GB retain the powers to implement new emergency import controls similar to those introduced following the initial accident.