

Review of Retained Regulation 2016/6 on Importing Food from Japan Following the Fukushima Nuclear Accident

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1. Summary

- 1.1 [Commission Implementing Regulation \(EU\) 2016/6](#) was retained in Great Britain (GB) law following the United Kingdom's (UK) 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 nuclear accident.
- 1.2 As the provisions contained in the legislation were emergency measures, the regulations included the requirement to review them to ensure they remain proportionate to protect public health. Following each review, the regulations have been amended or replaced as appropriate. This is the first scheduled review since the UK exited the EU and has followed the FSA's risk analysis process.
- 1.3 Subject to agreement of the FSA and Food Standards Scotland (FSS) 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 the GB ministers, laid before their respective Parliaments under the negative resolution procedure before coming into force.
- 1.4 The Board is invited to:
 - agree that the FSA should advise Ministers in England and Wales that, based on the outcome of the 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 FSA officials will continue to work closely with FSS and the devolved governments to ensure actions to remove these controls are co-ordinated.

2. Introduction

- 2.1 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.

- 2.2 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) where enhanced checks are required prior to export have reduced as monitoring has shown that fewer foods are contaminated.
- 2.3 The most recent review under EU law was in 2019 and a new review date was set in the retained EU legislation for 30 June 2021. This deadline was not met as we could not start our review until the FSA formally 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.
- 2.4 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)¹ applies. This level was set by the Japanese authorities in 2012 to provide reassurance to Japanese consumers, reduced from the previous national level of 600 Bq/kg. 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 or EU as set in [retained Council Regulation \(Euratom\) 2016/52](#). As a result, the FSA has maintained a long-standing position that the controls are not proportionate to the risk.
- 2.5 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, primarily catering for restaurants specialising in Japanese food and consumers of traditional Japanese foods. Details of the existing controls can be found in Annex A.
- 2.6 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 is the Secretary of State in England, the Welsh Ministers in Wales and the Scottish Ministers in Scotland. The FSA 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 Sections 6 and 9 of the Food Standards Act 1999.

¹ 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

3. Evidence and Discussion

Review

- 3.1 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 of food prior to export, obtaining the correct import 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.
- 3.2 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.
- 3.3 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 the FSA and FSS, 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

- 3.4 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 (see Figure 1) which are almost exclusively wild foods (wild mushrooms, foraged vegetables, fish and game meat) rather than agricultural products.
- 3.5 Japan continues to work closely with International Atomic Energy Agency (IAEA) and other international bodies in the recovery efforts and monitoring following the accident.

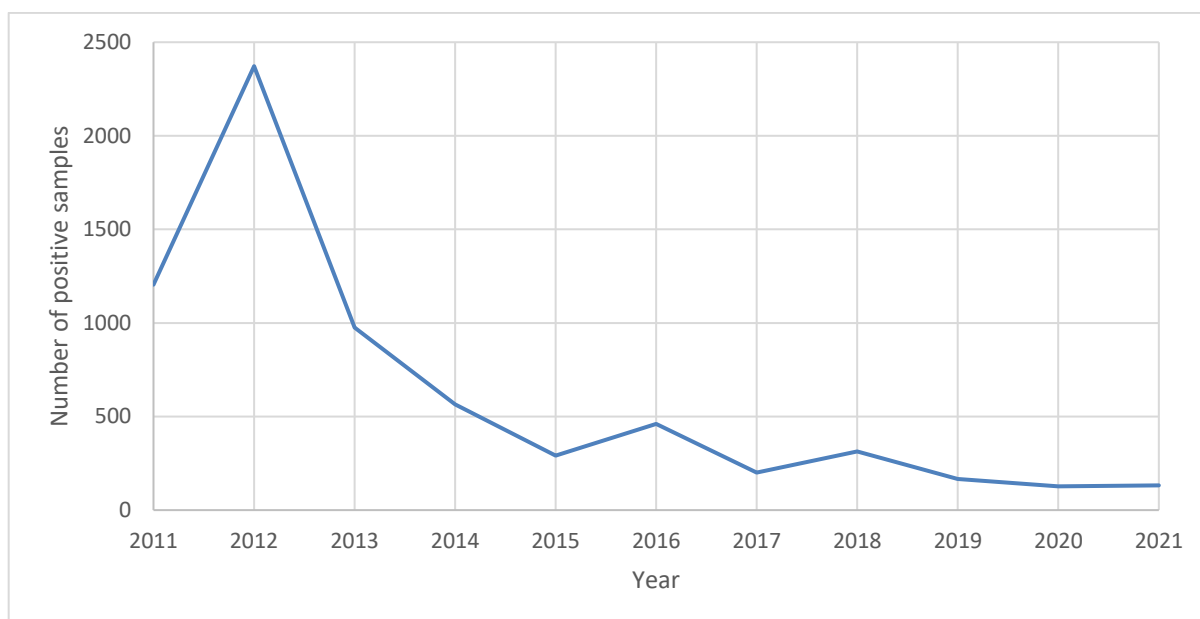


Figure 1: Number of samples of food in Japan reported as exceeding the maximum level of 100 Bq/kg in each year between 2011 and 2021 (as reported by the Japanese Ministry of Health and Welfare).

- 3.6 FSA risk assessors have produced [a risk assessment](#). The assessment was based on a model which estimated the committed effective dose (CED)² to different age groups, in millisieverts 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.
- 3.7 Radiocaesium activity concentrations extracted from Japanese monitoring data were used for the modelling throughout the risk assessment.
- 3.8 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 negligible associated risk to UK consumers.
- 3.9 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 FSA's risk assessment estimates the dose to UK consumers would be no more than 0.016 mSv per

² 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 t 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.

year as a result of consuming food from Japan which is less than 2% of the lower end of this range.

- 3.10 For comparison, the average radiation dose to members of the public in the UK is 2.7mSv from all natural and artificial sources, according to [UKHSA Radiation and You](#).
- 3.11 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.
- 3.12 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

- 3.13 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.
- 3.14 During the public consultation, no evidence was presented to alter the Impact Assessment.

Public consultation

- 3.15 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 consultation included three options:
- Option 1 – Do nothing and retain the current controls.
 - 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).
 - 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.
- 3.16 Option 2 was the FSA's 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.
- 3.17 A total of eight responses to the consultation were received and have been considered in finalising our recommendations. These responses did not

provide any evidence to contradict or challenge our proposals, and Option 2 remains our preferred option. A full summary of consultation responses will be published on the FSA website within three-months of the end of the consultation.

- 3.18 Details of the options considered in the consultation and an overview of the consultation responses received are provided in Annex B.

International and trade considerations

- 3.19 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.
- 3.20 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.
- 3.21 The EU had the same requirement to review this regulation. In September 2021, the EU published [Commission Implementing Regulation \(EU\) 2021/1533](#) which replaced Regulation 2016/6 in the EU. The EU has retained enhanced controls on any food where there is a single instance of exceeding the maximum level of 100 Bq/kg, similar, but not identical, to Option 3 of our consultation. 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.
- 3.22 The EU has not published a risk assessment. The FSA's risk assessment has considered typical consumption rates of the affected foods in the UK and the significant reduction in levels of contamination in Japanese foods as a whole since the accident and concludes that there is negligible risk to health when taking these factors into account.
- 3.23 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 international trading partners. 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. In the unlikely situation that the affected foods are imported into GB with the possibility of being re-exported, it will be the responsibility of food businesses to ensure they meet export requirements.

3.24 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.

Four-country approach

3.25 The FSA is working closely with FSS 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 FSA in England and Wales and FSS in Scotland.

3.26 Under the current terms of the Northern Ireland Protocol, Northern Ireland will continue to apply the EU Regulations. Please note that the UK Government has set out in its [Command Paper – The way forward](#) – potential changes to certain elements of the Protocol and is engaging with the EU on these proposals.

3.27 As Northern Ireland aligns with EU official control legislation, EU Regulation 2021/1533 applies and controls on Japanese imports into Northern Ireland will remain in place at least until the next scheduled review in June 2023.

3.28 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 GB food businesses place food from Japan on the market in Northern Ireland, EU requirements would need to be followed.

4. Conclusions

4.1 The Board is invited to:

- agree that we should advise Ministers in England and Wales that, based on the outcome of the 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 FSA officials will continue to work closely with FSS and the devolved governments to ensure actions to remove these controls are co-ordinated.

Annex A

5. Current enhanced controls in retained Regulation 2016/6

- 5.1 Retained Regulation 2016/6 applies maximum levels of radiocaesium on food and animal feed from Japan as a result of the Fukushima accident. These maximum levels are provided in Annex 1 of retained Regulation 2016/6.
- 5.2 There are different levels set for:
- foods for infants and young children;
 - milk and milk-based drinks;
 - mineral water and similar drinks and tea brewed from fermented leaves; and
 - other foods.
- 5.3 The majority of foods in Japan are well below these levels and so enhanced controls apply to only a limited number of food products, all of which are classified under the “other foods” category where a maximum level of 100 Bq/kg applies.
- 5.4 Annex 1 of retained Regulation 2016/6 also includes maximum levels for feed. Considering the available data, no products which may be used as animal feed are shown to exceed these levels.
- 5.5 The current enhanced controls require declarations and prior notification to be presented on import for certain foods, including mushrooms, wild vegetables and certain species of fish, from Japan. The declaration must certify that the product either did not originate in the listed prefectures (regions) or, if it did, that the product has been tested and the level of radiocaesium is below the limit of 100 Bq/kg. The listed foods for each affected prefecture can be found in [Annex 2 of retained Regulation 2016/6](#)³. Figure 2 is a map showing the prefectures covered in the enhanced controls.
- 5.6 Checks are also carried out when these products are imported into the UK, including taking samples for laboratory analysis on a random basis⁴.

³ EU Regulation 2016/6 was amended by Regulation 2017/2058 and Regulation 2019/1787, both of which updated and replaced Annex II. Retained Regulation 2016/6 refers to the Regulation as it existed at 11pm on 31 December 2020 (the end of the transition period following the UK’s exit from the EU) and incorporating amendments made by The Food and Feed Hygiene and Safety (Miscellaneous Amendments etc.) (EU Exit) Regulations 2020. Retained Regulation 2016/6 incorporates these previous amendments to Annex II.

⁴ in 2011, laboratory analysis was required for at least 10% of consignments and between 2012 and 2014 on 5% of consignments. Since 2014, laboratory analysis has been on a random basis of no more than 5% of consignments.

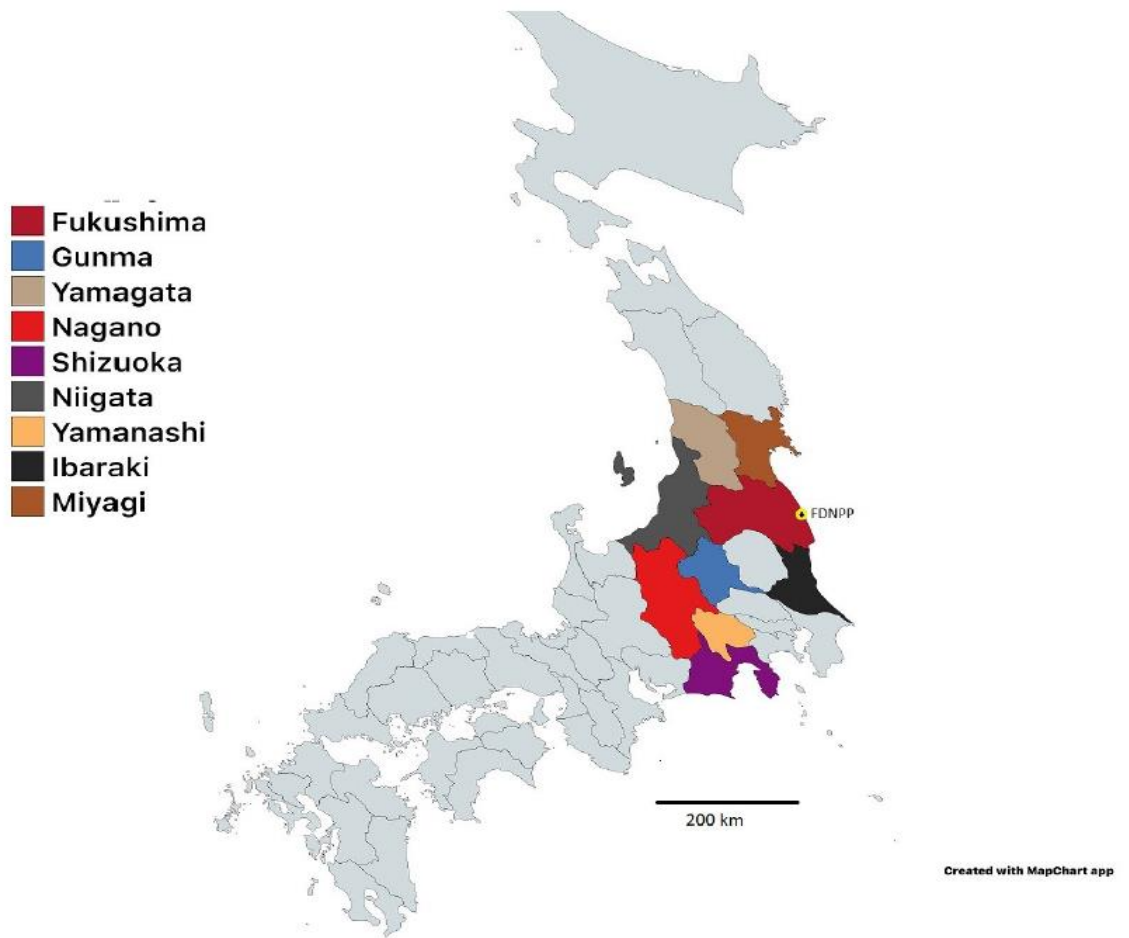


Figure 2: A map showing the current Japanese prefectures where pre-export checks are required on specified products to verify compliance against 100 Bq/kg limit (created by FSA using Mapchart).

Annex B

6. Public Consultation

Options considered in the consultation

6.1 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.

6.2 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.

6.3 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 England, Wales and Scotland 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 koshiabura⁵, 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 has 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

⁵ Koshiabura is a Japanese delicacy of the young buds foraged in spring from branches of certain trees

basis the EU have retained controls on a wider number of fish species as the extensive monitoring results published by the Japanese authorities show low levels of contamination in all other fish species monitored.

- This 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

- 6.4 A total of eight responses were received. These included three food businesses, one port health authority and four members of the public (three resident in the UK and one resident in Japan).
- 6.5 The three food businesses are importers specialising in food from Japan and Asia for restaurants and retailers. They acknowledged the need for controls to be risk based and supported the proposed removal of controls, noting that this would lead to smoother customs process for their businesses and UK consumers will regain access to a wider range of Japanese foods. The port health authority also supported the removal of controls based on the information provided showing little or no risk.
- 6.6 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.
- 6.7 Members of the public also expressed concerns about lifting import controls while remediation work continued, including proposals to release water currently stored on the Fukushima site⁶. Should this activity proceed, the IAEA will work closely with Japan before, during and after the discharge of the water. It is not anticipated that this release of treated water would significantly increase levels of radiocaesium in the environment as the majority of the radionuclides, including radiocaesium, will be removed from the water prior to the controlled release. 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.

⁶ Since the accident, over 1,300 million litres of water have been used to cool the damaged nuclear reactors and is currently being stored in temporary containers on the site. The Japanese authorities, in co-ordination with the IAEA, have considered long-term solutions and the preferred option is for a controlled release of this water into the Pacific Ocean. The water has been treated to remove as much radioactivity as possible and will be discharged in a controlled manner over several years to minimise the impact on the environment. Fukushima Daiichi Status Updates from the IAEA: <https://www.iaea.org/newscenter/focus/fukushima/status-update>