

<p>Title: Post Implementation Review of The Specified Products from China (Restriction on First Placing on the Market) (England) (Amendment) Regulations 2012 and The Specified Products from China (Restriction on First Placing on the Market) (England) (Amendment) Regulations 2013</p>	<p style="text-align: center;">Post Implementation Review</p>
<p>PIR No: FSA-PIR-005</p>	
<p>Original IA/RPC No: Click here to enter text.</p>	<p>Type of regulation: EU</p>
<p>Lead department or agency: FSA</p>	<p>Type of review: Statutory</p>
<p>Other departments or agencies: Click here to enter text.</p>	<p>Date measure came into force: 12/01/2012</p>
<p>Contact for enquiries: Sabrina Roberts</p>	<p>Recommendation: Keep</p> <p>RPC Opinion: Choose an item.</p>

1. What were the policy objectives of the measure? (Maximum 5 lines)

The two Statutory Instruments (SIs) subject of this PIR were introduced in England to implement emergency EU legislation laying down additional controls for the import into the UK of rice and rice products originating in, or consigned from China further to repeated non-compliance. The policy objective is to prevent food and feed products containing unauthorised genetically modified rice varieties from being placed on the UK market.

2. What evidence has informed the PIR? (Maximum 5 lines)

1. Data on unfavourable analytical test results notified to the EU Commission by EU Member States via the Rapid Alert System for Food and Feed (RASFF).
2. Quarterly UK returns to the EU Commission providing the results of analytical tests undertaken on specified rice and rice products from China;
3. Aggregated data based on quarterly returns by EU Member States to the Commission.
4. Food Standards Agency Biannual Public Attitudes Tracker – Report (November 2018). *(Impact Assessments were not produced for these emergency SIs).*

3. To what extent have the policy objectives been achieved? (Maximum 5 lines)

The EU measures and England implementing Regulations have been effective in preventing unauthorised genetically modified rice & rice products from China from being placed on the UK market. Whilst unauthorised GM rice continues to reach the UK border, 100% checks of specified products by Port Health Authorities have ensured that unauthorised GM varieties are identified and destroyed or re-dispatched to the country of origin, ensuring high levels of consumer protection.

Sign-off for Post Implementation Review: Chief economist/Head of Analysis and Minister

I have read the PIR and I am satisfied that it represents a fair and proportionate assessment of the impact of the measure.

Signed: [Click here to enter text.](#)

Date: [Click here to enter a date.](#)

Further information sheet

Please provide additional evidence in subsequent sheets, as required.

4. What were the original assumptions? (Maximum 5 lines)

The original assumption was that the measures would prevent rice and rice products containing unauthorised GM material being placed on the UK market.

5. Were there any unintended consequences? (Maximum 5 lines)

No, the FSA has identified no evidence of any unintended consequences from the introduction of these emergency Regulations. The measures have been effective in preventing rice and rice products containing unauthorised GM material being placed on the UK market.

6. Has the evidence identified any opportunities for reducing the burden on business? (Maximum 5 lines)

No. The England SIs provide the execution and enforcement for the EU Decisions, which provide a harmonised framework for managing the importation of rice and rice products from China. The relevant EU law comprises two directly applicable EU Commission Decisions which are clear, prescriptive and provide no scope for flexibility or discretion by Member States. The legislation prescribes the way in which desired outcomes must be achieved, including documentary checks at borders and sampling and analysis on 100% of relevant consignments.

7. For EU measures, how does the UK's implementation compare with that in other EU member states in terms of costs to business? (Maximum 5 lines)

The England SIs do not impose any national rules over and above the harmonised EU legislation they implement (i.e. there is no 'gold-plating'); they simply provide for the execution and enforcement of the directly applicable emergency EU measures in England. The harmonised EU legislation prescribes the way in which desired outcomes must be achieved by Member States.

Post Implementation Review

The Specified Products from China
(Restriction on First Placing on the Market)
(England) (Amendment) Regulations 2012

and

The Specified Products from China
(Restriction on First Placing on the Market)
(England) (Amendment) Regulations 2013

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The UK exited the EU on 31 January 2020. There is now a transition period until the end of 2020 while the UK and EU negotiate additional arrangements. EU law continues to apply in the UK during the transition period, including rules on food and feed.

1 EXECUTIVE SUMMARY

- 1.1 The Specified Products from China (Restriction on First Placing on the Market) (England) (Amendment) Regulations 2012 and The Specified Products from China (Restriction on First Placing on the Market) (England) (Amendment) Regulations 2013 make provisions for implementing emergency EU legislation which places additional controls on rice and rice products imported into the EU from China and for their enforcement. The EU measures non-exhaustively require that:
 - a. Rice and rice products originating or consigned from China are accompanied by an analytical report demonstrating they do not contain, consist of, nor have they been produced from an unauthorised genetically modified organism;
 - b. Each consignment must be accompanied by a Health Certificate, verified by the appropriate authority in China;
 - c. Sampling and analysis must be undertaken by Member States on 100% of relevant consignments;
 - d. In order to monitor the effectiveness of the measures, Member States must send a quarterly report to the European Commission summarising the results of analytical tests undertaken.
- 1.2 The harmonised EU law implemented by these SIs comprises of two directly applicable EU Commission Decisions which must be implemented by Member States; they are clear, prescriptive and provide no scope for flexibility or discretion. The harmonised EU legislation prescribes the way in which desired outcomes must be achieved, providing consistency in implementation across Member States.
- 1.3 The policy objective of these EU measures and the domestic implementing Regulations are to prevent food and feed products containing unauthorised genetically modified rice varieties from being placed on the UK/EU market.

- 1.4 This report on the Post Implementation Review (PIR) of the 2012 and 2013 Regulations assesses the actual effect of the Regulations five years after they were made, principally by referring to data obtained from a EU Commission web-based IT platform which collates data from the UK and other EU Member States in relation to the effectiveness of the measures.
- 1.5 The FSA carried out a public consultation on this joint PIR from 14 May - 20 June 2018 seeking comments from relevant stakeholders, including importers and Port Health Authorities in England, to capture their views on the effectiveness and effects of the legislation. The FSA received no responses to the consultation; nevertheless, broader consumer perspectives in relation to food safety/standards are captured within the report.
- 1.6 This joint PIR is a light touch review based on the temporary and emergency nature of the legislation, the low financial impact to UK stakeholders, and the on-going EU monitoring of its effectiveness. Due to the fact these SIs were introduced to implement emergency EU measures, Impact Assessments were not completed. This PIR assesses the costs and benefits of the Regulations to food and feed business operators, Port Health Authorities and consumers. At a minimum, this report seeks to establish whether the objectives of the 2012 and 2013 Regulations have been achieved.
- 1.7 The findings of this PIR indicate that the measures have been effective in preventing non-compliant genetically modified rice and rice products from being placed on the UK/EU market. Whilst unauthorised GM rice products from China continue to reach the UK border, 100% checks of specified products by Port Health Authorities have ensured that unauthorised GM varieties are being identified and rejected/destroyed at the border.
- 1.8 Costs to food and feed business operators and Port Health Authorities from complying with the EU measures and England SIs are nominal. In view of the benefits of enhanced resilience at ports, the costs of these measures are deemed to be proportionate and appropriate.
- 1.9 We recommend that the Specified Products from China (Restriction on First Placing on the Market) (England) (Amendment) Regulations 2012 and 2013 are retained.

2 Introduction

- 2.1 The UK exited the EU on 31 January 2020. There is now a transition period until the end of 2020 while the UK and EU negotiate additional arrangements. EU law continues to apply in the UK during the transition period, including rules on food and feed.
- 2.2 This report addresses the joint Post Implementation Review (PIR) on both The Specified Products from China (Restriction on First Placing on the Market) (England) (Amendment) Regulations 2012 and The Specified Products from China (Restriction on First Placing on the Market) (England) (Amendment) Regulations 2013. These two Statutory Instruments (SIs) were introduced in England to provide for the implementation of emergency EU legislation¹ introduced by the EU Commission ('the Commission') which placed additional controls on rice and rice products consigned to the EU from China. EU legislation to address these issues was first implemented in 2008 and was deemed necessary by the Commission and Member States due to rising incidences of GM rice that is not authorised in the EU being identified in consignments of rice and rice products from China. Due to the emergency nature of the EU legislation they implement, impact assessments were not prepared in respect of the two England SIs.
- 2.3 The emergency EU legislation is temporary and has undergone reviews at EU level since 2012 using data on the level of non-compliance collated from quarterly returns submitted by Member States. The most recent review took place at a meeting of the GM Food and Feed Section of the Standing Committee meeting on Plants, Animals, Food and Feed (GMFF SCOPAFF) in Brussels on 7 March 2019, at which the Commission and Member States noted that there was continued non-compliance in relation to the presence of unauthorised GM rice in rice and rice products consigned to the EU from China and that the measures and their objectives remain appropriate and proportionate and should not be lifted.

¹ Commission Decision 2008/289/EC, Commission Implementing Decision 2011/884/EU and Commission Implementing Decision 2013/287/EU

- 2.4 The key objective of the two SIs being reviewed (along with similar, equivalent legislation in place in the other countries of the UK which are not subject to this England-only review) is to prevent unauthorised genetically modified rice and rice products consigned from China from being placed on the UK/EU market.

3 Background

- 3.1 In September 2006, the UK, France and Germany identified consignments of rice and rice products from China that contained the unauthorised genetically modified rice variety 'Bt63' and notified this under the EU Rapid Alert System for Food and Feed (RASFF) which enables the swift exchange of information about emerging food and feed hazards between Member States, the European Commission, EFSA and others.
- 3.2 As a result, the Commission asked the Chinese competent authorities to provide detailed information on the unauthorised genetically modified rice 'Bt63'. The Chinese authorities were also asked to elaborate on the origin of the genetically modified rice within the Chinese market and how the Chinese competent authorities aim to ensure that exported products, such as rice, complied with the requirement that only GM that has been authorised in the EU can be placed on the EU market.
- 3.3 Chinese authorities responded to the request by conducting official controls on the specific cases that were notified under the RASFF and determined the export activities of the involved companies. The Chinese authorities also conducted further tests on exported rice and rice products and obliged exporting enterprises to extend and strengthen their internal testing around raw material purchasing. The Chinese authorities also informed the Commission of the overall approach to GM rice within the Chinese regulatory framework, and the status of genetically modified rice Bt63. The information provided confirmed that the genetically modified rice 'Bt63' is also unauthorised in China.
- 3.4 Member States were updated on these initial interactions between the Commission and the Chinese authorities at meetings of the EU Standing Committee on the Food Chain and Animal Health on 11 September and 23 October 2006. The Commission also wrote to Member States reminding them of their obligation to prevent unauthorised GMOs being placed on the EU market.

- 3.5 It initially appeared that the measures taken by the Chinese authorities had been effective, as no further incidences were notified. However, new RASFF notifications were raised by Germany and Greece concerning 'Bt63' in consignments that appeared to have left China after the implementation of the control measures by the Chinese authorities.
- 3.6 After the Commission informed the Chinese authorities of these new RASFF notifications, the latter implemented stronger and more frequent checks on rice exports. These included the requirement that every consignment of rice and/or rice products had to be accompanied by an official Chinese Inspection and Quarantine Certificate prior to export. On 2 March 2007, these developments were notified to the EU Standing Committee on the Food Chain and Animal Health.
- 3.7 Despite the Chinese authorities' efforts to improve the controls on rice products, further RASFF notifications were raised once more concerning 'Bt63'. The Commission asked their Joint Research Centre (JRC) which validates analytical methods for the detection and identification of GMOs in the food and feed chain to scrutinise the Chinese controls. The Chinese authorities were unable to provide the JRC with relevant control samples or a protocol for the detection method they were using that the JRC could validate.
- 3.8 In the light of the inability of the Chinese competent authorities to demonstrate effective measures or provide sufficient guarantees of the absence of the unauthorised genetically modified rice 'Bt63' in rice products originating from China, the European Commission concluded that it was appropriate to adopt emergency measures in respect of rice and rice products from China.
- 3.9 Initially, Commission Decision 2008/289/EC was introduced which came into force on 15 April 2008 with the aim of preventing unauthorised genetically modified rice 'Bt63' from being placed on the EU market. In 2010, besides 'Bt63' two further unauthorised GM rice varieties originating from China (known as Kefeng and KMD1) were found by Member States and notified under the RASFF.
- 3.10 The Commission's Food and Veterinary Office (FVO) conducted an inspection mission in 2011 which found that there was a significant risk of other varieties of unauthorised GM rice (including Kefeng and KMD1) being placed on the EU market in rice and rice products originating from China. As a consequence, the European Commission introduced a new measure, Commission Decision 2011/884/EU, to replace Commission Decision 2008/289/EC and apply strengthened controls on rice and rice products imported from China. The provisions of the 2011 measure were subsequently strengthened further still by Commission Decision 2013/287/EU.

- 3.11 China has currently seven rice-growing provinces where the production of GM rice on a commercial basis is prohibited. Although GM rice trials are currently being performed in the Hubei province, a biosafety control system is in place covering seed producing companies, markets and retailers in over 400 towns.
- 3.12 In November 2015, SANTE F (formerly the FVO) conducted a further audit in China of the controls and supervision system implemented by the Chinese authorities to ensure compliance with the requirements of the EU measures. They found that the supervisory system was supported by a well-established and suitably appropriate laboratory capacity that includes procedures to follow up on RASFF notifications, that GMO field trials in Hubei Province are adequately controlled, that extensive controls are in place to ensure that rice cultivation is not contaminated with GMOs and that some GMO controls in respect of rice cultivation are performed in other rice-growing provinces.
- 3.13 China is currently in the process of amending its Implementation Regulations on Safety Assessment of Agricultural Genetically Modified Organisms. The proposed amendments have been notified in accordance with WTO requirements and comments from WTO Members are being considered. Chinese authorities have vowed zero tolerance and harsh penalties for illegal growing and sales of GM crops since discovery of unauthorised GM rice in the Hubei province.
- 3.14 At the meeting of the GMFF SCOPAFF in Brussels on 7 March 2019, the European Commission and Member States decided to retain the measures. This decision was chiefly based on figures provided by Member States reported under the provisions of the measures that reflected an increase in non-compliance identified via documentary and analytical checks in 2017. It recognised that overall number of relevant RASFF notifications had decreased since the controls were first introduced in 2008 and attempts had been made by the Chinese authorities to combat illegal trade in this area which they have stated is the main type of non-compliance that is detected in respect of all their trade with the EU. As such, the Commission will continue to monitor Member States' returns and review the potential to lift the measures in the future.

4 Purpose and scope of report

- 4.1 As part of the Government's Commitment to review provisions in secondary legislation that regulate businesses, the 2012 and 2013 Regulations require the Food Standards Agency (FSA) to undertake a Post Implementation Review (PIR) of the Regulations and set out the conclusions in a report within 5 years of the measures coming into force.
- 4.2 This joint PIR is a light touch review based on the temporary and emergency nature of the legislation, the low financial impact likely to have resulted to UK stakeholders, and the on-going EU monitoring of its effectiveness. Due to the fact these SIs were introduced to implement emergency EU measures, Impact Assessments were not completed.
- 4.3 This report assesses the actual effect of the 2012 and 2013 Regulations, principally by analysing data relating to notifications of unauthorised varieties of GM rice in consignments of rice and rice products reported to the European Commission by the UK and other EU Member States. This report also assesses the costs and benefits of the Regulations to food and feed business operators, Port Health Authorities and consumers. The findings of this PIR will help inform, guide and shape the position in England.

5 Legislation

Controls to address unauthorised GM rice in rice and rice products consigned to the EU from China

EU Legislation	Implemented in England by:	Scope of Joint PIR
Commission Decision 2008/289/EC of 3 April 2008 on emergency measures regarding the unauthorised genetically modified organism 'Bt 63' in rice products.	The Specified Products from China (Restriction on First Placing on the Market) (England) Regulations 2008	The 2008 Regulations in their original form are not subject to this Joint PIR.
Commission Implementing Decision 2011/884/EU on emergency measures regarding unauthorised genetically modified rice in rice products originating from China and repealing Decision 2008/289/EC	The 2008 Regulations as amended by: The Specified Products from China (Restriction on First Placing on the Market) (England) (Amendment) Regulations 2012	Amendments to the 2008 Regulations made by the 2012 Regulations are subject to this Joint PIR by virtue of Regulation 3.
Commission Implementing Decision 2013/287/EU amending Implementing Decision 2011/884/EU on emergency measures regarding unauthorised genetically modified rice in rice products originating from China	The 2008 Regulations as amended for the second time by: The Specified Products from China (Restriction on First Placing on the Market) (England) (Amendment) Regulations 2013	Further amendments to the 2008 Regulations made by the 2013 Regulations are subject to this Joint PIR by virtue of Regulation 3.

5.1 The initial measure, Commission Decision 2008/289/EC, required that:

- Rice and rice products (including composite products) originating or consigned from China falling within specified customs classifications must be accompanied by an analytical report demonstrating they do not contain or consist of, nor have been produced from, the unauthorised genetically modified organism “Bt63”.
- Member States must take the measures necessary to ensure that non-compliant products are not placed on the market.
- Member States must take appropriate control measures, including random sampling and analysis carried out using a specified analytical method.
- Member States report positive results from official sampling activity to the European Commission immediately through the RASSF system and provide information on negative sampling results reported to the Commission on a quarterly basis.
- Costs incurred in implementing the requirements of the measure must be borne by food/feed business operators.

5.2 The Specified Products from China (Restriction on First Placing on the Market) (England) Regulations 2008, which are not subject to this PIR in their original form, provided for the execution and enforcement of the 2008 EU measure in England, including criminal sanctions.

5.3 In 2011, Commission Implementing Decision 2011/884/EU was adopted which repealed and replaced Commission Decision 2008/289/EC, with the aim of ensuring a comprehensive and common approach to prevent unauthorised genetically modified rice and rice products imported from China being placed on the EU market. Due to the variety of products that could potentially contain unauthorised genetically modified rice, a longer list of products was targeted which could contain, consist or be produced from rice originating from China. Replicating the core provisions of the 2008 measure, the 2011 measure:

- Updated and extended the list of products falling under the scope of the controls (See **Appendix I**);
- Required that in addition to the analytical report, each consignment must be accompanied by both a Health Certificate verified by an authorised representative of the ‘Entry Exit Inspection and Quarantine Bureau of the People’s Republic of China’ (AQSIQ), and provided model documents for these purposes (see **Appendices II and III**);

- Required Member States to undertake sampling and analysis on 100% of relevant consignments;
 - Provided harmonised methods of sampling and a testing approach, based on screening methods, capable of detecting a number of potential GM rice varieties in addition to Bt63;
 - Required Member States to monitor the effectiveness of the measure by sending a quarterly report to the Commission summarising the results of analytical tests that have been carried out.
- 5.4 The Specified Products from China (Restriction on First Placing on the Market) (England) (Amendment) Regulations 2012, which are being reviewed in this PIR, amended the 2008 Regulations to implement the 2011 EU measure in England.
- 5.5 In 2013, the Commission further strengthened the controls through the adoption of Commission Decision 2013/287/EU which amended Decision 2011/884/EU by:
- Extending the list of products falling under the scope of the emergency measures;
 - Emphasising the need for prior notifications of consignments to Border Inspection Posts or the Designated Point of Entry at least one working day before the arrival of the consignment;
 - Providing sampling methodologies for processed products.
- 5.6 The Specified Products from China (Restriction on First Placing on the Market) (England) (Amendment) Regulations 2013, which are being reviewed in this PIR, further amended the 2008 Regulations to implement the 2013 EU measure in England.

6 Costs and benefits

- 6.1 As the 2012 and 2013 Regulations relating to England were introduced to implement emergency EU measures, Impact Assessments were not completed. This post implementation review therefore seeks to identify the overall costs and benefits estimated for food and feed businesses, Port Health Authorities and consumers. The key assumptions and findings are as follows:

Consumers

6.2 Decreased likelihood of unauthorised genetically modified rice and rice products reaching the consumer and maintenance of high standards of consumer protection and confidence within the UK.

Food and feed businesses

6.3 Since 2008, all costs resulting from the Official Controls including sampling, analysis, storage and any measures taken following non-compliance, have been borne by food and feed business operators who import specified rice and rice products from China.

6.4 Between 2013 and 2017, an annual average of 86 consignments of rice and rice products from China subject to these EU measures were presented at UK borders, where they were subjected to documentary checks and analytical testing by Port Health Authorities.

6.5 Costs of Official Controls by Port Health Authorities cover document checks, product identify checks, physical checks, sampling and analysis of products and measures taken following non-compliance.

6.6 To estimate the costs borne by food and feed business operators, a desktop exercise was conducted to establish Port Health Authority charges for the exercise of their Official Controls duties. For consignments comprising solely of non-processed products, the average costs of Official Controls are estimated at £1,600 per consignment. The average costs for consignments comprising solely of processed products is estimated at £716 per consignment (due to less onerous analytical testing requirements).

6.7 The total annual cost to UK importers has been calculated by multiplying the annual average number of consignments between 2013-2017 (86) by the average cost of undertaking Official Controls (for both processed products (£716) and non-processed products (£1,600)). The average annual cost to UK importers is estimated to be between £61,576 at the lower end and £164,000 at the higher end. A yearly breakdown of total costs to UK importers between 2013-2017 is provided in **Table 1**.

6.8 The total cost to UK importers will lie at some point between these two extremities, as consignments in any given year will include a proportion of both processed and unprocessed products. The cost of sampling and analysis for any given consignment can also vary depending upon the size of the consignment. The number of consignments to the UK have been consistent since 2015, so there is no evidence to suggest that total costs to UK importers will significantly deviate from these estimates going forwards.

	Total number of consignments	Total costs to importers (higher end estimate)	Total cost to importers (lower end estimate)
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2013	52	£83,200	£37,232
2014	75	£120,000	£53,700
2015	100	£160,000	£71,600
2016	102	£163,200	£73,032
2017	103	£164,800	£73,748

Table 1: Total cost of Official Controls (UK) – 2013-2017

- 6.9 One-off familiarisation costs to food and feed business operators associated with reading and familiarising themselves with the 2011 and 2013 EU measures and the 2012 and 2013 Regulations relating to England that implement them. We estimate that it will have taken each business less than 45 minutes to read and understand the EU measures and implementing Regulations and then disseminate the information to key staff within their firm.
- 6.10 Between 2013 and 2017, an average of 86 consignments per annum have arrived at UK ports; this would suggest that 86 importers would be affected by these Regulations. In practice, this is a liberal estimate and we would expect the number of importers affected by these Regulations to be significantly lower than 86, as it is common for an importer to import multiple consignments per year.
- 6.11 One-off familiarisation costs per affected entity was estimated at £9.30; this figure was calculated by multiplying the median hourly wage rate for Managers and Directors in retail and wholesale (£12.40) - obtained from the 2017 Annual Survey of Hours and Earnings (ASHE) - by the time needed to assimilate and disseminate the information (Translated as 0.75 decimal hours, the equivalent of 45 minutes). The total one-off familiarisation costs to UK importers was obtained by multiplying the cost per entity by the total number of importers (86) and was estimated to be £799.80 (**Table 2**).

Affected Entity	Familiarisation time	Cost per entity	Total cost
Importers	45 minutes (translated as 0.75 decimal hours)	£9.30	£799.80

Table 2: One-off familiarisation costs to UK importers

- 6.12 The measures help protect UK businesses from placing unauthorised GM on the UK market. The provision and utilisation of analytical reports can help to increase the handling and processing speed at ports and decrease the rate of seizure and destruction of food and feed consignments containing unauthorised genetically modified rice and rice products.
- 6.13 Food and feed business operators may have experienced benefits arising from the changes to the methods of sampling and analysis introduced in 2013 through an overall reduction in the costs of testing processed foods which comprise the majority of imported products that fall within the scope of the measures.

Food and feed authorities (Port Health)

- 6.14 One-off costs to food and feed authorities associated with managers reading and familiarising themselves with the 2011 and 2013 EU measures and the 2012 and 2013 Regulations relating to England that implement them. We estimate that it will have taken food and feed authorities less than 45 minutes to read and understand the EU measures and implementing Regulations and then disseminate the information to key staff.
- 6.15 We estimate that 54 Port Health Authorities in England would be affected by these Regulations, 40 of which are Designated Points of Entry (DPEs) and 14 of which are Border Inspection Posts (BIPs).
- 6.16 One-off familiarisation costs per affected entity (£17.10) were calculated by multiplying the median hourly wage for managers (£22.80) - obtained from the 2017 Annual Survey of Hours and Earnings (ASHE) - by the time needed to assimilate and disseminate the information (Translated as 0.75 decimal hours, the equivalent of 45 minutes). The total one-off familiarisation costs to Port Health Authorities in England was obtained by multiplying the cost per entity by the total number of Designated Points of Entry and Border Inspection Posts (54) and was estimated to be £923.40 (**Table 3**).

Affected Entity	Familiarisation time	Cost per entity	Total cost
Port Health Authorities	45 minutes (translated as: 0.75 decimal hours)	£17.10	£923.40

Table 3: One-off familiarisation costs to Port Health Authorities in England

- 6.17 Since 2008, the measures have required the actual costs incurred by Port Health Authorities in undertaking the associated Official Controls to be borne by food and feed business operators. As such, no additional financial impact on the public sector was expected to arise from the 2011 and 2013 EU measures or the Regulations relating to England that implement them.
- 6.18 The provision and utilisation of analytical reports serve as a useful screening tool to help decrease the likelihood of unauthorised genetically modified rice and rice products being placed on the UK market. Where a consignment is not accompanied by a health certificate and/or analytical report, the consignment is re-dispatched to the country of origin or destroyed, negating the need for sampling and analytical testing, saving both time and resources.
- 6.19 In 2017, 8 out of 103 consignments which arrived at UK borders failed documentary checks and were either destroyed or re-dispatched to the country of origin.

7 Assessment of the extent to which the objectives of the Regulations are being achieved

- 7.1 This PIR uses data from the Rapid Alert System for Food and Feed (RASFF), quarterly returns provided by the UK to the Commission pursuant to Commission Implementing Decision 2011/884/EU and aggregated data based on quarterly returns provided by other Member States to the Commission pursuant to that measure.
- 7.2 The following sections give a brief outline of figures in relation to non-compliance with the measures and aim to reflect an assessment of the extent to which the objectives of the legislation have been achieved. Until now, the emergency measures and their objectives remain appropriate and proportionate/

Rapid Alert System for Food and Feed (RASFF) Notifications by EU Member States, EFTA States and the European Commission

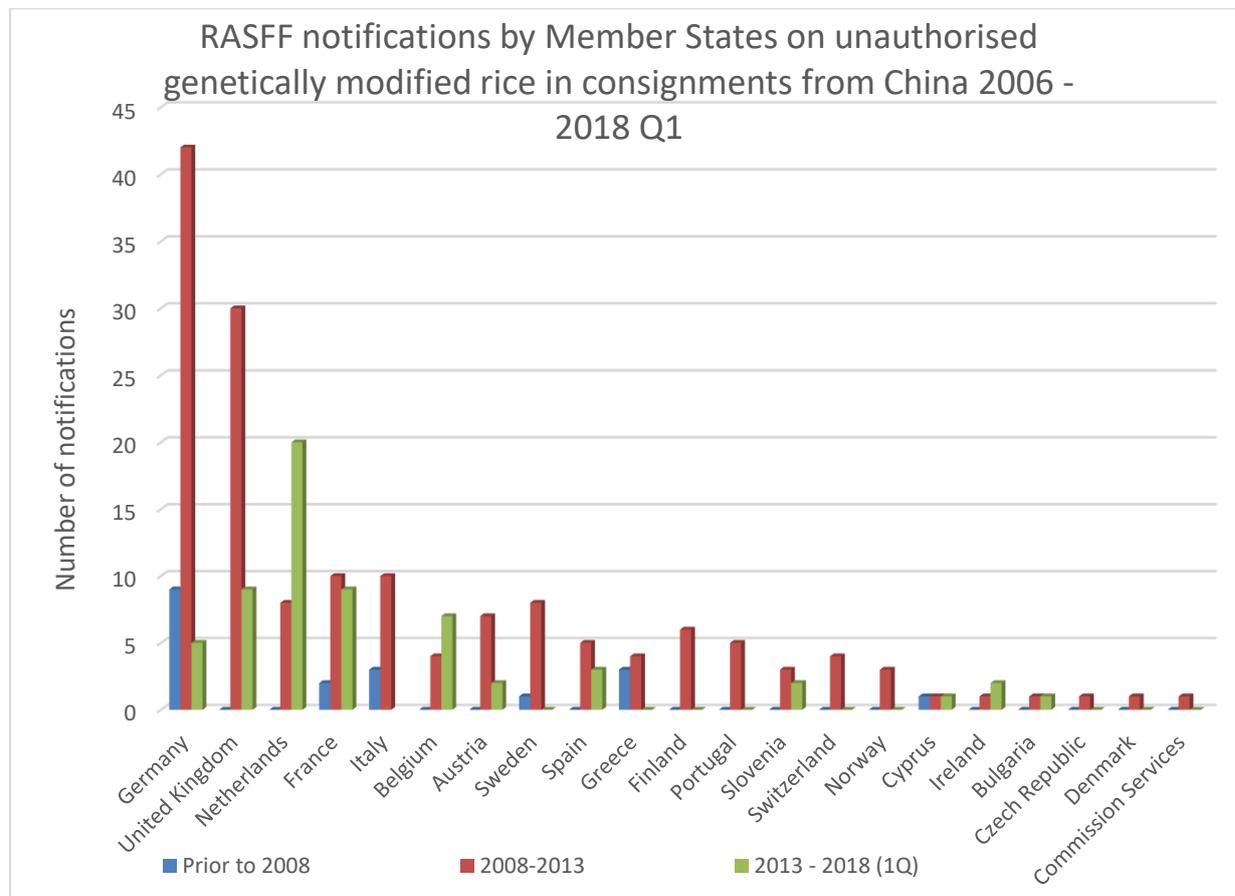


Figure 1: RASFF notifications by Member States concerning unauthorised genetically modified rice in consignments of rice and rice products from China

- 7.3 The graph at **Figure 1** shows that the overall number of relevant RASFF notifications raised across the EU/EFTA in respect of unauthorised GM in consignments of rice and rice products from China has decreased since the measures were first introduced in 2008.
- 7.4 A comparison of the RASFF notifications before and after the introduction of the measures show that there was a rise in the number of notifications from 2008 to 2013 by Germany, the UK and Netherlands in particular, predominantly concerned with the unauthorised genetically modified rice 'Bt63'. Commission Decision 2013/287/EU extended the list of products and genetically modified rice varieties that fall under the scope of the measures and data relating to the period following this extension (i.e. from 2013 to the first quarter of 2018) shows a decrease in RASFF notifications. This suggests that the measures have been effective in preventing non-compliant rice and rice products containing unauthorised GM from being placed on the EU market, particularly as more products and genetically modified rice varieties fall within the scope of the measure than was the case under earlier measures.

Incidences of unauthorised GM rice in consignments of rice and rice products from China reported by the UK

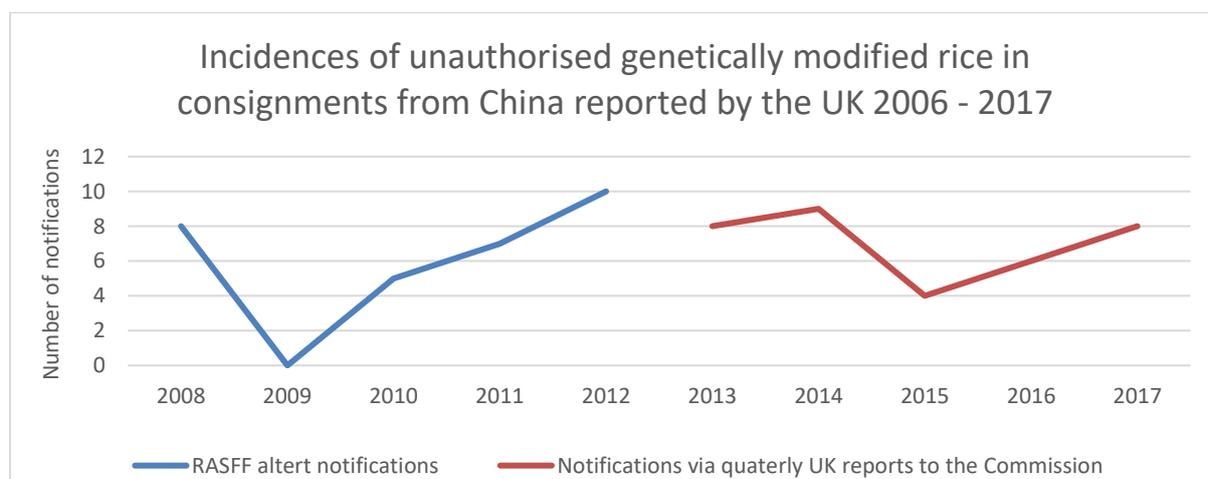


Figure 2: Incidences of unauthorised genetically modified rice in consignments from China reported by the UK 2008- 2017

7.5 The graph at **Figure 2** has two distinct sections. The first, covering 2008 to 2012, is based on the RASFF dataset and the second, covering 2013 to 2017, is based on UK quarterly returns to the Commission. This is because Commission Implementing Decision 2008/289/EC required Member States to notify incidences of non-compliance under the RASFF whereas Commission Implementing Decision 2011/884/EU which replaced it requires incidence of non-compliance to be reported via quarterly returns to the Commission. Data for 2008 to 2012 is therefore based on RASFF notifications and data for 2013 to 2017 is based on data from quarterly returns sent to the Commission by the UK and whilst indicative of trends cannot be compared on a like for like basis.

7.6 The RASFF data reflects a rise in notifications by the UK from 2008 to 2013 indicating that the measures were effective in helping identify non-compliant consignments. Data from the quarterly returns from 2013 show an initial decrease in notifications from 2013 to 2015, followed by an increase of notifications from 2016, indicating the continued efficacy of the measures.

Non-compliance identified by documentary and analytical checks on consignments of rice and rice products from China by all Member States

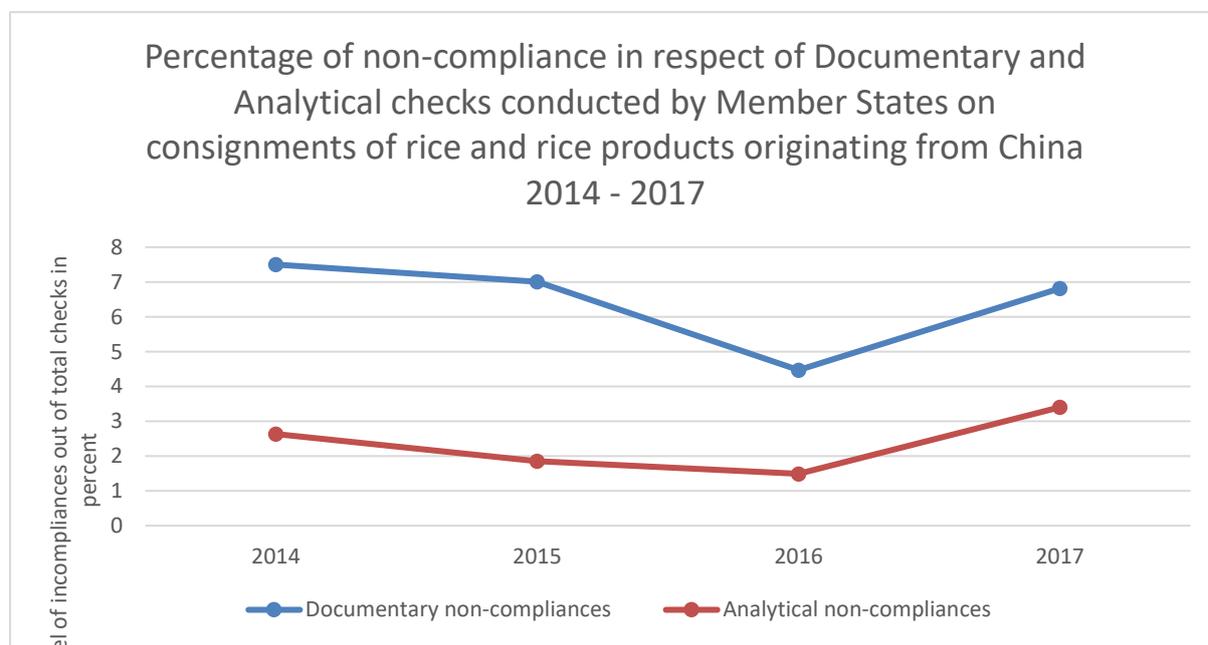


Figure 3: Non-compliance identified by documentary and analytical checks conducted by Member States on consignments of rice and rice products from China 2014-2017

7.7 The graph at **Figure 3** shows an overall rise in reported analytical non-compliance across the EU regarding unauthorised GM rice in consignments of rice and rice products originating from China from 2014 to 2017 and an overall decrease in documentary non-compliance over the same period. Whilst there was a decrease in reported documentary and analytical non-compliance from 2014 to 2016, there is an increase in both in 2017.

Non-compliance identified by documentary and analytical checks on consignments of rice and rice products from China by the UK

	Total number of consignments	Number of unsatisfactory document checks	Number of unsatisfactory analytical checks	Percentage of unsatisfactory document checks	Percentage of unsatisfactory analytical checks
2013	52	8	6	15.3	11.53
2014	75	9	4	12	5.3
2015	100	1	4	1	4
2016	102	1	1	0.98	0.98
2017	103	8	6	7.7	5.8

Table 4: Non-compliant consignments of rice and rice products from China identified by documentary and analytical checks carried out by the UK by number and percentage 2013-2017

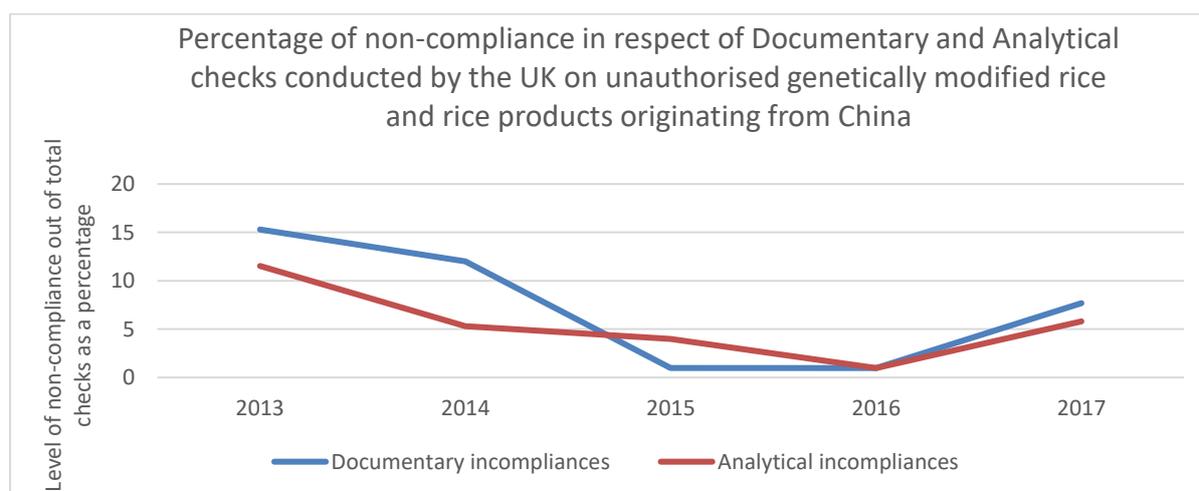


Figure 4: Percentage of non-compliant consignments of rice and rice products from China identified by documentary and analytical checks carried out by the UK 2013-2017

7.8 Analogous to the graph at Figure 3 summarising data from across the EU, **Table 1** and the graph at **Figure 4** show a similar decrease in documentary and analytical non-compliance reported by the UK from 2013-2017 and an increase in non-compliance from 2016 onwards demonstrating that unauthorised GM rice in consignments of rice and rice products from China continues to reach the UK and is being identified and rejected or destroyed at the border.

Consignments of rice and rice products from China imported into the UK

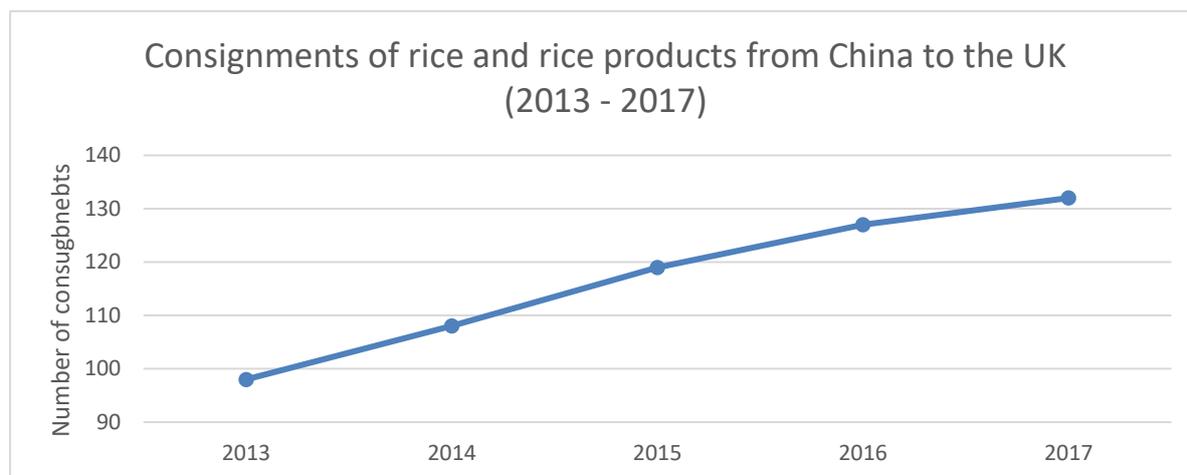


Figure 5: Consignments of rice and rice products from China to the UK 2013-2017

7.9 The graph at **Figure 5** shows an overall increase in consignments of rice and rice products from China to the UK from 2013 to 2017. The increased level of consignments to the UK and the increase in incidences of non-compliance as shown in Table 1 and Figure 4 suggest that the measures remain relevant and necessary.

8 Consumers' Perspective

8.1 Whilst the FSA did not receive specific comments or views from consumers in response to our consultation, the FSA routinely engages with consumers to gauge their preferences and perception of risks. Since 2001, the FSA has placed questions biannually on the regular TNS (now part of Kantar Public) face-to-face Omnibus survey to monitor key Agency issues. The most recent survey published in November 2018 interviewed a representative sample of 2,007 adults in England, Wales and Northern Ireland; relevant findings are outlined below:

8.2 In relation to trust in food labelling, 27% of respondents reported always feeling confident that food is what it says it is on the label or menu, whilst 73% reported not always feeling confident (**Figure 6**). This highlights the importance of effective risk communication and giving consumers confidence that the food supply chain is effectively regulated.

Confident that food is what it says it is on the label or menu (November 2017 – November 2018)

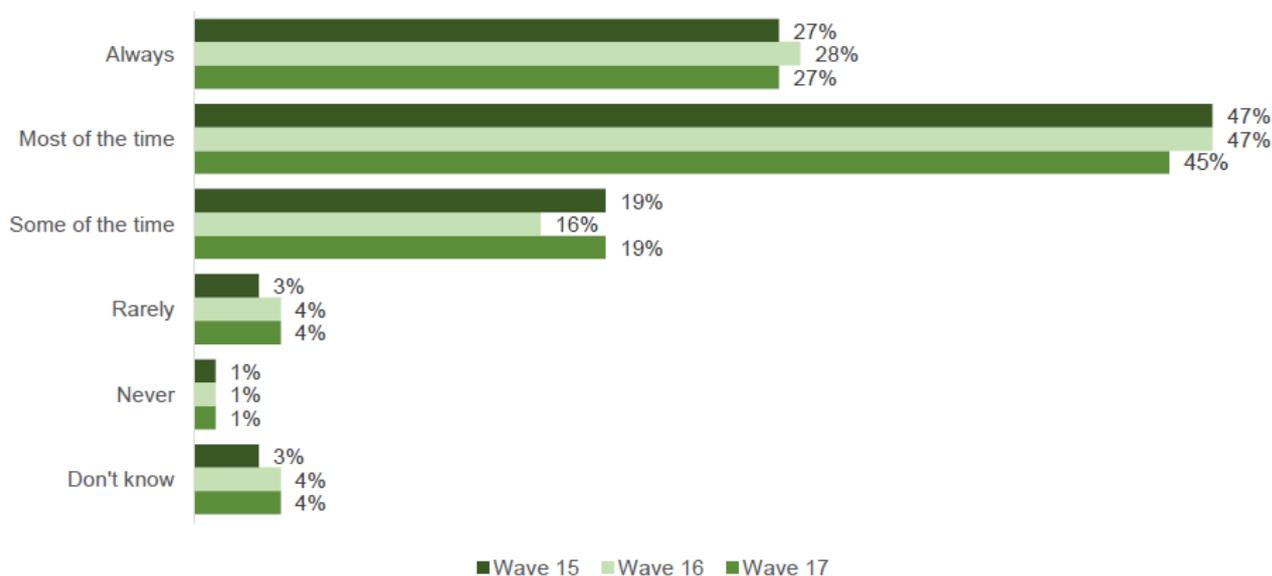


Figure 6: Consumer confidence in food labelling

- 8.3 Of the adults who reported not always feeling confident when buying or eating food, the most commonly reported issues were not believing the ingredient information on labels/menus as correct (7%), the horse meat scandal (6%), and being deliberately misled (6%). The above data highlights that consumer trust is fragile and can be detrimentally affected by food safety/standards incidents and personal experiences of being misled in relation to the authenticity of food. Effective, proportionate, risk-based regulation of food safety/standards would be expected to increase consumer confidence.
- 8.4 23% of respondents reported concern about GM food. Concern varied between groups of people, particularly between those in managerial, administrative and professional occupations (29%) compared to those in skilled-manual occupations (19%) and the unemployed and unskilled occupations (16%).
- 8.5 43% of respondents agreed that people who produce and sell food in the food industry have their best interests at heart (**Figure 7**). This figure varied between groups of people, particularly between those in Northern Ireland (76%) compared to those in Wales (38%) and England (41%).

Trust that the people who produce and sell food in the food industry have my best interests at heart (May 2018 – November 2018).

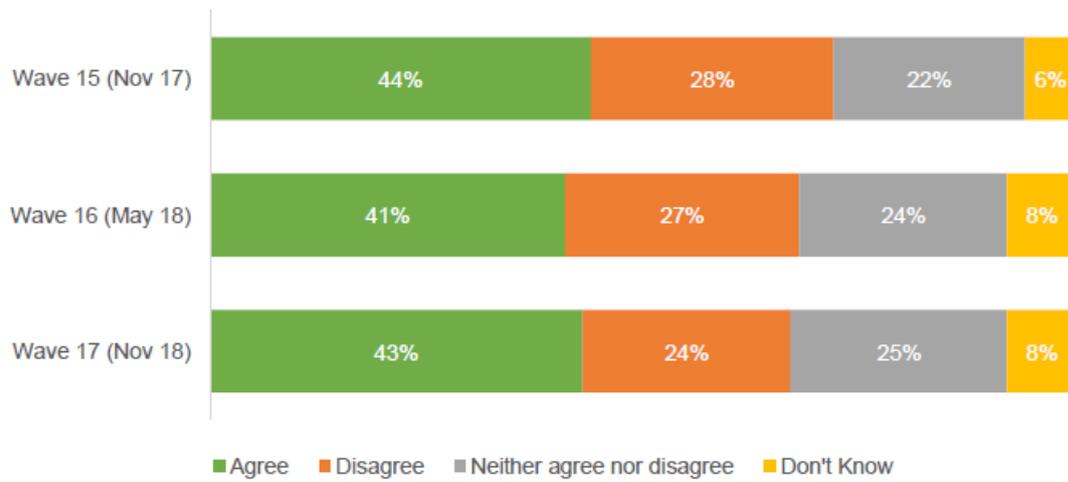


Figure 7: Consumer trust in the food industry to protect their interests

9 How does the UK's implementation compare with that in other EU Member States in terms of costs to business?

- 9.1 The Statutory Instruments do not impose national rules over and above those of the EU harmonised legislation which they implement (i.e. there is no 'gold-plating'); they simply provide for the execution and enforcement of the EU measures in England.
- 9.2 The relevant EU law comprises two directly applicable European Commission Decisions which must be implemented by Member States; they are clear, prescriptive and provide no scope for flexibility or discretion. The EU law prescribes the documentary and analytical checks which must be made by all Member States, before specified rice and rice products from China can be placed on the market. All Member States are required to undertake sampling and analysis on 100% of relevant consignments at the border. Analytical techniques to detect unauthorised varieties of GM rice are also prescribed in the EU legislation.
- 9.3 Where a consignment fails documentary or analytical checks at the border, the EU legislation requires that the consignment is either re-dispatched to the country of origin or destroyed; this applies to all EU Member States.
- 9.4 The EU legislation also specifies that all costs resulting from the Official Controls including sampling, analysis, storage and any measures taken following non-compliance, shall be borne by food and feed business operators. The EU measures implemented by these SIs are binding upon all Member States and so the costs borne by importers to cover Official Controls will be consistent throughout the EU.
- 9.5 In 2018, 430 consignments of rice and rice products subject to these EU measures were imported into the EU and were subject to documentary checks which identified 12 incidences of non-compliance and 381 analytical checks which identified 9 incidences of non-compliance, demonstrating that EU Member States have been carrying out their official controls obligations, thereby preventing unauthorised GM rice and rice products from entering the EU market.

10 Conclusions

- 10.1 The Specified Products from China (Restriction on First Placing on the Market) (England) (Amendment) Regulations 2012 and 2013 meet their objective of implementing emergency EU measures in England; the evidence suggests they have been effective in preventing food and feed products containing unauthorised genetically modified rice varieties from being placed on the UK/EU market.
- 10.2 Whilst unauthorised GM rice continues to reach the UK border, 100% documentary and analytical checks of rice and rice products from China have ensured that unauthorised GM varieties are being identified and rejected/destroyed at the border. In 2017, 103 consignments arrived at UK ports; 8 consignments failed documentary checks, whilst 6 consignments failed analytical tests, resulting in the products being destroyed or re-dispatched outside the EU.
- 10.3 Since 2008, the EU measures have required that costs incurred by Port Health Authorities in undertaking official controls are passed on to food and feed business operators. As such, there are no ongoing cost for the public sector as a consequence of the 2011 and 2013 EU measures or the Regulations relating to England that implement them.
- 10.4 The EU measures and England SIs impose a low financial impact on UK food and feed business operators. We estimate that a maximum of 86 UK importers are affected by these Regulations, based on import data between 2013-2017. The total annual cost to UK importers for covering the costs of Official Controls is estimated to be between £61,576 at the lower end and £164,000 at the higher end.
- 10.5 There is no evidence to suggest that the burdens on UK businesses to comply with the 2012 and 2013 Regulations exceed those on businesses complying with equivalent implementing Regulations in other Member States. The England SIs do not impose any national rules over and above the harmonised EU legislation they implement (i.e. there is no 'gold-plating'); they simply provide for the execution and enforcement of the directly applicable emergency EU measures in England. As a consequence, costs to importers are proportionate and not over and above what is required to comply with the EU measures.
- 10.6 The FSA is currently considering how to reduce reliance on criminal sanctions in food legislation in England. We included a number of questions in our consultation on the use and effectiveness of sanctions for this PIR. However, we did not receive any response to the consultation to enable us to draw any evidence on stakeholders' views on this matter. The FSA will be consulting more broadly on moving towards civil sanctions in existing Regulations in due course, but for the purposes of this review of this emergency and temporary legislation we do not propose any amendments to the legislation at this time.

11 Recommendations

- 11.1 The Specified Products from China (Restriction on First Placing on the Market) (England) (Amendment) Regulations 2012 and 2013 continue to play a critical role in protecting consumer health and other interests in relation to evidenced risks from imported rice and rice products from China. The evidence demonstrates that the Regulations continue to meet the intended objectives of the EU legislation to prevent food and feed products containing unauthorised genetically modified rice varieties from being placed on the UK/EU market. Under the current regulatory framework, the UK is still required to implement these legally binding EU Decisions.
- 11.2 It is recommended that the Specified Products from China (Restriction on First Placing on the Market) (England) (Amendment) Regulations 2012 and 2013 are retained.

Appendix I

Products Subject to the Controls

Product	CN Code
Rice in the husk ('paddy' or rough)	1006 10
Husked (brown) rice	1006 20
Semi-milled or wholly milled rice, whether or not polished or glazed	1006 30
Broken rice	1006 40 00
Rice flour	1102 90 50
Rice groats and meal	1103 19 50
Rice pellets	1103 20 50
Flaked rice grains	1104 19 91
Rolled or flaked cereal grains (excluding grains of oats, wheat, rye, maize and barley, and flaked rice)	1104 19 99
Rice starch	1108 19 10
Preparations for infant use, put up for retail sale	1901 10 00
Uncooked pasta, not stuffed or otherwise prepared, containing eggs	1902 11 00
Uncooked pasta, not stuffed or otherwise prepared, not containing eggs	1902 19
Stuffed pasta, whether or not cooked or otherwise prepared	1902 20
Other pasta (other than uncooked pasta, not stuffed or otherwise prepared, and other than stuffed pasta, whether or not cooked or otherwise prepared)	1902 30
Prepared foods obtained by swelling or roasting cereals or cereal products, obtained from rice	1904 10 30
Preparations of the muesli-type based on unroasted cereal flakes	1904 20 10
Prepared foods obtained from unroasted cereal flakes or from mixtures of unroasted cereal flakes and roasted cereal flakes or swelled cereals, obtained from rice excluding preparations of the muesli-type on the basis of unroasted cereal flakes)	1904 20 95
Rice, pre-cooked or otherwise prepared, not elsewhere specified or included (excluding flour, groats and meal, food preparations obtained by swelling or roasting or from unroasted cereal flakes or from mixtures of unroasted cereal flakes and roasted cereal flakes or swelled cereals)	1904 90 10
Ricepaper	ex 1905 90 20

Biscuits	1905 90 45
Extruded or expanded products, savoury or salted	1905 90 55
Bran, sharps and other residues, whether or not in the form of pellets, derived from the sifting, milling or other working of rice with a starch content not exceeding 35 % by weight	2302 40 02
Bran, sharps and other residues, whether or not in the form of pellets, derived from the sifting, milling or other working of rice other than with a starch content not exceeding 35 % by weight	2302 40 08
New Products Added by Commission Implementing Decision 2011/884/EU:	
Extruded or expanded products, sweetened	1905 90 60
Extruded or expanded products neither sweetened or savoured nor salted (e.g. Pizzas, quiches, and other unsweetened baker's wares)	1905 90 90
Sauces and preparations, mixed condiments and mixed seasonings [rice vinegar is covered but in practice analysis for GM content is not possible, consequently it is excluded from controls]	2103 90 90

Appendix II

ANNEX IV

MODEL OF ANALYTICAL REPORT

Note: please compile an annex form for each sample tested

Parameter to be reported	Information provided
Name and address of the test laboratory (*)	
Test report identification code (*)	<<000>>
Laboratory sample identification code (*)	<<000>>
Size of laboratory sample (*)	X kg
In case of sample division: Number and size of analytical samples	X analytical samples of Y g
Number and size of test portions analysed (*)	X test portions of Y mg
Total DNA amount analysed (*)	X ng/PCR
DNA sequence(s) tested for (*):	For each of the following provide reference to the method used and the average Ct number obtained Rice marker: 35S promoter: NOS terminator: CryLab/CryIAC:
Other sequence(s) tested for:	Validation status: (e.g. inter-laboratory validated, in-house validated [please indicate according to which standard, guideline]) Description of DNA sequences detected (reference + target genes): Specificity of the method (screening, construct-specific or event-specific): Absolute Limit of Detection (copy number): Practical Limit of Detection (LOD related to the sample analysed), if determined:
Description of positive controls for target DNA, and reference materials (*)	Source and nature of the positive control and reference materials (e.g. plasmid, genomic DNA, CRM ...)
Information on the positive control (*)	Please indicate the amount (in ng DNA) of positive control analysed and the average Ct number obtained
Comments	
(*) Obligatory fields	

Appendix III

23.12.2011

EN

Official Journal of the European Union

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ANNEX III

MODEL OF HEALTH CERTIFICATE

Header of the authority

Health Certificate for the importation into the European Union of

.....

Consignment Code: **Certificate Number:**

According to the provisions of Commission Implementing Decision 2011/884/EU on emergency measures regarding unauthorised genetically modified rice in rice products originating from China and repealing Decision 2008/289/EC

.....
(competent authority referred to in Article 4(1) of Implementing Decision 2011/884/EU)

CERTIFIES that the
(insert foodstuffs/feed referred to in Article 1 of Implementing Decision 2011/884/EU)

of this consignment composed of:
(description of consignment, product, number and type of packages, gross or net weight)

embarked at
(embarkation place)

by
(identification of transporter)

going to
(place and country of destination)

which comes from the establishment
(name and address of establishment)

have been produced, sorted, handled, processed, packaged and transported in line with good hygiene practices.

From this consignment, samples were taken in accordance with Annex II of Implementing Decision 2011/884/EU on (date), subjected to laboratory analysis on (date) in the (name of laboratory), to determine the absence of any unauthorised GM Rice.

The details of sampling, methods of analysis used and all results are attached.

This certificate is valid until

Done at: on

Stamp and signature of authorised representative of competent authority referred to in Article 4(1) of Implementing Decision 2011/884/EU