

Post Implementation Review of The Specified
Products from China (Restriction on First
Placing on the Market) (England) Regulations
2012 and The Specified Products from China
(Restriction on First Placing on the Market)
(England) (Amendment) Regulations 2013

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1 Introduction

On 23 June 2016, the EU referendum took place and the people of the United Kingdom voted to leave the European Union (EU). Until exit negotiations are concluded, the UK remains a full member of the European Union and all the rights and obligations of EU membership remain in force. During this period, the Government will continue to negotiate, implement and apply EU legislation. The outcome of these negotiations will determine what arrangements apply in relation to EU legislation in future once the UK has left the EU.

This report addresses the joint Post Implementation Review (PIR) on both **The Specified Products from China (Restriction on First Placing on the Market) (England) 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 EU legislation¹ introduced by the European 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 SIs.

The EU legislation is temporary and has also 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 19 March 2018, 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.

This 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. The findings of this PIR will help inform, guide and shape the position in England. The FSA is seeking comments from relevant stakeholders, including Importers and Port Health Authorities in England, to capture stakeholder views on the effectiveness and effects of the legislation.

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

The aim of the public consultation is to determine the real-world impact of the legislation. Stakeholders are invited to participate by providing relevant insights that might help to determine the effectiveness of the legislation which will be considered as part of the review.

The key objective of the two SIs being reviewed (along with similar, equivalent legislation in place in the other countries of the UK) is to prevent unauthorised genetically modified rice and rice products consigned from China from being placed on the UK/EU market.

2 Background

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

At the meeting of the GMFF SCOPAFF in Brussels on 19 March 2018, 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 has decreased since the controls were first introduced in 2008 and attempts have 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.

3 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 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) 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.
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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.

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.

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 allowing rapid and 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.

The Specified Products from China (Restriction on First Placing on the Market) (England) Regulations 2012, which are being reviewed in this PIR, amended the 2008 Regulations to implement the 2011 EU measure in England.

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.

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.

Consultation Question:

Do you think that that criminal sanctions are proportionate for enforcing breaches of the regulations? If not, what approach might be more proportionate?

4 Costs and benefits

Consultation Question:

Do you think that the regulations create any additional burdens compared to the way the EU measures have been implemented in other EU Member States? If so, how could the regulations be enhanced to minimise the burdens in England?

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, authorities and consumers. The key assumptions are as follows:

Consumers

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

Since 2008 the measures have required the actual costs incurred by Enforcement 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 2012 and 2013 measures or the regulations relating to England that implement them.

One-off costs to food and feed business operators associated with reading and familiarising themselves with the 2012 and 2013 EU measures and the 2012 and 2013 regulations relating to England that implement them.

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.

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

One-off costs to food and feed business operators associated with reading and familiarising themselves with the 2012 and 2013 EU measures and the 2012 and 2013 regulations relating to England that implement them.

Since 2008 the measures have required the actual costs incurred by Enforcement Authorities in undertaking the associated official controls to be borne by food and feed business operators. However, costs could potentially arise for any sampling and analysis that cannot be recovered from food and feed business operators.

The provision and utilisation of analytical reports can act as an enforcement tool to help decrease the likelihood of unauthorised genetically modified rice and rice products being placed on the UK market. This additional level of enforcement can lower committed offences under food and feed law and save time and costs in prosecuting these offences.

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

Consultation Questions:

To what extent do you think that the regulations have achieved their objective of preventing unauthorised genetically modified rice and rice products from China from being placed on the market in England?

Do you think that the regulations are sufficiently effective in achieving their objective of preventing unauthorised genetically modified rice and rice products from China from being placed on the market in England? If not, how could the regulations could be enhanced to better meet this objective?

This PIR uses data from the 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 under pursuant to that measure.

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 has been achieved. Until now the emergency measures and their objectives remain appropriate and proportionate.

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

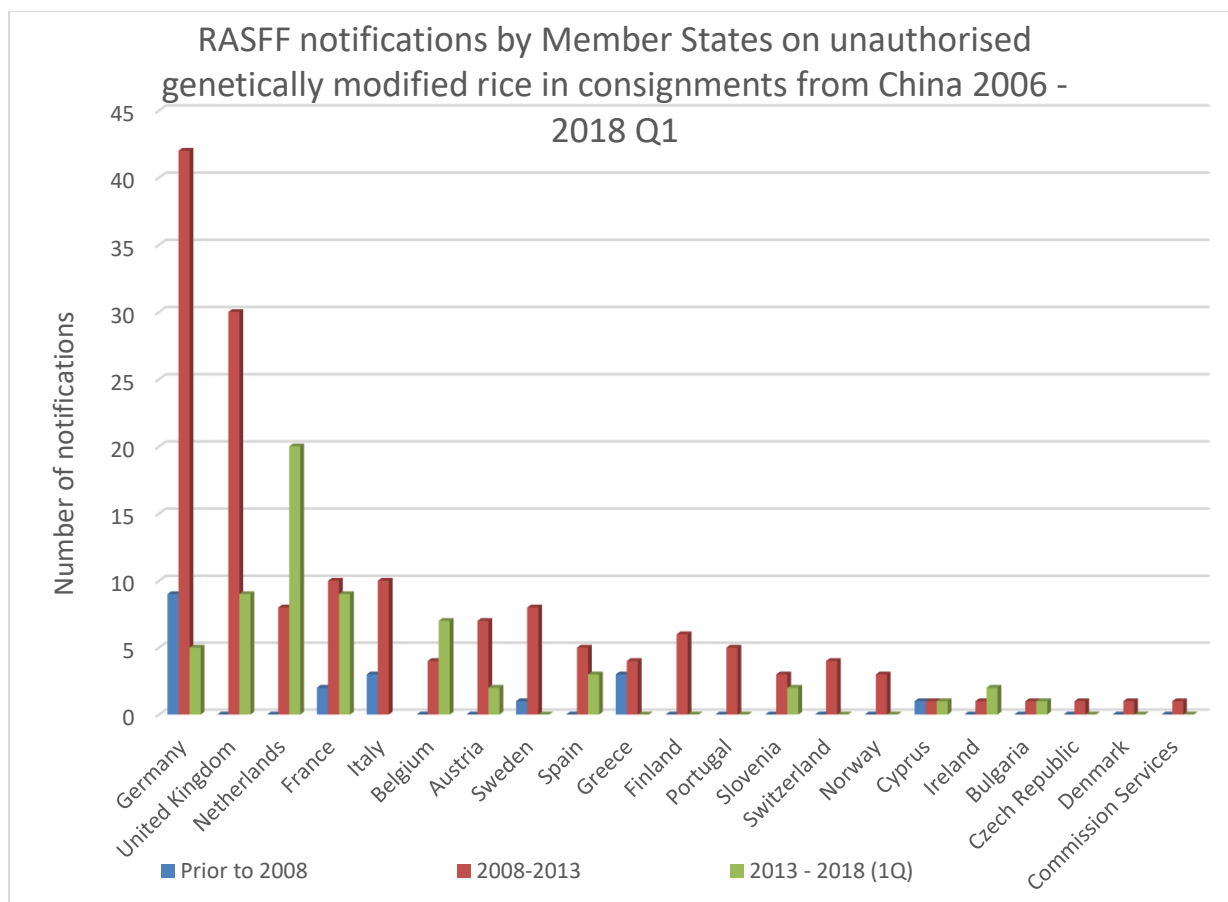


Figure 1: RASFF notifications by Member States concerning unauthorised genetically modified rice in consignments of rice and rice products from China

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. A comparison of the RASFF notifications before and after the introduction of the measures show that there was 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 an increase in RASFF notifications. This suggests that the measures from have been effective in identifying consignments of rice and rice products from China that contain unauthorised GM and in achieving the objective of preventing such non-compliant products from being placed on the EU market.

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

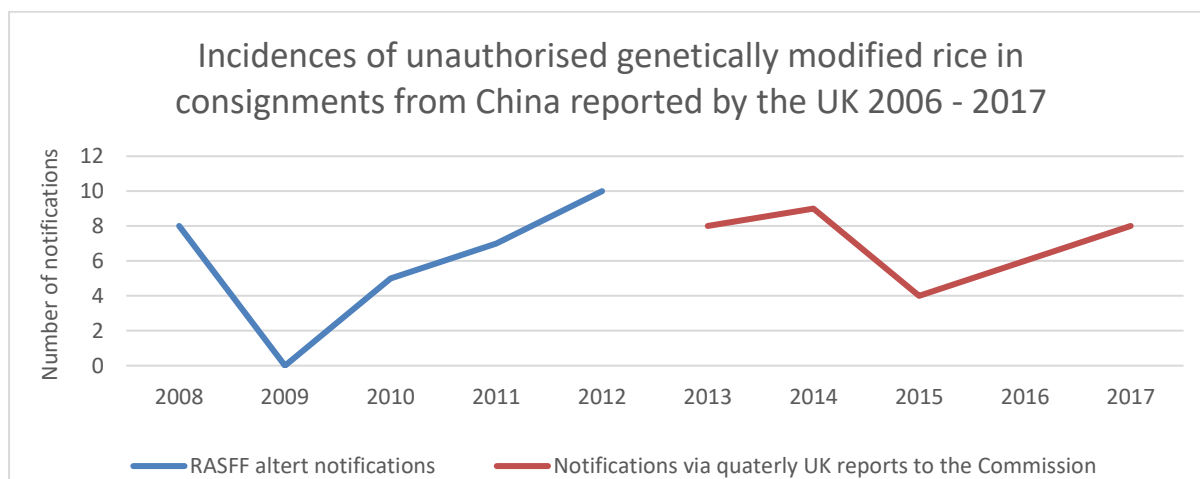


Figure 2: Incidences of unauthorised genetically modified rice in consignments from China reported by the UK 2006 - 2017

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. 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.

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.

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

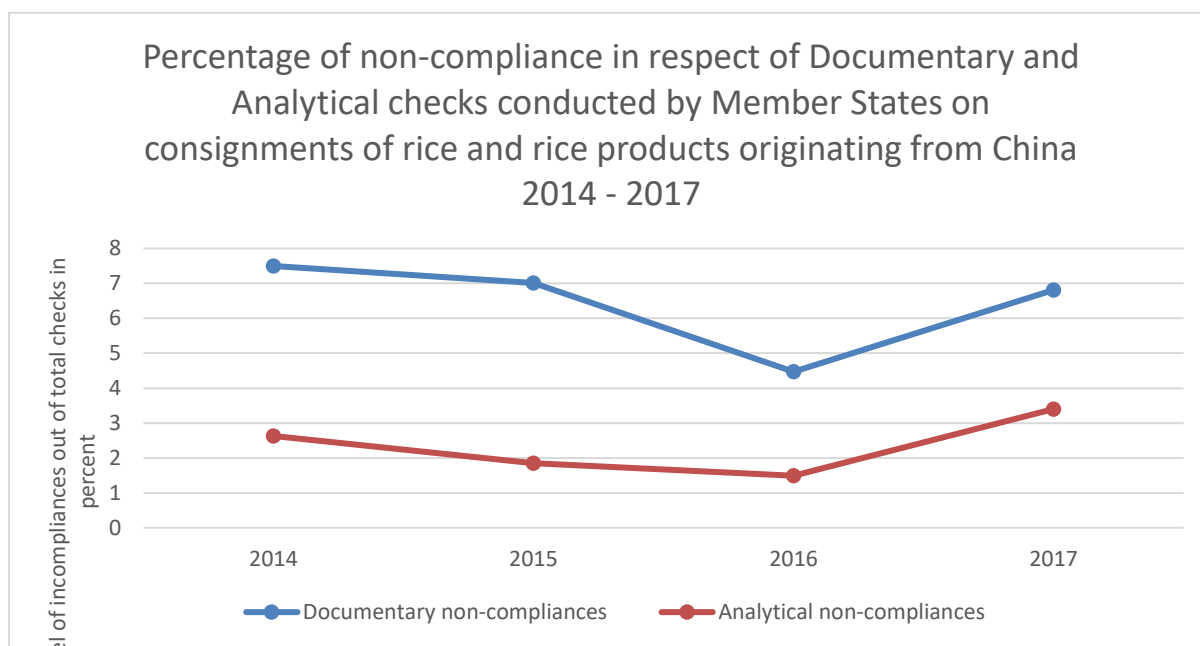


Figure 3: Non-compliance identified by documentary and analytical checks conducted by Member States on consignments of rice and rice products from China 2014-2017

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.

5.4 Non-compliance identified by documentary and analytical checks on consignments of rice in 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 1: 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

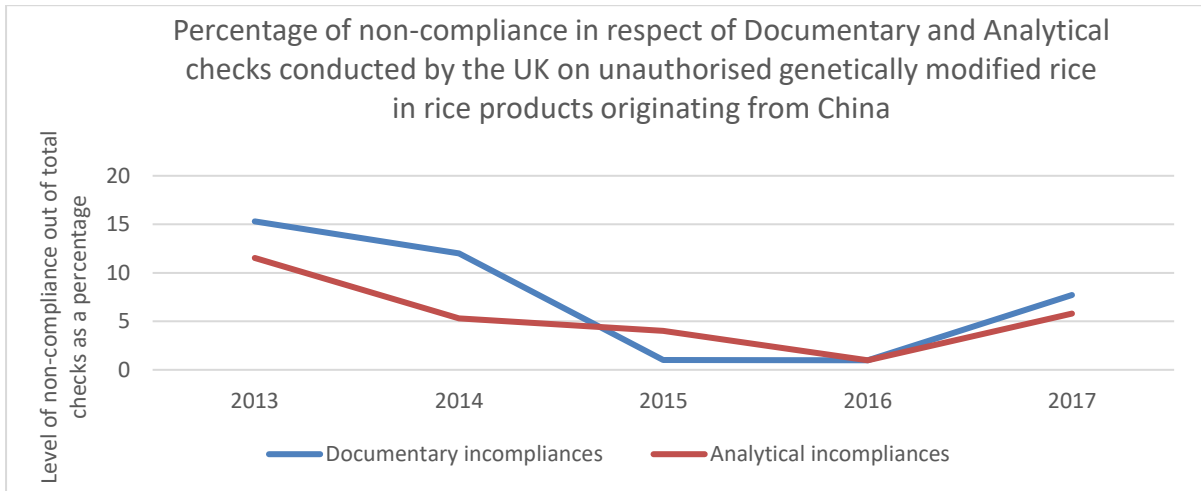


Figure 4: Percentage of non-compliant consignments of rice and rice products from China identified by documentary and analytical checks carried out by the UK 2013-2017

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.

5.5 Consignments of rice in rice products from China imported into the UK

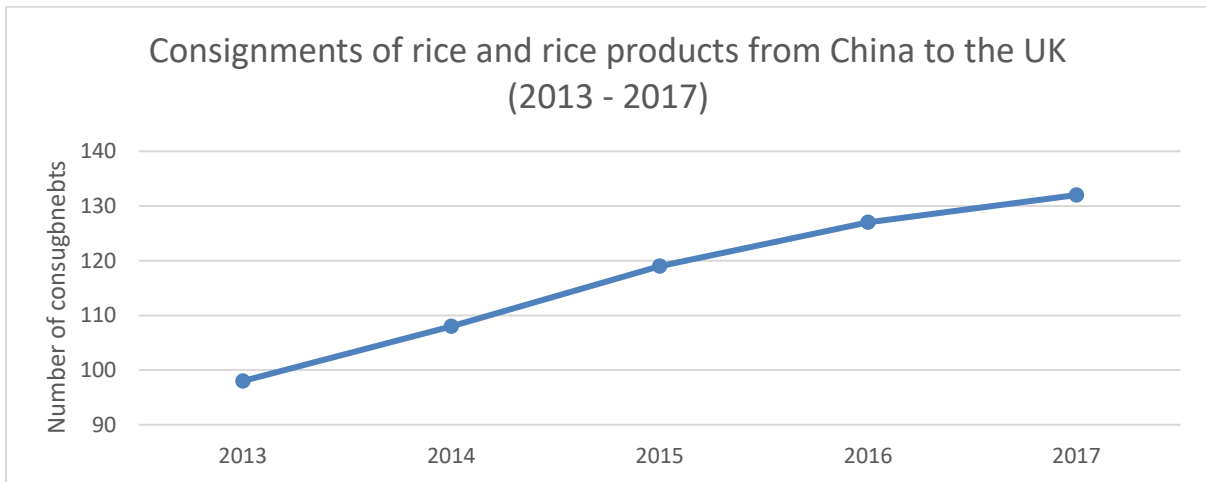


Figure 5: Consignments of rice and rice products from China to the UK 2013-2017

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.

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

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: CryIAb/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	

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
