

# **Food Safety of Foods of Non-Animal Origin Imported to Portugal Analysis of the Data Resulting from Official Controls on Imports between 2014 and 2017**

**Carolina de Arouca Golding**

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Orientador(es): Doutora Margarida Moldão  
Mestre Alexandra Isabel Lopes de Campos

**Júri:**

Presidente: Doutora Maria Luísa Lopes de Castro e Brito, Professora Auxiliar com Agregação do Instituto Superior de Agronomia.

Vogais:

Mestre Ana Paula Bico Rodrigues de Matos, Diretora de Serviço de Nutrição e Alimentação, Direção-Geral de Alimentação e Veterinária, na qualidade de especialista;  
Mestre Alexandra Isabel Lopes de Campos, Técnica Superior da Direção-Geral de Alimentação e Veterinária, orientadora.

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## Abstract

The Community sets specific standards regarding safety and hygiene of foodstuffs and feed to be met by food businesses. So as to check conformity with these standards of foodstuffs imported from 3<sup>rd</sup> countries, when these have been identified to pose a risk to consumers, there are several Community measures and national control plans aimed at laying down procedures for the official controls on these consignments. The aim of this study is to provide a description of the evolution of FNAO imports into Portugal between 2014 and 2017, including the number and type of rejections and resulting RASFF notifications. In order to do so, data was extracted from online platform TRACES and analysed on Excel and all relevant legal measures, communications and plans consulted. Results show that there was an increase in imports, specifically in the category of ‘Edible Fruits and Nuts’, most of which originating in Brazil. The number of rejections was similar throughout the four years, but those pertaining to groundnuts from China and food supplements from the USA revealed to be re-occurring and problematic. Overall, only 0.2% of imports over the four years were non-compliant, showing that the great majority of foodstuffs imported are safe for human consumption.

**Key Words:** Official Controls, FNAO, Rejection, Non-compliance, Food Law

## Resumo

A Comunidade estabelece normas específicas de higiene e segurança alimentar de géneros alimentícios e ração animal, a serem cumpridas pelas empresas alimentares. A verificação de conformidade com as normas relativas a géneros alimentícios importados de países fora da UE, quando estes constituem um risco à saúde pública, é feita através da implementação de vários diplomas legais Comunitários, e planos de controlo Nacionais, destinados a estabelecer procedimentos operativos ao controlo oficial destas remessas. O objectivo deste trabalho é fornecer uma descrição da evolução das importações de GAONA entre 2014 e 2017, incluindo o número e tipo de rejeições e as resultantes notificações RASFF. Para tal, extraíram-se dados da plataforma online TRACES, recorreu-se ao Excel para o tratamento de dados e aos vários diplomas legais, comunicações e planos para a discussão. Os resultados mostraram que houve um aumento de importações a Portugal durante os quatro anos, especialmente da categoria de ‘Fruta e frutos de casca rija’, dos quais a maioria provenientes do Brasil. O número de rejeições manteve-se relativamente constante, no entanto, aquelas referentes aos amendoins provenientes da China e aos suplementos alimentares dos Estados Unidos, foram recorrentes e em grande número, tendo-se relevado problemático. No global, apenas 0.2% das remessas importadas ao longo dos quatro anos, foram rejeitadas o que indica que a grande maioria dos GAONA provenientes de países terceiros, são seguros para a alimentação humana.

**Palavras Chave:** Controlos Oficiais, GAONA, Rejeição, Não conformidade, Lei Alimentar

## Resumo Prolongado

Com o Tratado de Roma, um dos objectivos principais da Comunidade, foi a criação de um mercado de livre, onde não deveria de haver barreiras ao comércio intra-Europeu. Para tal, a Comunidade procurou, através da harmonização da legislação dos Estados Membros e criação de Directivas verticais para a composição estandardizada de géneros alimentícios, a remoção de barreiras ao comércio interno. No entanto, disputas levadas a Tribunal Europeu relacionadas com barreiras ao comércio e a crise de BSE, levaram a várias reformas nos anos que se seguiram, nomeadamente, o Livro Verde sobre a Lei Alimentar e a Comunicação sobre a Saúde e Segurança do Consumidor em 1997 e o Livro Branco em 2002 sobre a segurança alimentar, que culminou com a criação e implementação do Regulamento (CE) No 178/2002. O Regulamento estabelece o princípio da precaução e a EFSA, e onde, ao contrário de diplomas legais anteriores relacionados com o comércio de géneros alimentícios, o objectivo principal é a segurança do consumidor. A partir do Regulamento (CE) No 178/2002, criaram-se vários outros Regulamentos e Decisões, relacionados com o comércio de géneros alimentícios, onde estão estabelecidos requisitos obrigatórios para empresas alimentares cumprirem de forma a proteger o consumidor, os animais e o ambiente. Outros diplomas que caem no âmbito deste trabalho estabelecem os procedimentos para o controlo oficial à importação, a certos géneros alimentícios provenientes de certos países fora da União Europeia que constituem um risco à saúde pública. Estes controlos oficiais podem ser do tipo ‘reforçados’ ou de ‘emergência’. Em adição aos diplomas Comunitários, no âmbito do Regulamento (CE) No 884/2002, cada Estado Membro necessita de criar um plano multianual de controlo à importação com base numa análise de risco, para a realização de controlos oficiais a géneros alimentícios e riscos que não estão incluídos na legislação Europeia. Este plano de controlo nacional permite identificar novos riscos quando estes surgem, e de informar a Comissão que certos géneros alimentícios provenientes de certos países, que já não apresentam risco para a saúde pública, levando assim à revisão das medidas Comunitárias para a inclusão de novos riscos, reajuste da frequência de controlo a certos riscos ou mesmo à remoção destes dos diplomas legais.

O objectivo deste trabalho é fornecer uma descrição das importações de géneros alimentícios de origem não animal para Portugal entre 2014 e 2017, especificamente, em termos do tipo de mercadoria importada, os países de origem, o número e tipo de rejeições e sob qual diploma legal caem essas rejeições (controlos oficiais reforçados, medidas de emergência, ou o plano de controlo nacional) e por fim, tentar elencar essas rejeições com as notificações RASFF a nível Europeu.

Para a realização do trabalho foi necessária a utilização da plataforma online europeia à importação, o TRACES, para a extracção de dados relativos à importação de remessas de géneros alimentícios de origem não animal para consumo humano, entre 2014 e 2017, inclusive. O tratamento de dados foi feito no Microsoft Office Excel, assim como a elaboração de quaisquer gráficos apresentados no trabalho. Por fim, a fim de apresentar os resultados e fornecer uma discussão, foram consultados todos os Regulamentos, Decisões, planos e comunicações pertinentes a este tema.

Durante os quatro anos analisados, registou-se um aumento de importações de remessas a Portugal, nomeadamente de géneros alimentícios da categoria de “Frutos comestíveis e frutos de casca rija”. O país que mais contribuiu para as importações, nos quatro anos, foi o Brasil com mangas e papaias. Outros países com grande contributo para importações foram a África do Sul, Chile e Costa Rica com géneros alimentícios da categoria de ‘Frutos Comestíveis e frutos de casca rija’, assim como a China e os Estados Unidos, com amendoins e suplementos alimentares.

No que diz respeito às importações que se inserem nos diplomas Europeus para controlos oficiais reforçados e medidas de emergência, assim como a Matriz de controlo, durante os quatro anos analisados houve um maior número de importações sujeitos a medidas de controlo oficial da Matriz (mais de 50%), seguido das medidas de emergência por risco de contaminação de aflatoxinas, a grande maioria amendoins provenientes da China, géneros alimentícios sujeitos a controlos oficiais reforçados, por vários riscos, nomeadamente resíduos de pesticidas e, por fim, por fim dentro das medidas de emergência: 1) importações de géneros alimentícios provenientes do Japão, após o acidente de Fukushima, por risco de contaminação com rádio nucleótidos, e; 2) importações de géneros alimentício de arroz, ou à base de arroz, provenientes da China, devido ao risco de conter OGMs.

Em relação a rejeições, houve um total de 89 nos quatro anos analisados, das quais, apenas 21 caem sob medidas de controlos oficiais nacionais e Comunitários. A grande maioria das rejeições não sujeitas a controlos oficiais reforçados, medidas de emergência ou à Matriz de controlo analítico foram suplementos alimentares, em grande parte provenientes dos Estados Unidos, devido à utilização de substâncias não autorizadas (botânicas e complexos de minerais e de amino ácidos). Muitas das rejeições de suplementos alimentares resultaram na criação de notificações RASFF. No âmbito de medidas controlo nacional, para as quais apenas se analisaram as importações de 2016 e 2017, houve 6 rejeições, que resultaram em 4 notificações RASFF. Estas rejeições foram devido à presença de aflatoxinas em amendoins de Israel assim como em amendoins da Nigéria, resíduos de pesticidas em passas, mangas e chá verde, provenientes do Irão, Brazil e do Japão, respectivamente, e à utilização de um colorante não autorizado em óleo de palma proveniente da Guiné Bissau. Em termos de rejeições de remessas sob medidas de controlos oficiais reforçados e de emergência, houve 15 rejeições no total (2/3 devido a contaminação de aflatoxinas e 1/3 devido a resíduos de pesticida) que resultaram em 13 notificações RASFF. A grande maioria das rejeições por contaminação por aflatoxinas deu-se em amendoins, enquanto as rejeições relacionadas com a presença de resíduos de pesticidas acima do LRM deu-se em frutos frescos (nomeadamente mangas e papaias).

As notificações RASFF por contaminação de aflatoxinas em amendoins, resíduos de pesticidas e utilização de substâncias não autorizadas em suplementos alimentares, foram recorrentes ao longo dos quatro anos analisados e por outros Estados Membros da União Europeia.

Para concluir, entre 2014 e 2017 houve um aumento significativo do número de importações a Portugal sujeitos a controlos oficiais, controlos esses, que na maior parte dos casos obedeceu à frequência mínima estipulada pela Comunidade e pelas medidas nacionais. Nos casos pontuais em que as Autoridades

Competentes não foram capazes de realizar um número suficiente de controlos, as razões deveram-se a: falta de recursos humanos e/ ou de ferramentas adequadas que possibilitassem uma colheita de amostras para controlo laboratorial e a um número reduzido de importações de um certo género alimentício. Outras limitações ao controlo oficial por parte das Autoridades Competentes foram identificadas pela equipa de auditoria da DG SANTE, que notou que as Autoridades Competentes falharam no controlo documental em certos casos onde eram necessário um Certificado Sanitário e um relatório de análises laboratoriais. No entanto, a DGAV reagiu às recomendações propostas pela DG SANTE e implementou várias medidas correctivas para resolver o problema.

O número de rejeições ao longo dos quatro anos manteve-se relativamente constante, apesar do aumento do número de importações, o que sugere uma melhoria por parte das empresas alimentares em seguir os requisitos legais Europeus e nacionais. No entanto, a recorrência de certas rejeições e certas notificações de RASFF sugere que os países responsáveis pela exportação dos géneros alimentícios não conformes, não estão a implementar medidas suficientes para garantir que os produtos são seguros para o consumo humano na UE, e por esta razão, Portugal deve manter e talvez re-enforçar medidas de controlo oficial associados a estes géneros alimentícios provenientes de países específicos.

O trabalho tem as suas limitações e estas devem ser referidas: 1) A utilização do TRACES não era obrigatória durante os anos que foram analisados, por isso, o número de remessas registadas no sistema, pode não reflectir o número real de importações a Portugal, e pode também explicar em parte, o aumento significativo do número de importações ao longo destes quatro anos (o número de dados inseridos no TRACES foi aumentando); os Documentos Comuns de Entrada para 2014 e 2015 não foram consultados, visto não fazer parte do âmbito deste trabalho, e por essa razão os números de importações para esses anos, sujeitos a controlos oficiais reforçados ou de emergência, podem não reflectir o número real; por fim, dado que o autor deste trabalho só teve acesso à ferramenta TRACES para a informação sobre as importações, em muitos casos de rejeições, não foi possível indicar a razão pela rejeição, visto o TRACES não fornecer esses detalhes.

Por fim, em termos de estudos futuros, e com a implementação do novo Regulamento (UE) No 2017/625, que obriga a utilização do TRACES, seria interessante poder comparar o número e tipo de importações e rejeições entre os vários Estados Membros.

**Palavras Chave:** Controlos Oficiais, GAONA, Rejeição, Não conformidade, Lei Alimentar

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# Acronyms & Initials

AC – Analytical control

CA – Competent Authority

CED – Common Entry Document

DG SANCO – Direction-Générale de la Santé et de la Protection des Consommateurs (Directorate-General for Health and Consumers)

DG SANTE – Direction Générale de la Santé e de la Sécurité Alimentaire (Directorate General for Health and Food Safety)

DGAV – Direcção-Geral de Alimentação e Veterinária (Directorate General for Food and Veterinary)

DPE – Designated Point of Entry

DPI – Designated Point of Import

DRA – Direcções Regionais de Agricultura (Regional Directorates of Agriculture)

DRAP – Direcções Regionais de Agricultura e Pescas (Regional Directorates of Agriculture and Fishery)

DSNA - Direcção de Serviço de Nutrição e Alimentação (Directorate for Food and Feed)

EC – European Commission

EFSA – European Food Safety Authority

EU – European Union

FNAO – Food of Non-Animal Origin

FVO – Food and Veterinary Office

ID – Identity (identity checks)

MS – Member State

Phys- Physical (physical checks)

RASFF – Rapid Alert System for Food and Feed



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# Chapter 1 Introduction

## Context and Aims

In the European Union, Member States are obliged by Community Law to perform border control checks at Community frontiers for certain foodstuffs from countries outside the Union, that pose a known risk to public health.

Procedures for the conduction of official checks are laid down in Community legislation that stem from General Food Law, Regulation (EC) No 178/2002. These measures are organised into two categories: 1) Official Food and Feed Control Regulation [Regulation (EC) No 882/2004] from which national official control plans are devised; 1) Increased level of official controls [Regulation (EC) No 669/2009] that establishes Designated Points of Entry (DPEs) into the Union and; 2) Emergency Measures for commodities that pose a high risk to public health [Regulations (EC) No 884/2014 and No 885/2014, Regulations (EU) No 2015/175, No 2016/6, No 2015/943, No 211/2013 and No 2016/166 repealed and replaced by No 2017/186, Decisions 2011/884/EU and 2014/88/EU and amendments thereof] and establishing Designated Points of Import (DPIs) for commodities listed under Reg. (EU) No 884/2014. National control plans for official controls on imported foodstuffs from 3<sup>rd</sup> countries, are for risks that are not covered under Community law, resulting in more efficient control on imports and acting as a tool for the update of Community measures based on the identification of new risks and re-evaluation of existing ones (leads to the modification of the frequency of checks required or even the removal of commodities/ countries from legislation)<sup>[72]</sup>.

In order to perform these duties, Member States nominate Competent Authorities that are responsible for creating national measures, coordinating and conducting border control checks, as well as, acting as points of communication with other Member States, the Commission and EFSA<sup>[68, 72]</sup>.

In Portugal, the Competent Authority responsible for creating the national plan for official control checks, liaising with authorities of other Member States, the Commission and EFSA, as well as, coordinating other Competent Authorities on the execution of border control checks, is DGAV (Directorate General of Food and Veterinary)<sup>[34]</sup>. Competent Authorities responsible for the conduction of official controls are the DRAP (Regional Directorates of Agriculture and Fishery) in the continent, and the DRA (Regional Directorates of Agriculture) in the autonomous regions of Azores and Madeira<sup>[29]</sup>.

<sup>[34]</sup>.

The aim of this study is to provide, with regard to the import of FNAO in Portugal:

- 1) A full description of the number and nature of the commodities subjected to border inspection controls for the period between 2014 and 2017 inclusive, as well as, of the consignments that were rejected due to non-compliance;

- 2) A brief comparison between the first two years (2014 and 2015) of the period under analysis, for which the volume of imports was smaller, and the latter two years (2016 and 2017), to note changes, if any, in official controls and rejections;
- 3) Identification of the risks associated with rejected commodities by Portuguese CA that lead to the generation of RASFF notifications and comparison with total RASFF notifications for those same risks, at Community level, for 2016 and 2017.
- 4) Provide suitable recommendations for the improvement of controls, if possible.

# Evolution of European Food Law

## *Phase 1: 1957 to 1985*

Following the devastation of the Second World War, there was a need to improve agricultural trade, in order to rebuild and feed people <sup>[56]</sup>. In 1943, during FAO's founding conference, the United Nations Conference on Food and Agriculture, it was recognised that different standards in different countries would create problems in trade and in the ability to adequately feed people in malnourished countries<sup>[56]</sup>. It called on FAO to help governments consider the formulation and adoption of similar international standards to facilitate and protect the interchange of products between countries <sup>[56]</sup>.

Domestic legislations were based on the characteristics of the food produced and consumed in each MS, such as their long-rooted tradition at national levels and their risk component, resulting in conflicting and contradictory regulations governing preservation, nomenclature and acceptable food standards between MS<sup>[1,56]</sup>.

In 1957, the Treaty of Rome or as it is also known, the Treaty Establishing the European Economic Community (EEC Treaty), was signed. Its objective was to set up a common market, facilitating the movement of goods, services, capital and people between members, and also a customs union among the founding states <sup>[3]</sup>.

Two events highlighted that different measures in different countries made it difficult to implement free trade in a common market, and these were: the first FAO Regional Conference in Europe in 1960; and the White Paper of 1985, twenty-five years later.

During the period between 1960 and 1985, the Community began regulating the food sector, setting up a Standing Committee for Foodstuffs and implementing several measures, in an effort to eliminate trade barriers, including nearly fifty Directives on compositional standards for individual foods; packaging and labelling of foodstuffs; antioxidants and other ingredients; as well as, the harmonization and simplification of customs procedures and controls <sup>[1,7,14,25,39,56]</sup>.

Furthermore, Judgment cases arising from the attempt of harmonization, such as the *Cassis de Dijon case* in 1979, led to further reforms which only began in earnest with the response to the White Paper of 1985, the 1985 Communication, highlighting that traditional ways of harmonisation (the adoption of Community of a nature equal to that of national provisions) through, namely, the 1969/73 programme, were not being successful in overcoming trade barriers <sup>[7]</sup>. The Community realised at this time, that not all matters need to be regulated so it defined a food legislation system that only contained justifiable and necessary provisions required to: protect public health; provide consumers with information and protection in matters other than health; ensure fair trading; and provide for the necessary public controls <sup>[7]</sup>. Examples of these measures, and pertaining to public controls, include Directive 85/591/EEC concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption <sup>[25]</sup>.

<sup>[7]</sup> *Cassis de Dijon case of 1979*: A German liquor importer was refused permission to import liquor 'cassis de dijon' from France on the grounds that it would violate German law, as it did not contain the minimum alcohol content of 25%. The plaintiff argued that imposing alcoholic strength requirements would create obstacles in the trade of alcoholic beverages freely marketed in other MS. At the time there was no Commission legislation regulating production and marketing of alcohol and thus the responsibility for the regulation is of each MS. Germany argued that the requirements of minimum alcoholic content are required for protection of public health and of the consumer against unfair commercial practices. The court ruled in favour of the plaintiff.

In conclusion, during the period between the establishment of the European Economic Community and 1985, and with regards to Article 8 of the Treaty of Rome that provided for the completion of a common market over a transitional period of 12 years, in three stages, ending on 31 December 1969 <sup>[65]</sup>, the Community was successful in achieving its first aim of creating a customs union, but was unsuccessful in creating an internal market with free movement of foodstuffs, as many of the EEC food laws dealt with a range of disparate, unrelated and somewhat unimportant issues, and therefore were poorly implemented by MS <sup>[1, 64, 65]</sup>.

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## RASFF

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Created in 1979, the Rapid Alert System for Feed and Food, is a well-established system for the exchange of risk information pertaining to food (and feed) on the European market<sup>[42]</sup>. National competent authorities input 'notifications' pertaining to food and feed risk to the Commission's RASFF division (part of DG SANCO) that are then disseminated to the whole group <sup>[63]</sup>. Notifications, available to the public, are classified, by the ECCP, into three principle categories:

- ◆ Alert notification: attributed to commodities that present a serious risk and are on the market, for which rapid action is or might be required in a country other than the notifying country. Foodstuffs subject to an alert notification have been or are in the process of being recalled from the market <sup>[49]</sup>
- ◆ Information notification: attributed to commodities for which there is an identified risk, but a rapid action is not required because the risk is not considered serious or because the commodity is not on the market at the time of the notification. Commission Regulation (EU) No 16/2011 defines two sub-types: 1) Information notifications for follow-up (commodity that is, or may be placed on the market in another MS) and; 2) Information for attention (commodity only present in the notifying country, or has not yet been placed on the market, or is no longer on the market) <sup>[49]</sup>
- ◆ Border rejection notification: concerns a consignment of food, feed or food contact material that was refused entry into the EU for reason of a risk to human health and also to animal health or to the environment if it concerns feed. <sup>[49]</sup>

### *Phase 2: 1986 to 1997*

The second phase accompanied the whole of the BSE crisis and spanned between the Single European Act (SEA) of 1986 and both the publication of the Green Paper in 1997, and the Communication on Consumer Health and Safety that same year. This phase is characterized by the introduction of an innovative approach to harmonization based on the mutual recognition principle of national regulations

and standards, for matters which do not require the adoption of Community legislative measures (based on Articles 30 to 36 of the EEC Treaty), combined with the use of the minimum harmonisation method, i.e., rules at Community level only for matters relating to public health, the protection of consumers, fairness of commercial transactions and environmental protection, except in cases where sectoral provisions are necessary in order to implement other Community policies (based on Article 100a of the EEC Treaty)<sup>[2.10]</sup>.

The new reform, which began shortly after the 1985 Communication, meant the abandonment of “recipe laws” for all European-made foodstuffs, but a reinforced labelling regime, allowing the consumer protection objective to be achieved by providing consumers with enough information for them to make informed decisions<sup>[2.7]</sup>. However, the harmonisation process only really “kicked in” properly in 1987 with the Single European Act, which was the first substantial change to the EEC Treaty<sup>[2.65]</sup>. Nonetheless, the 1989 Communication to the Council regarding the Free Movement of Foodstuffs within the Community was instrumental, regarding foodstuffs, to the harmonisation process.

As part of this new approach, the Community adopted several framework Directives, which were developed in part as a consequence to several Court Judgment cases, which established basic standards and acted as guides for Member States dealing with essential requirements in the fields of: additives; description, packaging quantity or capacity of packages of foods; labelling of foods for particular nutritional needs; hygiene; and official controls<sup>[2.62]</sup>. In the absence of harmonised Community rules, Member States had the power to lay down their own measures ensuring however that they admitted to their territory foodstuffs lawfully produced and marketed in other Member States as well as from third countries<sup>[60]</sup>.

Details regarding the verification of the compliance of foodstuffs with legislation were set out in Directive 89/397/EEC (based on COM(86)747; repealed by Regulation (EC) No 882/2004)<sup>[26]</sup>. However, this Directive did not lay down a particular programme based on appropriate criteria to effectively prevent food law infringement; instead, it relayed that responsibility primarily to Member States<sup>[26]</sup>. Later in 1993, there would be a Directive (Directive 93/99/EEC) that supplemented the aforementioned Directive, on the subject of additional measures concerning Official Control of Foodstuffs, including measures in cases of non-compliance<sup>[27]</sup>.

Although the Community tried in these years to re-orient the EC food policy towards the achievement of new goals, such as the protection of consumers and public health, these aspects of EC food law were still neglected at the time, the only priority being the completion of the internal market by 1992<sup>[61]</sup>. Even though much national food legislation had already been harmonised at the Community level, European food law continued to develop in a fragmented fashion<sup>[1.64]</sup>. There was no unifying text that clearly defined the responsibilities of the parties concerned<sup>[1.64]</sup>. Words by food lawyer Raymond O’Rourke “*Essentially though, EU food law in the run-up to the establishment of the Single Market in 1992 was still concentrated on questions of trade and free movement of goods. Consumer protection and public health aspects of food law were playing second fiddle to aspects of trade. Indeed, during this time there were*

<sup>60</sup>BSE crisis: in the late 1980s and early 1990s Bovine Spongiform Encephalopathy in cattle that quickly became a global animal health and food safety crisis, with major implications also on trade and export of animals and their derived products and resulting in over 185 000 deaths in the EU. The source of contamination is thought to be the MBM feed containing prion contaminated offal of sheep, cattle, pigs and chickens. This particular prion can be passed on to humans through meat consumption causing a variant disease, also a nervous system disorder, Creutzfeldt-Jakob disease.

*often calls for the deregulation of EU food law back to Member States and EU legislation relating to food was subject to criticism of over-regulation, incoherence, fragmentation and lack of transparency and innovation.”*<sup>166]</sup>

Finally, in 1997, in the wake of the BSE crisis, the Green Paper on Food Law and the Communication on Consumer Health and Safety were published<sup>12]</sup>. *“The BSE crisis has highlighted the need for a European food policy centred on the requirement that only foodstuffs which are safe, wholesome and fit for human consumption be placed on the market. Health protection in relation with consumption of foodstuffs is to be an absolute priority at any time and not only something to be looked at in emergency situations.”*<sup>18]</sup>

The protection of public health was gradually entering the EC Food law policy as a goal deserving as much coverage as the other economic goals related to the CAP (Common Agricultural Policy) and the free movement<sup>13]</sup>.

From a policy perspective, the aim of the Green Paper was to examine the extent to which current legislation was meeting the needs and expectations of consumers, producers, manufacturers, and traders; to consider whether official control and inspection systems were operating effectively; and to highlight that future food law be based on sound and recent scientific evidence and/ or a precautionary principles approach, something which was reiterated in more detail in the 1997 Communication<sup>12]</sup>. The ultimate objective was to provide legislation which took a harmonised approach to control and inspection for each part of the food production chain, by following three main orientations: 1) In view of the broad range of areas covered by the legislation, control and inspection were to follow a scheme of priorities established by risk assessment procedures and; 2) They were to ensure that the whole of the food production chain is covered; 3) The control activities were to be exercised through the introduction of formal audit procedures enabling the Community to assess the control systems operated by the national authorities. This new regime had to be implemented through the Food and Veterinary Office (FVO)(henceforth the Audit Unit of DG Health and Food Safety)<sup>13]</sup>. The Community role in the field of control was not to replace the Member States, but to verify that the necessary controls were being carried out in an effective and equivalent manner throughout the internal market<sup>12]</sup>.

The Communication also described the new approach in the way the Commission obtained and made use of scientific advice, and operated its control and inspection services, basing itself on three general principles: 1) Separation of legislative responsibilities (risk management) and those relating to scientific advice risk (risk assessment); 2) Separation of legislative responsibilities and those relating to controls and inspections and ; 3) Enhanced transparency and dissemination of information throughout the decision-making and monitoring activities<sup>12]</sup>.

The division between ‘responsibility for legislation’ and ‘scientific consultation’ was established by entrusting the latter to DG on Consumer Policy and Consumer Health Protection (DG SANCO), which thus became responsible for the scientific assessment system<sup>12]</sup>. The Audit Unit of DG Health and Food Safety is responsible, since 1997, in assuring effective control systems are put in place and assessing



compliance with EU standards within the EU as well as in third countries, with regards to their exports to the EU <sup>(2)</sup>.

### *Phase 3: 1998 to 2002*

The third phase of the evolution of European Food Law is characterised by the publication of the White Paper in 2000 on Food Safety and the entry into force of Commission Regulation (EC) No 178/2002, as well as the establishment of the European Food Safety Authority (EFSA).

In 1999, the Director General of DG SANCO (now DG SANTE), mandated three scientists to assess the current system of scientific advice and to conceive a better one in terms of independence, transparency and excellence in order to restore consumer confidence. Their report sketched out the blueprint for a European Food Authority and was immediately endorsed by the newly-appointed Commission president as one of his priorities<sup>(3)</sup>.

Several events during the 1990s contributed to speeding up the food safety policy reform by, decidedly, counteracting the Member States resistance to the establishment of EFSA, notably, the ongoing BSE crisis, the growing consumer concerns on the safety of GM foods and lastly the dioxin contamination outbreak in Belgium 1999 (accidental addition of polychlorinated biphenyls contaminated with dioxins, to poultry feed, resulting in a major food crisis that could only be resolved by the implementation of a large PCB/dioxin food monitoring programme <sup>(2,4)</sup>.

In its White Paper, the Commission outlined its strategic objectives, priorities and work programme in relation to food safety in particular, and food law in general, as well as, the elaboration of its commitment to develop a comprehensive integrated approach to regulating the food supply chain in its entirety, across all food sectors; between Member States; at the EC external frontier and within the EC; in international and EC decision-making for and at all stages of the policy-making process (the assumption was that a comprehensive, integrated, approach would lead to a more coherent, effective and dynamic food policy) <sup>(2,5)</sup>. It proposed, in particular, the establishment of a European Food Authority <sup>(6)</sup>.

Moreover, the White Paper advocated the adoption of eighty-four distinct measures (involving around thirty directives and regulations) forming a complete and coherent corpus of legislation covering all aspects of food products from “farm to table”, thus ensuring a high level of protection and the effective functioning of the internal market in food <sup>(2,6)</sup>. Two years after the publication of the White Paper, the Commission adopted a Communication, proposing for a regulation laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food. In both the White Paper and the subsequent Communication the precautionary principle is employed: the principle is to be used in cases where scientific evidence is insufficient, inconclusive or uncertain (i.e. the hazard is not yet well understood) but preliminary results or plausible causal hypothesis, show a risk to the environment, human, animal or plant health, in which cases measures should be adopted, proportional to the chosen level of protection, non-discriminatory in their

application and consistent with similar measures already taken, to prevent damages from happening <sup>[11, 40]</sup>. The new legal framework should have virtually covered the whole of food chain, including animal feedstuffs, the animal health and welfare, hygiene, contaminants and residues, new types of food, food additives and flavours, packaging materials and ionizing radiation <sup>[2]</sup>.

The Commission proposed to: 1) respond to the commitment outlined in its White Paper, by laying down the general principles and requirements of food law; 2) establish procedures in matters of food safety and 3) establish a rapid alert system for foods and feeds. Finally, it created a European Food Authority defining its scope, tasks and responsibilities <sup>[11]</sup>. This proposal, contained all the main features originally sketched out by the White Paper and was subsequently adopted, with few amendments, as Regulation (EC) No 178/2002 which is still in force and represents the first attempt to address all aspects of food safety at EU level, by laying down a comprehensive EU food policy covering horizontally all stages of production, processing and distribution of food and feed <sup>[2]</sup>.

The main principles of Commission Regulation (EC) No 178/2002 are that food law enacted either by the Community or by its member states, should seek to achieve a high level of protection of human health and consumers' interests, whilst ensuring the effective functioning of the internal market <sup>[2]</sup>. The Regulation seeks to achieve these two principles in two main ways:

- 1) The establishment of a comprehensive EC-wide food policy, addressed to both the Community and its Member States, by setting forth:
  - a. General Principles
  - b. Obligations and Requirements of Food Law
  - c. Some procedures in matters of food safety
- 2) By creating a new independent agency (the European Food Safety Authority)
- 3) Shifting the focus from Competent Authorities of MS as regards to the responsibility of ensuring safety and hygiene of foodstuffs, to food business operators<sup>[2, 68]</sup>.

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## EFSA

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EFSA was set up in 2002 following a series of food crisis in the late 1990s, to be a source of scientific advice and communication on risks associated with the food chain <sup>[51]</sup>.

It has no regulatory power and is entrusted with a number of key tasks comprising:

- Independent scientific advice on all aspects relating to food safety (risk assessment) and;
- Communication and dialogue with consumers on food safety and health issues (risk communication) <sup>[1, 51]</sup>.

## *Phase 4: 2003 to present day*

The existing EC food legislation has come into being as a result of the gradual harmonisation of national rules<sup>111</sup>. This harmonisation was a gradual process, taking several years, during which the initial efforts, were unsuccessful in overcoming trade barriers, due to ‘recipe laws’ and a pure economic perspective to food legislation. Gradually, the issue of public health and consumer protection started seeping into Community measures, which eventually lead to radical changes in policy making, allowing then for the proper harmonisation of legislation and the completion of an internal market. Factors that were crucial in the food policy reform include food scares and crisis, Court Judgment cases and general public discontent.

Currently, there are numerous regulatory measures in force regarding foodstuffs in the sectors of: hygiene of foodstuffs, official control inspections; food contact material; contaminants; GMO; pesticide residues; microbiological criteria; novel foods; additives, flavourings and enzymes; vitamins and minerals; foods destined to specific groups; organic agriculture farming system; trading norms and; analytical methods and sampling, to name a few.

## Present day: Imports of FNAO into the EU from 3<sup>rd</sup> countries

### *How it works*

When a country outside the Union exports food of non-animal origin to Union, there are steps that need to be taken by the business operators responsible for the consignment, namely the provision of accurate and up-to-date information on the general organisation and management of sanitary control systems, and the prior notification of the arrival of goods if the commodities fall within the scope of re-enforced border control checks <sup>172</sup>.

The definition of consignment according to Commission Regulation (EC) No 669/2009 implementing Regulation (EC) No 882/2004 as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC, is:

*“...a quantity of any of the feed or food of non-animal origin listed in Annex I to this Regulation of the same class or description, covered by the same document(s), conveyed by the same means of transport and coming from the same third country or part of such country.” Article 3 (c)<sup>171</sup>*

The documents that the quote above mentions, include the Common Entry Document (CED) (for which a blank example can be found in Annex I), bill of lading, proof of payment, list of ingredients (if required), declaration of absence of substances and<sup>7</sup> or of compliance with the Law, analytical report for laboratory analysis and health certificate (if required).

Regarding the CED, and according to the definition of consignment, commodities that belong to the same commodity category are accompanied by a single CED (unless the consignment is split or part of it rejected, in which case a new CED is generated to accompany the second consignment, or to

accompany the commodities that are compliant and allowed entry into the EU). However, due to the expenses related to the export of commodities under several different CEDs and the workload for Customs Authorities, permission to include various different commodities of different commodity groups under the same CED, is often given. For this reason, in Chapter 4, the terms used in description and analysis of imports, will be mostly in terms of commodities, as opposed to consignments.

The majority of products of food of non-animal origin is not, according to Community measures, channeled through specific border entities and does not need to undergo mandatory checks prior to their entry into the EU <sup>(41)</sup>. However, and with regards to Portugal, under provisions set by national control plans implemented to conform with guidelines set in Reg. (EC) No 882/2004, all the FNAO listed in the “Complementary Information” document, IC19<sup>(32)</sup>, need to undergo 100% frequency control of documentary checks and a set frequency of identity and physical controls performed by the DRAP/DRA. A consignment that originates in, or is consigned from, a 3<sup>rd</sup> country carrying commodities that are listed under EU legislation because they pose a risk to public safety and consumer health and therefore are subject to increased levels of control, is always channeled through specific border entities, Designated Points of Entry (DPEs) and/or Designated Points of Import (DPIs), where Competent Authorities enforce feed and food law and monitor and verify that the relevant requirements are met by business operators, by carrying out inspections, verifications, audits, sampling and testing of samples <sup>(71, 72, 91)</sup>.

In terms of controls performed by Competent Authorities, carry out three types of checks, as defined by Regulation (EC) No 882/2004<sup>(72)</sup>:

1. Documentary check: examination of commercial documents and, where appropriate, of documents required under Community Law, that are accompanying the CED; Documentary checks are always done at 100% frequency.
2. Identity check: a visual inspection of the consignment and its contents, to ensure that certificates and/ or other documents accompanying the consignment correspond with the information on the label and the contents of the consignment; Frequency of identity checks is determined based on the risk level posed by the commodity being consigned;
3. Physical check: a check of the commodity being consigned, which may include checks on the means of transport, on the packaging, labelling and temperature, as well as, sampling and laboratory testing, and any other checks necessary to verify compliance with feed and food law; Physical checks without sampling, usually match the frequency of identity checks, the frequency of sampling for laboratory analysis differs from the other checks, but it is also set based on the risk posed by the commodity being consigned.

When a consignment is found to be compliant it is allowed free circulation within the Union. When a consignment is suspected to be non-compliant, Competent Authorities can detain the consignment (official detention) until further clarification is given, or they can monitor, withdraw or recall a consignment, if it has already been placed on the market, pending the implementation of measures described in the next paragraph.

If a consignment is found to be non-compliant, one of three possible actions is taken: 1) Destruction; 2) Re-dispatch to the country of origin or to a different country outside the Union that has accepted to receive the consignment or; 3) Use for other purposes.

Rejections can, depending on the commodity and risks identified, lead to the generation of RASFF notifications, on behalf of the National Contact Point (NCP)<sup>(43)</sup>. The notifications are reviewed by the European Commission Contact Point (ECCP) and, depending on the seriousness of the risks identified and the distribution of the product on the market, be classified as alerts, information (for attention or for follow-up) or border rejections (always associated with consignments imported from outside the Union)<sup>(43, 49)</sup>.

The scope of this work, centres on the official control of foodstuffs of non-animal origin, subject to border control inspections by Competent Authorities, under EU legislation and national control measures. Therefore, due to the extensity of regulatory documents currently enforced in the field of foodstuffs, only those measures that are directly linked to the subject of this work, will be discussed.

Having said that, with regard to Official Control of Foodstuffs of Non-animal origin, there are currently eight Commission Regulations and two Commission Decisions organised into:

1. **General Principles and Requirements of Food Law:** *Regulation (EC) No 178/2002* laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (in force);
2. **Official Food and Feed Control Regulation:** *Commission Regulation (EC) No 882/ 2004* on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (in force). From 14<sup>th</sup> December 2019 this Regulation will be repealed and replaced by Regulation (EU) No 2017/625 on official controls and other activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products;
3. **Increased level of Official Controls:** *Commission Regulation (EC) No 669/ 2009* implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC (in force).
4. **Emergency measures:**
  - a. *Commission Implementing Regulation (EC) No 884/2014* imposing special conditions governing the import of certain feed and food from certain third countries due to contamination risk by aflatoxins and repealing Regulation (EC) No 1152/2009 (in force);
  - b. *Commission Implementing Regulation (EC) No 885/2014* laying down specific conditions applicable to the import of okra and curry leaves from India and repealing Implementing Regulation (EU) No 91/2013 (in force);

- c. *Commission Implementing Regulation (EU) No 2016/166* laying down specific conditions applicable to the import of foodstuffs containing or consisting of betel leaves ('Piper betle') from India and amending Regulation (EC) No 669/2009 (no longer in force. repealed by *Commission Implementing Regulation (EU) 2017/186* laying down specific conditions applicable to the introduction into the Union of consignments from certain third countries due to microbiological contamination and amending Regulation (EC) No 669/2009);
- d. *Commission Implementing Regulation (EC) No 2016/6* imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station and repealing Implementing Regulation (EU) No 322/2014 (in force).
- e. *Commission Implementing Regulation (EU) 2015/943* on emergency measures suspending imports of dried beans from Nigeria and amending Annex I to Regulation (EC) No 669/2009 (in force).
- f. *Commission Implementing Regulation (EU) 211/2013* on certification requirements for imports into the Union of sprouts and seeds intended for the production of sprouts (in force)
- g. *Commission Implementing Decision 2014/88/EU* suspending temporarily imports from Bangladesh of foodstuffs containing or consisting of betel leaves ('Piper betle') (in force).
- h. *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 (in force).

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## TRACES

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TRACES, Trade Control and Expert system, is effectively the end consequence of the outbreak in Europe of classic swine fever in 1997, as there was a need for improved traceability of animal movements within the single market<sup>(45)</sup>. The computerised system was initially known as Animo host centre and its use was limited to live animals and animal products<sup>(46)</sup>. It came into being as a necessity after the abandonment of veterinary inspections at the internal borders authorities, in order to link the central authorities of Member States, the designated local authorities and the border inspection posts with regards to veterinary checks on animal products and live animals arriving from third countries into Community<sup>(15, 16)</sup>.

It was only in 2003, several years after the classic swine flu fever of 1997, that the system was revised, by means of two Commission Decisions (Commission Decision 2003/24/EC concerning the

development of an integrated computerised veterinary system and Commission Decision 2003/623/EC concerning the development of an integrated computerised veterinary system known as Traces) which eventually lead to Commission Decision 2004/292/EC on the introduction of TRACES system<sup>[17, 18, 22, 45]</sup>.

TRACES is an online management tool for all sanitary requirements on intra-EU trade and importation of animals, semen and embryo, food, feed and plants<sup>[46]</sup>. It aims to strengthen cooperation with EU partners, facilitate trade, accelerate administrative procedures and improve the risk management of health threats, while combating fraud and enhancing the safety of the food chain, animal and plant health<sup>[46]</sup>.

Whereas the submission of the CVED (Common Veterinary Entry Document for animals and animal products) is obligatory for all Member States from 2005 onwards in TRACES<sup>[45]</sup> with regards to feed and food of non-animal origin, for which a CED is required, the submission of documents in TRACES is optional until December 2019, when the use of TRACES becomes compulsory for all MS, under Regulation (EU) No 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products<sup>[85]</sup>.

## Border Controls of FNAO Imports in Portugal

### *Competent Authorities and Official Control measures*

Portugal has a decentralised system for testing and controlling the food chain<sup>[60]</sup>. The Directorate General for Food and Veterinary (DGAV), a department within the Ministry of Agriculture, Forestry and Rural Development, is responsible for coordinating official controls on imports of feed, plants, live animals, animal products and food products of animal and non-animal origin, whereas other Competent Authorities are responsible for carrying out official controls at DPEs and DPIs, for commodities of non-animal origin, and are known as the Regional Directorates of Agriculture and Fisheries (DRAPs) and Regional Directorates of Agriculture (DRA), found in the continent (in case of the DRAPs) and the autonomous regions of Madeira and Azores (with respect to the DRAs):

1. DRAP North;
2. DRAP Centre;
3. DRAP LVT (Lisboa e Vale do Tejo);
4. DRAP Alentejo;
5. DRAg (Azores);
6. DRA Madeira (Madeira).

Customs authorities, also play a role in the control of imports of FNAO for commodities that are subject to official controls under all control measures (Community and National) that come listed in the IC19 (Complementary Information on imports of foodstuffs of non-animal origin) and IC39 (Complementary

Information on the clearance of food supplements). These documents are included in the Customs manual that establishes proceedings for clearance of consignments under food safety provisions.

## Legislation

In Portugal there are two official documents applicable to the control of imports of FNAO<sup>[34]</sup>:

- Decree No 136/ 2003 transposing Directive No 2002/46/EC with regards to the approximation of MS legislation on food supplements;
- Decree No 144/ 2003 which approves the MRLs for Plant Protection Products (PPP) authorized in plant products for human or animal consumption, and transposes the section of products of plant origin in Directive No 2002/63/CE;

In addition, DGAV has implemented a Control Plan of Foodstuffs of non-Animal Origin that includes several documents as work instructions and operating procedures, including the Matrix of Analytical Control<sup>[34]</sup>.

The Matrix of Analytical Control, is the official national measure of border inspection controls, product of the guidelines set under Regulation (EC) No 882/2004. Member States enforce food law by putting in place official controls to monitor and verify that the requirements of European law are met by food and feed business operators<sup>[72]</sup>. The national control plan monitors risks that are not listed in Community legislation and allows, along with results from official controls in other MS and resulting RASFF notifications, for the revision of Community Law on official controls and emergency measures, adding or removing commodities from the programme, or adjusting the frequency of controls. Under measures set by the Matrix, FNAO are subject to 100% documentary control frequency, 10% frequencies of identity and physical controls and 5% sampling for laboratory analysis, with the exception of fresh fruit and vegetables arriving by air to the airports, in which case the frequency is reduced to 2.5% (this particular DPE/ DPI receives a high volume of consignments so it is not possible to control perishable fruit and vegetables at a higher frequency)<sup>[33]</sup>. Official controls on commodities under the Matrix are performed at DPEs, and in exceptional circumstances, they can be performed at Approved Control Points<sup>[29]</sup>. The next page shows an explanatory figure of controls performed on commodities subject to official controls by the DRAP/ DRA.



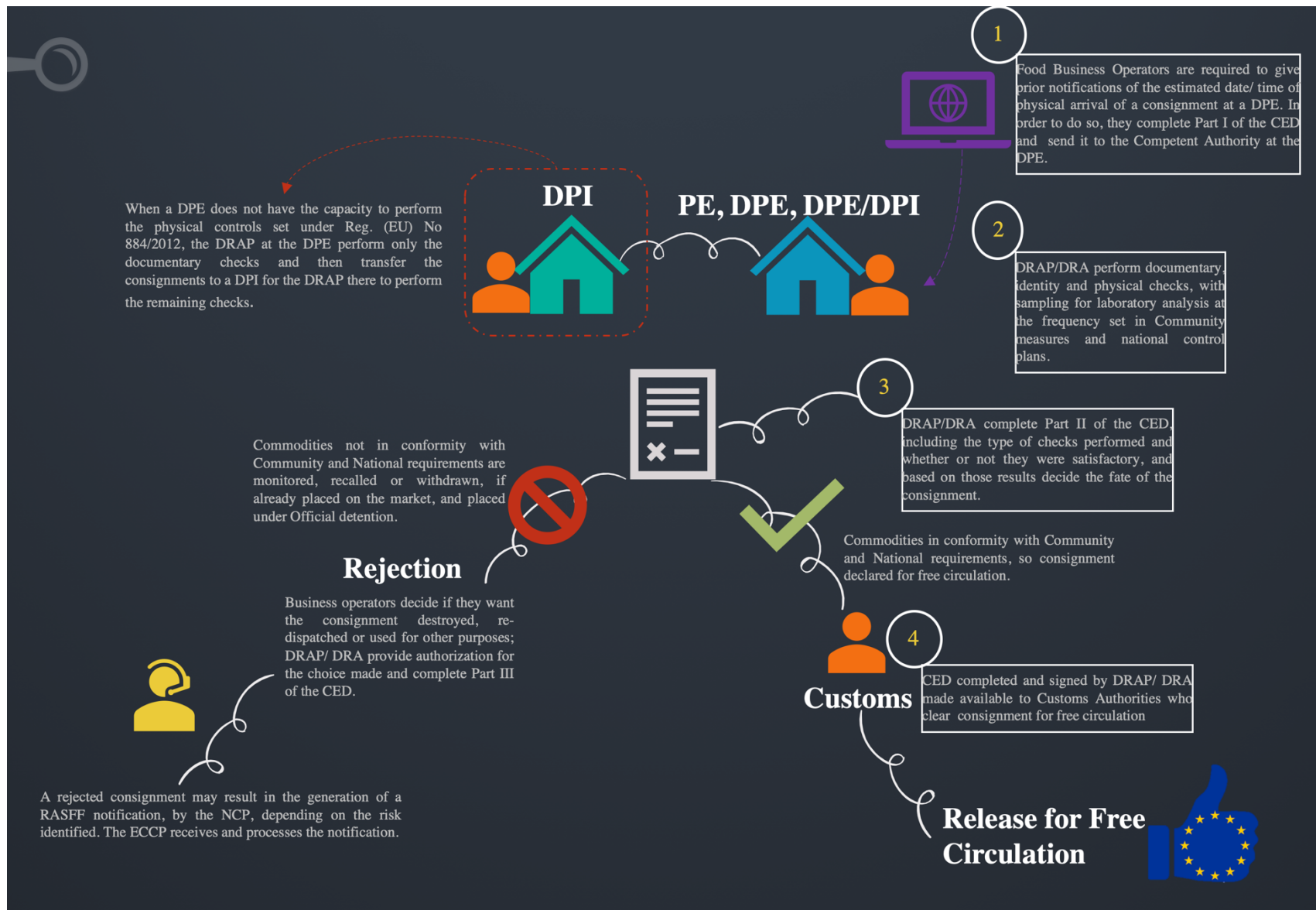


Figure 1. Import Control Procedures at DPEs and DPIs

# Chapter 2 Materials and Methods

## Design

Quantitative and qualitative analysis of numerical data on food import consignments of non-animal origin to Portugal, between the years of 2014 and 2017, inclusive, using the European Commission's online management tool (TRACES) for data retrieval. The purpose is to identify the number and type of consignments non-compliant to control checks, as stipulated by the Regulation (EC) No 669/ 2009 on increased level of official controls on imports of certain food of non-animal origin, and any Regulations and Decisions on emergency measures on the same matter, as well as, taking into account the country's own legal procedures implemented by DGAV.

The current paper will be organised into two analytical periods. The first period comprising of the years 2014 and 2015, for which an overview of imports and rejections will be given and the second period, 2016 and 2017, will receive a more detailed analysis of imports, rejections and RASFF notifications.

## Procedure

For the execution of this work it was necessary to resort to the following materials:

- TRACES online management tool for the extraction of excel files containing the data of consignments reaching Portugal for the years of 2014, 2015, 2016 and 2017;
- Microsoft Office Excel for the handling of the data retrieved from TRACES, as well as, the calculation of means and medians on official controls performed in 2016 and 2017;
- EU Regulations, Decisions, Communications and reports for the description of the evolution of Food Law in the European Union and the analysis and discussion on the data retrieved from TRACES;
- National measures on import controls for FNAO in force during 2016 and 2017 for the analysis and discussion of the data in those years

# Chapter 3 Community Legislation and National Import Control Plans on Official Controls on Feed and Food of Non- Animal Origin

## Community Legislation

### *General Food Law*

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Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

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General food regulation that focuses particularly on food and feed safety, detailing procedures in matters of direct or indirect impact on the integrity of food and feed which could raise public health concerns, animal health or the environment<sup>[61, 68]</sup>.

It applies to all stages of production, processing and distribution of food and feed<sup>[68]</sup>; it is not relevant for primary production, or for food for private domestic usage (preparation, handling, storage or consumption)<sup>[68]</sup>.

Regarding trade control, the Regulation states that food and feed imported into the European Union, for circulation within the Union shall comply with the relevant requirements of food law, or conditions recognised by the Community as being equivalent to such law (Article 11, Section 3, Reg (EC) No 178/2002). It aids in the definition of unsafe food and food injurious to health, in general and in a trading activity, Section III, Article 14<sup>[68]</sup>.

### **Rapid Alert System for Food and Feed (RASFF)**

Article 50, Section 1 in Chapter IV of the Regulation details the purpose and procedure for the use of the RAS system in cases of food safety emergencies. It involves Member States, the Commission and the Authority, whereby information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed is, through RAS, sent to the Commission who acts upon it quickly and effectively posteriorly communicating with members of the network, who shall act as appropriate to reduce or mitigate the risk<sup>[68]</sup>.

### **Emergencies and crisis management**

The Regulation also states a set of emergency measures implemented by the Commission, for food and feed originating within the Community or imported from third countries, that is likely to pose a serious

risk to human health, animal health or the environment, which cannot be dealt with satisfactorily by the Member State(s) concerned (Article 53, Section 2), and interim measures to be adopted by such Member State(s) when the Commission is unable to act in accordance with Article 53, until the Community measures have been adopted (Article 54, Section 2)<sup>681</sup>.

Finally, a general plan for crisis management shall be drawn up by the Commission, in close cooperation with the Authority and the Member States, when emergency measures cannot by themselves prevent, eliminate or reduce the risks imposed by unsafe food or feed (Article 55, Section 3)<sup>681</sup>.

### *Official Food and Feed Control Regulation*

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Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

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Regulation on the official controls performed by competent authorities, to ensure the verification of compliance with feed and food law, animal health and animal welfare rules<sup>721</sup>. Specifically, it aims at a) preventing, eliminating or reducing to acceptable levels, risks to humans and animals, either directly or through the environment, and; b) guaranteeing fair practices in feed and food trade and protecting consumer interests (through labelling and other relevant consumer information) (Article 1)<sup>721</sup>.

Article 15 of the present regulation, details official controls on feed and food of non-animal origin imported into territories referred to in Annex I of such Regulation, that are not included in the scope of Directive 97/78/EC<sup>721</sup>. Such controls, whose nature and frequency are detailed in the procedure, are to be conducted by competent authorities at an appropriate place (Article 15(2), Chapter V)<sup>721</sup>. The official controls consist, at least, of a systematic documentary check, random identity check and where appropriate, a physical check at a specific frequency (Article 16(1), Chapter V)<sup>721</sup>. It is the responsibility of each Member State to designate particular points of entry into their territory of consignments, and to inform food business operators of the need of prior notification of the arrival of such consignments, to the point of entry (Article 17(1))<sup>721</sup>.

In case of suspicion of non-compliance or doubt as to the identity or actual destination of the consignment, the Competent Authority will place the consignment in question, under official detention, and shall carry out official controls that will lead to the confirmation or elimination of such suspicion or doubt (Article 18)<sup>721</sup>. In case of a confirmed non-compliance, and after communicating it to the food business operator responsible for the consignment, the Competent Authority shall implement one of three possible measures: a) destruction of consignment; b) re-shipment or; c) redirected for other purposes [Article 19(1)(a)]. If the consignment is already in free circulation, the Competent Authority shall monitor it (verify that it does not give rise to any adverse health or environmental effects), and if

necessary order its recall or withdrawal, after which, the CA will implement one of the afore mentioned measures, followed by notification of the Commission and other Member States of its findings and the identity of the consignment, as well as to custom services of its decisions, including the consignment's final destination [Article 19(1)(2)(3)]<sup>(72)</sup>.

This Regulation will be repealed from 14<sup>th</sup> of March 2019, by Regulation (EU) No 2017/625, although it is already being partially implemented.

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Regulation (EU) No 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products

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Regulation (EU) No 2017/625 amends and repeals several Regulations and Directives, including, from the 14<sup>th</sup> December 2019, the afore mentioned Regulation. However, parts of this Regulation are already being implemented (requirements in relation to Reference Laboratories and Reference Centres, and on management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material)<sup>(57)</sup>.

There are several reasons for its proposal in 2013, in COM(2013)265, however those related to the main changes observed are: 1) The need to review the system of financing of official controls, as results of reports on the then current system of inspection fees showed that MS had difficulties in implementing the rules on the financing of official controls, and that existing provisions on financing official controls from fees were not achieving the objective of ensuring an adequate level of resources to conduct adequately official controls<sup>(44)</sup>. With the implementation of the new Regulations, there is an extension of mandatory fees to most official controls performed on operators and more control transparency<sup>(44)</sup>. This system should guarantee that MS are able to resource their control activities;

2) The need to integrate current rules applicable to official controls in specific areas, in order to rationalise and simplify the overall legislative framework, whilst simultaneously pursuing the objective of better regulation, aiming at establishing a harmonised Union framework for the organisation of official controls and other official activities<sup>(9,85)</sup>.

## *Increased Level of Official Controls*

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Regulation (EC) No 669/2009 implementing Regulation (EC) No 882/2004 as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC

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Commission Regulation (EC) No 669/2009 applies to feed and food of non-animal origin listed in Annex I of the Regulation and it lays down rules concerning the increased level of official controls to be carried out pursuant to Article 15(5) of Regulation (EC) No 882/2004 at the DPEs of the imported feed and food of non-animal origin (Article 1)<sup>(71)</sup>. It states that, with regards to increased level of official controls, documentary checks shall be performed on all consignments, and identity and physical checks, including laboratory analysis, will be carried out at the frequency set out in Annex I, and that Part II of the CED will be completed and signed by the CA (Article 8(1)(2))<sup>(71)</sup>. In case of non-compliance, the CA fills in Part III of the CED, and consignments shall be re-dispatched to the country of origin or a different country, outside the Union, that has agreed to receive it, destroyed, or used for alternative purposes<sup>(72)</sup>.

In order to provide a brief comparison between imports in 1<sup>st</sup> period of analysis, 2014 and 2015, and the 2<sup>nd</sup> period, under control measures set by Regulation (EC) No 669/2009, nine versions of the Regulations were consulted for the first period (as amended by Commission Implementing Regulations (EU) Nos 1355/2013, 323/2014, 718/2014, 1021/2014, 1295/2014, 2015/525, 2015/943, 2015/1012 and 2015/1607) and eight versions consulted for the 2<sup>nd</sup> period (due to amendments by [Commission Implementing Regulations (EU) No 2015/2383, No 2016/24, No 2016/166 (repealed by Commission Implementing Regulation No 2017/186), No 2016/443, No 2016/1024, No 2016/2107, No 2017/186 and No 2017/1142]).

## *Emergency Measures*

Pursuant to Article 53, Section II of Regulation 178/2002, the Commission, on its own initiative or at the request of a Member State, has adopted several emergency measures as a result of foodstuffs imported from certain third countries that pose a serious risk to human health or to the environment<sup>(68)</sup>.

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Commission Implementing Regulation (EU) No 884/2014 imposing special conditions governing the import of certain feed and food from certain third countries due to contamination risk by aflatoxins and repealing Regulation (EC) No 1152/2009

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The creation of this Regulation comes as a response to the re-occurrence of imported commodities from certain 3<sup>rd</sup> countries contaminated with high levels of aflatoxins, exceeding the maximum permitted

levels as set under Commission Regulation (EC) No 1881/2006, and therefore requiring an increased level of control<sup>[91]</sup>.

Commission Implementing Regulation (EU) No 884/2014 lays down the procedures to be followed in order for feed and food described in Article 1 (1) and (2) to be imported into the Union [Article 3]<sup>[91]</sup>.

Each consignment falling under the scope of Annex I of the Regulation shall be accompanied by the results of sampling and analysis performed by the Competent Authorities of the country of origin, or of the country where the consignment is being consigned from (if different from the country of origin), to ascertain compliance with Union legislation on maximum levels of aflatoxins [Article 4 (1)]<sup>[91]</sup>. Consignments shall also be accompanied by a Health Certificate in accordance with the model set out in Annex II, which shall be completed, signed and verified by an authorised representative of the competent authority of the country of origin, or the competent authority of the country where consignment is being consigned from, and which will remain valid for a period of four months [Article 5(1)(2)(4)]<sup>[91]</sup>.

Documentary checks will be performed by the DPE at a frequency of 100%. Where a consignment of feed and food is not accompanied by the results of laboratory analysis and the health certificate, or if either of these two documents show that the feed or food is non-compliant, the consignment shall not enter the Union for import and must be re-dispatched to the country of origin or destroyed [Article 9(2)(3)]<sup>[91]</sup>. Physical and identity checks, including analytical control, shall be carried out by Competent Authorities at the Designated Point of Import (DPI)[Article 9(5)]<sup>[91]</sup>. In case of non-compliance, the same measures afore mentioned in Commission Regulation (EC) No 882/2004, shall apply.

This Regulation was amended by Commission Implementing Regulations (EU) Nos 2016/2106 and 2016/24 therefore, for the analysis of the consignments imported in 2016 and 2017, under measures pertaining to this diploma, two versions were consulted. With regards to 2014 and 2015, Commission Implementing Regulation (EC) No 1152/2009<sup>[93]</sup> was consulted until the 13<sup>th</sup> August 2014, after which the above diploma was used, pre-amendments.

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#### Commission Implementing Regulation (EU) No 885/2014 on the import of okra and curry leaves from India

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The creation of this Regulation comes as a consequence of continuous high frequency of non-compliance with maximum residue levels of pesticide residues established in Union legislation<sup>[90]</sup>. Curry leaves from India had already been established for more than two years prior to the creation of this Regulation, for an increased frequency of official controls on import, under Regulation (EC) No 669/2009, as regards to pesticide residues.

Commission Implementing Regulation (EU) N° 885/2014, came into force in mid-August 2014 and repeals Commission Regulation (EU) No 91/2013<sup>[92]</sup>. It lays down specific conditions regarding the

import of okra and curry leaves from India, whether it be originating there or elsewhere but consigned from India. It applies to okra (food, fresh and frozen), curry leaves (food, herbs) and compound food that contains any of the afore mentioned ingredients in quantities above 20%<sup>[92]</sup>.

In the instances where the Regulation is applicable, consignments shall be accompanied by the results of sampling and analysis performed by the Competent Authorities of the country of origin, or of the country where the consignment is consigned from, if different from the country of origin, on levels of pesticide residues [Article 4(1)]<sup>[92]</sup>.

The consignment shall also be accompanied by a Health Certificate in accordance with the model set out in Annex II of the Regulation, which shall be completed, signed and verified by an authorized representative of the Competent Authority of the country of origin or country where consignment is being consigned from, if different from country of origin. This Health Certificate is only valid for four months from the date of issue. [Article 5(1)(2),4)]<sup>[92]</sup>.

Frequency of physical and identity checks at import is set to 20% for both the feed and food ingredients mentioned, as indicated in Annex I<sup>[92]</sup>.

During the 1<sup>st</sup> stage of analysis, years 2014 and 2015, two Regulations were consulted: Commission Implementing Regulation (EU) No 91/2013<sup>[87]</sup> laying down specific conditions applicable to the import of groundnuts from Ghana and India, okra and curry leaves from India and watermelon seeds from Nigeria, and the current Regulation under discussion.

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Commission Regulation (EU) No 211/2013 on certification requirements for imports of sprouts and seeds intended for the production of sprouts

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Commission Regulation (EU) No 211/2013 comes as a response to the outbreak of Shiga toxin-producing E.coli (STEC) in May 2011, for which the consumption of sprouted seeds was identified as the origin of the outbreaks<sup>[88]</sup>. In EFSA's opinion in October 2011, EFSA concludes that the contamination of dry seeds with bacterial pathogens is the most likely initial source of sprout-associated outbreaks<sup>[88]</sup>. In addition, *“In order to ensure an adequate level of protection of public health, it is appropriate that sprouts and seeds intended for the production of sprouts imported into the Union also comply with the requirements laid down in Regulation (EC) No 852/2004, and, for sprouts, with the traceability requirements laid down in Implementing Regulation (EU) No 208/2013 and with the microbiological criteria laid down in Commission Regulation (EC) No 2073/2005”*<sup>[88]</sup>.

To conclude, the present Regulation is the harmonization of the above cited Regulations with measures for official controls on imported sprouts and seeds intended for sprouting.

According to Commission Regulation (EU) No 211/2013, in the event of the import into the Union of sprouts and seeds intended for sprouting, that have not undergone treatment for the elimination of microbiological hazards, the consignments must hold a Certificate in accordance with the model set out



in the Annex of the present Regulation, attesting that the sprouts or seeds were produced under conditions complying with provisions and microbiological criteria set out by Union legislation (Regulation (EC) No 852/2004 on hygiene of foodstuffs), in establishments approved in accordance with requirements laid down by the Union.[Article 1 and Article 3(1)]<sup>[81]</sup>.

Given that there is no CN code assigned to sprouts, a list of codes that could indicate the presence of sprouts or seeds for the production of sprouts, was created and is used as reference in controls. Please see the table below with the list of codes.

Table 1. List of CN codes that could indicate the presence of sprouts or seeds intended for the production of sprouts.

CN Code Class	Full CN Code	CN Code Class	Full CN Code
0704	0704 90 00	1201	1201 00 00
0706	0706 90 00	1207	1207 50 00 1207 99 00
0708	0708 00 00	1209	1209 10 00 1209 21 00 1209 91 00
0713	0713 10 00 0713 33 00 0713 34 00 0713 35 00 0713 39 00 0713 40 00 0713 50 00 0713 60 00 0713 90 00	1214	1214 90 00
0910	0910 99 10 0910 99 33 0910 99 91		

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**Commission Implementing Regulation (EU) No 2015/943 on emergency measures suspending imports of dried beans from Nigeria and amending Annex I to Regulation (EC) No 669/2009**

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Amended by Commission Implementing Regulation (EU) No 2016/874, it applies to all dried beans originating from Nigeria under CN codes 0713 35 00, 0713 39 00 and 0713 90 00 [Article 1] <sup>[79], [83]</sup>

*“...any consignments carrying such a commodity shall be prohibited entry into the Union (Article 2) at least until the 30th of June 2019, when this measure shall be revised and amended if necessary”*<sup>[83]</sup>

It was created as a response to a high frequency of non-compliance with food law requirements as regards pesticide residues, of dried beans from Nigeria under measures set in Regulation (EC) No 669/2009, which have been in force since the 1<sup>st</sup> of July 2013<sup>[79]</sup>.

In terms of import analysis in this study, for the year 2014 and up until the 20<sup>th</sup> of June 2015, any consignments from Nigeria containing dried beans would have been subjected to increased level of

official controls under Regulation (EC) No 669/2009; from the 20<sup>th</sup> of June 2015, consignments would have been rejected at border control points, not requiring any border control inspections<sup>(71, 79)</sup>.

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Commission Implementing Regulation (EU) No 2016/166 on conditions for the import of foodstuffs containing or consisting of betel leaves from India and repealed by Commission Implementing Regulation (EU) No 2017/186

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Regulation (EU) No 2016/166 was published because consignments carrying betel leaves originating in, or consigned from India, and subjected to re-enforced controls under Regulation (EC) No 669/2009 showed a consistently high frequency of non-compliances with microbiological criteria for foodstuffs, specifically pertaining to the presence of various Salmonella strains<sup>(81)</sup>. Given the high number of non-conformities and the lack of assurances on behalf of the Indian authorities, the Community has places additional measures in order to ensure public health safety<sup>(82)</sup>.

This Regulation applies to the period of analysis between the 1<sup>st</sup> of January 2016 and the 31<sup>st</sup> of January 2017, as it was then repealed and replaced by Commission Implementing Regulation (EU) No 2017/186 laying down specific conditions applicable to the introduction into the Union of consignments from certain third countries due to microbiological contamination and amending Regulation (EC) No 669/2009<sup>(84)</sup>.

Commission Implementing Regulation (EU) No 2016/166 applies to consignments of foodstuffs containing or consisting of, betel leaves ('Piper betle L.') including those declared under CN Codes 1404 90 00, originating in, or consigned from India [Article 1(1)]<sup>(82)</sup>. It does not apply to consignments intended for private persons for private use or consumption [Article 1(2)]<sup>(82)</sup>.

Consignments that contain betel leaves, shall be accompanied by the results of sampling and analysis performed by the Competent Authorities of India, to ascertain compliance with Union legislation on microbiological criteria of Salmonella [Article 4(1)], as well as, a Health Certificate in accordance with the model set out in Annex II of the present Regulation, that shall be completed, signed and verified by an authorized representative of the Competent Authority of India [Article 5(1)(2)]<sup>(82)</sup>.

With regards to official controls at import by Competent Authorities at the DPEs, the frequency of documentary checks shall be 100%, whereas that of physical and identity checks will be 10%<sup>(82)</sup>.

In 2014 and 2015, increased level of controls for betel leaves from India were found under measures set in Commission Regulation (EC) No 669/2009, therefore for the analysis of imports during those two years was done under consultation of the afore mentioned Regulation<sup>(71)</sup>.

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Commission Implementing Regulation (EU) No 2016/6 on the import of feed and food originating in, or consigned from, Japan following the accident of Fukushima nuclear power station and amended by Commission Implementing Regulation (EU) No 2017/2058

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Following the accident at the Fukushima nuclear power station on the 21<sup>st</sup> of March 2011, certain foodstuffs imported into the Union contained radionuclide levels that exceeded the action levels in force at the time, in food in Japan, presenting a serious risk to public health safety<sup>[81]</sup>. For this reason, the Union adopted and replaced several Commission Implementing Regulations: Implementing Regulation (EU) No 297/2011, No 961/2011, No 284/2012, No 996/2012 and No 322/2014. This last Regulation was repealed and replaced by the current Regulation under analysis.

With regard to Implementing Regulation (EU) No 2016/6, pre-amendment by Implementing Regulation (EU) No 2017/2058, it applies to feed and food, including minor food, originating in, or consigned from Japan, with the exclusion of (within the scope of this work): a) products that have been harvested and/or processed before 11th March 2011 and; b) personal consignments of feed and food other than of animal origin, which are non-commercial and destined to an individual for personal consumption and use, only [Article 1]<sup>[81]</sup>.

Products shall comply with the maximum level for the sum of caesium-134 and caesium-137 as set out in Annex I of this Regulation [Article 4]<sup>[81]</sup>.

Each consignment of feed and food referred to and falling under the CN codes listed in Annex II, and the compound feed and food containing more than 50% of these feed and food, originating in, or consigned from Japan, with the exception of scallops, shall be accompanied by a valid original declaration drawn up and signed in accordance with the model set out in Annex III of the present Regulation [Article 5(1), Article 6(1)]<sup>[81]</sup>.

Note the following:

- If the product has been harvested and/or processed before 11th March 2011;
- If the product does not originate in, and is not consigned from one the prefectures listed in Annex II;
- If the product is consigned from, but does not originate in, one of the prefectures listed in Annex II (sampling and analysis required; no exposure to radioactivity during transit or process).

The declaration shall be signed by an authorised representative of the Competent Japanese Authority, or by an authorised of an instance authorised by the Competent Japanese Authority, alongside supervision of the Competent Japanese Authority [Article 5(3), Article 6(2)]<sup>[81]</sup>.

Also:

- If the product originates in one the prefectures listed in Annex II for which an analytical report with results from sampling is required;

- If the origin of the product or of its ingredients at more than 50% is unknown (some requirements as above).

The declaration shall be signed by an authorised representative of the Competent Authority [Article 5(3), Article 6(3)]<sup>[81]</sup>.

With regards to Official controls at DPEs, documentary checks will be performed at 100%, and physical (including analytical controls) and identity checks will be carried out at a random frequency [Article 10(1)]<sup>[81]</sup>.

If a consignment is found to be non-compliant, it will be safely disposed of, or returned to Japan.

With the amendment by Commission Implementing Regulation (EU) No 2017/ 2058 of the 10<sup>th</sup> of November 2017, that came into force on the 30<sup>th</sup> of November, the following changes were made to Regulation (EU) No 2016/6: 1) There is no longer a requirement of sampling and analysing before export to the Union, of rice and products thereof; 2) For the prefectures of Gunma, Ibaraki, Tochigi, Iwate and Chiba it is no longer required to sample and analyse some of the feed and food commodities, before export into the Union; 3) It is no longer required to analyse feed and food originating in the prefecture of Akita, and it is appropriate to no longer required sampling and analysis for some of the edible wild plants from the prefectures of Yamagata and Nagano, before export into the Union<sup>[80]</sup>.

The analysis performed on consignments arriving during 2016 and 2017 take into consideration the measures in the Regulation, pre- and post-amendment. The analysis of consignments imported during 2014 and 2015 were done consulting Commission Implementing Regulation (EU) No 996/2012 applied until 31<sup>st</sup> March 2014 and Commission Implementing Regulation (EU) No 322/2014 of 28<sup>th</sup> March 2014<sup>[89]</sup>.

<sup>[93]</sup>.

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Commission Implementing Decision No 2011/884/EU on GMO rice products originating or consigned from China and repealing Decision 2008/289/EC

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According to Regulation (EC) No 1829/2003 on genetically modified food and feed, no genetically modified food or feed is to be placed on the Union market, unless authorisation is granted, in accordance with that Regulation<sup>[20]</sup>. Given that, since 2006, there have been identified in the Union market, genetically modified rice from China, which have resulted in the generation of RASFF notifications, and the lack of sufficient guarantees from Chinese Competent Authorities that rice products originating or consigned from China do not have Bt 63, Decision 2008/289/EC was implemented, and later repealed and replaced by Decision (EU) No 2011/884 due to the identification of several other rice varieties carrying unauthorised genetic elements encoding insect resistance that led to numerous RASFF notifications and therefore there was a requirement for the enhancement of measures provided by

Decision 2008/289/EC to include all genetically modified organisms found in rice, to ensure that no contaminated product is placed on the Union market [120].

Under Decision 2011/884/EU, each consignment of products listed in Annex I of the Decision, that have originated in, or consigned from China, must be accompanied by an analytical report for each lot that makes up the consignment in question, as well as, a Health Certificate in accordance with the models provided by the same legislative document, that shall be signed by the Competent Authority 'Entry Exit Inspection and Quarantine Bureau of the People's Republic of China' (AQSIQ) [Article 4(1)]<sup>[20]</sup>

In the event of there being a consignment whose CN code figures in Annex I, but does not contain, consist of, or produced from rice, there is no need for an analytical report or Health Certificate. Instead, the consignor, shall include a declaration where it is clearly stated that the products consigned do not contain, consist of, or are produced from rice. [Article 4(2)]<sup>[20]</sup>

Regarding official controls at the DPE, the Competent Authority shall perform documentary checks on all consignments for the products referred to in Article I, whether or not the food or feed contains, consists of, or is produced from rice [Article 5(1)]<sup>[20]</sup>. Consignments that must, but do not hold Health Certificates and Analytical Reports, shall be re-dispatched to the country of origin or destroyed [Article 5 (2)]<sup>[20]</sup>.

For every conforming consignment, the Competent Authority shall submit a sample of analysis of every lot that makes up the consignment, to test presence of unauthorised GMOs [Article 5(3)]<sup>[20]</sup>.

Only this diploma was consulted for the analysis of the four years.

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Commission Implementing Decision No 2014/88/EU suspending temporarily imports from Bangladesh of foodstuffs containing or consisting of betel leaves ('Piper betle')

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Commission Implementing Decision (EU) No 2014/88 of the 13<sup>th</sup> February 2014 was implemented because a significantly large number of RASFF notifications due to the presence of a wide range of pathogenic salmonella strains were found in foodstuffs containing or consisting of betel leaves, as well as, weaknesses and flaws identified in the programme implemented by Bangladesh for the export of pathogen-free betel leaves<sup>[21]</sup>.

Commission Implementing Decision (EU) No 2014/88 is applicable to foodstuffs containing or consisting of betel leaves ('Piper betle') including, but not limited to, those declared under CN Codes 1404 90 00, originating in, or consigned from, Bangladesh, and it states that the import of such foodstuffs into the Union shall be prohibited until the 31<sup>st</sup> of July 2014. (Article 1, Article 2, Article 4)<sup>[21]</sup>.

This Decision was amended by Commission Implementing Decision (EU) No 2016/884, extending its date of enforcement to the 30<sup>th</sup> of June 2018<sup>[23]</sup>.

# National Control Plan for the import of FNAO

## *Matrix of Analytical Control*

According to Regulation (EC) No 882/2004 each Member State is responsible for creating and implementing a programme for official controls on commodities not subject to safety measures, re-enforced control checks or other recommendations set by the Commission<sup>(72)</sup>.

In Portugal, the control plan for border checks includes the Matrix of Analytical Control, renewed every year as it is based on a risk analysis of imports from previous years, that covers food of non-animal origin, and that applies to both commodities with a known frequency of non-conformities and commodities that are imported frequently and/ or in large quantities for which there is an interest in subjecting them to official controls<sup>(34)</sup>. It applies to particular commodities, which do not need to originate in, or be consigned from, any particular country.

As a general rule, for each consignment carrying a CN code listed in the Matrix, the minimum analytical control requirement is set at 5% per annum, although DGAV ask Competent Authorities responsible for carrying out such checks (DRAPs/ DRA), to achieve this target quarterly (every three months), to ensure that the minimum frequency is achieved<sup>(34)</sup>.

The exception to this rule applies to consignments that are perishable (fresh fruit and vegetables) and are imported by air, for which the analytical control is reduced to 2.5% per annum<sup>(34)</sup>. With regards to identity controls and overall physical controls (with or without sampling for analysis) the minimum frequency is 10%, and as seen with all Community measures, documentary checks are performed at 100% frequency<sup>(34)</sup>.

This study only analysed imports carrying commodities listed in the 2016 and 2017 Matrices, so no comments are provided for 2014 and 2015.

## Chapter 4 Results and Discussion

### Overview of imports to Portugal from 2014 to 2017

The evolution of imports of FNAO to Portugal from 2014 to 2017 is depicted in the figure below:

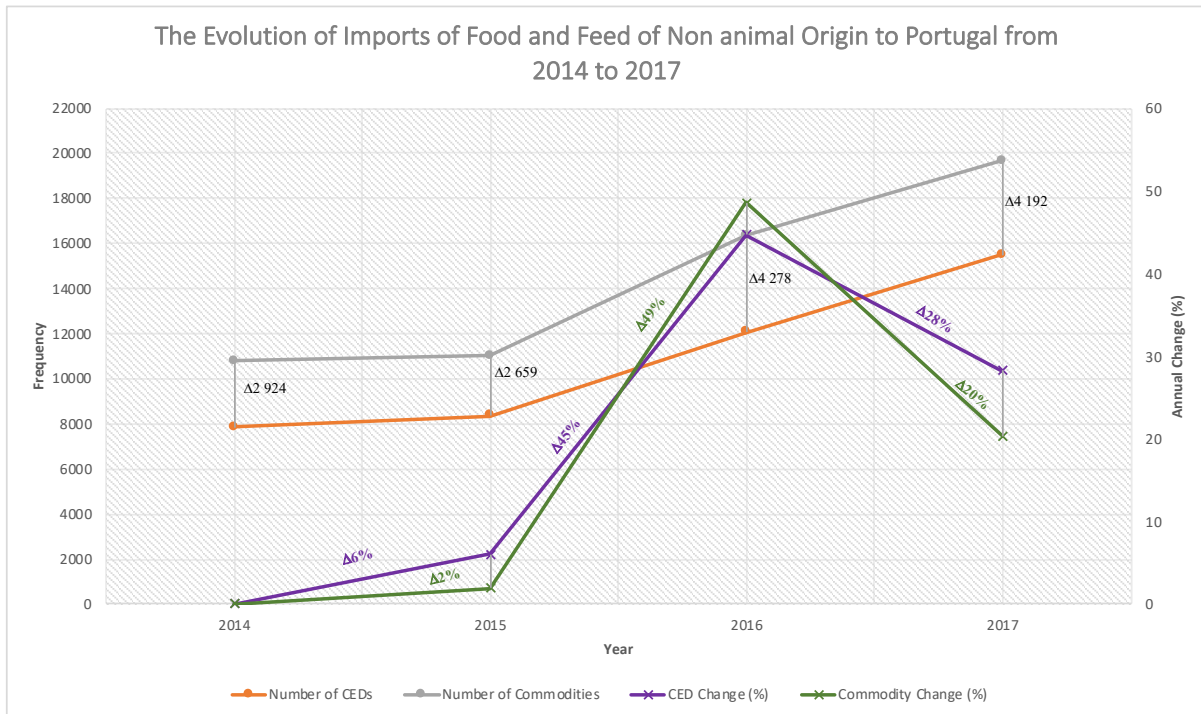


Figure 2. Evolution of imported consignments and commodities over the period of four years and the percentage change between years.

In 2014, the total number of consignments reaching Portuguese PEs was 7 873 carrying 10 797 products of non-animal origin. In 2015, those figures rose to 8 347 consignments with 11 006 products. By the end of 2016 there had been an increase in 3 727 consignments (for a total of 12 074 CEDs) and 5 346 products (for a total of 16 352 products). Finally, by the end of 2017, the number of CEDs that had reached Portugal that year had increased to 15 485 and the number of products imported had risen to 19 677. The largest difference in imports of FNAO took place from 2015 to 2016, with a 45% increase in number of CEDs (49% increase in number of commodities). The increase from 2016 to 2017, although not as marked, is still significant given that there were 28% more CEDs and 20% more commodities, with regards to the previous year.

Overall, between 2014 and 2017 a total of 43 779 CEDs carrying 57 832 commodities reached Portuguese PEs. Over 60% of these totals were from the latter two years being analysed (2016 and 2017). This marked increase in imports from 2015 to 2016 is thought to be due to the gradual implementation of the use of TRACES by business operators (as Portugal started using TRACES for FNAO in 2014) and also the ability to list a higher number of commodities in the system (TRACES began with an incomplete list of CN Codes).

The commodity category that had the highest number of consignments imported was ‘Edible fruits and nuts’. Below is a figure showing the evolution of imports of consignments for each commodity category over the period of four years analysed (Figure 3).

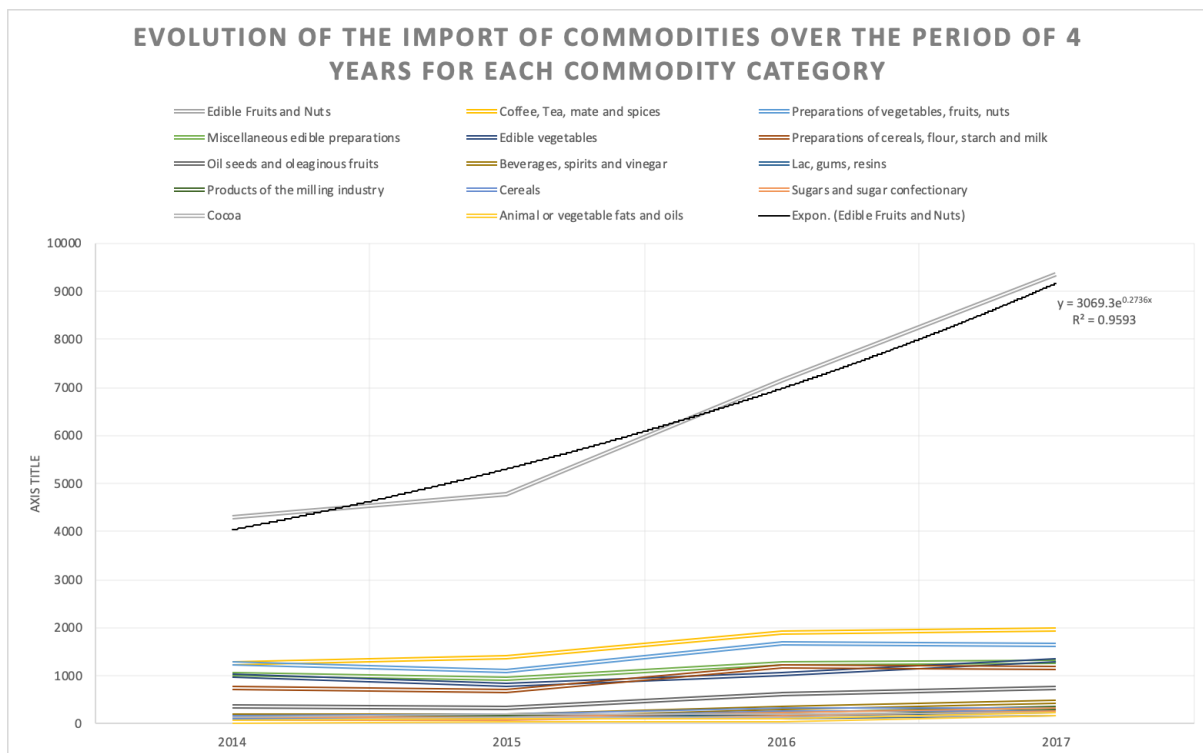


Figure 3. Evolution of imported commodities over the period of four years for each commodity category.

The grey line is for the commodity category of ‘Edible fruits and nuts’ and it is clear to see that there is both a significant difference between the number of imports for this category and all the other categories, as well as, the difference in pattern of increase, where most categories show a small increase, whereas the category ‘Edible fruits and nuts’ appears to grow at an exponential rate ( $R^2 = 0.9593$ ). However, due to the limited number of years analysed for this commodity category, as well as the fact that it relates to commodities that are seasonal and perishable, it is not possible to predict with any degree of confidence, future volume of imports for this category.

The above pattern can be magnified at an EU level, where imports of fresh fruit and vegetables surpass those for other commodity categories; in fact the trade balance (imports versus exports) is negative for both, but with a marked difference for fruits where the EU depends mostly on imports for bananas and other tropical fruits that it cannot produce<sup>[58]</sup>. In fact, in terms of yearly growth, fruits have a 6% annual growth whereas vegetables only increase in about 1% year-on-year<sup>[5]</sup>. In terms of volume of imports from 3<sup>rd</sup> countries, the leading imported commodity is bananas and plantains, followed by oranges and pineapples<sup>[5]</sup>. The figure below (Figure 4) depicts the volume of imports into the EU between 2014 and 2017 for fruit and vegetables from 3<sup>rd</sup> countries and from intra-EU trade (for which Spain, the Netherlands and Italy are the most important origins) resulting in a shift of the contribution of certain commodities that are largely produced in the EU (ex. apples, grapes and watermelons)<sup>[58]</sup>.



IMPORTS				
VOLUME ('000 tonnes)				
FRESH FRUIT	2014	2015	2016	2017p
Bananas	7,805	8,133	8,466	9,300
Oranges	2,679	2,936	2,938	2,800
Apples, fresh market	2,507	2,906	2,530	2,530
Easy Peelers	2,048	2,112	2,181	2,000
Table Grapes	1,525	1,554	1,564	1,690
Watermelons	1,218	1,387	1,535	1,660
Pineapples	1,406	1,231	1,304	1,390
Lemons	943	1,088	1,168	1,260
Pears	1,109	1,109	1,099	1,090
Other	6,646	7,286	7,553	8,080
<b>TOTAL</b>	<b>27,886</b>	<b>29,743</b>	<b>30,339</b>	<b>31,800</b>
FRESH VEGETABLES	2014	2015	2016	2017p
Tomatoes	3,072	3,182	3,047	3,020
Onions	1,493	1,419	1,478	1,400
Peppers	1,339	1,352	1,348	1,360
Lettuce	1,271	1,305	1,314	1,370
Cucumbers	1,252	1,306	1,301	1,290
Carrots	972	1,096	1,113	1,060
Cauliflower	538	531	520	590
Courgettes	405	389	454	440
Mushrooms	409	435	418	410
Other	3,314	3,331	3,491	3,690
<b>TOTAL</b>	<b>14,064</b>	<b>14,346</b>	<b>14,485</b>	<b>14,630</b>

Figure 4. Imports of fresh fruit and vegetables for the EU between 2014 and 2017 in thousand tonnes<sup>[58]</sup>.

Despite Portugal barely receiving imports of tomatoes during the years analysed, this commodity is the main vegetable imported by the EU from 3<sup>rd</sup> countries<sup>[5]</sup>.

With regards to trade into Portugal, in terms of countries of origin, during the whole period studied, Brazil, China and the United States were the highest contributors, with 2 844, 1 575 and 1 074 exported commodities, respectively. Brazil exported mostly within four categories ('Edible fruits and nuts', 'Coffee, tea, mate and spices', 'Preparations of cereals, flour, starch or milk' and 'Preparations of vegetables, fruit, nuts') whereas

both China and the US exported for several commodity categories but in fewer quantities in each. Nonetheless, in terms of value, the US was the highest contributor due to the nature of commodities exported (food supplements and groundnuts).

Other countries that exported in high volumes throughout the four years were: South Africa (Edible fruits and nuts), Colombia (Edible fruits and nuts), Costa Rica (Edible fruits and nuts), Chile (Edible fruits and nuts) and Viet Nam (Coffee, tea, mate and spices).

At an EU level, in terms of fruits, the main sources were Costa Rica, Colombia, Ecuador and South Africa<sup>[58]</sup>. The highest exporters of vegetables were Morocco, Israel and Egypt<sup>[58]</sup>.

In terms of controls, the table below provides a breakdown of the type and frequency of controls performed over the four years (Table 2):

Table 2. Number and type of official controls performed by DRAP/ DRA from 2014 to 2017 at BIPs.

CONTROL	2014	2015	2016	2017	TOTAL
<b>IDENTITY</b>	883 (8 Not Satisfactory)	1 037 (4 Not Satisfactory)	2 740 (4 Not Satisfactory)	4 397 (1 Not Satisfactory)	<b>9 057</b>
<b>PHYSICAL (TOTAL)</b>	861 (15 Not Satisfactory)	998 (7 Not Satisfactory)	2 464 (8 Not Satisfactory)	3 815 (17 Not Satisfactory)	<b>8 138</b>
<b>ANALYTICAL SAMPLING</b>	173 (4 Not Satisfactory)	303 (12 Not Satisfactory)	404 (6 Not Satisfactory)	934 (19 Not Satisfactory)	<b>1 814</b>

In 2014, identity and physical checks were performed on 11% of the total number of consignments imported, and analytical sampling on 2%. Those frequency percentages of controls increased substantially three years later, reaching in 2017, 28% of the total number of imports subjected to identity checks, 25% were subjected to physical checks and 6% to analytical sampling for laboratory tests. This increase in frequency of controls in spite of the increase in the number of imports could indicate an

improvement on the efficiency of competent authorities in carrying out official controls, but could also be a product of a better use of TRACES.

Most of the consignments arriving at Portuguese borders were imported by Portuguese food business operators; 15% - 20% crossed the border to Spain and few commodities went on to other countries of the European Union (334 commodities to France, 284 to Italy, 519 to the Netherlands, 15 to the UK, 32 to Germany and 3 to Austria), Switzerland, a member of the Schengen border-free area, imported 1 consignment.

# Imports under specific Community and National measures

## *Official Food Regulation [Regulation (EC) No 882/2004]*

### Matrix of Analytical Control

Before presenting and discussing this section of the work, it is necessary to point out that some commodities listed in the Matrix are also listed in Community measures, for which only the Community official controls are enforced (for example, peanuts are listed in the Matrix; if a consignment carrying peanuts from China arrives at a DPE/DPI, it will be subjected to controls under Reg. (EU) No 884/2014 and not the Matrix).

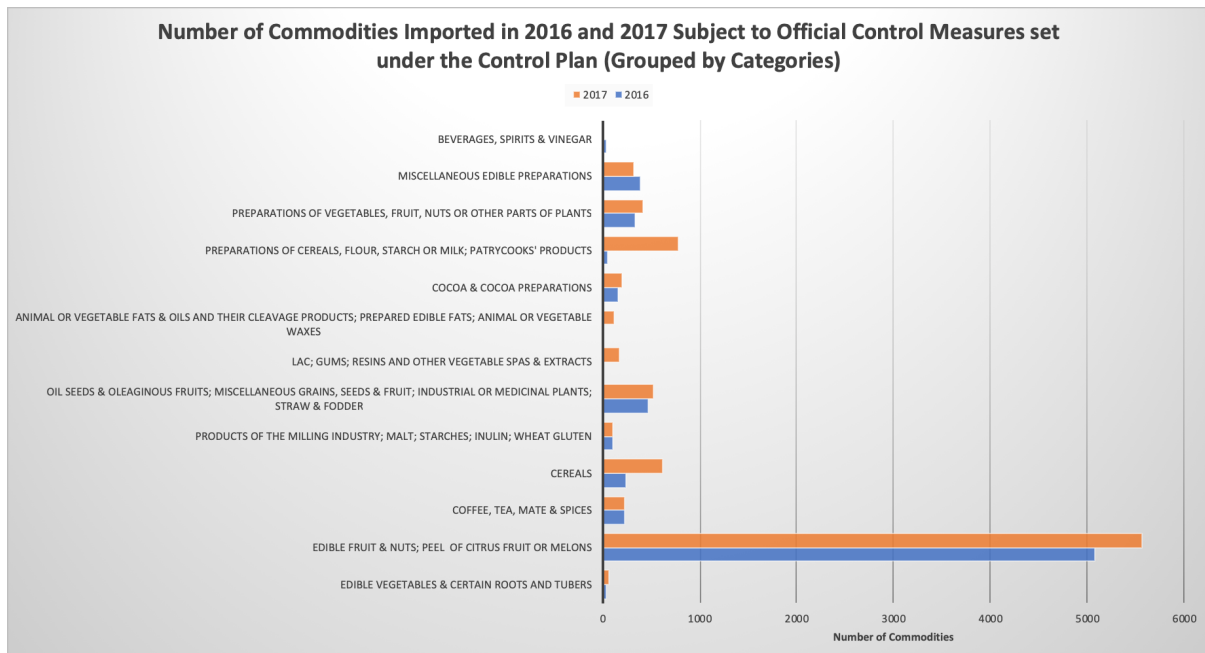


Figure 5. Number of commodities imported in 2016 and 2017 listed in the Matrices of 2016 and 2017.

In 2016, 7 076 commodities were imported, and in 2017 the number of imports rose to 8 852, totaling over the course of two years, 15 928 imported commodities listed for official controls under Matrix of Analytical Control (an overestimation of the numbers actually subjected to controls due to commodities that fall under Community measures). Over 85% of these commodities were imported by Portuguese food business operators, with the remaining 15% carrying on journey to other countries of the Union (Spain, France, Italy, the Netherlands, the UK and Germany) and Switzerland.

Figure 5 shows the number of commodities imported in both 2016 and 2017, grouped by categories, that were imported to Portuguese PEs. The great majority of commodities belong to the category of 'Edible fruits and nuts' (around 70% of imports). Other categories with high numbers of imports that together account to 17% are 'Oil seeds and oleaginous fruits', 'Preparations of vegetables, fruits, nuts' and 'Miscellaneous edible preparations'.

With regards to the countries of origin, and supported by the doughnut chart below (figure 6), Brazil was the country that exported the highest number of commodities subjected to official controls, principally with fresh papayas and mangoes (mangoes was in both 2016 and 2017, the second highest fresh fruit exported from the country, preceded only by melons). Other countries exporting large quantities of commodities listed in the Matrix were: South Africa with fresh sweet oranges, lemons and pears; Chile with table grapes and apples; China with groundnuts (subject to emergency measures under Reg. (EU) No 884/2014), the US with food supplements and groundnuts, and specifically in 2017, there was a high registered import from Costa Rica, for bananas and apples.

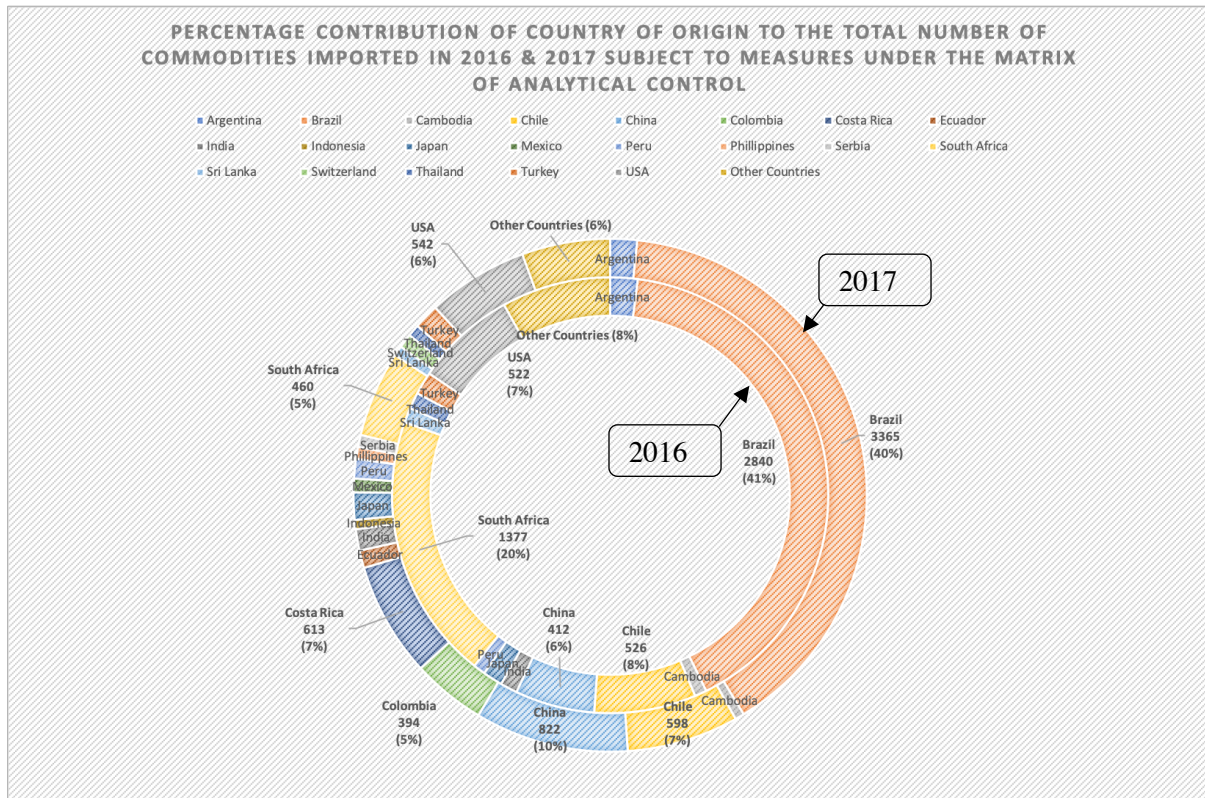


Figure 6. Number of imported commodities listed in the Matrices of 2016 and 2017, expressed as percentages by importing country.

In terms of rejections, in 2016 there were 17 rejected commodities, that accounted for less than 1% of the total number of commodities listed for controls that year. In 2017, the number of rejections was 31 (0.4% of the total number of commodities), which represents an increase of 82% of rejections from one year to the following, but still negligible compared to the total number of imports subjected to controls. In terms of frequency of official controls, there were 28 commodity categories in 2016 that fell short of the minimum requirements (10% frequency controls for identity and physical checks without sampling, and 5% of analytical sampling for laboratory analysis). In 2017, the number fell to 23 commodity categories. In this paper, only those controls that fell below 8% and 3%, inclusive, were considered and the details for control insufficiencies can be seen in the table below:

Table 3. List of commodities not subjected to minimum frequency requirements set under the National Control plan.

Commodity description	Number of Commodities	Official Control Insufficiency
<b>Common to both 2016 and 2017</b>		
<b>Coffee, roasted, whole of ground, decaffeinated</b>	10 (year 2016) 10 (year 2017)	AC (0%)
<b>2016</b>		
<b>Coffee, not roasted, not Decaff</b>	43	AC (0%)
<b>Other green tea, not fermented</b>	9	All (0%)
<b>Aromatic plants or herbs, including supplements, fresh</b>	12	Phys (8%) AC (0%)
<b>Seaweeds and other algae fit for human consumption</b>	62	AC (3%)
<b>Cocoa butter, fat and oil</b>	7	All (0%)
<b>Prepared foods obtained by the swelling and roasting of cereals or cereal products obtained from corn (maize)</b>	9	All (0%)
<b>Prepared foods obtained from unroasted cereal flakes or from mixtures of unroasted cereal flakes and roasted cereal flakes or swelled cereals obtained from corn (maize)</b>	8	AC (0%)
<b>Peanuts, whether or not mixed with other seeds or nuts</b>	18	AC (0%)
<b>Soya derivatives and food supplements not elsewhere specified</b>	41	AC (2%)
<b>Food supplements not containing products of headings 0401 to 0404 or fat obtained from products under headings 0401 to 0404</b>	35	ID (6%) Phys (6%)
<b>2017</b>		
<b>Mushrooms of the genus Agaricus, dried</b>	6	AC (0%)
<b>Coffee, roasted, whole or ground, not Decaff</b>	45	AC (2%)
<b>Wheat and meslin</b>	10	Phys (0%) AC (0%)

<b>Vegetable extracts, dried or powdered</b>	174	ID (6%) Phys (6%)
<b>Olive oil and its fractions, whether or not refined, but not chemically modified</b>	10	AC (0%)
<b>Virgin olive oil</b>	54	AC (2%)
<b>Sunflower seed, safflower or cotton seed oil and their fractions, for human consumption</b>	13	ID (8%) Phys (8%) AC (0%)
<b>Cocoa paste, whether or not Defatted</b>	25	ID (4%) Phys (4%) AC (0%)
<b>Fruit juices including nectar juices, concentrated or reconstituted</b>	296	AC (0%)

Those commodities that originate from particular countries, that come listed under Community measures, are insufficiencies of controls under Community legislation, as is the case with most of the peanuts being imported, originating in China. The other commodity that was not controlled enough, but, over the four periods analysed, resulted in several RASFF notifications was food supplements (whether or not containing or derived from soya).

Insufficiencies of official controls occur for several reasons, namely: scarce human resources for carrying out official controls (the same competent authorities carry out other official activities); lack of the necessary tools to adequately identify commodities subject to official controls and; a high influx of consignments in a single day, which can be overwhelming with the limited number of inspectors available.

In addition to the shortcomings related to the Matrix, in 2017 DG SANTE performed an audit in Portugal with the objective of assessing the official controls related to the documentary checks and, where relevant, the evaluation of the organization of the import control system in place<sup>[50]</sup>. In its report, the audit team noted that several consignments subject to control measures were not notified prior to their physical arrival at the DPEs/DPIs and the competent authorities “...had not taken any measures to discourage the late pre-notifications of the consignments in the last two years.”<sup>[50]</sup>, thus breaching requirements set in Article 17(1) of Reg. (EC) No 882/2004, Article 6 of Reg (EC) No 669/2009, Article 7(2) of Reg. (EU) No 884/2014 and Article 3 of Decision 2011/884/EU <sup>[50]</sup> and therefore highlighting other sources of official control limitations, beyond insufficiency of controls.

The central Competent Authority, DSNA-DGAV, reacted to findings in the audit and responded to recommendations appropriately, rectifying these issues promptly. Furthermore, since 2016, DSNA-DGAV has elaborated a supervision plan to check for compliance of the official controls performed at the DPEs, that includes measures such as: validating quarterly reports on safeguard measures, verifying

automatic TRACES notifications and performing weekly random verification of CEDs validated by CA at the DPEs.<sup>150</sup>.

### *Increased Level of Official Controls*

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Commission Regulation (EC) No 669/2009 implementing Regulation (EC) No 882/2004 regarding the increased level of official controls on imports of certain feed and food of non-animal origin

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*Table 4. Number of commodities imported from 2014 to 2017 subject to increased level of official controls and the resulting rejections.*

<i>Year</i>	<i>2014</i>	<i>2015</i>	<i>2016</i>	<i>2017</i>
<i>Number of Commodities</i>	61*	46*	55	93
<i>Number of Rejections</i>	2	1	1	1

For the analysis of imports subject to increased level of official controls under Reg. (EC) No 669/2009, nine versions of the legal document were consulted for the first period, and eight versions were consulted for the second period. However, for the year of 2014 and 2015 it was not possible to verify the contents of all consignments, therefore the number of imports could indicate an overestimation of the actual imported commodities subject to safeguard measures.

In 2014, there were 61 consignments originating in Brazil, China, India and Peru carrying commodities listed in Annex I of this Regulation and therefore subject to increased level of official controls. Twenty-two identity checks (36%), 21 physical checks (34%) from which 14 analytical samples (23%) were collected were performed, resulting in two consignments rejected, originating in China and India due to contamination of commodities with pesticide residues in exceedance of the MRL. With regards to imports in 2015, there were a total of 46 that year, originating in Afghanistan, Australia, Brazil, China, Dominican Republic, India, Indonesia, Peru, Turkey and the US. A total of 26 identity and physical checks (57%) were performed, with collection of 15 analytical samples (33%) for laboratory analysis. Only one consignment was rejected (tea from China, pesticide residues above the set MRL).

In 2016, 55 commodities qualifying for increased level of official controls reached Portuguese DPEs, resulting in one rejection (fresh chillies from the Dominican Republic containing high levels of pesticide residues). The number for 2017 rose significantly to 93 imported commodities, but only one consignment was rejected (fresh chillies from the Dominican Republic exceeding the MRL for pesticide residues).



The number of imports subjected to increased level of official controls as well as the frequency of official controls performed, versus that which is required for that particular commodity, for 2016, can be seen in figure below (Figure 7):

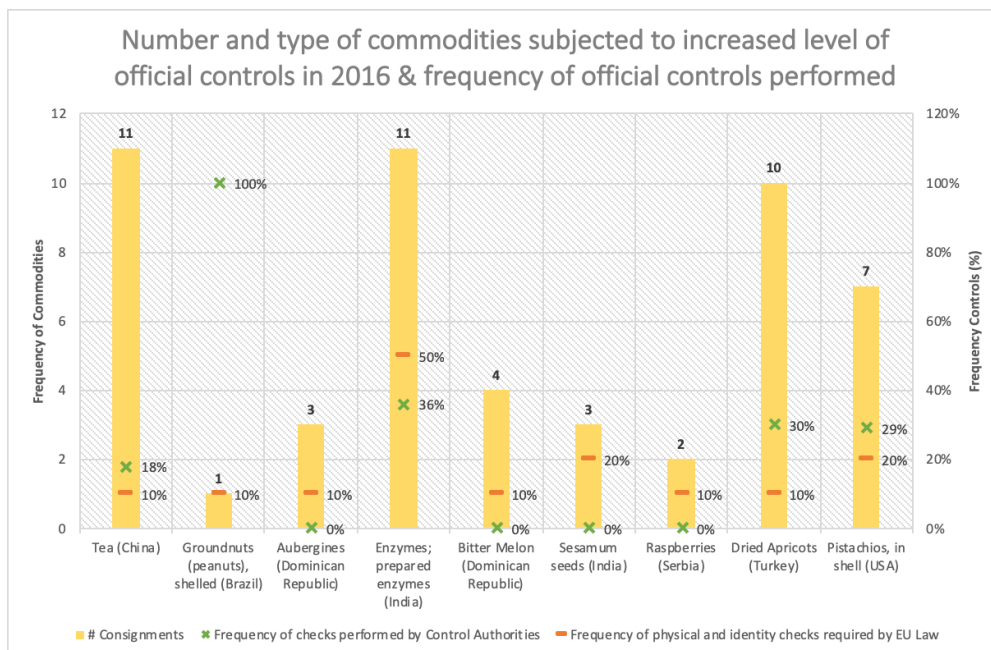


Figure 7. Commodities subjected to increased level of official controls in 2016 and the frequency of official controls performed versus the minimum frequency requirement set by the Regulation.

For most cases of official control insufficiency on behalf of the DRAP/DRA, the reasons were due to a small number of commodities entering the country during the year, which if not controlled at the first opportunity presented, then it becomes challenging to meet the control requirements. The only exception to this pattern was seen in 2016, when 11 consignments carrying enzymes originating from India, where not sampled enough times to meet the 50% minimum frequency established under Community Law.

Frequency of official controls in 2017 improved compared to 2016, but the cases where insufficiency of increased level of official controls were identified, the reasons were the same as in the previous year (Figure 8), possibly due to lack of human resources to carry out the task, or the lack of adequate tools to collect samples.



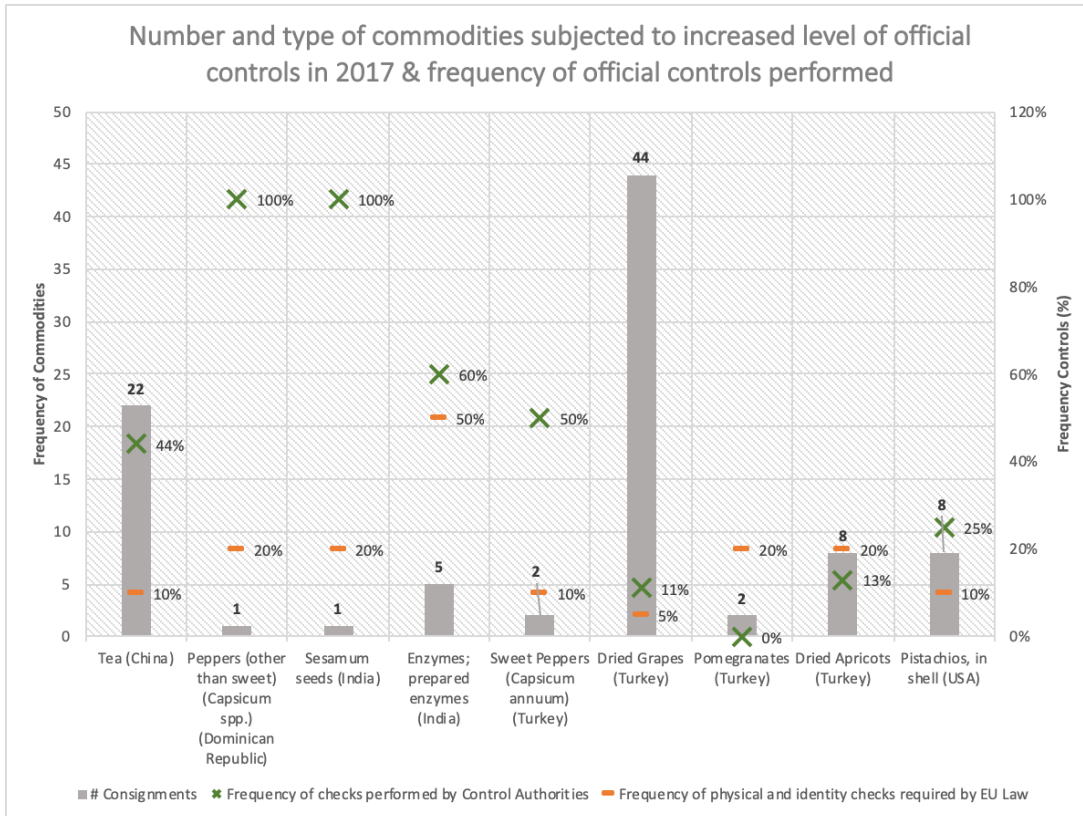


Figure 8. Commodities subjected to increased level of official controls in 2017 and the frequency of official controls performed versus the minimum frequency requirement set by the Regulation.

## Emergency Measures

Legislation applicable, and amendments thereof:

Table 5. List of Community legislation on emergency measures.

1. **Regulations (EC) No 884/2014** on the contamination risks by aflatoxins in certain feed and food from certain 3<sup>rd</sup> countries<sup>[91]</sup>
2. **Regulations (EC) No 885/2014** laying down specific conditions regarding the import of okra and curry leaves from India<sup>[92]</sup>
3. **Regulations (EU) No 2015/175** laying down special conditions applicable to the import of guar gum originating in, or consigned from, India<sup>[78]</sup>
4. **Regulations (EU) No 2016/6** imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima<sup>[81]</sup>
5. **Regulations (EU) 2015/943** suspending imports from Nigeria<sup>[79]</sup>
6. **Regulations (EU) No 211/2013** on certification requirements for imports into the Union of sprouts and seeds intended for the production of sprouts<sup>[88]</sup>
7. **Regulations (EU) No 2016/166** laying down specific conditions applicable to the import of foodstuffs containing or consisting of betel leaves from India [repealed and replaced by Reg. (EU) No 2017/186]
8. **Decision 2011/884/EU** on emergency measures regarding unauthorised genetically modified rice in rice products originating from China<sup>[20]</sup>
9. **Decision 2014/88/EU** suspending temporarily imports from Bangladesh of foodstuffs containing or consisting of betel leaves<sup>[21]</sup>

Regarding emergency measures, there were 952 consignments, over the four years, carrying commodities subject to official controls under Reg. (EC) No 884/2014, Reg. (EU) No 2016/6 and, for 2017 alone, Reg. (EU) No 2015/175 and Decision 2011/884/EU, the distribution of which, for each legal measure, can be seen in the table below (Table 6):

Table 6. Number of commodities imported from 2014 to 2017 subject to emergency measures of official border control checks.

LEGAL MEASURE	YEAR			
	2014	2015	2016	2017
REG. (EC) NO 884/2014 & REG. (EC) NO 1152/2009	59	85	247	397
REG. (EU) NO 2016/6, REG. (EU) NO 322/2014 & REG. (EU) NO 996/2012	21	28	54	31
REG. (EU) NO 2015/175	-	-	-	1
DECISION 2011/884/EU*	-	-	20	9

Results are going to be presented and discussed in order of the legal measures listed in the table.

Table 7 shows the commodities by country of origin subject to measures under Reg (EC) No 884/2014 that were imported in 2016 and 2017.

Table 7. Number of commodities imported in 2016 and 2017 subject to emergency measures set under Reg. (EC) No 884/2014

Commodity (Country of Origin)	2016	2017
	Number of Commodities	Number of Commodities
Groundnuts (peanuts), in shell (Brazil)	22	2
Groundnuts (peanuts), shelled (Brazil)	-	18
Groundnuts (peanuts), otherwise prepared or preserved (Brazil)	-	1
Groundnuts (peanuts), in shell (China)	180	234 (1 Rejection)
Groundnuts (peanuts), shelled (China)	10	93 (2 Rejections)
Peanut Butter (China)	2	5
Groundnuts (peanuts), otherwise prepared or preserved (China)	-	4
Groundnuts (peanuts), in shell (Egypt)	-	1
Peanut Butter (India)	-	1
Capsicum annum, crushed or ground (India)	7	-
Nutmeg (Myristica fragans) (India)	2	-
Pistachios, in shell (Iran)	3 (1 Rejection)	-
Pistachios, shelled (Iran)	-	1 (Rejected)
Hazelnuts (Corylus, sp.) shelled (Turkey)	3	10
Dried Figs (Turkey)	17	16

<b>Hazelnuts otherwise prepared or preserved, including mixtures (Turkey)</b>	1	8
<b>Pistachios, in shell (Turkey)</b>	-	2
<b>Pistachios, shelled (Turkey)</b>	-	1

In 2016, 247 consignments reached Portuguese DPE/DPIs subject to emergency measures of official controls. Of this total there was one rejection (pistachios in shell from Iran).

In 2017 there were 397 consignment reaching Portuguese DPE/DPIs, of which four were found to be non-compliant and rejected upon border control checks (shelled groundnuts from China, groundnuts in shell also from China and shelled pistachios from Iran). A further consignment, dried figs from Turkey, was recalled due to the presence of aflatoxins exceeding the set MRL.

With regards to the first period under analysis, and having consulted the Annex in Regulation (EC) No 1152/2009<sup>(73)</sup> for the period until 13<sup>th</sup> of August 2014, there were in both years, a total 144 consignments reaching Portugal subject to emergency measures of official controls due to a high risk of mycotoxin contamination in the commodities. The consignments originated in China, India, Turkey and the US. In total, there were 5 rejections due to aflatoxin contaminations: 1 consignment carrying stemless red chillies from India in 2014, and 4 consignments carrying groundnuts in shell from China in 2015. Comparing all four years, there has not been, with the exception of 2016, much change in the number of rejections due to aflatoxin contamination.

With regards to sufficiency of official controls and according to the Regulation, frequency of analytical controls must match that set for identity and physical controls, and therefore, the number of analytical controls should correspond to the number of identity controls if it is to meet the requirements (i.e. ID checks=Phys checks=AC sampling): *“The competent authority at the DPI shall carry out an identity check and a physical check by taking a sample for analysis of aflatoxin B1 for feed or aflatoxin B1 and total aflatoxin contamination for food on certain consignments at a frequency set out in Annex I to this Regulation...”* [Article 9 (5)]<sup>(9)</sup>. Therefore, compliance with the Regulation is only the case when these conditions are met. Below is a figure (Figure 9) that shows the frequency of checks required by the Regulation (line) and the frequency of controls carried out by Portuguese DPEs/ DPIs (bars).

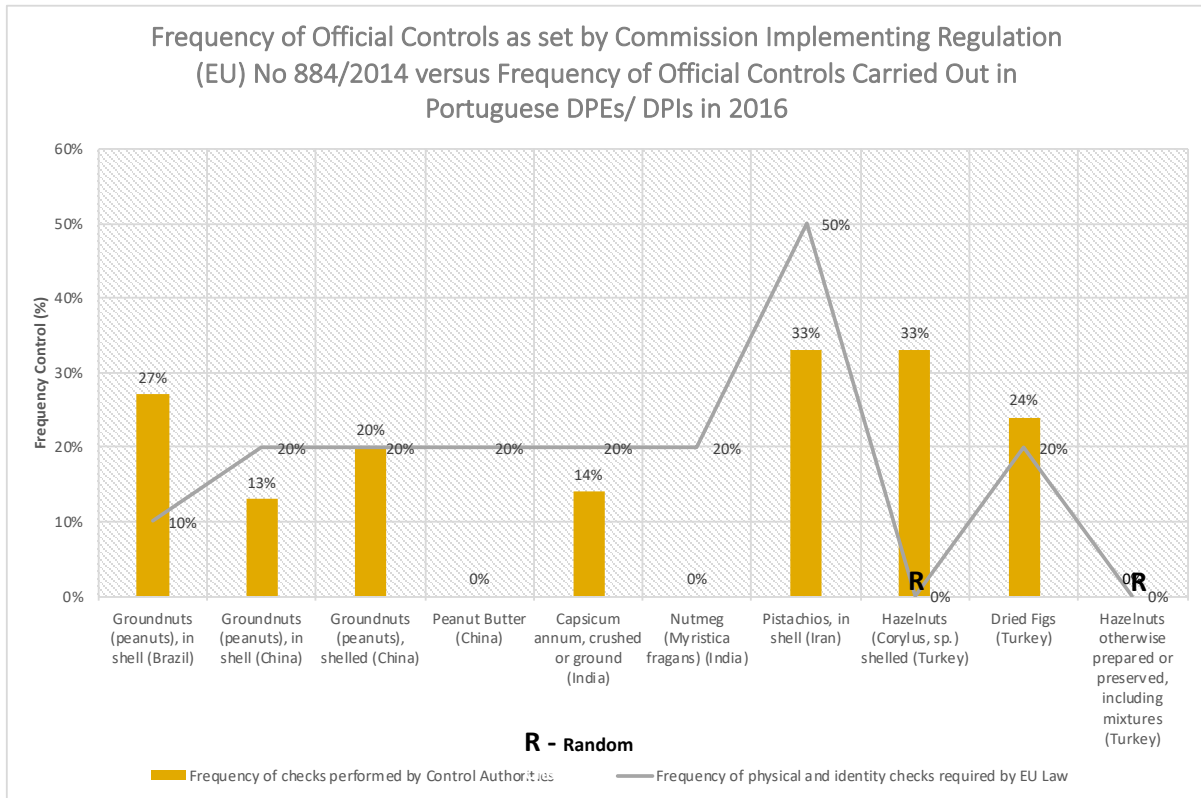


Figure 9. Frequency of official controls performed on commodities subject to control measures under Regulation (EC) No 884/2014 in 2016.

It is clear to see that there are quite a few consignments that were not controlled to the minimum frequency required by Community Law. There were 180 consignments carrying peanuts originating in China, of these, 31 were subjected to identity checks but only 24 were subjected to physical checks with sampling for analysis. Given that a control is only compliant with requirements when it has performed both identity and physical checks, with sampling, the lowest number of checks performed, is the one used to calculate the frequency of control checks (shown in the figure). In this case, it was the number of analytical sampling, 24, which lead to the frequency percentage of 13% falling short of the minimum requirement of 20%. An insufficient number of analytical sampling is also the cause of a low frequency percentage for the pistachios in shell originating in Iran. The audit performed by DG SANTE in 2017 stated that the DPE that physically received two consignments from India carrying peppers, allowed free circulation despite the absence of the required Health Certificates, and for one the consignments, the analytical report was not available (breaches under Articles 4, 5 and 9(3) of the Regulation). The competent authority's response to the draft report of the audit was that, during the audit, DRAP LVT in conjunction with the Directorate for Nutrition, Food and Feed (DSNA), sent several instructions to alert the technicians of the point of entry in question, about the non-conformity.

The other official control insufficiencies were due to a small number of consignments carrying particular commodities, for which no controls were performed, a problem that was recurring and can be seen in the graph below for the frequency of official controls performed in 2017 (Figure 10).

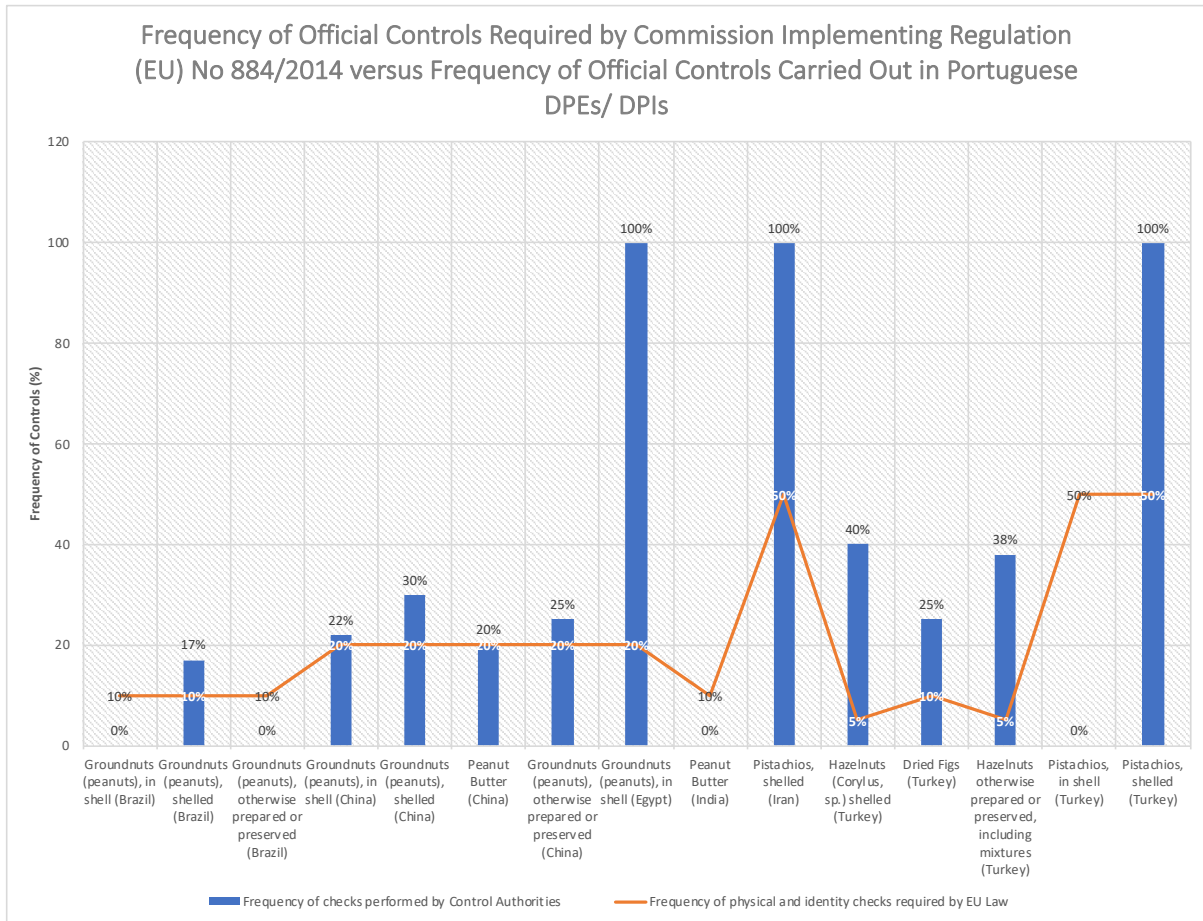


Figure 10. Frequency of official controls performed on commodities subject to control measures under Regulation (EC) No 884/2014 in 2017.

In 2017 the insufficient controls were a consequence of a lack of analytical sampling for laboratory analysis, due to, as has been mentioned earlier in this dissertation, lack of human resources to perform sampling, or lack of the necessary up-to-date tools to adequately carry out sampling.

Overall, and compared to the data available for 2014 and 2015, the number of rejections of groundnuts originating in China, due to aflatoxin contamination above the set MRL continued to be problematic, for reasons that will be explained in the next Chapter. All but one rejection resulted in RASFF notifications.

Moving on to results on consignments subject to measures under Regulation (EU) No 2016/6, and for which previous regulations on the control of products originating in, or consigned from Japan, following the Fukushima incident, were consulted in order to provide data for 2014 and 2015, the number of imports over the four years can be seen in the table below (Table 8):

Table 8. Number of consignments imported subject to emergency measures under Regulation (EU) No 2016/6, and number and type of official controls performed, from 2014 to 2017.

Year	Number of consignments	Identity Checks	Physical checks w/out sampling	Physical checks w/ sampling
2014	21*	5	3	2
2015	28*	10	7	3
2016	54	7	4	2
2017	31	12	10	2

\*The number of consignments imported in 2014 and 2015 carry commodities with CN codes listed in Annex II of the regulations consulted, however, given that the CEDs for these years were not opened, it is not possible to ascertain the exact number of consignments that contained commodities listed in the Annex and the prefectures from where they were consigned, therefore the numbers may be an overestimation of imports.

Over the two periods analysed, there were no consignment rejections.

In terms of official controls, under this Regulation, identity and physical controls are set at random frequency, therefore there is no minimum requirement to be met. Nonetheless, in terms of what was observed, identity and physical controls were quite high for all years except in 2016 (frequency checks ranged from 24% to 39% in 2014, 2015 and 2017, but were, on average, 12% for 2016). Analytical sampling was performed, at a higher frequency during the first half of the period analysed, 10% and 11% in 2014 and 2015 respectively, and the for the latter period, the frequency dropped to 4% (2016) and 6% (2017), possibly due to the higher number of imports occurring in these years, as well as, a reduced number of commodities requiring control, as a consequence of the reduction of listed prefectures in the Regulation.

However, despite the high frequency of official checks performed, a consignment of mushrooms from Japan was allowed to be imported without the declaration, required by Articles 5 and 6 of the Regulation<sup>[50]</sup>, for which DGAV has since, reminded repeatedly, all DPEs about the requirements to perform documentary checks as stipulated in the Regulation.<sup>[30,31]</sup>

There was only one consignment originating in India, containing the commodity guar gum that is subjected to emergency measures under Regulation (EU) No 2015/175. The consignment in question was found to be compliant but was not submitted to identity or physical official control checks, therefore the enforcement of the measures set under this Regulation were not abided by the DRAP/DRA.

Finally, with regards to imports of consignments under Decision 2011/884/EU, the table below shows the number of consignments reaching points of entry over the course of the four years analysed (Table 9).

Table 9. Number of consignments imported subject to emergency measures under Decision 2011/884/EU, and number and type of official controls performed, from 2014 to 2017.

Year	Number of consignments	Identity Checks	Physical checks w/out sampling	Physical checks w/ sampling
2014	111	25 (23%)	3 (3%)	22 (20%)
2015	31	9 (29%)	8 (26%)	1 (11%)
2016	246 (20)	47 (19%)	15 (6%)	30 (12%)
2017	154 (9)	40 (26%)	12 (8%)	28 (18%)

Note that for the years of 2014 and 2015, the CEDs were not consulted and therefore the number of consignments that carried products consisting of or containing rice, are unknown, and therefore it is also not possible to check documentary conformity for the presence of health certificates and analytical reports and whether official controls by the DRAP/DRA were performed according to control plans. However, it is clear to see that, in terms of number of imports carrying commodities with listed CN codes, the number has more than doubled from the first period (142 consignments) to the second period (400) (for which all CEDs were consulted).

In 2016, there were 246 consignments carrying products with CN codes listed in the Decision Annex. Of this total, 20 consignments were found to carry products consisting of, or derived of, rice. One consignment did not have submitted in TRACES, a Health Certificate or an Analytical Report, this consignment was rejected with unsatisfactory identity and physical checks performed at the port of Porto, because the ID mis-matched with the documents, and was destroyed. There was a second rejected consignment, with unsatisfactory identity and physical controls performed at the port of Sines, for reasons other than those listed in TRACES; this particular consignment was re-dispatched to a country outside the Union.

In 2017, of the possible 154 consignments carrying products under a CN code listed in Annex I, only 9 contained or consisted of rice. Of those 154 consignments, it was possible to trace back declarations for 124 consignments. The remaining 30 did not have a declaration attached to their CED in TRACES, which does not mean they were not sent, just that the operators may have sent it directly to the CA at the DPE, rather than annexing it to the CED on TRACES.

Nine consignments contained or consisted of rice, 6 had both Health Certificate and Analytical Report attached to the CED in TRACES and so was possible to check for conformity under Article 5(2)(3) of the Decision<sup>[50]</sup>; it was not possible to check conformity for the remaining 3 consignments because they were missing one or both documents in TRACES. All of the 9 consignments containing rice were subjected to documentary, identity and physical controls, with sampling for analytical control. All 154 consignments were found to be compliant.

The audit report performed by DG SANTE in 2017, found that a consignment of rice products originating in China, had been allowed free circulation into the Union, although the analytical report was incorrect, which was a clear breach under Article 5(2) of the Decision<sup>[50]</sup>.



In summary, from 2014 to 2017 there were no rejections for consignments under the listed CN codes, whether they actually included rice or products thereof, or not. Border control inspections were relatively similar for most years. In 2016, when there was a higher number of imported consignments, the frequency of border control inspections reduced slightly. Given the possibility of consignors emailing Competent Authorities Analytical Reports, Health Certificates and declarations, it is not possible to comment on infringements to Article 5 on Official controls, but the audit report performed by the audit team of DG Health and Food safety did note that there were irregularities with regards to documentary control, a fact that was later confirmed by DSNA-DGAV.

## Rejections and RASFF: The evolution from 2014 to 2017

### *Rejections*

Regarding rejections, the period of analysis will, once more, span across 2014 to 2017 in order to provide a better picture of the evolution of number of non-conformities and efficiency of controls. Any rejections that have resulted in RASFF notifications are indicated as well as the legal measure that was breached, where known. Regarding other official documents that do not pertain to official controls but are also in breach, they are listed below:

1. *Commission Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC; sets MRLs for certain pesticide residues (the list of authorized substances for plant protection products for which MRLs are set, can be found in Regulation (EU) No 540/2011)<sup>(70)</sup>;*
2. *Commission Regulation (EC) No 1881/2006 on setting maximum levels for certain contaminants in foodstuffs (includes levels for mycotoxins)<sup>(76)</sup>;*
3. Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements<sup>(28)</sup>;
4. Commission Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods (lists authorized vitamin formulations and mineral substances in Annex II, as well as, those that are prohibited, restricted or under Community scrutiny in Annex III)<sup>(71)</sup>;
5. Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (lists in its Annex, authorized Vitamins, Minerals, Amino acids, Carnitine & taurine, nucleotides and Choline & inositol for the formulations described in the Regulation)<sup>(60)</sup>;
6. Commission Regulation (EC) No 258/97 concerning novel foods and novel food ingredients (in force until the end of December 2017), which has since been repealed and replaced by Commission Implementing Regulation (EU) 2015/2283 (the list of authorized Novel foods can be found under Commission Implementing Regulation (EC) No 2017/2470)<sup>(69)</sup>;

The definition of novel food, according to Implementing Regulation (EU) No 2015/2283 is: “*any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession of Member States to the Union, and that falls under at least one of the following categories:...*”<sup>(80)</sup>

There are 10 categories referred to in the above quote for which the description is extensive and for this reason will not be included in this work (please refer to Annex I for the full definition of novel food).

7. Regulation (EC) No 1333/2008 on food additives<sup>(74)</sup>;

8. Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC<sup>[75]</sup>;
9. Regulation (EC) No 1332/2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97<sup>[75]</sup>.

Below is a table (Table 10) summarizing the number of rejections at the borders and the resulting RASFF notifications (the table does not include numbers for recalled consignments, although these are briefly described in this section), according to the legal measure that has been under analysis in this dissertation, and the year. Regulations without any rejections are shown collapsed.

*Table 10. Summary of the number of rejections from 2014 and 2017 and the resulting RAFF notifications.*

<b>Official Control Measure</b>	<b>Number of Border rejections</b>	<b>Number of RASFF Notifications</b>
<b>Emergency Measures (TOTAL)</b>	<b>10</b>	<b>9</b>
Decision (EU) No 2011/884		
Decision (EU) No 2014/88		
Reg. (EU) No 2015/175		
Reg. (EU) No 996/2012, No 322/2014, No 2016/6		
Reg. (EC) No 669/2009, Reg. (EU) No 2015/943, No 2016/874		
Reg. (EC) No 669/2009, Reg. (EU) No 2016/166, No 2017/186		
Reg. (EU) No 211/2013		
Reg. (EC) No 1152/2009, Reg. (EU) No 884/2014	10	9
2014	1	1
2015	4	4
2016	1	1
2017	4	3
Reg. (EU) No 91/2013, Np 885/2014		
<b>Increased Level of Official Controls (TOTAL)</b>	<b>5</b>	<b>4</b>
Reg. (EC) No 669/2009	5	4
2014	2	2
2015	1	1
2016	1	1
2017	1	0
<b>Official Food &amp; Feed Regulation – Reg (EC) No 882/2004 (TOTAL)</b>	<b>6</b>	<b>4</b>
Matrix	6	4
2016	3	3
2017	3	1

The number and type of rejections for 2014 is given in the table below (Table 11).

Table 11. Consignment rejections of 2014.

Commodity Groups	Description of Commodity	Reason for Refusal	Decision	Country of Origin	Country of Destination
1.Oil seeds and oleaginous fruits	Confrei ( <i>Symphytum officinalis</i> )	A suitable justification of consumption was not presented	Destruction	Brazil	Portugal
2.Miscellaneous edible preparations	Food Supplements	Other (ID & Phys Not Sat)	Destruction	United States	Portugal
3.Edible vegetables	Gourd	Other (ID & Phys Not Sat)	Destruction	India	Portugal
4.Miscellaneous edible preparations	Food Supplements	Absence/Invalid certificate	Re-dispatching	United States	Spain
5.Inorganic chemicals	Silicon dioxide	Other (Phys Not Sat)	Destruction	United States	Spain
6.Miscellaneous edible preparations	Food Supplements	Other (Doc Not Sat)	Destruction	United States	Portugal
7.Oil seeds and oleaginous fruits	Unknown (no documents)	Other (Doc Not Sat)	Destruction	India	Portugal
8.Miscellaneous edible preparations	Food Supplements	Other (Doc & Phys Not Sat)	Destruction	United States	Spain
9.Miscellaneous edible preparations	Food Supplements	Other (Doc & Phys Not Sat)	Destruction	United States	Portugal
10.Miscellaneous edible preparations	Organic Food Supplements	Chemical hazards identified	Destruction	United States	Portugal
11.Miscellaneous edible preparations	Food Supplements	Chemical contamination (Chromium picolinate) & Unauthorized botanical substances	Destruction	United States	Portugal
12.Coffee, tea, mate and spices	Green Tea Extract	Pesticide Residues (Carbendazim & Benomyl)	Unknown	China	Portugal
13.Miscellaneous edible preparations	Soups and broths	Other (Doc Not Sat)	Destruction	Switzerland	Portugal
14.Coffee, tea, mate and spices	Stemless Red Chilies	Mycotoxins (Aflatoxins)	Destruction	India	Portugal
15.Miscellaneous edible preparations	Food Supplements	Other (Doc, ID, Phys Not Sat)	Re-dispatching	United States	Portugal
16.Edible fruits and nuts	Dried Figs	Other (Doc and ID Not Sat)	Destruction	Turkey	Portugal

<b>17.Miscellaneous edible preparations</b>	Food Supplements	Unauthorised botanical substance	Destruction	United States	Portugal
<b>18.Miscellaneous edible preparations</b>	Food Supplements	Unauthorised minerals and amino acid complex	Re-dispatching	United States	Portugal
<b>19.Lac; gums, resins</b>	Vegetable extract powder	Chemical contamination (Aluminium)	Re-dispatching	China	Portugal
<b>20.Oil seeds and oleaginous fruits</b>	Parts of plants	Other (Phys Not Sat)	Destruction	Brazil	Portugal

Rejections were done by Competent Authorities at the airport of Lisbon (14 consignments), the port of Lisbon (4 consignments), the airport of Porto (1 consignment) and the Delegação Aduaneira da Covilhã (1 consignment).

Referring back to Table 10 where it is possible to see that, during 2014, there were 2 breaches to Regulation (EC) No 669/2009 that lead to the generation of 2 valid RASFF notifications. These breaches are for the consignments from India (stemless chillies) due the presence of mycotoxins (also in breach of Regulation (EC) No 1881/2006) and from China (green tea extract) due to the presence of pesticide residues (also breaching Regulation (EC) No 396/2005). Both consignments were destroyed. With regards to the breach of Regulation (EC) No 1152/2009 and Regulation (EU) No 884/2014, the single non-conforming consignment is from Turkey, carrying dried figs, which was destroyed. The reason for non-conformity is not clear, in TRACES, specifically the RASFF link, the CA states that it is in breach of Reg. (EU) No 884/2014, however the tabs for Checks don't show any physical and analytical checks, and the reason for refusal is given as 'Other' (both the documentary and identity checks were not satisfactory).

With regards to non-conformities under other legal documents, the commodity that was most occurring in the rejections, was food supplements within the category of 'Miscellaneous edible preparations', present in 11 consignments and breaching Directive 2002/46/EC due to the use of unauthorized minerals and Commission Regulation (EC) No 258/97 due to the use of unauthorized novel food ingredients. All of the food supplements rejected had originated in the United States.

The remaining non-conformities registered in 2014 were due to: 1) Chemical contamination and; 3) Other reasons than those available on TRACES (whether it be as a result of unsatisfactory documentary checks, identity checks, physical checks, or a combination thereof) so the exact reason for the rejection is unknown to the author without resorting to other sources of information. The countries of origin for these rejected consignments were: Brazil (2 consignments), India (2 consignments), Switzerland (1 consignment) and China (1 consignment).

In 2015, the number and type of rejections were as follows:

Table 12. Consignment rejections in 2015.

Commodity Group	Description of Commodity	Reason for refusal	Decision	Country of Origin	Country of Destination
1. Miscellaneous edible preparations	Food Supplements	Unauthorised botanical substances	Destruction	India	Portugal
2. Preparations of vegetables, fruit, nuts	Peanut Butter	Mycotoxins (Aflatoxins)	Re-dispatching	Philippines	Spain
3. Lac; gums, resins	Vegetable extracts, powder	Other (Phys Not Satisfactory)	Re-dispatching	India	Portugal
4. Coffee, tea, mate and spices	Green Tea	Pesticide Residues (Acetamipride)	Re-dispatching	China	Portugal
5. Miscellaneous edible preparations	Gingseng Tonic	Unauthorised botanical substance	Destruction	Korea, Republic Of	Portugal
6. Beverages, spirits and vinegar Essential oils and resinoids Miscellaneous edible preparations	Various	Other (Doc Not Satisfactory)	Destruction	Brazil	Portugal
7. Oil seeds and oleaginous fruits	Dried fruits and nuts	Other (Doc, ID and Phys Not Satisfactory)	Destruction	United Arab Emirates	Portugal
8. Miscellaneous edible preparations	Food Supplements	Unauthorized botanical substances	Destruction	United States	Portugal
9. Edible fruits and nuts	Papaws (papaya), fresh	Other (ID & Phys Not Satisfactory)	Destruction	Colombia	Portugal
10. Oil seeds and oleaginous fruits	Groundnuts (peanuts), in shell	Mycotoxins	Re-dispatching	China	Portugal
11. Oil seeds and oleaginous fruits	Groundnuts (peanuts), in shell	Mycotoxins	Re-dispatching	China	Portugal
12. Edible fruits and nuts	Mangoes, fresh	Pesticide Residues	Destruction	Brazil	Portugal

<b>13.Edible fruits and nuts</b>	Papaws (papayas), fresh	Pesticide Residues (unauthorized)	Destruction	Brazil	Portugal
<b>14.Edible fruits and nuts</b>	Papaws (papaya), fresh	Pesticide Residues (Clorfenapir)	Destruction	Brazil	Portugal
<b>15.Miscellaneous edible preparations</b>	Food Supplements	Unauthorised substances (mineral and amino acid complexes and botanical substances)	Re-dispatching	United States	Portugal
<b>16.Edible fruits and nuts</b>	Mangoes, fresh	Pesticide Residues (Difenoconazole)	Destruction	Brazil	Portugal
<b>17.Oil seeds and oleaginous fruits</b>	Groundnuts (peanuts), in shell	Mycotoxins (Aflatoxins)	Re-dispatching	China	Portugal
<b>18.Edible fruits and nuts</b>	Almonds, shelled	Mycotoxins (Aflatoxins)	Re-dispatching	United States	Portugal
<b>19.Lac; gums, resins</b>	Guaçatonga & Sete Sangrias	Unauthorised botanical substances		Brazil	Portugal
<b>20.Edible fruits and nuts</b>	Fresh Sweet Oranges	Other (ID & Phys Not Satisfactory)	Destruction	Uruguay	Portugal
<b>21.Miscellaneous edible preparations</b>	Food Supplements	Unauthorised botanical substance		United States	Portugal
<b>22.Oil seeds and oleaginous fruits</b>	Groundnuts (peanuts) in shell	Mycotoxins	Re-dispatching	China	Portugal
<b>23.Edible fruits and nuts</b>	Mangoes, fresh	Other (Phys Not Satisfactory)	Destruction	Dominican Republic	Portugal

Rejections in 2015 were at the following points of entry: the airport of Lisbon (12 consignments), the port of Lisbon (6 consignments), the airport of Port (1 consignment) and the port of Porto (4 consignments).

One more consignment was found to have contradictory laboratory check results, but its fate is unknown as the information available in TRACES does not provide clarification:

Table 13. Consignments that show contradictory results for official controls and therefore their fates are not known to the author.

Commodity category	Commodity description	Reasons for Recall*	Country of Origin	RASFF Notification	Further information
Edible fruits and nuts	Pine Nuts	Mycotoxins *Not Recalled, instead 'Valid'	Turkey	None	Unclear: Laboratory tests marked as both Satisfactory and Not Satisfactory in different tabs

Referring to the particular EU measures discussed in this work, in 2015 under Regulation (EC) No 669/2009 there was 1 rejection that resulted in a valid RASFF notification. The consignment in question was from China and contained green tea. It was rejected due to pesticide residue Acetamipride being above its MRL (also a breach under Regulation (EC) No 396/2005) and it was re-dispatched to a country outside the Union.

Breaches under Regulation (EU) No 884/2014 totaled 4 consignments all of which containing groundnuts, in shell or shelled, from China, all of which contained mycotoxins above the acceptable MRL (breach to Regulation (EC) No 1881/2006) and were re-dispatched.

With regards to the remaining rejections not falling under either Regulation (EC) No 669/2009 or Regulation (EU) No 884/2014, 'Edible fruits and nuts' was the most prominent category, having had 8 consignments rejected, carrying fresh mangoes (3 consignments), fresh papayas/ papaws (3 consignments), fresh sweet oranges (1 consignment) and shelled almonds (1 consignment). The countries of origin for the commodities in the category of 'Edible fruits and nuts' were: Dominican Republic (1 consignment), Uruguay (1 consignment), United States (1 consignment), Brazil (4 consignments) and Colombia (1 consignment). For most cases the non-conformity was due to the presence of pesticide residues above the set MRL and thus in breach of Regulation (EC) No 396/2005. This particular category led to the creation of 5 RASFF notifications, all except one were valid (one was rejected, due to acceptable levels of pesticide residue Clofenapir found on the consignment carrying papayas/papaws from Brazil, i.e., according to the ECCP, a level of 0.016 mg/kg was not in exceedance of the MRL when a 50% uncertainty level is taken into account).

The other category that, as had been seen in 2014, had had quite a few commodities rejected (6 consignments), was 'Miscellaneous edible preparations', due to non-conforming food supplements. Three of the food supplements rejected had originated in the United States, the other 3 originated in Brazil, India and the Republic of Korea. The reasons for rejection were the presence of unauthorized substances breaching Directive 2002/46/EC and Commission Regulation (EC) No 258/97 on the use of unauthorized novel ingredients. Food supplements led to the generation of 5 RASFF notifications, 4 of



which were found valid and one rejected due to insufficient information on the hazards or risks to human health, found in the documents accompanying the consignment from the United States.

Finally, there were 6 non-conformities due to reasons other than those available on TRACES (whether it be as a result of unsatisfactory documentary checks, identity checks, physical checks, or a combination thereof) for which the exact reason of rejection remains unknown, none of which resulted in the creation of RASFF notifications.

Moving on to the second period of analysis, in 2016 the number and type of rejections can be seen in Table 14:

Table 14. Consignment rejections in 2016.

<b>Commodity Group</b>	<b>Commodity</b>	<b>Reason for Refusal</b>	<b>Decision</b>	<b>Country of Origin</b>	<b>Country of Destination</b>
<b>1.Miscellaneous edible preparations</b>	Probiotics, Food Supplements	ID: Mis-match with documents	Re-dispatching	United States	Portugal
<b>2.Miscellaneous edible preparations</b>	Food Supplements	Unauthorised substance (Sodium Metavanadate)	Re-dispatching	United States	Portugal
<b>3.Edible fruits and nuts</b>	Dried Grapes	Pesticide Residues (Ethion)	Re-dispatching	Iran (Islamic Republic Of)	Portugal
<b>4.Edible fruits and nuts</b>	Papayas/ Papaws, fresh	Other (ID & Phys Not Sat)	Destruction	Brazil	Portugal
<b>5.Edible vegetables</b>	Fresh chilies	Pesticide Residues (Clorfenapir)	Destruction	India	Portugal
<b>6.Edible fruits and nuts Edible vegetables</b>	Gourd, beans, jujube, taro and papayas	Other (Phys Not Sat)	Destruction	Bangladesh	Portugal
<b>7.Edible fruits and nuts</b>	Mangoes, fresh	Pesticide Residues (Tetraconazol)	Destruction	Brazil	Portugal
<b>8.Oil seeds and oleaginous fruits</b>	Groundnuts (peanuts) in shell	Mycotoxins (Aflatoxins)	Use for other purposes	Israel	Portugal
<b>9.Edible fruits and nuts</b>	Fresh pineapple, mangoes and papayas	Other (Phys Not Sat)	Destruction	Colombia	Portugal
<b>10.Miscellaneous edible preparations</b>	Food Supplements	Other (Doc Not Sat)	Destruction	India	Portugal
<b>11.Miscellaneous edible preparations</b>	Food Supplements	Other (Doc Not Sat)	Destruction	India	Portugal
<b>12.Miscellaneous edible preparations</b>	Food Supplements	Other (Doc Not Sat)	Unknown	Canada	Portugal
<b>13.Miscellaneous edible preparations</b>	Food Supplements	Other (Doc Not Sat)	Re-Dispatching	United States	Portugal

<b>14.Miscellaneous edible preparations</b>	Food Supplements	Other (Doc Not Sat)	Unknown	United States	Portugal
<b>15.Edible vegetables</b>	Chilies, fresh	Pesticide Residues (Fipronil)	Destruction	Dominican Republic	Portugal
<b>16.Edible fruits and nuts</b>	Pistachios, in shell	Mycotoxins (Aflatoxins)	Re-dispatching	Iran (Islamic Republic Of)	Portugal
<b>17.Miscellaneous edible preparations</b>	Food Supplements	Other (Doc Not Sat)	Re-dispatching	United States	Portugal
<b>18.Cereals Edible vegetables Miscellaneous edible preparations Preparations of vegetables, fruit, nuts</b>	Rice, round grain Mushrooms Other vegetables, including mixtures, some of which preserved in sugar sauces	ID: Mis-match with documents	Destruction	China	Portugal
<b>19.Preparations of cereals, flour, starch or milk</b>	Bread	Other (Phys Not Sat)	Destruction	United States	Portugal
<b>20.Edible fruits and nuts</b>	Plums, fresh	Other (Phys Not Sat)	Destruction	Brazil	Portugal
<b>21.Preparations of cereals, flour, starch or milk</b>	Biscuits, Cakes	Other (ID & Phys Not Sat)	Re-Dispatching	China	Spain

The 21 rejections registered in 2016 were at the following points of entry: the airport of Lisbon (13 consignments), the port of Lisbon (2 consignments), the port of Port (3 consignment), the port of Sines (2 consignments) and Setubal (1 consignment).

Referring to the particular EU measures discussed in this work, in 2016 under Decision (EU) No 2011/884 there weren't any rejections due to the presence of GMO in rice and rice products. However, when analysing consignments carrying commodities with CN codes listed under the Decision, it was identified that 2 consignments were rejected, none resulting in any RASFF notifications. Rejections were due, in one case, to a mis-match between identity and documents, and in the other case, unsatisfactory identity and physical checks. The consignment carrying rice, mushrooms and other vegetables, was destroyed, whereas the one carrying biscuits and cakes was re-dispatched to a country outside the Union.

There was one consignment in breach of Regulation (EU) No 884/2014, pistachios in shell from Iran, contaminated with aflatoxins that lead to the generation of a valid RASFF notification. This consignment was also in breach of Regulation (EC) No1881/2006.

One consignment was in breach under Reg. (EC) No 669/2009, fresh chillies from the Dominican Republic, contaminated with pesticide residue, fipronil. This consignment lead to the creation of a RASFF notification that was rejected on the grounds that the pesticide residue was estimated to represent an acceptable ARfD value for children therefore not posing a risk to public health. The consignment was destroyed. Compared to results at an EU level, during 2016, 65 000 consignments of products covered by Regulation (EC) No 669/2009 were imported to the EU, 8 092 of which were sampled for laboratory analysis, resulting in 343 (4.3%) rejections due pesticide residue exceeding MRLs, when taking into account the measure uncertainty<sup>(55)</sup>.

There were 3 rejections under measures set by the Matrix of Analytical Control, all of which resulted in RASFF notifications: 2 were valid (groundnuts in shell from Israel contaminated with aflatoxins and dried grapes from Iran contaminated with pesticide residue, ethion) and 1 was rejected (the commodity fresh mangoes from Brazil was rejected because the pesticide residue represented 9.6% of children's ARfD so it did not pose a risk to public health). These consignments also breached Regulation (EC) No 396/2005 and Regulation (EC) No 1881/2006.

Rejected consignments that have not yet been discussed, either were not included in any legal document or subject national safeguard measures or, were rejected due to unclear reasons to the author (whether it be as a result of unsatisfactory documentary checks, identity checks, physical checks, or a combination thereof). Many of the rejections for perishable commodities, refused for other reasons, were due to rot.

Finally, with regards to 2017, details for rejected consignments are provided in Table 15:

Table 15. Consignment rejections in 2017.

Commodity Group	Commodity	Decision	Reason for Refusal	Country of Origin	Country of Destination
<b>1.Edible fruits and nuts</b> <b>Edible vegetables</b>	Bananas, papayas, jujube, broad beans, chili, gourd, paleval, taro	Other (Phys Not Sat)	Destruction	Bangladesh	Portugal
<b>2.Edible fruits and nuts</b>	Passion fruit, Avocados, Papayas and Pineapples, fresh	Other (Phys Not Sat)	Destruction	Dominican Republic	Portugal
<b>3.Edible fruits and nuts</b>	Papayas	Other (Phys Not Sat)	Destruction	Brazil	Portugal
<b>4.Oil seeds and oleaginous fruits</b>	Groundnuts (peanuts) shelled	Mycotoxins (Aflatoxins)	Re-Dispatching	China	Portugal
<b>5.Edible fruits and nuts</b>	Mangoes, fresh	Other (Phys Not Sat)	Unknown	Angola	Portugal
<b>6.Edible fruits and nuts</b>	Mangoes, fresh	Other (Phys Not Sat)	Destruction	Angola	Portugal
<b>7.Edible fruits and nuts</b>	Fresh Chilies	Pesticide Residues (Cipermetrine)	Destruction	Dominican Republic	Portugal
<b>8.Oil seeds and oleaginous fruits</b>	Groundnuts (peanuts) shelled	Mycotoxins (Aflatoxins)	Re-Dispatching	Nigeria	Portugal
<b>9.Edible fruits and nuts</b>	Table grapes, fresh	ID: Mis-match with documents	Re-Dispatching	Chile	Spain
<b>10.Oil seeds and oleaginous fruits</b>	Groundnuts (peanuts) shelled	Mycotoxins (Aflatoxins)	Re-Dispatching	China	Portugal
<b>11.Animal or vegetable fats and oils</b>	Palm oil	Chemical contamination Sudan colours	Re-Dispatching	Guinea-Bissau	Portugal
<b>12.Edible fruits and nuts</b>	Melon, fresh	Other (Phys Not Sat)	Destruction	Guinea-Bissau	Portugal
<b>13.Edible fruits and nuts</b>	Bananas, fresh	Other (Phys Not Sat)	Destruction	Peru	Portugal
<b>14.Edible fruits and nuts</b>	Mangoes, fresh	Other (Phys Not Sat)	Destruction	Dominican Republic	Spain
<b>15.Oil seeds and oleaginous fruits</b>	Groundnuts (peanuts) in shell	Mycotoxins (Aflatoxins)	Unknown	China	Portugal
<b>16.Edible fruits and nuts</b>	Passion fruit, fresh	Other (Phys Not Sat)	Destruction	Angola	Portugal

<b>17.Edible fruits and nuts</b>	Bananas, fresh	Other (Phys Not Sat)	Destruction	Angola	Portugal
<b>18.Edible fruits and nuts</b>	Sweet Oranges, fresh	Other (unknown, all checks Sat)	Re-Dispatching	South Africa	Portugal
<b>19.Coffee, tea, mate and spices</b>	Green Tea, not fermented	Pesticide Residues	Destruction	Japan	Spain
<b>20.Oil seeds and oleaginous fruits</b>	Groundnuts (peanuts) in shell	Mycotoxins (Aflatoxins)	Re-dispatching	China	Portugal
<b>21.Preparations of vegetables, fruit, nuts</b>	Açai sorbet	Ice cream melted	Destruction	Brazil	Portugal
<b>22.Miscellaneous edible preparations</b>	Food Supplements	Unauthorised mineral substances	Destruction	United States	Portugal
<b>23.Edible fruits and nuts</b>	Pistachios, shelled	Mycotoxins (Aflatoxins)	Re-Dispatching	Iran (Islamic Republic Of)	Portugal
<b>24.Edible fruits and nuts</b>	Pineapples, fresh	Other (Phys Not Sat)	Destruction	Dominican Republic	Portugal
<b>25.Miscellaneous edible preparations</b>	Food supplements	Other (Doc Not Satisfactory)	Destruction	United States	Portugal

In 2017 there were 25 rejections as a result of unsatisfactory control checks performed at the airport of Lisbon (4 consignments) the port of Lisbon (10 consignments), the port of Porto (3 consignments), the port of Sines (7 consignments) and in Setubal (1 consignment).

There were a further 6 consignments which were placed on the market pending results from laboratory analysis, but were then recalled due to unsatisfactory laboratory results, 2 of which lead to the generation of valid RASFF notifications. Two further consignments had unsatisfactory laboratory results but the destination of the consignments is unknown (from the information provided by TRACES). The details for which are provided in the table in the next page (Table 16):

Table 16. Number and nature of consignments whose fate is unknown or that have been recalled from the market.

<b>Commodity category</b>	<b>Commodity description</b>	<b>Reasons for Recall*</b>	<b>Country of Origin</b>	<b>RASFF Notification</b>	<b>Further information</b>
<b>Edible fruits and nuts</b>	Papayas/papaws	Pesticide Residue (Flutriafol)	Brazil	Rejected	Levels found do not pose a risk to public health
<b>Edible fruits and nuts</b>	Limes	Pesticide Residue (Propargite)	Brazil	Annulled	According to the risk-based assessment carried out by DSMDS/DGAV, there is no risk to public health
<b>Edible fruits and nuts</b>	Papayas/papaws	Pesticide Residue (Mandipropamide)	Brazil	Annulled	
<b>Edible fruits and nuts</b>	Dried Figs	Aflatoxins	Turkey	Valid	-
<b>Coffee, Tea, Maté and Spices</b>	Black Pepper, neither crushed or ground	Ochratoxin A	Indonesia	Valid	-
<b>Edible fruits and nuts</b>	Papayas/papaws	Pesticide Residue (Fenpropatrine)	Brazil	Annulled	According to the risk-based assessment carried out by DSMDS/DGAV, there is no risk to public health
<b>Oil seeds and oleaginous fruits</b>	Groundnuts, in shell	Aflatoxins *Not 'Recalled', instead 'In Progress'	China	None	Unclear fate of consignment: Laboratory tests Not Satisfactory
<b>Oil seeds and oleaginous fruits</b>	Groundnuts, in shell	Aflatoxins *Not 'Recalled', instead 'In Progress'	China	None	

Regarding breaches to official EU measures, there was one breach under Regulation (EC) No 669/2009 that resulted in an annulled RASFF notification (possibly because the hazard identified was not at a level that posed a risk to consumer health). This consignment was from the Dominican Republic, carrying fresh chillies contaminated with pesticide residue, Cipermetrine, and was destroyed. It was also in breach of Regulation (EC) No 396/2005.

There were 4 consignments carrying groundnuts from China, contaminated with aflatoxins, as well as 1 consignment from Iran carrying pistachios also contaminated with aflatoxins, both breaching Regulation (EU) No 884/2014 and Regulation (EC) No 1881/2006. These non-conforming consignments resulted in 4 valid or confirmed RASFF notifications.

Finally, with regards to breached under the Matrix of Analytical Control, there were 3 consignments rejected and 1 RASFF notification generated. The consignments in question were: shelled groundnuts from Nigeria contaminated with aflatoxins (resulted in the only RASFF notification), palm-oil from Guinea-Bissau contaminated with Sudan colour IV and, green tea from Japan due to pesticide residues. As has been indicated thus far, consignments are also in breach of Regulation (EC) No 396/2005 (MRLs for pesticide residues), Regulation (EC) No 1881/2006 (MRLs for mycotoxins) and Regulation (EC) No 1333/2008 (on additives). The contamination of palm oil with Sudan IV dye used to be in breach under Commission Decision 2005/402/EC, but this Community measure has since been repealed by Regulation (EC) No 669/2009, due to significant improvements in the presence of Sudan dyes in chilli, chilli products, curcuma and palm oil and was instead a uniform, increased level of control from 25<sup>th</sup> January 2010 until 7<sup>th</sup> of April 2012 (currently, under the same Regulation, Sudan dyes are of concern only for products originating in Ghana)<sup>(19,71)</sup>.

Reasons for refusal of other consignments not covered by Community legislation on official controls or national control plans, were: 1) Unauthorised substances in food supplements (that are, however, in breach under Directive 2002/46/EC) and; 2) Reasons other than those available on TRACES (whether it be as a result of unsatisfactory documentary checks, identity checks, physical checks, or a combination thereof).

In 2017, there were a total of 7 RASFF notifications resulting from import official controls on food of non-animal origin, resulting in consignment rejections and a further 2 RASFF notifications from recalled consignments. Five were valid, three confirmed (informs the European Commission's Contact Point, ECCP, that the National Contact Point, NCP, has confirmed the RASFF notification in TRACES) and one new (new type of risk with no past evaluations). One notification was annulled (NCP annuls RASFF notification in TRACES).

## ***RASFF***

In this section a discussion will be provided for the rejected consignments that resulted in RASFF notifications, grouped by the hazard category that lead to the generation of the notification.

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### Composition of foodstuffs

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All rejections regarding the composition of foodstuffs between 2014 and 2017 concerned food supplements. Food supplements are concentrated sources of nutrients intended to correct nutritional imbalances or to support specific physiological functions, and therefore must not contain medicinal ingredients and as such, cannot exert a pharmacological, immunological or metabolic action<sup>(52)</sup>. As a consequence, and in an effort to provide the means to regulate this area of nutrition, there is a Community regulatory framework concerning authorized ingredients in food supplements dietetic foods and infant formulae, as well as, several published scientific opinions, by EFSA, on different ingredients used in food supplements and the risk they pose to consumer health, including tolerable upper intake levels for different population groups. The regulation of food supplements is particularly challenging due to differing definitions for this commodity category across the globe, resulting in different regulatory frameworks adopted in different countries<sup>(53)</sup>, and therefore, as it is often the case, substances that are approved to be used in the US, China or India where traditional medicine and phytomedicine are commonplace, are included in food supplements imported into the Union. Directive 2002/46/EC attempts to overcome this obstacle by providing a harmonised definition of food supplement, thus ensuring the uniform application of trade controls by MS throughout the Union. However, the limited European regulatory framework for compositional requirements has led to differing detailed legislation in certain Member States which inadvertently give rise to import barriers (ex. Belgium and Italy)<sup>(12, 28)</sup>.

Whereas in some cases, the inclusion of unauthorised substances are mineral and amino acid complexes, in many cases, rejections and RASFF notifications are due to unauthorised botanical substances. The problem arising from botanical substances is that they are often ambivalent, in the sense that they have both medicinal properties and general health promoting properties and therefore the distinction with regards to the legal framework under which they are regulated, is decided upon the intended use of the substance, which leads to the question of dose requirements: How much before the botanical substance goes from having health promoting properties to medicinal ones<sup>(13)</sup>. The assessment of botanical substances for use as food supplements, when these are not conventionally used in food or food supplements, is done in case-by-case manner; taking into consideration established scientific evidence on the safety of the herb when taken isolated or in combination with medicines that target the same ailment (for example herbs that claim to reduce high blood glucose levels consumed alongside, antidiabetic drugs)<sup>(13)</sup>



In 2014 there were 3 rejected consignments carrying food supplements containing unauthorized substances, 2 of which were botanical substances. In 2015 there were 4 consignments rejected for the same reasons.

In spite of the number of RASFF notifications generated due to botanical substances, the presence of unauthorised amino acid and mineral complexes account for the majority of notifications. In 2016, there was only one rejection due to unauthorized substance, sodium metavanadate, identified in food supplements originating in the US. Despite a study performed by Goldfine et al, 1995 demonstrating positive effects of this substance in insulin sensitivity, without any major adverse side effects, this substance remains unauthorised in the EU due to limited dose-response data available for EFSA to assess its safe use<sup>(57, 59)</sup>. According to the 2016 RASFF report the inclusion of non-authorized substances in foodstuffs is one of the top 10 food hazards, found specially in commodity category ‘dietetic foods, food supplements and fortified foods’. In fact, in terms of notifications due to composition issues, there were a total of 125 RASFF notifications that year; 81 due to use of unauthorized substances, 58 from the use of unauthorized novel food ingredients, 65 from the use of unauthorized ingredients, 12 from unauthorized colours and 15 notifications from having ingredients in too high a content. Of these notifications, 96 were deemed to be of serious risk to public health. The country of origin which used unauthorized ingredients was the United States.

In fact, it is that same country that lead to the RASFF notification notified by Portugal in 2016 due to the presence of sodium metavanadate in food supplements. The issue of the composition of food supplements and dietetic products has been of big concern for food control authorities since 2014, when it was first included in the RASFF report. The difficulties in controlling imports of this kind are due to the incomplete list of ingredients on labels and because there is a significant volume of supplements and dietetic foods ordered online making it challenging to perform effective enforcement<sup>(47)</sup>.

*“Among the most frequently notified unauthorised substances in 2014 are mineral or amino acid compounds that are not listed in Directive 2002/46/EC for addition to food supplements. These substances very often are produced in the United States and can be ordered through the internet. Usually these compounds are not listed on the label and the products are legally on the market in the US”<sup>(47)</sup>*

With regard to the use of novel food ingredients, the number of notifications rose significantly in 2016 compared to previous years.

In 2016, the 125 RASFF notifications pertaining to composition of foodstuffs resulted in 15 Border rejections. Specifically, for product category of ‘dietetic foods, food supplements, fortified foods’ there were 16 RASFF notifications from border rejections (one of these notifications has nothing to do with composition issues).

Finally, in 2017, there was also one consignment originating in the US, carrying food supplements, found to contain magnesium and zinc aspartate (magnesium aspartate lead to 2 RASFF notifications in 2015 and 16 notifications in 2014, in the EU). Magnesium aspartate is only allowed in food for special medicinal purposes. With regards to zinc aspartate, which was also present in the commodity, it appears

to be of no concern or related to the rejection, given that the opinion provided by EFSA in 2008 concluded that the individual or combined use of zinc and copper aspartates as sources of zinc and copper, at the proposed use levels, are not of safety concern<sup>(8)</sup>. This conclusion by the EFSA Panel is further corroborated by the inclusion of this substance in the list of authorized ingredients under Directive 2002/46/EC as of March 2015<sup>(28)</sup>

Another consignment that had originated in Guinea-Bissau and carrying palm oil, was rejected due to the use of unauthorized substance Sudan IV dye.

In 2017, food hazard category 'composition' was still in the top 10 of food hazards on notified products from non-member countries.

The total number of notifications under hazard category 'composition' was 161, of which 9 were border rejections, a slight increase compared to 2016, and for product category 'dietetic foods, food supplements, fortified foods' the number of RASFF notifications was 314, 9 of which due to border rejections.

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## Pesticide Residues

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Pesticide residues include biocides and plant protection products used for non-plant pest control and disease carriers and for crop protection against disease and infection<sup>(54)</sup>. In order for a PPP to be placed on the market, it requires prior authorization by the Commission. EFSA gives independent scientific advice to risk managers based on risk assessments, whereas the Commission and Member States take risk management decisions on regulatory issues, including the approval of active substances and setting of MRLs for pesticide residues in food and feed<sup>(54)</sup>. Legal limits for pesticide residues in food and feed are covered by Regulation (EC) No 396/2005 which also contains provisions on official controls of pesticide residues<sup>(54)</sup>.

In 2014 there was only one consignment rejected due to pesticide residues being above the legal MRL. In 2015 that figure rose to 5, and in 2016 there were 4 consignments rejected due to pesticide residues, Ethion, Clorfenapir, Tetraconazole and Fipronil (the RASFF notification for the consignment contaminated with fipronil that had originated in the Dominican Republic was later rejected as the levels were not found to pose a risk to public health) found in fresh mangoes from Brazil, fresh chillies from India and dried grapes from Iran.

In 2016, in the EU, there were a total of 222 pesticide residue RASFF notifications, mostly for the commodity group of 'fruits and vegetables', of which 142 were border rejections, thought to be due to the enforcement of increased official controls under Reg. (EC) No 669/2009<sup>(58)</sup> (RASFF, 2016).

From January 2016 the manner in which the assessment of a risk is done, changed: the evaluation of a risk posed by pesticide residue notifications is done on a short-term (acute) intake exceeding the ARfD

for a pesticide active substance. If there is no exceedance then it is considered not to pose a risk to public health<sup>[58]</sup>

Fruits and vegetables are the commodity category resulting in the highest RASFF notifications, having generated a total of 497 notifications in 2016 (272 Border rejections).

The 2016 European Union report on pesticide residues in food of both plant and animal origin, concluded, based on results of official controls carried out by MS Iceland and Norway, that over 90% of the 84 657 samples analysed, fell within the legal limits (either non-quantifiable quantities or below the MRL) and therefore the probability of European citizens being exposed to pesticide residue levels that would negatively impact their health, was low<sup>[59]</sup>. It did also, however, state that in terms of frequency of commodities exceeding the MRL, there was an increase in 2016 compared to 2015, mainly due to the detection of chlorpyrifos in lettuce, peaches and head cabbage, and dimethoate in tomatoes, and with regards to results of national control programmes, the presence of residues of chlorate<sup>[59]</sup>.

Finally, in 2017 there were 2 rejected consignments due to pesticide residues in fresh chillies from the Dominican Republic and in green tea from Japan. However, the only RASFF notification generated, for chillies, was rejected as the levels of Cipermetrine were not found to pose a public health risk. In the EU, that year, a total of 186 notifications were generated regarding pesticide residues, which is a significant decrease from the previous year. Of that total, 132 notifications were rejections at EEA borders, due to enforcement of Reg. (EC) No 669/2009.

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## Mycotoxins

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Mycotoxins are toxic compounds produced by different types of fungi, belonging mainly to the *Aspergillus*, *Penicillium* and *Fusarium* genera<sup>[53]</sup>. Transference of mycotoxins to foodstuffs is usually through contaminated food and feed crops, especially cereals<sup>[53]</sup>. Mycotoxins are cancerous, mutagenic and can lead to disorders in the gastrointestinal tract and the kidneys<sup>[53]</sup>. The role of EFSA is to collect and evaluate occurrences of mycotoxins in food and feed and provide scientific advice to risk managers when setting MRLs for mycotoxins, which can be found under Regulation (EC) No 1881/ 2006 and subsequent amendments<sup>[53]</sup>. In the EU, the MRL for ‘aflatoxin total’ (sum of aflatoxins B1, B2, G1 and G2) is set at 4µg/kg, which is a very tight control, often resulting in rejections of foodstuffs imported from other countries that do not have such stringent controls (in China for example, the limit is set at 20 µg/kg). So, would it be possible to increase the MRL for aflatoxins, without harming the consumer? In answering this question, EFSA was asked to address the effect on public health of a possible increase of the maximum level for ‘aflatoxin total’ from 4 to 10µg/kg. The study showed that an increase of the MRL to 10µg/kg would further increase the risk of developing cancer, by a factor of 1.6-1.8, when considering ARfDs for children and teenagers<sup>[36]</sup>.

In 2014 there was only consignment contaminated with high levels of aflatoxins that resulted in a RASFF notification (stemless red chillies from India), whereas in 2015 there were 6 consignments rejected due to aflatoxin contamination (all of which leading to the generation of RASFF notifications) on groundnuts from China, peanut butter from the Philippines and almonds from the US.

In 2016, there were only 2 consignments rejected due to aflatoxin contamination in groundnuts from Israel and pistachios from Iran (a recurrent notification, having been notified 56 times and resulted in 49 border rejections across the EEA borders). Both rejections resulted in RASFF notifications.

In 2016, the most occurring food hazard in imported feed and food, was mycotoxins, resulting in 489 RASFF notifications, the great majority of which due to the presence of aflatoxins. Of these, 418 notifications were border rejections. Nuts, nut products and seeds generated a total of 443 RASFF notifications, with border rejections accounting for 82% of those notifications.

In 2017, the number of rejections rose to seven (five from border rejections, 2 from consignment recalls). With respect to border rejection notifications, four were on groundnuts from China contaminated with high levels of aflatoxins (a recurrent notification, having been notified 81 times, of which 80 were border rejections) and one on groundnuts, from Nigeria, also contaminated with aflatoxins in exceedance of the MRL. With respect to the recalled consignments and the RASFF notifications generated thereof, one was due to the presence of aflatoxins in dried figs in Turkey (a recurrent notification at EU level) and the other was due to the contamination of black pepper with ochratoxin A, originating in Indonesia.

In 2017 there were a total of 529 notifications (464 Border rejection) related to contamination with mycotoxins for commodities imported from non-member countries. Just as had been seen in 2016, aflatoxins represented the great majority of the types of mycotoxins identified (even more so than in 2016). In 2017, the surplus of aflatoxin contaminated consignments was mainly due to groundnuts originating in China. In fact, of the 7 notifications generated by Portugal, 4 of them were groundnuts originating in China. The reasons for which was reported by DG Health and Food safety audit team, that carried out an audit in China due to the high number of RASFF notifications related to aflatoxin contamination in peanuts that year. The audit revealed limitations in the Chinese control system to prevent and detect aflatoxin contamination in foodstuffs, in particular, official controls of good hygiene practices and prevention of aflatoxin contamination did not apply to all categories of operators acting in the supply chain of peanuts, there was, in particular, a lack of supervision of the pre-processing stages, and also of dispatch and transport conditions to the EU. There were also weaknesses identified in the manner sampling and analysis were performed, creating a risk of failure in preventing and detecting aflatoxin contamination<sup>291</sup>.

Even though there was a boom in notifications regarding contaminated groundnuts from China, a high number of notifications on dried figs from Turkey kept the country at the top as the most notified country of origin for aflatoxin contamination (RASFF, 2017).

## Chapter 5 Conclusion

To conclude, between 2014 and 2017 there was a significant increase in the number of commodities imported into the Union subject to official border control checks by Portuguese authorities at several different points of entry; the frequency of controls performed increased substantially over the four years as a consequence of an increase in number of commodities subject to official controls (and possibly an improvement in the use of TRACES for registering the data on official controls), most abiding by the minimum frequencies set and detecting efficiently non-conformities when these were present. Nonetheless, and despite all relevant commodities subject to official control measures under Community legislation and national control plans, having been presented to DRAP/DRA competent authorities for checks, there were some shortcomings identified for commodities subject to Community measures, in terms of documentary checks (especially with regards to the presence of health certificates and analytical reports required under Decision 2011/884/EU), and insufficient analytical sampling to meet Community and national control plans. Concerns were addressed, and corrective measures for all of the shortcomings flagged by DG SANTE during the audit performed in March 2017 were implemented. Even so, insufficient checks on small numbers of commodities arriving during the course of the year, continued to be problematic right up towards the end of 2017.

In terms of the breakdown of imports by type of control, over 50% of commodities subject to official controls came listed under the Matrix of Analytical Control. A large number of commodities were subjected to emergency measures under Regulation (EC) No 884/2014 due to the risk of aflatoxins, followed by increased level of official controls under Reg. (EC) No 669/2009 and two other emergency measures (Reg. (EU) No 2016/6 and Decision 2011/884/EU). Overall, and across all Community and national measures, the number of commodities subjected to official controls increased over the period analysed.

The number of rejections did not change significantly during the four years with regards to Community measures and national measures, despite the increase in imports, indicating that food business operators are complying with Community and national requirements in exporting safe foodstuffs. However, the number of RASFF notifications derived from rejections has fluctuated over the four years, starting with 8 in 2014 (3 notifications for mycotoxins, 4 for unauthorized substances and 1 for pesticide residues), rising to 15 in 2015 (6 notifications for mycotoxin contamination, 5 for use of unauthorized substances and 4 for pesticide residues), then decreasing to 4 in 2016 (2 notifications due to mycotoxins, 1 to unauthorized substances and 1 to pesticide residues) and rising once more in 2017 to 9 (7 notifications due to mycotoxins, one due to unauthorized substances and 1 due to the use of unauthorized additives). The re-occurrence of rejections and generation of RASFF notifications for certain commodities from certain countries could indicate that the countries in question are not implementing enough measures to guarantee that their products abide to Union Law (this was actually the case with groundnuts from China

in 2017) and therefore Portugal needs to retain or increase official control measures associated with these commodities from these particular countries, when such commodities are not already subject to Community measures.

The majority of imports belonged to the commodity category of 'Edible fruits and nuts', and they originated, mostly, in Brazil (Portugal's largest supplier of edible fruits and nuts from outside the Union). Over 80% of imports were meant to stay within national borders with much of the remaining percentage of imports crossing the border to Spain.

To summarise, DSNA-DGAV have put in place a system that allows for efficient coordination between the several competent authorities and implemented a rigorous control plan of official controls for commodities not subject to Community measures, resulting in strict controls of imports of commodities originating from non-member countries. The majority of official controls resulted in satisfactory outcomes, with only 0.2% of the total of imports during the four years, being rejected due to non-compliance. Portugal has shown to play an active and responsible role with regards to food safety, by generating RASFF notifications when a risk was identified and acting on recommendations proposed by DG Health and Food Safety by implementing corrective measures.

A few recommendations are given based on the results provided in this work:

1. It seems appropriate to increase the frequency of controls for groundnuts, supplements and papayas in the Matrix of analytical control, as these commodities resulted in a high number of rejections over the four years analysed. Furthermore, due to an increase in consumption of protein-rich foodstuffs and tropical fruits that are associated with particular health benefits and dietetic lifestyles, the import of these commodities is believed to remain high.
2. In order to perform the necessary border control inspections on commodities that are few and far between, the creation and implementation of a national online platform for real time communication between the different CA at the various BIPs would allow CAs to scan and register the nature of the commodity and the type and number of controls performed, information that would be immediately available for consultation by CA located at a different PE in the country, and also by DGAV for more efficient monitoring of controls. Competent Authorities would therefore be able to consult the number of consignments, carrying a particular commodity, imported at any point in time and know whether or not there is need to carry out any further control checks based on those that have already been performed (please refer to Annex IV for a visual representation of how the software would work).

Regarding limitations of this study, there are a couple that should be mentioned:

1. Prior to the implementation of Regulation (EU) No 2017/625, the use of TRACES for FNAO was not compulsory, and therefore it was up to each MS to decide whether they wished to use the system. For this reason, and in spite of Portugal implementing its use in 2013, the process

was gradual and therefore the number of consignments registered in TRACES for 2014 and 2015 may not reflect the real number of imports in those years;

2. The CEDs for 2014 and 2015 were not consulted during the execution of this work, as it was outside the scope of this work, therefore the number of imports under particular Community measures for official controls, could be in most cases, an overestimation of the real number of consignments imported;
3. In terms of compliance with emergency measures requiring the presence of a Health Certificate and Analytical Report, it was not possible to ascertain frequency of non-compliances given that business operators could email these documents to the Cas rather than attach them to the CED on TRACES;
4. Finally, due to the limited resources available to the author, in many cases of rejections it was not possible to detail the reason of rejection, as the details were not provided in TRACES.

Finally, in terms of future study, with the implementation of Regulation (EU) No 2017/625, it would be interesting to see further research on the matter of official controls for FNAO across all MS, allowing for a comparison between countries within the Union of number and type of commodities imported, number and type of rejections and generation of RASFF notifications resulting from those rejections.

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# Annexes

## Annex I – Definition of Novel Food as provided under Article 3(2a) of Regulation (EU) No 2015/2283

- (a) 'novel food' means any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession of Member States to the Union, and that falls under at least one of the following categories:
- (i) food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997;
  - (ii) food consisting of, isolated from or produced from microorganisms, fungi or algae;
  - (iii) food consisting of, isolated from or produced from material of mineral origin;
  - (iv) food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by:
    - traditional propagating practices which have been used for food production within the Union before 15 May 1997; or
    - non-traditional propagating practices which have not been used for food production within the Union before 15 May 1997, where those practices do not give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances;
  - (v) food consisting of, isolated from or produced from animals or their parts, except for animals obtained by traditional breeding practices which have been used for food production within the Union before 15 May 1997 and the food from those animals has a history of safe food use within the Union;
  - (vi) food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, microorganisms, fungi or algae;
  - (vii) food resulting from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances;
  - (viii) food consisting of engineered nanomaterials as defined in point (f) of this paragraph;
  - (ix) vitamins, minerals and other substances used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, where:
    - a production process not used for food production within the Union before 15 May 1997 has been applied as referred to in point (a) (vii) of this paragraph; or
    - they contain or consist of engineered nanomaterials as defined in point (f) of this paragraph;
  - (x) food used exclusively in food supplements within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements as defined in point (a) of Article 2 of Directive 2002/46/EC;

Annex III – Blank CED [Reg (EC) No 669/2009]

EUROPEAN UNION		Common Entry Document (CED)	
Part II: Decision on consignment	II.1. CED Reference Number	II.2. Customs Document Reference	
	II.3. Documentary Check Satisfactory <input type="checkbox"/> Not Satisfactory <input type="checkbox"/>	II.4. Consignment selected for physical checks  Yes <input type="checkbox"/> No <input type="checkbox"/>	
	II.5. ACCEPTABLE for transfer <input type="checkbox"/> Control point Control point unit No  Consignment authorised for onward transportation (pending results of laboratory tests) – consignment not to be released <input type="checkbox"/>		
	II.6. NOT ACCEPTABLE <input type="checkbox"/> 1. Re-dispatching <input type="checkbox"/> 2. Destruction <input type="checkbox"/> 3. Transformation <input type="checkbox"/> 4. Use for other purpose <input type="checkbox"/>	II.7. Details of Controlled Destinations (II.6)  Approval no (where relevant) Address Postal Code	
	II.8. Full identification of DPE and official stamp <input type="checkbox"/> DPE Stamp DPE Unit N°	II.9. Official Inspector I, the undersigned official inspector of the DPE, certify that the checks on the consignment have been carried out in accordance with Union requirements.  Name (in capital)  Date Signature	
	<del>II.10.</del>	II.11. Identity check Yes <input type="checkbox"/> No <input type="checkbox"/> Satisfactory <input type="checkbox"/> Not Satisfactory <input type="checkbox"/>	
	II.12. Physical check Satisfactory <input type="checkbox"/> Not Satisfactory <input type="checkbox"/>	II.13. Laboratory Tests  Yes <input type="checkbox"/> No <input type="checkbox"/> Tested for: Results: Satisfactory <input type="checkbox"/> Not Satisfactory <input type="checkbox"/>	
	II.14. ACCEPTABLE for release for free circulation <input type="checkbox"/> 1. Human consumption <input type="checkbox"/> 2. Further process <input type="checkbox"/> 3. Feedingstuff <input type="checkbox"/> 4. Other <input type="checkbox"/>	<del>II.15.</del>	
	II.16. NOT ACCEPTABLE <input type="checkbox"/> 1. Re-dispatching <input type="checkbox"/> 2. Destruction <input type="checkbox"/> 3. Transformation <input type="checkbox"/> 4. Use for other purpose <input type="checkbox"/>	II.17. Reason for refusal 1. Absence/Invalid certificate (if applicable) <input type="checkbox"/> 2. ID: Mismatch with documents <input type="checkbox"/> 3. Physical hygiene failure <input type="checkbox"/> 4. Chemical contamination <input type="checkbox"/> 5. Microbiological contamination <input type="checkbox"/> 6. Other <input type="checkbox"/>	
	II.18. Details of controlled Destinations (II.16) Approval No (where relevant) Address Postal Code		
	II.19. Consignment resealed New seal No.		
	II.20. Full identification of DPE/Control Point and official stamp  Stamp	II.21. Official inspector I, the undersigned official inspector of the DPE/Control Point, certify that the checks on the consignment have been carried out in accordance with Union requirements  Name (in capital)  Date Signature	

