

Chapter 2

Managing Risks in Imports of Non-animal Origin: The EU System of Reinforced Border Surveillance

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Abstract This chapter illustrates the full range of policy tools that are currently available to the European Union (EU) for counteracting risks associated with imports of feed and food of non-animal origin. While verification of compliance is performed by EU Member States by means of official controls, place and intensity of controls may vary depending on the seriousness of the risk to be addressed. Policy tools available to the European Commission and EU Member States in their capacity as risk managers include market surveillance, reinforced border controls, emergency measures, special import conditions and approval of checks prior to export. Following a general introduction on the European legal framework governing imports of non-animal origin, the present work analyses the main features of the EU system of reinforced border controls designed by the Regulation (EC) No. 669/2009.

Keywords Feed • Food • Imports • Non-animal origin • Non-EU countries • Official controls • Reinforced border surveillance

Abbreviations

| | |
|------|--------------------------------|
| BCP | Border Control Post |
| BIP | Border Inspection Post |
| CED | Common Entry Document |
| CHED | Common Health Entry Document |
| CP | Control Point |
| DPE | Designated Point of Entry |
| EFSA | European Food Safety Authority |
| EU | European Union |

| | |
|--------|--|
| FVO | Food and Veterinary Office |
| GFL | General Food Law |
| ISO | International Standard Organisation |
| MANCP | Multi-Annual National Control Plan |
| OECD | Organisation for Economic Co-operation and Development |
| RASFF | Rapid Alert System for Food and Feed |
| SPS | Sanitary and Phytosanitary |
| TRACES | TRAdE Control and Expert System |
| USA | United States of America |
| WTO | World Trade Organisation |

2.1 Introduction

2.1.1 Official Controls: An Introduction

Following two major food scares during the 1990s, the European Commission published a ‘White Paper on Food Safety’ in January 2000 (European Commission 2000). Conceived as a blueprint document, the White Paper set down the overarching principles of the current legislative framework governing the food chain of the European Union (EU).

While calling for a more integrated approach in risk management along the food chain, the White Paper stressed the need to better clarify the obligations of the different stakeholders operating in said chain. It thus envisaged the setting up of a policy framework where feed and food business operators would be fully accountable for the safety of the products placed on the market and where public authorities would perform a supervising role.

Indeed, with regard to national authorities of EU Member States, subsequent EU legislation has clearly assigned them the task of ascertaining business operators’ compliance with EU food safety, animal health or animal welfare requirements. In practice, this monitoring activity is possible by means of official controls.

Accordingly, Regulation (EC) No. 882/2004 (European Parliament and Council 2004) has introduced a set of harmonised provisions governing official controls performed by Member States’ competent authorities, with effect as of 1 January 2006. Along with Regulation (EC) No. 178/2002 (European Parliament and Council 2002), commonly known as the ‘General Food Law’ (GFL), Regulation 882/2004 represents today a reference text for gaining a full understanding of this policy area.

2.1.2 Definition and Organisation of Official Controls

Regulation 882/2004 defines official controls as ‘any form of control that the competent authority [...] performs for the verification of compliance with feed

and food law, animal health and animal welfare rules’ (Article 2, point 1). In turn, ‘verification’, which is the ultimate purpose of official control, is intended as an activity encompassing the ‘checking, by examination and the consideration of objective evidence, whether specified requirements have been fulfilled’ (Article 2, point 2). EU Member States are responsible for the overall organisation of official controls and the efficacy of the relevant national control system. To this end, the Regulation specifies that official controls must be planned taking into account the risk involved and performed at an appropriate frequency and without prior warning (Article 3).

Furthermore, national competent authorities are responsible for ensuring that staff conducting official controls are adequately qualified and trained in their area of competence (Article 6). Generally, official controls are performed by either national central administrations or by any regional or local authority to which relevant powers have been conferred upon. On the other hand, specific tasks relevant to official controls may be delegated to independent control bodies, provided that certain conditions are met (Article 5).

2.1.3 Types of Checks

Usually, official controls on feed and food may consist of three different, though sequenced, types of checks: documentary, identity and physical checks. Table 2.1 portrays basic definitions for each of the checks in question.

Documentary checks may include the examination by official control authorities of commercial documents (e.g. invoices), transport documents (e.g. bill of lading, ship manifest for imports arriving at EU borders) or of any other document or certificate required by the EU law (e.g. veterinary, sanitary or phytosanitary certificates; results of laboratory analysis performed prior to export to the EU).

Physical checks may include activities such as sampling and laboratory testing. While sampling is normally conducted by an inspector pertaining to or, in

Table 2.1 The system of official controls in the EU according to Regulation (EC) No. 882/2004

| Control activities: key definitions | |
|---|---|
| Documentary check Article 2 point 17 | ‘Means the examination of commercial documents and, where appropriate, of documents required under feed or food law that are accompanying the consignment’ |
| Identity check Article 2 point 18 | ‘Means a visual inspection to ensure that certificate or other documents accompanying the consignment tally with the labelling and the content of the consignment’ |
| Physical check Article 2 point 19 | ‘Means a check on the feed or food itself which may include checks on the mean of transports, on the packaging, labelling and temperature, the sampling for analysis and laboratory testing and any other check necessary to verify compliance with feed or food law’ |

any event, under the supervision of the competent authority, analytical tests are carried out by official laboratories designated for this purpose by Member States and accredited against specific international standards such as EN ISO/IEC 17025 (Article 12, paragraphs 1 and 2).

2.1.4 Procedural Guarantees

Regulation 882/2004 provides feed and food business operators with a set of procedural rights when subject to official controls. For instance, when sampling for analysis is performed, the competent authority must comply with the following obligations (Article 11, paragraphs 5 and 6):

- Appropriate procedures must be in place to guarantee the right of the business operator to request a supplementary expert opinion, and, to this end,
- A sufficient number of samples must be made available to the same operator.

If one or more non-conformities are detected as a result of an official control, the competent authority would be also requested (Article 54, paragraph 3):

- To notify the concerned operator of the actions undertaken or those being planned in order to remove the non-compliance(s) identified, and
- To inform him/her of the reasons underpinning its decision as well as of his rights to appeal that decision.

2.1.5 Effectiveness of Official Controls

The European Commission verifies the effectiveness of the official control systems in the Member States by means of general and sector-specific audits carried out by the Food and Veterinary Office (FVO). While auditing a Member State, the FVO would normally verify (Article 45):

- The organisation and the functioning of the competent authorities responsible for the national control system
- The occurrence or persistence of problems in that context, as well as
- The level of implementation of the Multi-Annual National Control Plan (MANCP) that each Member State must have in place in accordance with Article 41 of Regulation 882/2004.

Moreover, the FVO carries out audits in non-EU countries, generally focussing on the assessment of the official control system applicable to feed and food products intended for export to the EU (Article 46).

With specific regard to the MANCP, it should be noted that Member States must submit annual reports on their implementation to the European Commission. The Commission is supposed to process the information received, together with relevant findings stemming from FVO audits or other sectoral reports, and produce an annual report on the overall operation of official controls in the EU (Article 44, paragraph 4).

The latest of these reports was published in October 2013, signalling a general improvement as regards the level of implementation of EU legislation on official controls (European Commission 2013a; González Vaqué 2013a). The report indicates that, overall, official controls organised by Member States appear to be increasingly risk-based, although not in same manner in all areas. In addition, available resources are often redeployed to ensure greater efficiency in the planning and execution of enforcement activities. The report claims, however, that there is some room for improvement especially as regards data collection: indeed, Member States do not compile (yet) relevant data in a way that is sufficiently consistent to cater for their full comparability.

2.1.6 Review of Regulation (EC) No. 882/2004

Regulation 882/2004 is currently under review. In May 2013, the European Commission launched a package of four legislative proposals in order to simplify and streamline the existing legislative framework governing animal health, plant health, seeds and official controls¹ (European Commission 2013b–e). The four proposals are currently under examination of the European Parliament and Member States in the Council.

In relation to the proposal on official controls (European Commission 2013e), the Commission intends to further strengthen the EU integrated approach to the food chain, by making rules on official controls applicable to areas that have been excluded so far (e.g. animal-by-products, veterinary residues) or only partially covered (e.g. plant health). Moreover, the proposal seeks to harmonise and improve EU rules concerning imports from non-EU countries (Sect. 2.2). Finally, since the proposal was finalised precisely when the horsemeat scandal hit the

¹ The four proposals have been announced as a part of the policy initiative ‘Smarter rules for safer food’ and preceded by the umbrella Communication from the Commission to the European Parliament and the Council with the title ‘Healthier Animal and Plants and a Safer Agri-food chain’, COM (2013) 264.

media in the EU,² it contains a number of new provisions aimed at improving EU and Member States' capability to detect food frauds and sanction them as appropriate (González Vaqué 2013b; Laurenza 2013; Montanari 2013).

At present, the outcome of the legislative negotiations is uncertain. It is however to be hoped that stakeholders involved will strive to agree on common solutions that will not lower or compromise the level of consumer protection that the EU has been able to ensure so far.

2.2 EU Import Control Policy

Provisions regarding official controls on import of animals, plants, feed and food into the EU are currently scattered across several EU legislative acts with horizontal or vertical scope and, sometimes, with a varying degree of harmonisation.

This piecemeal approach is mainly due to the different circumstances and policy drivers that, over time, have influenced the evolution of EU legislation relating to imports. In fact, the application of an integrated approach to the food chain, as introduced by the GFL and further enhanced through Regulation 882/2004, is a relatively recent milestone and, despite its merits, still incomplete.

Ultimately, the approach referred above has led to a complex framework consisting of different import control requirements and/or import conditions, depending on:

- (a) The type of goods destined to the EU market (e.g. live animals, products of animal and non-animal origin, food contact materials, live plants and plant products), and/ or
- (b) The seriousness of the risk involved.

² The horsemeat scandal can be regarded as the very first case of food fraud with an EU dimension. In essence, meat presented or labelled as beef was instead of *equidae* not destined to human consumption and thus used for being a cheaper ingredient. When control authorities of several Member States first detected the fraud in the first quarter of 2013, concerns arose that the fraud might also have some safety implications. Indeed, first sampling revealed, in certain instances, presence of residues of phenylbutazone, a veterinary drug usually administered to horses employed in sports competition. For this reason, based on Article 53 of Regulation No. 882/2004, the European Commission recommended the organisation of a coordinated control plan across the EU. Results of the control plan indicated that, although the prevalence of veterinary residues was relatively limited, conversely, fraudulent mislabelling emerged as a widespread practice. In the wake of this fraud, the European Commission undertook a wide range of actions, including strengthening of requirements for controls on movement of horses within the EU, in order to prevent frauds of such an extent from happening again. Nearly one year after the scandal and while some criminal proceedings were still pending before national courts, in March 2014 the Commission launched a new round of coordinated controls aimed at ascertaining the prevalence of fraudulent practices as regards processing and labelling of bovine meat (Recommendation 2014/180/EU).

2.2.1 General Food Law and Imports

With regard to imports of feed and food, Article 11 GFL enshrines the fundamental principle whereby imported products, as much as EU products, must fulfil the relevant safety requirements laid down in EU law or ‘equivalent conditions’, where relevant. Yet, the EU may foresee, on emergency grounds, additional controls or conditions to be met, when faced with a serious risk associated with a product originating from outside the EU (Article 53 GFL). The margin of manoeuvre that the EU enjoys in such cases appears to be quite broad, with the spectrum of measures that can be adopted ranging from the suspension of relevant imports to any other interim measure that is deemed appropriate (including, for instance, the provision of export certificates and/or reinforced official controls on the EU territory).

2.2.2 Regulation (EC) No. 882/2004 and Import Controls

Regulation 882/2004 provides for a general framework for the organisation of official controls on imports of feed and food originating from non-EU countries (Chapter V, Articles 14 to 25).

Provisions of Regulation 882/2004 are supplemented by earlier Council Directives 91/496/EEC and 97/78/EC concerning, respectively, veterinary checks on imports of live animals and products of animal origin (Council of the European Communities 1991; Council of the European Union 1997). Although more than two decades have passed from the adoption of the above said Directives, the overarching principles in this area have remained substantially unchanged.

Essentially, import of veterinary goods into the EU is allowed only from authorised non-EU countries and, within their territory, from approved establishments. At their arrival in the EU, those goods must be presented at approved Border Inspection Posts (BIP) and accompanied by a veterinary certificate (to be duly signed by the competent authorities of the exporting country). While live animals entering the EU are subject to systematic documentary, identity and physical checks, feed and food of animal origin may be subject to reduced control frequencies for physical checks, if the relevant risk so allows.

In this respect, it is worth noting that the EU import control legislation in the veterinary sector is particularly strict as opposed to other areas. Indeed, as a rule, imports of feed and food of non-animal origin, including herbs, spices, fruits and vegetables, can freely enter the EU territory, unless there is a specifically regulated risk (Alemanno 2010).

As regards imports of feed and food of non-animal origin, the organisational principles set in Regulation 882/2004 are further elaborated by means of implementing legislation. As already anticipated, the overall philosophy governing this area is that specific EU import requirements may be set for cereals, fruits,

vegetables intended for the EU market and verified at Designated Points of Entry (DPEs) whenever the risk they present so requires (Sect. 2.2.3).

Overall, one could question the reasons of maintaining two distinct regimes for imports of animal origin, on the one hand, and products of non-animal origin, on the other. In fact, several of the most recent food scares have been triggered from imported products of non-animal origin (Sects. 1.3.3.1 and 1.3.3.2). Recent events should at least call into question the current EU approach whereby products of non-animal origin are thought as involving a lower degree of chemical, physical or microbiological risk as opposed to products of animal origin. Finally, it is also worth recalling that the coexistence of different import control regimes may render the implementation of official controls a challenging task for national control authorities, besides being perceived as a potential hindrance to trade.

Despite the differences highlighted above, Regulation 882/2004 also foresees a set of provisions that are applicable to all imports, including products of non-animal origin. First among those provisions, Article 48 of this Regulation provides a legal basis for the adoption of specific import conditions for feed and food originating from non-EU countries, including lists of countries authorised to export specific products, export certificates and special import conditions. To some extent, the content of this provision may seem to overlap in part with Article 53 GFL. However, legislative practice have shown that Article 48 of Regulation 882/2004 has been applied in a relatively limited number of cases and, generally, with a view to setting import conditions on a permanent basis rather than tackling emergency situations that are, by definitions, limited in time.

Secondly, Article 49 of the same Regulation stipulates that the EU may recognise the equivalence of the official control system of another non-EU country with its own one, based on an international agreement or a favourable FVO audit. However, to date, the EU has not yet adopted an equivalence decision in accordance with this provision.

Thirdly, Article 23 of Regulation 882/2004 foresees the possibility for the EU to approve official controls carried out by an exporting country immediately prior to the dispatch of the relevant products to the EU. This approval may only be granted following appropriate verification that:

- The concerned feed and food exports are fully compliant with applicable EU requirements, and
- Official controls performed by the exporting country are conducted effectively enough to justify the replacement or the reduction of EU surveillance (Article 23, paragraph 3).

As a result of the granting of the approval, the intensity of import controls on the EU side is to be reduced. In any event, competent authorities in the Member States are required to maintain an adequate level of import surveillance in order to verify that the effectiveness of the pre-export checks approved by the EU remains unaltered. Similarly to Article 48, this provision has been used in a limited number of cases.

2.2.3 Towards a New EU Import Control Policy?

The European Commission seems conscious of the need of greater consistency across EU legislation on import controls. Indeed, in October 2010, the Commission published a ‘Report on the effectiveness and consistency of sanitary and phytosanitary controls on imports of food, feed, animals and plants’ (European Commission 2010d).

In essence, the Commission report acknowledges that further improvements may be necessary, in spite of the current system of EU import control functioning relatively well. One of the issues on which the report focuses is the need to make import controls and, in particular, physical checks more risk-based. Should this approach be embraced, the (limited) resources currently available at national level for official controls could be possibly better allocated and employed. In addition to that, the report notes that the differences across the various policy areas where import controls take place should be smoothed with a view to ensuring a more coherent EU import surveillance.

According to the Commission’s proposal reviewing the framework for official controls (Sect. 2.1.6), in future all goods destined to import into the EU—be animals, plants, seeds food or feed—should be channelled through Border Control Posts (BCPs). The latter, located across the EU territory, should eventually replace the existing BIPs, DPEs and Points of Entry (for plants and plants products). In addition to that, arrival of consignments would require prior notification by business operators of a Common Health Entry Document (CHED). Depending on the technical feasibility, there are also plans to extend the use of the TRAdE Control and Expert System (TRACES)—the electronic platform currently used in the veterinary sector to trace imports and intra-EU movement of live animals and products of animal origin—to other areas such as plants and plant products.

2.3 Imports of Feed and Food of Non-animal Origin: The Relevant EU Legal Framework

Article 15 of Regulation 882/2004 on official controls is at present the main provision governing EU policy on imports of feed and food of non-animal origin.

2.3.1 Market Surveillance

As a rule, feed and food products of non-animal origin from non-EU countries destined to import into the EU are subject to the control activities that Member States’ national authorities perform in accordance with their MANCP. In this respect, Member States enjoy a relatively broad discretion in identifying those

imports of non-animal origin that should be subject to official controls. In fact, Regulation 882/2004 merely prescribes that import controls in this area must be conducted on a regular basis, at an appropriate frequency and in light of potential risks (Article 15, paragraph 1). Similarly, the Regulation leaves Member States free to decide the most appropriate place for controls, including (Article 15, paragraph 2):

- The point of introduction into the EU territory
- The point of import
- Custom warehouses
- The premises of the importing business operator
- Any other stage within the feed or the food chain.

Generally, imports of non-animal origin that are merely subject to market surveillance do not raise serious safety concern and, from a risk management perspective, are regarded as low-risk products.

2.3.2 Reinforced Border Surveillance

Besides the general import regime set out in Article 15, paragraphs 1 and 2 of Regulation 882/2004 (Sect. 2.3.1), this provision foresees as well the establishment of a list of imports of feed and food of non-animal origin that, presenting a known or emerging risk, must be subject to reinforced surveillance at EU borders (Article 15, paragraph 5).

Overall, the EU reinforced surveillance regime for imports of non-animal origin is based on the following key elements (Regulation 882/2004, Article 17, paragraph 1):

- (a) The designation of DPEs by EU Member States, i.e. ports, airports and terrestrial frontiers with non-EU countries equipped with adequate facilities
- (b) The prior notification of the physical arrival of relevant consignments to the concerned DPE by business operators.

In accordance with Regulation 882/2004 (Articles 15, paragraph 5, and 17), the European Commission has adopted Regulation (EC) No. 669/2009 on an increased level of official controls on certain imports of feed and food of non-animal origin in July 2009³ (European Commission 2009a). The Regulation formally entered into application on 25 January 2010.

³ In this respect, it should be noted that the Regulation is based on Article 53 GFL as a legal basis in addition to Article 15 paragraph 5 of Regulation 882/2004. The use of Article 53 GFL as a legal basis can be explained considering that, when adopted, Regulation 669/2009 incorporated some imports that, at that time, were subject to emergency measures based on that provision (notably, Decision 2006/504/EC). This interpretation would be confirmed by the subsequent amendments of Annex I to Regulation 669/2009, which are systematically based only on Article 15 paragraph 5 of Regulation 882/2004.

The EU system of reinforced border surveillance introduced by Regulation 669/2009 has been designed in such a way that impact on trade should be minimal. Effectively, the system neither prevents the concerned products from entering the EU territory nor requires further assurances to be provided (e.g. sanitary certificates or analytical reports). Therefore, from a risk management perspective, imports of non-animal origin subject to reinforced border surveillance should be considered as presenting a ‘medium risk’.

2.3.3 Emergency Measures

Whenever serious risks are associated with imports of non-animal origin, the latter may be subject to EU decisions commonly known as ‘safeguard measures’ or ‘emergency measures’. These decisions may involve the suspension of imports or require compliance with other conditions that have trade-restrictive effects.

Generally, emergency measures are adopted to tackle situations that are considered serious from a public health perspective and, thus, based on Article 53 GFL. Two examples of emergency measures laying down specific requirements for imports of non-animal origin are as follows:

- (a) Regulation (EU) No. 884/2014 (European Commission 2014e) imposing special conditions for the import of certain products from several non-EU countries because of aflatoxins contamination,⁴
- (b) Regulation (EC) No. 258/2010 setting import requirements for guar gum from India (European Commission 2010a).

On the other hand, EU trade bans in this area are relatively rare and, generally, limited in time either because the emergency ceases to exist or following provision of appropriate guarantees by the exporting country. The EU decision to suspend imports of fenugreek seeds from Egypt following the outbreak of *E. coli* in Germany and France in 2011 (Sect. 1.3.3.1) is one recent example of a trade ban adopted at EU level in relation to imports of non-animal origin (European Commission 2011a, b). Most recently, the EU has introduced a temporary ban on imports of betel leaves from Bangladesh because of microbiological contamination by *salmonella spp* (European Commission 2014a, b).

Figure 2.1 exemplifies the existing relation between the seriousness of the risk that an import of non-animal origin may present (i.e. low, medium or high risk) and the policy instruments currently available to risk managers (i.e. European Commission together with Member States). Figure 2.1 also shows how:

- (a) The seriousness of a given risk may increase from ‘low’ to ‘medium’ or ‘high’ and vice versa, depending on the circumstances of the case
- (b) The qualification of a risk as ‘low’, ‘medium’ and ‘high’ ultimately impacts on the choice of the policy instrument to be used by risk managers.

⁴ This Regulation replaces Regulation (EC) No. 1152/2009 (European Commission 2009b).

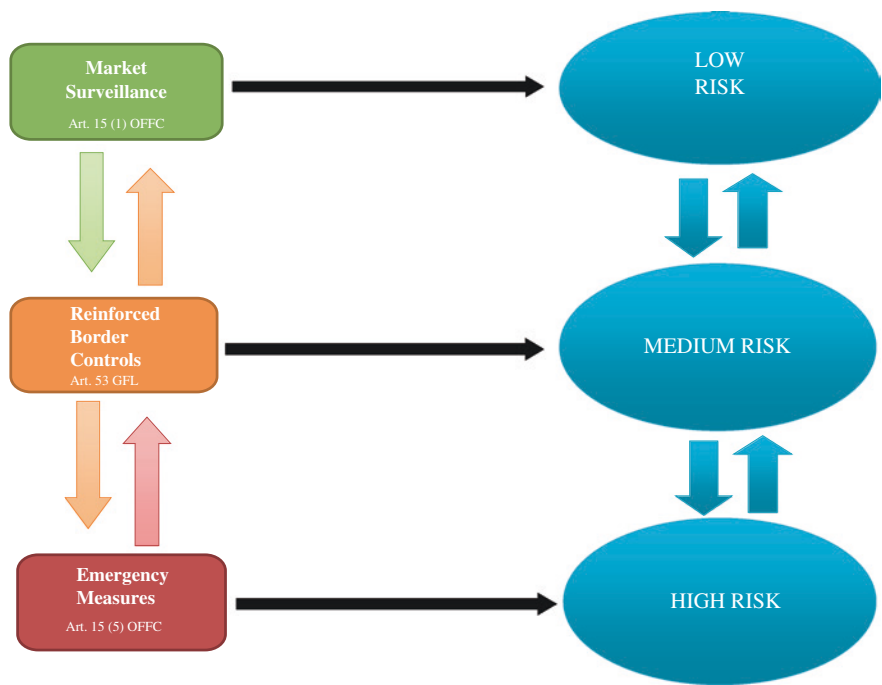


Fig. 2.1 Relation between risk and risk management policy tools

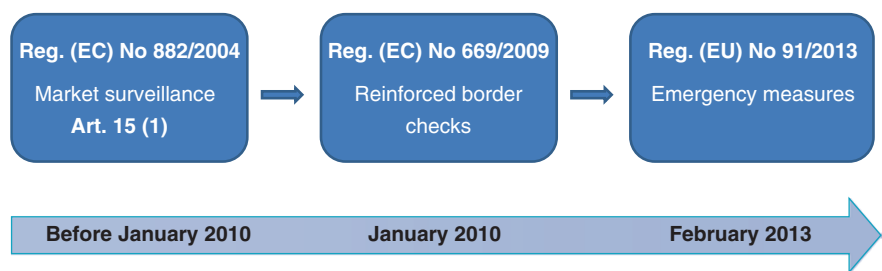


Fig. 2.2 Groundnuts and derived products from India for aflatoxin contamination. The EU legislation has progressively raised the attention level from the original ‘low-risk’ to ‘high-risk’ status

Two practical applications of EU risk management in this area are shown in Figs. 2.2 and 2.3.

2.3.4 Specific Import Conditions

As previously highlighted, Article 48 of Regulation 882/2004 is a provision of general relevance to all imports whereby specific import conditions (i.e. listing of

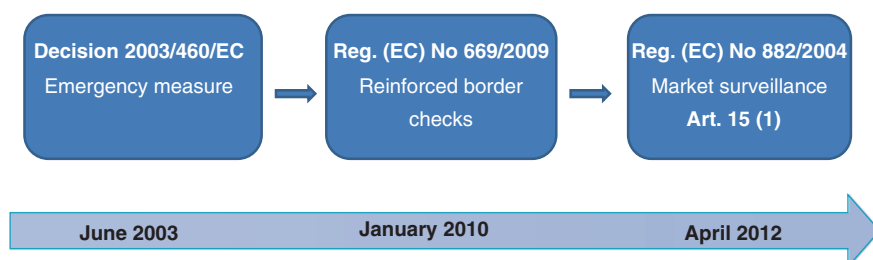


Fig. 2.3 *Chilli, chilli products, curcuma and palm oil from all non-EU countries for Sudan dyes adulteration*. The EU legislation has progressively lowered the attention level from the original 'high-risk' to 'low-risk' status

non-EU countries authorised to export, export certificates and/or special import conditions) can be imposed.

Since the entry into force of Regulation 882/2004, this provision has been used only twice. It was first used to adopt Regulation (EU) No. 284/2011 laying down specific import conditions on polyamide and melamine plastic kitchenware from China and Hong Kong (European Commission 2011c). More recently, the EU established specific certification requirements for sprouts and seeds for sprouting under Regulation (EU) No. 211/2013 (European Commission 2013f; Paganizza 2013; Rodriguez Font 2012). Adopted nearly 2 years after the biggest outbreak of *E. coli* the EU has ever known, this Regulation is part of a package of control measures, including, e.g. traceability requirements and listing of establishments approved for export, designed to prevent food-borne disease associated with such imports from happening again.

From the above, it would appear that the choice of Article 48 as a legal basis has to do with the permanent nature of the import conditions that the EU legislator can impose on the basis of that provision. On the other hand, an emergency situation, that is, by definition, limited in time, would be most appropriately addressed through measures based on Article 53 GFL.⁵

2.3.5 Approval of Pre-export Checks

As referred above (Sect. 2.2.2), Article 23 of Regulation 882/2004 provides the EU with a legal basis for the formal approval of the pre-export checks performed

⁵ If the different rationale behind the two legal bases that can be used for imposing import requirements at EU level may appear clear in theory, practice shows that the EU legislator does not seem to abide by this interpretation systematically. For instance, one could question why Article 53 GFL is still used as a legal basis of Regulation 884/2014, when several imports covered (e.g. pistachios from Iran, groundnuts from Egypt) have been subject to import conditions for more than a decade. Hardly classifiable as emergency situations, those referred rather appear as recurring or structural safety issues, which, from a mere legal perspective, Article 48 Regulation 882/2004 would address more effectively.

by a non-EU country. Since the entry into force of the Regulation, use of this provision has been relatively limited. Indeed, it has been used only twice and namely in the area of imports of non-animal origin:

- Decision 2008/47/EC (European Commission 2008) regarding the risk of aflatoxins in peanuts and derived products from the United States of America (USA), and
- Regulation (EU) No. 844/2011 concerning the risk of ochratoxin A in wheat and wheat flour from Canada (European Commission 2011d).

Decision 2008/47/EC was adopted following a specific request submitted in 2005 by USA competent authorities as well as a FVO satisfactory audit. Overall, it allows the import peanuts and related products from USA provided that the following documents accompany the products:

- A health certificate contained in the Annex to the Decision with a 4-month validity from the date of issue,
- An analytical report containing results of sampling and analysis performed by an official laboratory of the exporting country in accordance with relevant EU standards.

With regard to official controls, in light of the guarantees provided by the exporting country, the Decision foresees that the frequency of physical checks should be ‘significantly reduced’ (Article 2). This means, that pre-export checks do not replace completely control activities at import stage. In other words, EU Member States must maintain a level of import surveillance that, though reduced, is proportionate to the risk (Regulation 882/2004, Article 16, paragraph 2). The notifications reported by Member States through the Rapid Alert System for Food and Feed (RASFF) over the past few years (2012: 5 detections, 2013: 6 detections) do confirm that national authorities still ensure a certain degree of surveillance on the products covered by the decision.

Similarly, Regulation 844/2011 requires the provision of a health certificate and an analytical report, both issued under the responsibility of the Canadian Grain Commission, attesting compliance of wheat and wheat flour from Canada, in particular, with EU standards for Ochratoxin A.

Concerning the reduced intensity for physical checks, the Regulation sets out a maximum 1 % control rate on all arriving consignments. Since 2011, official controls performed by EU Member States have apparently led to no detection.

2.4 Regulation (EC) No. 669/2009: Main Features of the System

Besides qualifying for as a special regime, the system of reinforced surveillance introduced by Regulation 669/2009 represents the first attempt, at EU level, at coordinating border control activities performed on imports of feed and food of non-animal origin by EU Member States.

Considering the impact of the novelties introduced by the Regulation, this latter has envisaged (Article 19):

- A six-month time interval between the entry into force of the Regulation (14 August 2009) and the actual date of its application (25 January 2010)
- A five-year transitional period in which control activities can be carried out away from the EU border (thus, from the premises of a DPE).

The provisions of Regulation 669/2009 have to be considered in conjunction with the Guidance document that the European Commission published following its entry into application.⁶ Conceived as a ‘living’ document and aimed at ensuring uniform application of the control regime across the EU, the Guidance provides interpretations that, at times, go beyond the actual text of the Regulation. As an example, the document indicates the following categories of products as not being covered by the Regulation (and, thus, not subject to reinforced border surveillance):

- Composite products containing one or more of the feed or food listed in Annex I (e.g. salad or fruit mixes), unless otherwise specified by the Annex
- Products imported for research or laboratory purposes, as long as their intended use is well documented
- Products that are introduced in the territory of the EU for personal consumption
- Products transiting through the territory of the EU but destined to non-EU countries.

Further references to the content of the Guidance document will be made in the course of the following paragraphs as the main features of Regulation 669/2009 are presented.

2.4.1 Control Activities

As a rule, Regulation 669/2009 foresees that official controls on EU imports of non-animal origin requiring increased border surveillance should take place at the premises of DPEs. In terms of control activities, the Regulation requires relevant imports to undergo:

- Systematic (i.e. 100 %) documentary checks, and
- Identity and physical checks at a lower control rate (e.g. 5, 10, 20 and 50 %), as specified in Annex I.

⁶ The European Commission’s ‘*Question and Answers Paper on the provisions of Commission Regulation (EC) No. 669/2009 on an increased level of official controls on certain imports of feed and food of non-animal origin*’ currently deals with 35 issues related to the application of that Regulation. Issues are grouped under six different headings: General concepts, Scope, Listing under Annex I, Implementation, Common Entry Document and, finally, Control Activities. The latest version of the Guidance document is available at the following web page: http://ec.europa.eu/food/food/controls/increased_checks/docs/QandA_paper_en.pdf.

Definitions of documentary, identity and physical checks contained in Article 2 Regulation 882/2004 (Table 1) apply also to control activities performed under Regulation 669/2009.

With regard to documentary checks, the Regulation sets out a precise timeframe (i.e. 2 working days) within which the competent authority of the DPE should perform them (Article 8 paragraph 1 (a)). On the other hand, the Regulation does not set a maximum timeframe for identity and physical checks: these controls should be carried out ‘as soon as technically possible’ (Article 8 paragraph 1 (b)). The lack of a specific timeframe may be justified if one considers the wide range of risks that Annex I to Regulation 669/2009 lists and the differences in turnaround times that may ensue from that.

In any event, feed and food business operators importing products covered by the Regulation 669/2009 may reasonably expect identity and physical checks (including delivery of the results of laboratory analysis) to be performed within the specific timeframes that other relevant EU legislation may set. Based on this interpretation, the 15-working day timeframe foreseen for the completion of official controls on products with high risk of aflatoxin contamination under Regulation 884/2014 would also apply to border controls on products listed for the same hazard in Annex I to Regulation 669/2009.

2.4.2 Designated Points of Entry

Designation of DPEs is an exclusive responsibility of EU Member States’ competent authorities.⁷ However, Regulation 669/2009 lists a set of minimum requirements that ports, airports or terrestrial borders must meet and namely (Article 4):

- Presence of suitably qualified and trained staff and in sufficient number
- Appropriate facilities for the performance of official controls including, where appropriate, storage and cold rooms, and a sheltered place where to perform sampling
- Appropriate unloading and sampling equipment
- Detailed instructions concerning sampling for analysis and the sending of samples to an accredited laboratory identified for this purpose
- An accredited laboratory, located at a reasonable distance from the DPE where samples can be sent for analysis.

Interestingly, the Regulation is silent as regards the possibility for veterinary BIPs and DPEs to share the same facilities. Should the use of shared facilities for veterinary and non-veterinary controls be allowed, national authorities of Member States would be reasonably expected to ensure that relevant hygiene standards are respected and cross-contamination is avoided.

⁷ On the other hand, in the veterinary area, designation of BIPs is subject to the European Commission’s prior approval and regular auditing by the FVO.

EU Member States must communicate to the European Commission the list of national DPEs. The Commission has, in turn, the obligation to make accessible the list of existing DPEs on its website.⁸

2.4.2.1 Use of Control Points

It should be noted that Regulation 669/2009 envisages a number of circumstances under which part of official controls may be performed away from DPEs. In any event, documentary checks must always be performed at the premises of the concerned DPE. Sections 2.4.2.1–2.4.2.3 illustrate the situations where derogations from the general border control regime are allowed.

As referred earlier above, Regulation 669/2009 has foreseen a five-year transitional period to provide EU Member States with sufficient time to equip DPEs (Article 19). However, due to practical difficulties encountered by some Member States in establishing DPEs within the timeframe initially foreseen, Regulation (EU) No. 718/2014 has prolonged the transitional period until 14 August 2019 (European Commission 2014c).

During the transitional period, Member States may decide to make use of control points (CPs) located away from EU borders for the performance of identity and physical checks. In any event, CPs must fulfil the same minimum requirements foreseen for DPEs and be authorised by the competent authorities of the concerned Member State. Article 19, paragraph 2 clarifies that Member States have to make available to the public relevant details of CPs: as a result, CPs are listed together with DPEs in national lists as required by Article 5 of Regulation 669/2009.

2.4.2.2 Special Geographical Circumstances

Article 9, paragraph 1, of Regulation 669/2009 provides for the possibility of performing physical checks at the premises of the feed or food business operator, whenever the DPE operates under special geographical circumstances, i.e. location in mountainous areas, ports or airports located on a small island. EU Member States interested in obtaining this derogation must seek an authorisation with the European Commission.

At present, only two Member States have requested such an authorisation. The following DPEs are authorised to perform part of the controls under Regulation 669/2009 at the premises of approved business operators (European Commission 2010b, c):

- Floriana port (Malta)
- Larnaca airport (Cyprus)
- Limassol port (Cyprus).

⁸ The full list of DPE is available at the following web page: http://ec.europa.eu/food/food/controls/increased_checks/list_DPE_en.htm.

The relevant Commission's decisions clarify that the authorisations are granted, in principle, on a permanent basis, unless the assurances provided by the concerned Member State cease to exist.

2.4.2.3 Highly Perishable Products and Packaging with Special Characteristics

Regulation 669/2009 also foresees (Article 9, paragraph 2) that, under exceptional circumstances, identity and physical checks may be carried out directly by the competent authorities of the place of destination of the consignment, i.e. anywhere in the EU territory. These arrangements would be justifiable, in particular, when sampling at DPE might compromise the safety or the quality of products to an unacceptable extent. More precisely, the concerned products should be 'highly perishable'; alternatively, their packaging materials should present special characteristics.

Whether a product is 'highly perishable' or its packaging has special characteristics, these are requirements that have to be specified in Annex I to Regulation 669/2009. At present, no import of feed or food of non-animal origin has been listed in Annex I under such conditions, although the possibility of making use of the regime under discussion has been considered a few times (e.g. in relation to herbs and spices or hazelnut paste in vacuum packages).

2.4.2.4 Onward Transportation

Article 8, paragraph 2, of Regulation 669/2009 foresees that competent authorities of a DPE may authorise the onward transportation of the products to be imported until their final destination, while results of physical checks are still pending. Competent authorities of the DPE may consider taking this decision, in particular, when perishable products such as fruits and vegetables are subject to border controls. Current practice shows that several Member States allow onward transportation.

The purpose of this provision is quite evident: by allowing onward transportation, the EU legislator wants to ensure that the impact of Regulation 669/2009 on trade is minimised.

Some difficulties may arise when the final destination of the consignment is in the territory of a Member State other than the one through which the products have entered the EU. In such cases, the coordination and the communication between competent authorities of the DPE, on the one hand, and the competent authorities of the place of destination, on the other, are not always as smooth as they should.

For this reason, besides providing further clarifications in this area through its Guidance, Q&A n. 16 (Sect. 2.4), the European Commission has set up a network of competent authorities in Member States with a view to ensuring appropriate implementation of onward transportation throughout the EU.

2.4.2.5 Outcome of Official Controls

Release for free circulation into the EU of consignments under Regulation 669/2009 is possible only:

- Upon presentation of a Common Entry Document (CED) to the competent custom office by the feed or food business operator (Sect. 2.5)
- Whether all official controls (i.e. documentary checks and, where applicable, identity and physical checks) have been carried out successfully.

In this regard, Regulation 669/2009 fully mirrors the approach followed by the EU legislator for other emergency measures applying to imports of non-animal origin (European Commission 2009b, 2013g, 2014e, f). The same can be said for the provision of the Regulation concerning splitting of consignments (Article 12): splitting is allowed only after the completion of official controls by the competent authorities.⁹

Official controls performed pursuant to Regulation 669/2009 may lead to the identification of one or more non-compliances. The latter may consist of the following:

- (a) Failure of documentary checks (e.g. absence or inadequate completion of CED)
- (b) Unfavourable results of laboratory tests, whenever physical checks are required.

For such cases, Article 13 of Regulation 669/2009 refers back to the set of actions that competent authorities may undertake following detection of non-compliant consignments in accordance with Articles 19, 20 and 21 of Regulation 882/2004. These actions include destruction, special treatment and redispach.

2.5 Obligations for Feed and Food Business Operators

Regulation 669/2009 lays down some requirements for feed and food business operators willing to import into the EU products that fall into its scope.

First of all, business operators must present their feed or food products to a DPE and ensure adequate prior notification—one working day in advance—of the physical arrival of the consignment (Article 6). The prior notification involves the submission (by fax, e-mail or through electronic platforms such as TRACES) of a CED (Annex II to the Regulation) and, in particular, completion by the business operator (or its representative) of Part I of that document.¹⁰ It is worth noting that

⁹ Furthermore, all these provisions foresee that, following splitting, each part of the consignment must be accompanied by an authenticated copy of the original CED until it is released for free circulation.

¹⁰ On the other hand, Parts II and III of the CED are to be filled in by the competent authorities.

at present several Member States are using TRACES, on a voluntary basis, for tracing and recording information on imports of non-animal origin (Sect. 2.2.3).

Secondly, business operators importing consignments with special characteristics are expected to provide staff at the DPE with the unloading and sampling equipment that may be necessary for the performance of official controls.

Thirdly, business operators are required to bear costs of official controls: these costs have to be paid in the form of fees (Regulation 669/2009, Article 14, paragraph 2). For the determination of fees occasioned by reinforced border controls, Regulation 669/2009 refers to the relevant provisions of Regulation 882/2004. This approach results in fees not being fully harmonised across in the EU and, in certain instances, with considerable differences between Member States.

Eventually, it is worth mentioning that business operators whose products undergo reinforced controls under Regulation 669/2009 are also subject to general obligations and rights set in EU food law. They are thus required to ensure the safety of feed and food products they import and market into the EU territory in accordance with the GFL, besides being accountable for any civil and/or criminal liability directly stemming from breaches of EU feed and food safety requirements (Regulation 882/2004, Article 1, paragraph 4). On the other hand, whenever subject to official controls, they enjoy the procedural guarantees provided by Regulation 882/2004 (Sect. 2.1.4).

2.6 Obligations for Competent Authorities in the Member States

Regulation 669/2009 lays down a number of specific requirements also for national authorities of EU Member States. As referred above, Member States are responsible for the designation of DPEs and must have system in place to levy fees occasioned by official controls. In addition to that, Member States must regularly inform the European Commission of the results of their border control activities. More precisely, they must submit quarterly reports detailing the following information (Article 15):

- Number of incoming consignments of imports listed under Annex I to Regulation 669/2009 and relevant volumes,
- Number of consignments sampled and analysed,
- Number of non-compliances detected.

Based on this information, the European Commission and EU Member States can ensure a continuous assessment of the food safety risks that are associated with the imports listed in Annex I.

Finally, the general obligations applying to Member States as per Regulation 882/2004 are also relevant in the context of the reinforced controls required by Regulation 669/2009. One of these obligations is, for example, the requirement to have in place, at national level, proportionate, dissuasive and effective penalties for sanctioning non-compliances (Regulation 882/2004, Article 55).

2.7 Audits of the Food and Veterinary Office

During the period 2010–2011, the FVO has carried out a series of audits to evaluate official controls on imports of food of non-animal origin in several EU Member States¹¹ (European Commission, Directorate-General for Health and Consumers 2011).

Overall, FVO's findings have revealed that the audited Member States implemented Regulation 669/2009 to a satisfactory extent, except for some minor shortcomings concerning:

- Prior notification of CED by business operators,
- Onward transportation (in particular, inefficient communication between competent authorities of different Member States),
- Respect of control frequencies for physical checks set in Annex I.

Similarly, subsequent audits performed in other Member States during the period 2012–2013 have shown a satisfactory level of implementation of the provisions of Regulation 669/2009. However, onward transportation and cooperation between competent authorities still stand out as areas requiring improvements.¹²

2.8 Annex I to Regulation (EC) No. 669/2009

Staff of DPE must conduct reinforced controls on imports listed in Annex I to Regulation 669/2009 at the control intensity therein specified. The Regulation requires regular reviews of the Annex to be carried out, at least, on a quarterly basis (Article 2, last sentence). Based on that, Annex I was updated several times since the entry into application of the Regulation. Table 2.2 provides a chronological summary of all the legislative amendments of Annex I occurred so far.

2.8.1 Scope

By definition, the list of imports contained in Annex I covers feed and food of non-animal origin that present a known or emerging risk. Groundnuts, tropical fruits, vegetables, herbs and spices are the products known to recur more often in

¹¹ The series of audits covered, in particular, the following countries: Sweden, Luxembourg, Denmark, Romania, Italy, Bulgaria, France, United Kingdom, Belgium, the Netherlands, Germany and Lithuania. A previous series of audits on import controls on food of non-animal origin was conducted over the period 2006–2008 (European Commission, Directorate-General for Health and Consumer Protection 2009).

¹² During 2012, the FVO performed audits also in Greece and Poland, in addition to a follow-up mission to Bulgaria. During 2013, the FVO visited Austria, Czech Republic and Hungary.

Table 2.2 Quarterly reviews of Annex I to Regulation 669/2009 (Sect. 2.8)

| Amendment | Entry into application | Amendment | Entry into application |
|-------------------------|------------------------|-------------------------|------------------------|
| Reg. (EU) No. 878/2010 | 1 October 2010 | Reg. (EU) No. 1235/2012 | 1 January 2013 |
| Reg. (EU) No. 1099/2010 | 1 January 2011 | Reg. (EU) No. 270/2013 | 1 April 2013 |
| Reg. (EU) No. 187/2011 | 1 April 2011 | Reg. (EU) No. 618/2013 | 1 July 2013 |
| Reg. (EU) No. 433/2011 | 1 July 2011 | Reg. (EU) No. 925/2013 | 1 October 2013 |
| Reg. (EU) No. 799/2011 | 1 October 2011 | Reg. (EU) No. 1355/2013 | 1 January 2014 |
| Reg. (EU) No. 1277/2011 | 1 January 2012 | Reg. (EU) No. 323/2014 | 1 April 2014 |
| Reg. (EU) No. 294/2012 | 1 April 2012 | Reg. (EU) No. 718/2014 | 1 July 2014 |
| Reg. (EU) No. 514/2012 | 1 July 2012 | Reg. (EU) No. 1021/2014 | 1 October 2014 |
| Reg. (EU) No. 889/2012 | 1 October 2012 | Reg. (EU) No. 1295/2014 | 1 January 2015 |

the Annex. For each product or group of products listed, Annex I specifies whether the relevant entry refers to products destined to animal nutrition, human consumption or both of them. The frequency required for the performance of identity and physical checks (5, 10, 20 or 50 %) by DPEs is also spelled out. To date, the hazards that are most commonly targeted in Annex I include:

- Mycotoxins (aflatoxins and Ochratoxin A)
- Pesticide residues
- Heavy metals
- Microbiological contamination (e.g. *salmonella* spp, norovirus and hepatitis A).

However, in this respect, it should be noted that the range of product/hazard combinations that may be subject to inclusion in Annex I is virtually unlimited. This means that other products of non-animal origin (e.g. food supplements, improvement agents, novel foods or feed and food containing unauthorised ‘genetically modified organisms’) and other hazards might as well be included in Annex I in future. In one of the most recent reviews of Annex I, in fact, enzymes of Indian origin were listed for the very first time for possible presence of veterinary residues (European Commission 2014d).

2.8.2 Listing and Quarterly Updates

Regulation 669/2009 enumerates the information sources that may be used for the inclusion of imports in Annex I, although in a not exhaustive manner (Article 2). Those sources include:

- Information reported by Member States and other associated countries (e.g. Norway, Iceland etc.) through the RASFF
- Outcome of FVO audits in non-EU countries
- Any report, information and other assurances supplied by concerned non-EU countries

- Data and information supplied by EU Member States or exchanged between them, the European Commission and the European Food Safety Authority (EFSA)
- Any relevant scientific assessment or information (e.g. EFSA opinions).

As already anticipated, results of border controls that Member States regularly submit to the European Commission constitute other key information to assess compliance levels of listed imports. The Commission makes regularly available annual reports on results of border controls to stakeholders and the general public.¹³

Current practice shows that listed imports tend to remain subject to reinforced border surveillance for at least 6 months before controls can be lifted, provided that satisfactory levels of compliance are consistently reported by Member States.

Interestingly, recital 3 of Regulation 669/2009 makes reference to a standardised methodology for the setting of Annex I. Despite some attempts, said methodology has not been established. Indeed, the difficulties in setting a rigorous methodology to apply when reviewing Annex I are apparent if one considers all the variables that may come into play for any given listing (e.g. nature of the product, risk, number of RASFF notifications and severity of the findings, outcome of FVO audits, and trade volumes). Those difficulties eventually led the Commission and the Member States to embrace a case-by-case approach when reviewing Annex I—approach that, in any event, is always based on expert assessment.

2.8.3 From Reinforced Controls to Emergency Measures

During 2012, the European Commission identified, among the imports listed in Annex I, a number of products for which compliance levels worsened or did not point to any significant improvement. Consequently, based on quarterly results of official controls and RASFF notifications, the Commission decided to impose additional import conditions on such products.

As a result, the following products have been included in Regulation (EU) No. 91/2013—now replaced by Regulation (EU) No. 885/2014 (European Commission 2013g, 2014f)—an emergency measure which is applicable as of 18 February 2013:

- Groundnuts and derived products from Ghana and India for possible aflatoxins contamination
- Watermelon seeds from Nigeria for possible aflatoxins contamination
- Curry leaves and okra from India for possible presence of pesticide residues.

¹³ EU reports containing consolidated results on official controls performed by EU Member States and Norway pursuant to Regulation 669/2009 for the period 2010–2013 are available at http://ec.europa.eu/food/food/controls/increased_checks/index_en.htm.

Under this emergency measure, whereas a certain level of official controls is maintained at EU borders, business operators are required to provide, in addition to a CED, the following documents:

- A valid health certificate, signed and stamped by the competent authorities of the exporting country, and
- Analytical results of laboratory tests performed in accordance with EU requirements and prior to export in the country of origin.

Overall, the tightening of control requirements for products presenting high levels of non-compliance appears consistent with the approach that the EU applies to imports of non-animal origin, whereby the intensity of surveillance must be proportionate to the seriousness of the risk involved.

Because of the regular reviews to which Annex I is subject, very few imports have been listed since the entry into force of the Regulation: moreover, in most cases, they have undergone changes entailing, e.g. decreasing or increasing of the frequency for physical inspections. In only one case—vine fruit from Uzbekistan for possible contamination with ochratoxin A—the relevant control requirements have remained systematically unaltered. The discontinuity observed in the trade patterns concerning this product as well as the inconsistencies in compliance levels may explain why the control frequency for physical checks initially set (i.e. 50 %) has not been modified so far.

2.9 EU Reinforced Border Surveillance in the Context of Multilateral Trade Rules

By establishing a system designed to counteract public health risks that are associated with imports of feed and food of non-animal origin, Regulation 669/2009 is to be considered a ‘sanitary measure’ within the meaning of the Sanitary and Phytosanitary (SPS) Agreement of the World Trade Organisation (WTO).

In accordance with the provisions on transparency of the SPS Agreement (Article 7 and Annex B), the EU duly notified the draft Regulation to the SPS Secretariat and WTO members (G/SPS/N/EEC/341 of 28 April 2009).

Overall, the main criticisms raised by EU trade partners in relation to the reinforced surveillance mechanism introduced by the Regulation revolved around the lack of:

- Clear and objective conditions upon which listing of imports of non-animal origin in Annex I and subsequent modifications, including de-listing, are decided
- Maximum timelimits for the performance of physical checks (in relation to which the Regulation only requires the national competent authorities to carry them out ‘as soon as technically possible’).

With regard to both issues, the European Commission has provided further clarifications within the relevant Guidance document (Sect. 2.8), Q&A n. 8, 9, 10 and 25.

Interestingly, a few new listings ensuing from the quarterly reviews of Annex I led some WTO members to voice their concerns directly at official meetings of the SPS Committee.¹⁴

In March 2012, for instance, China has expressed strong concerns over the listing in Annex I of its exports of noodles due to the unauthorised presence of aluminium. Besides complaining about the adverse impact of border controls on trade, China openly contested the maximum limit (10 mg/kg) set by the EU for presence in food of that substance. The limit in question was based on a scientific opinion that EFSA issued in 2008 (EFSA AFC 2008) and determined in a way that the average weekly intake would be inferior to 1 mg/kg per bodyweight. China argued, instead, the weekly intake being below 2 mg/kg, following the later advice by the FAO/WHO Joint Expert Committee on Food Additives of the *Codex Alimentarius*. Notwithstanding this divergence of views on the maximum limit allowed for aluminium, according to the EU, the high non-compliance rate emerging from official controls as well as the severity of the findings reported (in some cases up to 50 mg/kg) fully justified an increased level of border surveillance.

A year earlier, concerns over the implementation of Regulation 669/2009 by EU Member States had been raised by the Dominican Republic. At that time, this country had several tropical fruits and vegetables subject to reinforced checks because of the occurrence of pesticide residues. The Dominican authorities referred that some of their products (i.e. bananas and mangoes) continued to be subject to an increased level of checks at EU borders, despite the recent lifting of the relevant control requirements.

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¹⁴ The SPS Committee is an intergovernmental body established by the SPS Agreement (Article 14). Any WTO member has the right to be represented at meetings of the Committee. International organisations such as *Codex Alimentarius*, World Animal Health Organization and the International Plant Protection Convention enjoy the status of permanent observers within the Committee. Other international organisations, such as the Organisation for Economic Co-operation and Development (OECD) and the International Organisation for Standardisation (ISO), may take part in meetings as observers on ad-hoc basis. The SPS Committee is a forum designed to monitor and ensure the appropriate application of the SPS Agreement. In such a context, it encourages and facilitates the exchange of views between WTO members on animal health, food safety and plant health issues. It can also elaborate procedures and guidance in order to ensure WTO members fulfil the obligations stemming from the SPS Agreement. The Committee normally meets three times per year in Geneva.

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