

Questions & Answers Paper

on the provisions of Commission Regulation (EC) No 669/2009 as regards the increased level of official controls on imports of certain feed and food of non-animal origin

IMPORTANT DISCLAIMER

The present document aims at addressing a number of issues which have arisen during the first application period of the import control regime for feed and food of non-animal origin which was established by Commission Regulation (EC) No 669/2009. As such, this paper is a tool designed to ensure a common and uniform understanding of the principles and the operational functioning of the above said regime by all parties concerned by its application.

The list of Questions and Answers provided hereinafter will be subject to regular updates so as to take into account and reflect the experience gained during the application of the Regulation across the EU.

This document has no formal legal status. Ultimate responsibility for the interpretation of the law lies with the Court of Justice of the European Union.

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List of Acronyms

Competent Authority (CA)

Common Entry Document (CED)

Control Point (CP)

Designated Point of Entry (DPE)

Food and Veterinary Office (FVO)

European Food Safety Authority (EFSA)

National Reference Laboratory (NRL)

Rapid Alert System for Feed and Food (RASFF)

A. General Concepts

1. Does the Regulation lay down new import requirements to be complied with by third countries' exports to the EU?

The Regulation does not establish any new import requirement in addition to those which are already applicable to any of the products which may be listed in Annex I to the Regulation. The Regulation only establishes a new control regime whereby control activities by Member States are harmonized and focus on the same imported products.

2. What does the Regulation provide in relation to private certification in the context of official controls?

Guidelines are being drafted jointly by Commission's services concerned with a view to establishing a common EU approach on this issue.

The Regulation does not provide for any formal recognition of private certification schemes. Accordingly, no derogation or preferential regime for imported commodities which are certified against such schemes is foreseen.

However, the above does not prevent Member States from considering private certification as one of the factors which may be taken into account when setting priorities within the context of the organisation of official controls.

3. To what extent does the Regulation take into account the highly perishable nature of certain products?

Pursuant to Article 8 (1) of the Regulation, the competent authority at the Designated Point of Entry (DPE) shall carry out controls without undue delay. By derogation to this provision, Article 9 (2) read in conjunction with Article 9 (2) (a) and (b) of the Regulation provides for a special regime for products which may be regarded as 'highly perishable' by their very nature or due to the special characteristics of their packaging. Because of these characteristics, sampling at the Designated Point of Entry (DPE) premises may result in a serious risk to food safety or in the product being damaged to an unacceptable extent.

In such exceptional circumstances, Article 9 (2) provides that identity and physical checks, when required, may be carried out by the Competent Authority (CA) at the place of destination of the consignment. In any event, the CA of the DPE would remain responsible for the performance of the necessary documentary checks.

The applicability of the special regime provided by Article 9 (2) is subject to certain conditions. First of all, Article 9 (2) of the Regulation specifies that its applicability to any of the commodities listed in Annex I must specifically refer to the derogation provided for in Article 9 (2) when the relevant decision to list the commodity is taken. Secondly, pursuant to Article 9(2)(b) of the Regulation, appropriate arrangements should be put in place between the CA of DPE and the CA of the place of destination in order to ensure that, whenever identity or physical checks are required, the consignment, while reaching the point of final destination, cannot be tampered with in any manner throughout all checks. Thirdly, the CAs concerned should also make sure that reporting of the results of the checks performed under the special circumstances referred to by Article 9 (2) of the Regulation is done in conformity with the requirements laid down in Article 15.

Furthermore, provisions in Article 9 (1) (b) and (c) must be satisfied as to ensure that premises fulfil the minimum requirements laid down in Article 4 and that they are approved for that purpose by the Member State; and that appropriate arrangements are in place to guarantee that the consignment remains under the continuous control of the competent authorities of the DPE.

Currently, the regime provided for by Article 9 (2) has not been applied to any of the commodities listed in Annex I.

B. Scope

4. Are products containing a commodity listed in Annex I or derived from it covered by the scope of the Regulation?

These products are not subject to the control regime set by the Regulation, unless otherwise specified in Annex I.

Thus, for example, vegetable and fruit mixes containing any of the commodities listed in Annex I amongst their ingredients, or juices and extracts from a listed product are outside the scope of the Regulation (unless otherwise indicated).

5. Does the Regulation provide for an exemption for consignments of small size or weight?

Currently, no such an exception is provided by the Regulation. Consignments of products listed under Annex I are subject to the control regime provided by the Regulation regardless of their weight or size. Thus, Article 3 (c) of the Regulation which provides for a definition of 'consignment' does not refer to their weight or size.

6. *Does the Regulation distinguish between consignments intended for commercial use and those which are intended for personal use?*

At present, the Regulation does not provide for such a distinction.

However, the Regulation refers to feed and food business operators and therefore obligations are laid down for feed and food business purposes (commercial use).

The only criterion in this regard is whether the intention of the import is for placing the goods on the market (feed and food business purposes) or not.

For example: traveler arriving to an EU airport with a packet of peanuts from Argentina in his/her baggage does not have to fill out a CED (does not fall under the scope of the Regulation)

7. *Does the Regulation apply to products imported for research purposes?*

The Regulation only applies to 'food' (or 'foodstuff') and 'feed' (or 'feedingstuff') of non-animal origin as defined in the 'General Food Law' Regulation (EC) No 178/2002¹. 'Food' (or 'foodstuff') is defined in Article 2 of that Regulation as meaning 'any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans'. 'Feed' (or 'feedingstuff') is defined in Article 3 (4) of that Regulation as meaning 'any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals'.

Therefore, when a product listed in Annex I is imported for other purposes, such as documented research purposes (e.g. laboratory tests), it is **not** considered to be subject to the control regime provided for by the Regulation (consequently no Common Entry Document is required)

C. Listing under Annex I

8. *Under which conditions is a product of non-animal origin originating from a third country likely to be subject to an increased level of controls as foreseen by the Regulation?*

Pursuant to Article 15 (5) of Regulation (EC) 882/2004, the decision to include an imported commodity of non-animal origin in Annex I to the Regulation is taken by the Commission, assisted by Member States, in their role of risk managers. Regulation (EC) No 882/2004 requires the Commission and Member States to agree on a coordinated response, in terms of controls at the border, to known and emerging risks that might be posed by feed and food of non-animal origin.

¹ Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 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, OJ L 31, 1.2.2002

The approach is evidence-based. To this end, a number of information sources, including notifications by national authorities through the Rapid Alert System for Food and Feed (RASFF), quarterly reports from Member States under Article 15 of the Regulation, findings of the missions carried out in third countries by the EU Commission's Food and Veterinary Office (FVO), EFSA scientific opinions, and any other relevant information provided by Member States and third countries are taken into account.

When the above sources indicate that there is the need to step up controls at EU borders because of the possible occurrence of a known or emerging risk, and in order to ensure a uniform intensity of such controls, the imported commodity which is associated with that risk is proposed for listing in Annex I to the Regulation.

9. How often is the list of commodities in Annex I to be reviewed?

Review of Annex I is to be carried out regularly and at least on a quarterly basis as set by Article 2 of the Regulation. To this effect, relevant updates regarding any of the information sources listed in Question 8 above are taken into account.

The review may lead to an update of the existing list (including de-listing and changes to the frequency of controls). In this context, other feed and food may also be included in Annex I where appropriate.

10. Is there a time limit for a feed/ food import to remain in Annex I before being de-listed?

There is no time limit established in the Regulation in this respect as de-listing depends on a number of factors which may vary from one feed/food to another one.

Seasonal patterns, relevance of trade volumes and outcome of control activities performed by Member States over a given period of time are amongst the factors that may condition the duration of the listing of a given import of non-animal origin.

11. Are Member States allowed to establish higher frequencies of physical checks than those foreseen in Annex I?

Member States cannot do so within the scope of Regulation (EC) No 669/2009. Member States are bound by the frequency of physical and identity checks in percentage laid down in Annex I of the Regulation.

Nevertheless, higher frequencies (and further measures) might be required on the basis of the general provisions of Regulation (EC) No 882/2004 in case of suspicion of non-compliance or of doubt (see Articles 18, 19 of that Regulation).

12. How are stakeholders informed of changes to Annex I?

Amendments to Annex I will be published in the Official Journal of the European Union as appropriate. Additionally, information regarding amendments under consideration can be found at the following webpage of DG SANCO website:

http://ec.europa.eu/food/food/controls/increased_checks/latest_news_en.htm

The Commission ensures that concerned third countries are informed in a timely manner of any measure within the scope of the Regulation which may concern their feed and food exports.

D. Implementation

13. Where can information about Designated Points of Entry be found?

CA in Member States are responsible for the designation of the points of entry into the territory of the EU (i.e. DPEs) for the purposes of the Regulation. A list of DPEs in their territory is made available on the Internet and communicated to the Commission as foreseen by Article 5 of the Regulation.

The full list of DPEs is currently available on DG SANCO website at the following webpage:

http://ec.europa.eu/food/food/controls/increased_checks/national_links_en.htm.

14. Under which conditions may the Commission authorize certain DPE operating under specific geographical constraints to carry out checks at the premises of food businesses operators?

Article 9 (1) of Regulation (EC) No 669/2009 enables the Commission to authorize the CA of a certain DPE operating under specific geographical constraints to perform physical checks at the premises of a feed or food business operator.

The following conditions laid down in Article 9 (1) (a), (b) and (c) of the Regulation must be met for the Commission to be able to issue such authorization.

1. The DPE for which the authorization is sought operates under ‘specific geographical constraints’. Specific geographical constraints may relate to the accessibility of the DPE itself (which is for instance located on a site of particularly difficult access, the mountainous nature of which prevents its equipment with all the facilities that would be required to handle the expected throughput), or to the overall geographical situation of the territory on which the DPE is situated. The latter is the case for the two requests for authorization received so far by the Commission, which relate to DPEs located on small size islands, characterized by the small scale throughput of the DPE and by short

distances between the DPE and the final destination points of imported consignments, which facilitates continuous control.

2. The feed and food operator's premises for which the authorization is sought must comply with the minimum requirements for a DPE set by Article 4 of the Regulation, as relevant (e.g. appropriate facilities to carry out the required checks, loading/unloading and storage equipment, possibility of sampling in a sheltered place etc.) and be approved for this purpose under the national law.
3. The CA of the DPE in question must ensure that consignments subject to checks in accordance with Regulation (EC) No 669/2009 remain under continuous control of the DPE staff during their transportation from the DPE to the feed and food operator's premises.
4. The Member State concerned must provide reassurance that the performing of the physical checks at premises other than the DPE does not adversely affect the overall efficiency of controls. This means that the performance of physical checks by DPE personnel away from the DPE premises must not hinder the smooth operation of the controls that still need to be carried out at the DPE. The Commission should be informed without delay if any of the circumstances that have led to granting the authorization cease to exist.

A detailed list of feed and food business premises approved under Article 9 (1) is made available by the concerned Member State on the link which lists national DPEs.

Authorizations granted by the Commission under Article 9 (1) are available at the following webpage of DG SANCO website:

http://ec.europa.eu/food/food/controls/increased_checks/national_links_en.htm.

15. Under which conditions can Member States make use of the transitional period provided by Article 19?

Article 19 provides for a transitional period of 5 years during which, if one or more DPEs in a Member State are not fully equipped to perform identity and physical checks, such checks may take place at another Control Point (CP) in the same Member State, while awaiting for the DPE(s) concerned to be fully equipped to suit the purposes of Regulation (EC) No 669/2009.

In order to make use of this transitional regime Member States must make sure that the identified CP fulfils the minimum requirements for DPEs as set by Article 4 of the Regulation.

Member States must also make publicly available the details of the control point(s) that have been identified for the purposes of Article 19 through the national link listing its DPE(s).

At the end of the transitional period, i.e. by 13 August 2014, all necessary arrangements must have been put in place by Member States so that identity and physical checks on consignments of the listed imports of non-animal origin can all be performed within the premises of the DPE.

The list of DPEs including CPs, can be found at:

http://ec.europa.eu/food/food/controls/increased_checks/national_links_en.htm

16. Under which circumstances can onward transportation of the consignment to its final destination, pending the results of physical checks, be authorized?

Regulation (EC) No 669/2009 does not require the CA of the DPE to physically detain consignments which have been selected for physical checks. Accordingly, Article 8 (2) of the Regulation provides that the CA of the DPE may authorise onward transportation of the consignment which has been selected for physical checks to the place of destination, while the above said checks, including the results of laboratory tests, are being performed.

Whether or not onward transportation in the terms above described is allowed, is a decision which solely lies with the CA of the DPE.

It is however understood that Article 8 (2) of Regulation (EC) No 669/2009 applies without prejudice to what is provided for by Articles 18 to 20 of Regulation (EC) No 882/2004, which require the CA to take specific action, including physical detention, in cases of suspicion of non-compliance. CAs of DPEs must of course act in accordance with those rules.

Whenever onward transportation of an imported consignment is authorized, it is the responsibility of the CA of the DPE to notify the CA at the place of destination. In this respect, Article 8 (2) provides that CAs should ensure that the consignment remains under customs control and cannot be tampered with in any manner, pending the result of the physical checks and that appropriate arrangements are in place to this effect between the CA of the DPE and the CA at the place of destination.

A certified copy of the original CED needs to be issued for that purpose.

Pending the establishment of a network of CAs for the purposes of Article 8 (2) of the Regulation under the lead of the Commission, it is essential for the smooth and correct implementation of this provision that information concerning the CA responsible in each Member State of destination is fully and readily available to the CA of the DPE. Member States' Country Profiles should provide sufficient information on contact details (e.g. telephone and fax numbers, email addresses, etc.) in order to ensure effective communication between concerned CAs.

E. Common Entry Document

17. Can the Common Entry Document (CED) be completed / transmitted electronically?

Article 10 of the Regulation gives Member States the option to use a paper version of the CED or an electronic equivalent.

Current practice seems to indicate that a computerized system for issuing, processing and clearing the CED is operational in a number of Member States.

The CED is downloadable in all EU languages from DG SANCO website at the following webpage.

(link to be added as soon as pending corrections to certain linguistic versions are made)

18. Would the use of the English version of the CED be accepted in all Member States?

Article 7 of the Regulation gives Member States the option to accept that the CED is drawn up in an EU language other than their official language(s).

Current practice in this respect shows that this possibility is being used by CAs in Member States to a significant extent. English is the most accepted language.

19. Would a CED be needed if a consignment of feed/food listed under Annex I is stopped by the authorities at a DPE in a Member State which is subsequently directed to a non-EU country?

Notification of the CED would **not** be needed in this case as the consignment is not intended for import into the territory of the EU as foreseen by Article 1 of the Regulation.

20. What is the exact definition of 'consignment' of an imported feed and food listed in Annex I for the purposes of the Regulation?

The definition of 'consignment' for the purposes of the Regulation is provided for in Article 3 (c). Accordingly, a 'consignment' is a quantity of any of the feed or food product listed in Annex I of the same class or description, covered by the same documents and means of transport and coming from the same third country or a part of this latter.

Consequently, *for example*:

Case 1: The same invoice lists both 'ground chilli (size: 500kg, price:...€)' and 'crushed chilli (size: 1000kg, price:...€)' separately. Both products are covered by the same CN code. In this case they should be considered as two separate consignments as certain characteristics (e.g. quantity indicated in the invoice) are different. Therefore two separate CED is needed.

Case 2: The same invoice covers together 'ground and crushed chilli (size 2000kg, price:...€)'. In this case the consignment can be considered as one, as the same CN code covers both products and the quantity indicated in the invoice cannot be differentiated. Therefore one CED is needed.

Case 3: The invoice contains several different "lots" (entries) of peanuts with the exact same characteristics. In this case these entries can be treated together and be considered as one consignment. Therefore there is no need to introduce separate CEDs for each of these products.

21. What does the Regulation foresee for 'mixed consignments'?

Based on the above definition of consignment, there cannot be such a thing as 'mixed' consignments.

On the other hand, more containers or batches can be regarded as a single consignment for the purposes of the Regulation provided that the requirements set in the above definition are fully met. Under these circumstances, the concerned containers or batches may be covered by the same CED.

22. Should a container or a truck carry several products of a different nature, some of which are listed in Annex I, could these latter be covered by the same CED or would a separate CED be needed for each group of products of the same nature? What about the other products which would fall out of the scope of the Regulation?

According to the definition of consignment provided in Article 3 (c), in such cases each group of products listed under Annex I of the same nature and classification must be regarded as a single consignment for the purposes of the import control regime established by the Regulation. A separate CED would be therefore needed for each of the above groups.

As to the products that are not listed in Annex I and as such, are not subject to the control regime set by Regulation (EC) No 669/2009, these do not have to appear on the CED although they might have to be covered by the relevant commercial documents. However, these products are subject to the general provisions of Chapter V of Regulation (EC) No 882/2004, and in particular to Article 18 in case there is a suspicion of non-compliance, in addition to any other feed or food law requirement which may apply to them.

23. Is it necessary for feed and food business operators to notify the complete CED or would submission of Part I be sufficient?

The CED is a single document consisting of three different parts. The first part (Part I) is to be completed by the feed and food business operator (or its representative), whereas Part II and III are to be completed by the CA of the DPE.

The submission by feed and food business operators of the CED consisting of all its three parts is recommended. However, the CA of the DPE could also accept that only Part I is notified provided that it is duly completed.

F. Control Activities

24. What documents are to be checked during the 'Documentary check'?

According to the definition laid down in Article 2 (17) of Regulation (EC) No 882/2004, 'documentary check' means the examination of commercial documents and, where appropriate, of documents required under feed or food law that are accompanying the consignment.

Based on this definition, for the purposes of Regulation (EC) No 669/2009, "commercial documents" checked by the CA should proof the information given in the CED, and allow comparison that the information provided in the CED is correct and matches with the content of these documents (origin, amount, CN code, destination, importer etc).

The CED itself should also be verified to see whether all information is included.

The most commonly requested 'commercial documents' are the invoice and bills (airway bills) or ships manifests, but phytosanitary certificates, certificate of origin of the goods, results of laboratory tests (if available) and/or health certificates (if available) can also be taken into account.

25. Documentary checks must be carried out on all consignments within 2 working days. What is the timeframe within which identity and physical checks must be carried out?

The Regulation does not provide for any timeframe for the performance of identity and physical checks. However, Article 8 (1) of the Regulation specifies that the competent authority shall carry out documentary checks and identity and physical checks without undue delay.

Results of the physical checks must be available as soon as technically possible.

In any event, in accordance with the conditions laid down by Article 8 (2) of the Regulation, the onward transportation of the consignment, pending the results of the physical checks, may be authorized by the CA of the DPE (see also Q&A 16).

26. How are feed and food business operators informed of the results of the physical checks?

The CA of the DPE is responsible for informing the concerned feed and food business operator of the results of the physical checks.

In cases where onward transportation of the consignment, pending the results of physical checks, is authorized under Article 8 (2) of the Regulation, the CA of the DPE should inform the CA of the place of destination of the results of the physical checks.

27. Are fees determined in the same way and at the same levels across Member States?

Under Article 14 of Regulation (EC) No 669/2009 the modalities regarding calculation and collection of fees occasioned by the control activities required by the same Regulation lie with Member States in accordance with the conditions laid down in Article 27 (4) of Regulation (EC) 882/2004 and the criteria laid down in Annex VI to Regulation (EC) 882/2004.

This means that fees which feed and food business operators have to bear when importing into the EU under the control regime set by the Regulation may vary amongst Member States, depending on the level of the costs which the fees are intended to compensate.

Fees are publicly available as a rule.

28. How do non-EU goods in transit through the EU have to be handled under the Regulation?

Non-EU goods in transit through the EU move under a so called "customs T1 transit declaration" and are by definition under customs supervision. Moreover, consignments of commodities listed in Regulation (EC) No 669/2009 which have not undergone the checks required by Article 8 therein (because they were not at first indicated as destined to be released for free circulation) cannot be accepted for release for circulation.

Article 15(5) of Regulation (EC) No 882/2004 refers to increased controls to be carried out **at the point of entry** into the EU. On the other hand, Article 1 of Regulation (EC) 669/2009, as currently drafted, refers to "official controls [...] **on imports** of the feed and food of non-animal origin [...]". Import is defined in Article 2 (15) of Regulation (EC) No 882/2004 as "**the release for free circulation** of feed or food or the **intention to release** feed or food for free circulation within the meaning of Article 79 of Regulation (EEC) No 2913/92 in one of the territories referred to in Annex I."

Therefore, goods listed in Annex I to this Regulation in transit covered by a T1 transit declaration that are subsequently intended to be released for free circulation (i.e.

imported) in the EU are subject to increased level of controls. Conversely, consignments in transit not intended to be released for free circulation into the EU are not subject to the provisions of Regulation (EC) No 669/2009.

For example:

Case 1: *Goods placed in transit that are likely to be declared for the release for free circulation in the EU as the intended office of destination in the original transit declaration is within the EU. In this case this consignment is subject to increased level of controls.*

Case 2: *External transit of goods by a truck that contains consignments of non-EU goods simply crossing the EU territory (for example from CH to Russia or those loaded in the port of Rotterdam and destined to Russia). In this case this consignment is **not** subject to increased level of official controls.*

29. What about free zones?

Goods placed in free zones must comply with the customs provisions in place and are per definition under customs supervision. The above therefore applies mutatis mutandis also to consignments placed in a free zone.

30. What about harmonised interpretation of analytical results listed in all Member States?

Where EU legislation exists for products which are also subject to Annex I, e.g. contaminants legislation, the analytical methods, interpretation etc. set out in the EU legislation will also apply to the controls carried out in the context of Regulation (EC) No 669/2009.

A guidance document has been published for the interpretation of analytical results and discussing issues such as the use of measurement uncertainty.

See also:

- Guidance document for competent authorities for the control of compliance with EU legislation on aflatoxins
<http://ec.europa.eu/food/food/chemicalsafety/contaminants/guidance-22-03-2010.pdf>
- Guidance document on the controls on pesticide residues:
[http://ec.europa.eu/food/plant/protection/resources/publications_en.htm#residues.](http://ec.europa.eu/food/plant/protection/resources/publications_en.htm#residues)

31. Can private laboratories be used for carrying out the analyses required by the Regulation?

Private laboratories can be used for official control purposes. To this end, they must be accredited against EN ISO/IEC 17025 for the tests being carried out and be designated by CA in accordance with Article 12 (2) of Regulation (EC) No 882/2004.

32. Do feed and food business operators whose products are subject to sampling and analyses as required by the Regulation have the right to a second expert opinion?

Yes. The provisions of Article 11 (5) and (6) of Regulation (EC) No 882/2004 are applicable.

The relevant analyses can also be performed by an accredited private laboratory.

33. What if physical checks indicate that the consignment is not fit for human consumption as declared by the food business operator but it turns out to be fit for animal nutrition?

The following is suggested for cases where the concerned commodity listed in Annex I to the Regulation is also intended for animal nutrition in order for the consignment to be imported as feed.

The CA of the DPE should mark box II. 14 ("Acceptable for release for free circulation") of the CED and tick off box "Feedingstuff".

However, the operator must change box I.8 of the CED in most of these cases as the original destination of the consignment will no longer be valid, and also change box I.18 of the CED in all these cases. These boxes would need to be initialled by the inspector who signs in box II.21 before the box II. 14 ("Acceptable for release for free circulation") can be eventually ticked off.

In this case the repetition of documentary controls (boxes II.1 - to II 9) can be reasonably avoided.

34. Will the results of Member States' border controls pursuant Article 15 of the Regulation be made available to the public?

The Commission intends to publish a report with the results of the checks performed by Member States at the end of each year of application of the Regulation.

35. To what extent do Member States take into account voluntary destruction by food business operators when reporting under Article 15 of the Regulation?

It appears that, in some cases, the business operator whose consignment is selected for physical checks decides to surrender it i.e. to renounce to import it and choose to have it destroyed.

Member States are expected to report cases of voluntary destruction under Article 15 of the Regulation. However, since under these circumstances no physical checks are performed, cases of voluntary destruction should not be considered and reported as non-compliances, and therefore the quantity of these consignments do not count as volume of consignments for determining the frequency of checks.

End