



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
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final

Draft

COMMISSION DECISION

of

**amending Decision 2006/504/EC on special conditions governing certain foodstuffs
imported from certain third countries due to contamination risks of these products by
aflatoxins**

(Text with EEA relevance)

(Memorandum from Mr M. KYPRIANOU)

Draft

COMMISSION DECISION

of

amending Decision 2006/504/EC special conditions governing certain foodstuffs imported from certain third countries due to contamination risks of these products by aflatoxins

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 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 safety¹, and in particular Article 53 (1)(b)(ii) thereof,

Whereas:

- (1) Commission Decision 2006/504/EC² establishes special conditions governing certain foodstuffs imported from certain third countries due to contamination risks of these products by aflatoxins.
- (2) The Scientific Committee for Food has noted that aflatoxin B1 is a potent genotoxic carcinogen and, even at extremely low levels, contributes to the risk of liver cancer. Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs³ lays down permitted maximum levels of aflatoxins in foodstuffs. However, in 2005 and 2006 an increasing number of notifications through the Rapid Alert System for Feed and Food (RASFF) indicated that those maximum levels have been regularly exceeded in almonds and derived products from the United States of America.
- (3) Such contamination constitutes a threat to public health in the Community. It is therefore appropriate to adopt special measures at Community level.

¹ OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 3).

² OJ L 199, 21.7.2006, p. 21.

³ OJ L 77, 16.3.2001, p. 1. Regulation as last amended by Regulation (EC) No 199/2006 (OJ L 32, 4.2.2006, p. 34).

- (4) The Commission Food and Veterinary Office ('FVO') carried out a mission in the United States of America from 11 to 15 September 2006 to assess the control systems in place to prevent aflatoxin contamination levels in almonds intended for export to the Community⁴. That mission revealed the absence of any compulsory legal requirements to control aflatoxin levels in almond production and processing and the inadequacy of the current control system to offer guarantees concerning the compliance of exported products with Community standards. Furthermore, it showed the inadequacy of the laboratories visited to provide any guarantees for exports and demonstrated failures to comply with almost all aspects of EN ISO/IEC 17025 on "General requirements for the competence of testing and calibration laboratories".
- (5) In response to that FVO report, the United States of America announced its intention to undertake action to address those shortcomings. However, the proposed action is insufficient to provide guarantees for compliance of future shipments of almonds with Community legislation on aflatoxins, in particular due the voluntary nature of the aflatoxin control system. It is therefore appropriate to submit almonds and derived products originating in or consigned from the United States of America to strict conditions in order to provide a high level of protection to public health.
- (6) In the interest of public health, all consignments of almonds and derived products imported into the Community from the United States of America should be subjected to sampling and analysis for aflatoxin levels by the competent authority of the importing Member State, prior to release onto the market insofar as they are not covered by the Voluntary Aflatoxin Sampling Plan set up by the Almond Board of California in May 2006 (VASP). The consignments covered by the VASP should be accompanied by a health certificate and made subject to random controls at the point of import into the Community. The measures will be reviewed after one year on the basis of the reports by the Member States and additional guarantees provided by the competent authorities of the United States of America.
- (7) Moreover, the application of Decision 2006/504/EC has revealed that certain amendments are necessary. The list of designated points of import through which the products covered by that Decision may be imported into the Community should be updated, particularly in the framework of the accession of Bulgaria and Romania to the European Union,.
- (8) Decision 2006/504/EC provides that Member State may only permit imports of certain foodstuffs where the consignment is accompanied by, *inter alia*, a health certificate. That requirement applies from 1 October 2006. In order to avoid diverging implementation of that Decision, it appears necessary to clarify that the requirement regarding the health certificate relates to the consignments which left the country of origin after 1 October 2006.

⁴ Report of a mission carried out in the United States of America from 11 September to 15 September 2006 in order to assess the control systems in place to control aflatoxin contamination in almonds intended for export to the European Union (DG (SANCO)/8300/2006 – MR).

- (9) Moreover, the model health certificate set out in that Decision should be amended as regards the information to be provided between the competent authorities of the Member States, where the competent authority for the point of physical entry into the Community is different from the competent authority for the designated point of import, or where a physical check is not mandatory.
- (10) Commission Decisions 2006/504/EC should therefore be amended accordingly.
- (11) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Decision 2006/504/EC is amended as follows:

- (1) Article 1 is amended as follows:
- (a) The first paragraph is replaced by the following:
- “This Decision shall apply to the foodstuffs referred to in points (a) to (g) and to processed and compound foodstuffs derived from or containing the foodstuffs referred to in points (b) to (g).”
- (b) In the second paragraph, the following points (f) and (g) are added:
- “(f) the following foodstuffs imported from the United States of America, covered by the Voluntary Aflatoxin Sampling plan set up by the Almond Board of California in May 2006
- (i) almonds in shell or shelled falling within CN code 0802 11 or 0802 12 ;
- (ii) roasted almonds falling within CN codes 2008 19 13 (in immediate packings of a net content exceeding 1 kg) and 2008 19 93 (in immediate packings of a net content not exceeding 1 kg);
- (iii) mixtures of nuts or dried fruits falling within CN code 0813 50 and containing almonds;
- (g) the following foodstuffs imported from the United States of America, not covered by the Voluntary Aflatoxin Sampling plan set up by the Almond Board of California in May 2006
- (i) almonds in shell or shelled falling within CN code 0802 11 or 0802 12;

- (ii) roasted almonds falling within CN codes 2008 19 13 (in immediate packings of a net content exceeding 1 kg) and 2008 19 93 (in immediate packings of a net content not exceeding 1 kg);
- (iii) mixtures of nuts or dried fruits falling within CN code 0813 50 and containing almonds;”

(2) Article 3 is amended as follows:

(a) In the first paragraph, the following point (f) is added:

“(f) the United States Department of Agriculture (USDA) for foodstuffs from the United States of America.”

(b) The following paragraph 7 is inserted:

“7. By way of derogation from paragraphs 1 to 6, consignments of foodstuffs referred to in point (g) of the second paragraph of Article 1 may be imported into the Community without being accompanied by the results of sampling and analysis and a health certificate. Such consignments shall be exempted from the provisions of this Decision which are related to the health certificate but shall be subject to all other provisions of this Decision.”

(3) Article 5 (2) is amended as follows:

(a) Point (e) is replaced by the following:

“(e) approximately 5 % of the consignments for each category of hazelnuts referred to in point (e) (ii), (iv), (vi) and (viii) of the second paragraph of Article 1 and derived products from such hazelnuts from Turkey and approximately 10 % of the consignments of other categories of foodstuffs from Turkey;”

(b) The following points (f) and (g) are added:

“(f) approximately 5% of the consignments of foodstuffs from the United States of America, referred to in point (f) of the second paragraph of Article 1;

(g) each consignment of foodstuffs from the United States of America, referred to in point (g) of the second paragraph of Article 1.”

- (4) The following Article 7a is inserted:

*"Article 7a
Additional conditions as regards imports of foodstuffs from
the United States of America"*

1. As regards imports from the United States of America, the analysis provided for in Article 3(1) must be performed by an USDA approved laboratory for aflatoxin analysis which has been accredited in accordance with EN ISO/IEC 17025. However, where the laboratory has not yet been so accredited, it must:
 - (a) have initiated and be pursuing the necessary accreditation procedures; and
 - (b) provide sufficient guarantees that quality control schemes for the aflatoxin analyses it conducts are in place.
2. The health certificate provided for in Article 3(1) accompanying consignments of foodstuffs referred to in point (f) of the second paragraph of Article 1 shall make a reference to the Voluntary Aflatoxin Sampling plan set up by the Almond Board of California in May 2006.

- (5) Article 8 is replaced by the following:

*"Article 8
Costs related to imports of foodstuffs from Brazil, Iran and the
United States of America"*

1. All costs resulting from sampling, analysis, storage and issuing of accompanying official documents and of copies of the health certificate and accompanying documents pursuant to Articles 3(1) and 5(3) for foodstuffs from Brazil, Iran and the United States of America as referred to in points (a), (d) and (g) of the second paragraph of Article 1 and to processed and compound foodstuffs derived from or containing the foodstuffs referred to in those points shall be borne by the food business operator responsible for the consignment or its representative.
2. All costs related to official measures taken by the competent authorities as regards non compliance of consignments of foodstuffs from Brazil, Iran and the United States of America as referred to in points (a), (d) and (g) of the second paragraph of Article 1 and to processed and compound foodstuffs derived from or containing the foodstuffs referred to in these points shall be borne by the food business operator responsible for the consignment or its representative."

- (6) The following Article 8a is inserted:

*"Article 8a
Transitional provisions*

By way of derogation from Article 3(1), the Member States shall authorise the imports of consignments which left the country of origin before 1 October 2006, accompanied by a health certificate as provided for by Commission Decision 2000/49/EC⁵ as regards foodstuffs imported from Egypt, Commission Decision 2002/79/EC⁶ as regards foodstuffs imported from China, Commission Decision 2002/80/EC⁷ as regards foodstuffs imported from Turkey, Commission Decision 2003/493/EC⁸ as regards foodstuffs from Brazil and Commission Decision 2005/85/EC⁹ as regards foodstuffs from Iran. ”

- (7) Annexes I and II are replaced by the text in the Annex to this Decision.

*Article 2
Applicability*

This Decision shall apply from the third day following that of its publication in the *Official Journal of the European Union*.

However, Article 1(6) shall apply from 1 October 2006.

*Article 3
Addressees*

This Decision is addressed to the Member States.

Done at Brussels,

*For the Commission
Markos KYPRIANOU
Member of the Commission*

⁵ OJ L 19, 25.1.2000, p. 46.

⁶ OJ L 34, 5.2.2002, p. 21.

⁷ OJ L 34, 5.2.2002, p. 26.

⁸ OJ L 168, 5.7.2003, p. 33.

⁹ OJ L 30, 3.2.2005, p. 12.

ANNEX

Annexes I and II to Decision 2006/504/EC are replaced by the following:

"ANNEX I

Health Certificate for the importation into the European Community of.....*

Consignment Code..... Certificate Number

According to the provisions of European Commission Decision 2006/504/EC on special conditions governing certain foodstuffs imported from certain third countries due to contamination risks of these products by aflatoxins,

The.....
(competent authority referred to in Article 3 (1))

CERTIFIES:

that the of this consignment, Code Number
..... (Insert Consignment Code Number) composed of:

.....
.....
(description of consignment, product, number and type of packages, gross or net weight)

embarked at
(embarkation place)

by
(identification of transporter)

going to.....
(place and country of destination)

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

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

From this consignment, (number of samples) samples were taken on
..... (date), subjected to laboratory analysis on (date) in
the (name of laboratory), to
determine the level of aflatoxin B1 and level of total aflatoxin contamination, and the details of
sampling, methods of analysis used and all results are attached.

* Product and country of origin.

This certificate is valid until

Done at on.....

Stamp and Signature of

Authorised representative of competent authority referred to in Article 3 (1)

The consignment covered by this health certificate has been subjected to the following check (tick off as appropriate) with favourable result

- Documentary check** – consignment released for free circulation or Documentary check – release of the consignment awaits physical check*** or Documentary check – consignment in transit to the designated point of import****

.....
(Competent authority, Member State)

Date

Stamp

Signature

Identity check

- Certificates and other documents accompanying the consignment tally with the labelling of the consignment
- Certificates and other documents accompanying the consignment tally with the content of the consignment
- Identification codes on the certificates and other documents accompanying the consignment correspond to the identification code of individual entities of the consignment

.....
(Competent authority, Member State)

Date

Stamp

Signature

** The documentary check consists of checking the commercial documents and if the consignment is accompanied by the health certificate, completed and signed and the results of sampling and analysis. Also the validity of the health certificate will be verified.

*** The signed certificate must be forwarded to the competent authority at the place of physical check.

**** The signed certificate must be forwarded to the competent authority at the designated point of import.

- Physical check (sampling and analysis) – accompanying official documents enclosed (according to Article 5(3))

.....
(Competent authority, Member State)

.....
Date

Stamp

Signature

"

"ANNEX II

List of designated points of import through which foodstuffs covered by Article 1 may be imported into the Community

Member State	Designated points of import
Belgium	Antwerpen, Zeebrugge, Brussel/Bruxelles, Aalst
Bulgaria	Burgas, Airport, Burgas "West-Fish port", Varna Airport, Varna port, Varna – ferry-boat, Svilengrad – rail way station, Kapitan Andreevo, Ruse – terminal east port, Sofia – Airport
Czech Republic	Celní úřad Praha D5
Denmark	All Danish ports and airports
Germany	HZA Lörrach – ZA Weil am Rhein–Autobahn, HZA Stuttgart – ZA Flughafen, HZA München – ZA München – Flughafen, HZA Berlin – ZA Dreilinden, HZA Frankfurt (Oder) – ZA Frankfurt (Oder) Autobahn, HZA Frankfurt (Oder) – ZA Forst–Autobahn, HZA Bremen – ZA Neustädter Hafen, HZA Bremen – ZA Bremerhaven, HZA Hamburg – Hafen – ZA Waltershof, HZA Hamburg – Stadt, HZA Itzehoe – ZA Hamburg – Flughafen, HZA Frankfurt–am–Main–Flughafen, HZA Braunschweig – ZA Braunschweig–Broitzem, HZA Hannover – ZA Hamburger Allee, HZA Koblenz – ZA Hahn – Flughafen, HZA Oldenburg – ZA Wilhelmshaven, HZA Bielefeld – ZA Eckendorfer Straße Bielefeld, HZA Erfurt – ZA Eisenach, HZA Potsdam – ZA Ludwigsfelde, HZA Potsdam – ZA Berlin–Flughafen Schönefeld, HZA Potsdam – ZA Berlin – Flughafen Schönefeld, HZA Potsdam – ZA Berlin – Flughafen Tegel, HZA Augsburg – ZA Memmingen, HZA Ulm – ZA Ulm (Donautal), HZA Karlsruhe – ZA Karlsruhe, HZA Gießen – ZA Gießen, HZA Gießen – ZA Marburg, HZA Singen – ZA Bahnhof, HZA Lörrach – ZA Weil am Rhein – Schusterinsel, HZA Hamburg–Stadt – ZA Oberelbe, HZA Hamburg–Stadt – ZA Oberelbe – Abfertigungsstelle Billbrook, HZA Hamburg–Stadt – ZA Oberelbe – Abfertigungsstelle Großmarkt, HZA Düsseldorf – ZA Düsseldorf Nord, HZA Köln – ZA Köln Niehl
Estonia	All Estonian Customs Offices
Greece	Athina, Pireas, Elefsina, Athina International Airport, Thessaloniki, Volos, Patra, Iraklion Kritis, Larisa, Katerini, Veria, Drama, Serres, Kavala, Xanthi, Alexandroupolis, Rodos
Spain	Algeciras (Puerto), Alicante (Puerto), Almería (Puerto), Barcelona (Puerto), Bilbao (Puerto), Cádiz (Puerto), Ceuta (Puerto), Las Palmas de Gran Canaria (puerto), Málaga (Puerto), Melilla (Puerto), Sevilla (Puerto), Tarragona (Puerto), Valencia (Puerto), Juan Escoda S.A. – Tarragona (Puerto), Importaco – Valencia(Puerto)
France	Marseille (Bouches–du–Rhône), Le Havre (Seine–Maritime), Rungis MIN (Val–de–Marne), Lyon Chassieu CRD (Rhône), Strasbourg CRD (Bas–Rhin), Lille CRD (Nord), Saint–Nazaire Montoir CRD (Loire–Atlantique), Agen (Lot–et–Garonne), Port de la Pointe des Galets à la Réunion
Ireland	Dublin – Port , Shannon – Airport

Member State	Designated points of import
Italy	Ufficio Sanità Marittima ed Aerea di Ancona Ufficio Sanità Marittima ed Aerea di Bari Ufficio Sanità Marittima ed Aerea di Genova Ufficio Sanità Marittima di Livorno Ufficio Sanità Marittima ed Aerea di Napoli Ufficio Sanità Marittima di Cagliari Ufficio Sanità Marittima di Ravenna Ufficio Sanità Marittima di Savona Ufficio Sanità Marittima di Salerno Ufficio Sanità Marittima e aerea di Trieste, compresa Dogana di Ferneti-Interporto Monrupino Ufficio di Sanità Marittima di La Spezia Ufficio di Sanità Marittima e Aerea di Venezia Ufficio di Sanità Marittima e Aerea di Reggio Calabria Ufficio Sanità Marittima ed Aerea di Brindisi
Cyprus	Limassol Port, Larnaca Airport
Latvia	Grebneva – road with Russia Terehova – road with Russia Pātarnieki – road with Byelorussia Silene – road with Byelorussia Daugavpils – railway commodity station Rēzekne – railway commodity station Liepāja – sea port Ventspils – sea port Rīga – sea port Rīga – airport Rīga Rīga – Latvian Post
Lithuania	Road: Kybartai, Lavoriškės, Medininkai, Panemunė, Šalčininkai Airport: Vilnius Seaport: Malkū įlankos, Molo, Pilies Railway: Kena, Kybartai, Pagėgiai
Luxembourg	Centre Douanier, Croix de Gasperich, Luxembourg Administration des Douanes et Accises, Bureau Luxembourg–Aéroport, Niederanven
Hungary	Ferihegy – Budapest – airport Záhony – Szabolcs–Szatmár–Bereg – road Eperjeske – Szabolcs–Szatmár–Bereg – railway Nagylak – Csongrád – road Lökösháza – Békés – railway Rőszke – Csongrád – road Kelebia – Bács-Kiskun – railway Letenye – Zala – road Gyékényes – Somogy – railway Mohács – Baranya – port All Hungarian Chief Customs Offices
Malta	Malta Freeport, the Malta International Airport and the Grand Harbour.
Netherlands	All harbours and airports and all border stations
Austria	Zollamt Feldkirch, Zollamt Graz, Zollstellen Nickelsdorf und Sopron/Bahnhof im Bereich des Zollamtes Eisenstadt, Zollamt Wien, Zollamt Wels, Zollamt Flughafen Wien, Zollamt Salzburg, Zollamt Villach

Member State	Designated points of import
Poland	Bezledy – Warmińsko – Mazurskie – road border point Kuźnica Białostocka – Podlaskie – road border point Bobrowniki – Podlaskie – road border point Koroszczyn – Lubelskie – road border point Dorohusk – Lubelskie – road and railway border point Gdynia – Pomorskie – seaport border point Gdańsk – Pomorskie – seaport border point Medyka – Przemyśl – Podkarpackie – railway border point Medyka – Podkarpackie – road border point Korczoza – Podkarpackie – road border point Jasionka – Podkarpackie – airport border point Szczecin – Zachodnio – Pomorskie – seaport border point Świnoujście – Zachodnio – Pomorskie – seaport border point Kołobrzeg – Zachodnio – Pomorskie – seaport border point
Portugal	Lisboa, Leixões Sines, Alverca, Riachos, Setúbal, Bodadela, Lisbon airport, Porto airport
Romania	Constanta Nord harbour, Constanta Sud harbour, Otopeni International Airport, Sculeni – on the road, Halmeu –on the road Siret – on the road, Stamora Moravita – on the road Albita – on the road
Slovenia	Obrežje – road border crossing Koper – port border crossing Dobova – railway border crossing Brnik – airport border crossing Jelšane – road border crossing Ljubljana – railway and road border crossing Gruškovje – road border crossing Sežana – railway and road border crossing
Slovakia	Customs Offices: Banská Bystrica, Bratislava, , Košice, Žilina, Nitra, Prešov, Trnava, Trenčín, Čierna nad Tisou
Finland	All Finnish Customs Offices.
Sweden	Göteborg, Stockholm, Helsingborg, Landvetter, Arlanda
United Kingdom	Belfast, Dover, Felixstowe, Gatwick Airport, Goole, Harwich, Heathrow Airport, Hull, Ipswich, Liverpool, London (including Tilbury, Thamesport and Sheerness), Manchester Airport, Manchester Container Base, Manchester International Freight Terminal, Manchester (Ellesmere Port only), Southampton, Teesport

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