Official Journal of the European Union

L 115

English edition

Legislation

Volume 60

4 May 2017

Contents

[1] Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

DIRECTIVES

DECISIONS

[1] Text with EEA relevance.

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

COUNCIL DECISION (EU) 2017/768

of 18 July 2016

on the signing, on behalf of the European Union and its Member States, and provisional application of a Protocol to the Euro-Mediterranean Agreement establishing an Association between the European Communities and their Member States, of the one part, and the Arab Republic of Egypt, of the other part, to take account of the accession of the Republic of Croatia to the European Union

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 217, in conjunction with Article 218(5) thereof,

Having regard to the Act of Accession of the Republic of Croatia, and in particular Article 6(2) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) The Euro-Mediterranean Agreement establishing an Association between the European Communities and their Member States, of the one part, and the Arab Republic of Egypt, of the other part [1] ('the Agreement'), was signed on 25 June 2001. The Agreement entered into force on 1 June 2004.

(2) The Republic of Croatia became a Member State of the European Union on 1 July 2013.

(3) In accordance with Article 6(2) of the Act of Accession of the Republic of Croatia, the accession of the Republic of Croatia to the Agreement is to be agreed by means of a protocol to the Agreement concluded between the Council, acting unanimously on behalf of the Member States, and the Arab Republic of Egypt.

(4) On 14 September 2012, the Council authorised the Commission to open negotiations with the Arab Republic of Egypt. The negotiations were successfully concluded by the initialling of a Protocol in Brussels on 29 October 2015.

(5) Article 8(3) of the Protocol provides for its provisional application before its entry into force.

(6) The Protocol should be signed, subject to its conclusion, and applied on a provisional basis,

HAS ADOPTED THIS DECISION:

Article 1

The signing on behalf of the Union and its Member States of the Protocol to the Euro-Mediterranean Agreement establishing an Association between the European Communities and their Member States, of the one part, and the Arab Republic of Egypt, of the other part to take account of the accession of the Republic of Croatia to the European Union, is hereby authorised, subject to the conclusion of the Protocol.

[1] OJ L 304, 30.9.2004, p. 39.

The text of the Protocol is attached to this Decision.

Article 2

The President of the Council is hereby authorised to designate the person(s) empowered to sign the Protocol on behalf of the European Union and its Member States.

Article 3

The Protocol shall be applied on a provisional basis with effect from 1 July 2013, in accordance with Article 8(3) thereof, pending the completion of the procedures necessary for its conclusion.

Article 4

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 18 July 2016.

For the Council
The President
F. MOGHERINI

PROTOCOL

to the Euro-Mediterranean Agreement establishing an Association between the European Communities and their Member States, of the one part, and the Arab Republic of Egypt, of the other part, to take account of the accession of the Republic of Croatia to the European Union

THE KINGDOM OF BELGIUM,

THE REPUBLIC OF BULGARIA,

THE CZECH REPUBLIC,

THE KINGDOM OF DENMARK,

THE FEDERAL REPUBLIC OF GERMANY,

THE REPUBLIC OF ESTONIA,

IRELAND,

THE HELLENIC REPUBLIC,

THE KINGDOM OF SPAIN,

THE FRENCH REPUBLIC,

THE REPUBLIC OF CROATIA,

THE ITALIAN REPUBLIC,

THE REPUBLIC OF CYPRUS,

THE REPUBLIC OF LATVIA,

THE REPUBLIC OF LITHUANIA,

THE GRAND DUCHY OF LUXEMBOURG,

HUNGARY,

THE REPUBLIC OF MALTA,

THE KINGDOM OF THE NETHERLANDS,

THE REPUBLIC OF AUSTRIA,

THE REPUBLIC OF POLAND,

THE PORTUGUESE REPUBLIC,

ROMANIA,

THE REPUBLIC OF SLOVENIA,

THE SLOVAK REPUBLIC,

THE REPUBLIC OF FINLAND,

THE KINGDOM OF SWEDEN,

THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND

Contracting Parties to the Treaty on European Union, the Treaty on the Functioning of the European Union, hereinafter referred to as the 'Member States', and

THE EUROPEAN UNION, hereinafter referred to as the 'Union'

of the one part, and

THE ARAB REPUBLIC OF EGYPT, hereinafter referred to as 'Egypt'

of the other part,

hereinafter referred to together as the 'Contracting Parties' for the purposes of this Protocol,

Whereas:

(1) Euro-Mediterranean Agreement establishing an Association between the European Communities and their Member States, of the one part, and the Arab Republic of Egypt, of the other part ('the Agreement', was signed in Luxembourg on 25 June 2001 and entered into force on 1 June 2004;

(2) The Treaty of Accession of the Republic of Croatia to the European Union was signed in Brussels on 9 December 2011 and entered into force on 1 July 2013;

(3) Pursuant to Article 6(2) of the Act of Accession of the Republic of Croatia its accession to the Agreement is to be agreed by the conclusion of a protocol to the Agreement;

(4) Consultations pursuant to Article 21(2) of the Agreement have taken place in order to ensure that account has been taken of mutual interests of the Union and Egypt,

HAVE AGREED AS FOLLOWS:

Article 1

The Republic of Croatia hereby accedes as Party to the Euro-Mediterranean Agreement establishing an Association between the European Communities and its Member States, of the one part, and the Arab Republic of Egypt, of the other part and shall respectively adopt and take note, in the same manner as the other Member States of the Union, of the texts of the Agreement, as well as of the Joint Declarations, Declarations and Exchanges of Letters.

CHAPTER I

AMENDMENTS TO THE TEXT OF THE AGREEMENT, INCLUDING ITS ANNEXES AND PROTOCOLS

Article 2

Agricultural products, processed agricultural products and fish and fishery products

The table annexed to the Protocol 1 of the Agreement shall be modified by the table in Annex to this Protocol.

Article 3

Rules of origin

For the period between 1 July 2013 and 31 January 2016, Protocol 4 shall be amended as follows:

1. Annex IVa shall be replaced by the following:

'*ANNEX IVA*

TEXT OF THE INVOICE DECLARATION

The invoice declaration, the text of which is given below, must be made out in accordance with the footnotes. However, the footnotes do not have to be reproduced.

Bulgarian version

Износителят на продуктите, обхванати от този документ (митническо разрешение № … ([1])) декларира, че освен където е отбелязано друго, тези продукти са с … преференциален произход ([2]).

Spanish version

El exportador de los productos incluidos en el presente documento [autorización aduanera nº … ([1])] declara que, salvo indicación expresa en sentido contrario, estos productos gozan de un origen preferencial … ([2]).

Czech version

Vývozce výrobků uvedených v tomto dokumentu (číslo povolení … ([1])) prohlašuje, že kromě zřetelně označených mají tyto výrobky preferenční původ v … ([2]).

Danish version

Eksportøren af varer, der er omfattet af nærværende dokument, (toldmyndighedernes tilladelse nr. … ([1])), erklærer, at varerne, medmindre andet tydeligt er angivet, har præferenceoprindelse i … ([2]).

German version

Der Ausführer (Ermächtigter Ausführer; Bewilligungs-Nr. … ([1])) der Waren, auf die sich dieses Handelspapier bezieht, erklärt, dass diese Waren, soweit nicht anders angegeben, präferenzbegünstigte … ([2]) Ursprungswaren sind.

Estonian version

Käesoleva dokumendiga hõlmatud toodete eksportija (tolli luba nr … ([1])) deklareerib, et need tooted on … ([2]) sooduspäritoluga, välja arvatud juhul, kui on selgelt näidatud teisiti.

Greek version

Ο εξαγωγέας των προϊόντων που καλύπτονται από το παρόν έγγραφο [άδεια τελωνείου υπ' αριθ. … ([1])] δηλώνει ότι, εκτός εάν δηλώνεται σαφώς άλλως, τα προϊόντα αυτά είναι προτιμησιακής καταγωγής … ([2]).

English version

The exporter of the products covered by this document (customs authorisation No … ([1])) declares that, except where otherwise clearly indicated, these products are of … ([2]) preferential origin.

French version

L'exportateur des produits couverts par le présent document [autorisation douanière nº … ([1])] déclare que, sauf indication claire du contraire, ces produits ont l'origine préférentielle … ([2]).

Croatian version

Izvoznik proizvoda obuhvaćenih ovom ispravom (carinsko ovlaštenje br. … ([1])) izjavljuje da su, osim ako je drugačije izričito navedeno, ovi proizvodi … ([2]) preferencijalnog podrijetla.

Italian version

L'esportatore delle merci contemplate nel presente documento [autorizzazione doganale n. … ([1])] dichiarache, salvo indicazione contraria, le merci sono di origine preferenziale … ([2]).

Latvian version

To produktu eksportētājs, kuri ietverti šajā dokumentā (muitas atļauja Nr. … ([1])), deklarē, ka, izņemot tur, kur ir citādi skaidri noteikts, šiem produktiem ir preferenciāla izcelsme … ([2]).

Lithuanian version

Šiame dokumente išvardintų produktų eksportuotojas (muitinės liudijimo Nr … ([1])) deklaruoja, kad, jeigu kitaip nenurodyta, tai yra … ([2]) preferencinės kilmės produktai.

Hungarian version

A jelen okmányban szereplő áruk exportőre (vámfelhatalmazási szám: … ([1])) kijelentem, hogy egyértelmű eltérő jelzés hiányában az áruk preferenciális … ([2]) származásúak.

Maltese version

L-esportatur tal-prodotti koperti b'dan id-dokument (awtorizzazzjoni tad-dwana nru … ([1])) jiddikjara li, ħlief fejn indikat b'mod ċar li mhux hekk, dawn il-prodotti huma ta' oriġini preferenzjali … ([2]).

Dutch version

De exporteur van de goederen waarop dit document van toepassing is (douanevergunning nr. … ([1])), verklaart dat, behoudens uitdrukkelijke andersluidende vermelding, deze goederen van preferentiële … oorsprong zijn ([2]).

Polish version

Eksporter produktów objętych tym dokumentem (upoważnienie władz celnych nr … ([1])) deklaruje, że z wyjątkiem gdzie jest to wyraźnie określone, produkty te mają … ([2]) preferencyjne pochodzenie.

Portuguese version

O exportador dos produtos abrangidos pelo presente documento [autorização aduaneira n.º … ([1])], declara que, salvo declaração expressa em contrário, estes produtos são de origem preferencial … ([2]).

Romanian version

Exportatorul produselor ce fac obiectul acestui document [autorizația vamală nr. … ([1])] declară că, exceptând cazul în care în mod expres este indicat altfel, aceste produse sunt de origine preferențială … ([2]).

Slovenian version

Izvoznik blaga, zajetega s tem dokumentom (pooblastilo carinskih organov št. … ([1])) izjavlja, da, razen če ni drugače jasno navedeno, ima to blago preferencialno poreklo … ([2]).

Slovak version

Vývozca výrobkov uvedených v tomto dokumente [číslo povolenia … ([1])] vyhlasuje, že okrem zreteľne označených, majú tieto výrobky preferenčný pôvod v … ([2]).

Finnish version

Tässä asiakirjassa mainittujen tuotteiden viejä (tullin lupa nro … ([1])) ilmoittaa, että nämä tuotteet ovat, ellei toisin ole selvästi merkitty, etuuskohteluun oikeutettuja … ([2]) alkuperätuotteita.

Swedish version

Exportören av de varor som omfattas av detta dokument (tullmyndighetens tillstånd nr … ([1])) försäkrar att dessa varor, om inte annat tydligt markerats, har förmånsberättigande … ursprung ([2]).

Arabic version

يصرح مصدر المنتجات التي تشملها هذه الوثيقة (التصريح الجمركي رقم .....([1])) بإستثناء ما ينص بوضوح على خلاف ذلك، بأن هذه المنتجات من منشأ تفضيلي من .....([2]).

..... ([3])

(Place and date)

.....

(Signature of exporter; in addition the name of the person signing the declaration has to be indicated in clear script)

([1]) When the invoice declaration is made out by an approved exporter within the meaning of Article 23 of the Protocol, the authorisation number of the approved exporter must be entered in this space. When the invoice declaration is not made out by an approved exporter, the words in brackets must be omitted or the space left blank.

([2]) Origin of products to be indicated. When the invoice declaration relates in whole or in part, to products originating in Ceuta and Melilla within the meaning of Article 38 of the Protocol, the exporter must clearly indicate them in the document on which the declaration is made out by means of the symbol 'CM'.

([3]) These indications may be omitted if the information is contained on the document itself.'.

2. Annex IVb shall be replaced by the following:

'*ANNEX IVB*

TEXT OF THE INVOICE DECLARATION EUR-MED

The invoice declaration EUR-MED, the text is which is given below, must be made in accordance with the footnotes. However, the footnotes do not have to be reproduced.

Bulgarian version

Износителят на продуктите, обхванати от този документ (митническо разрешение № … ([1])) декларира, че освен където ясно е отбелязано друго, тези продукти са с … преференциален произход ([2]).

— cumulation applied with ..... (name of the country/countries)

— no cumulation applied ([3])

Spanish version

El exportador de los productos incluidos en el presente documento [autorización aduanera nº … ([1])] declara que, salvo indicación expresa en sentido contrario, estos productos gozan de un origen preferencial … ([2]).

— cumulation applied with ..... (name of the country/countries)

— no cumulation applied ([3])

Czech version

Vývozce výrobků uvedených v tomto dokumentu (číslo povolení … ([1])) prohlašuje, že kromě zřetelně označených mají tyto výrobky preferenční původ v … ([2]).

— cumulation applied with ..... (name of country/countries)

— no cumulation applied ([3])

Danish version

Eksportøren af varer, der er omfattet af nærværende dokument, (toldmyndighedernes tilladelse nr. … ([1])), erklærer, at varerne, medmindre andet tydeligt er angivet, har præferenceoprindelse i … ([2]).

— cumulation applied with ..... (name of country/countries)

— no cumulation applied ([3])

German version

Der Ausführer (Ermächtigter Ausführer; Bewilligungs-Nr. … ([1])) der Waren, auf die sich dieses Handelspapier bezieht, erklärt, dass diese Waren, soweit nicht anderes angegeben, präferenzbegünstigte … ([2]) Ursprungswaren sind.

— cumulation applied with ..... (name of country/countries)

— no cumulation applied ([3])

Estonian version

Käesoleva dokumendiga hõlmatud toodete eksportija (tolli luba nr. … ([1])) deklareerib, et need tooted on … ([2]) soodus-päritoluga, välja arvatud juhul kui on selgelt näidatud teisiti.

— cumulation applied with ..... (name of country/countries)

— no cumulation applied ([3])

Greek version

Ο εξαγωγέας των προϊόντων που καλύπτονται από το παρόν έγγραφο (άδεια τελωνείου υπ'αριθ. … ([1])) δηλώνει ότι, εκτός εάν δηλώνεται σαφώς άλλως, τα προϊόντα αυτά είναι προτιμησιακής καταγωγής … ([2]).

— cumulation applied with ..... (name of country/countries)

— no cumulation applied ([3])

English version

The exporter of the products covered by this document (customs authorization No … ([1])) declares that, except where otherwise clearly indicated, these products are of … ([2]) preferential origin.

— cumulation applied with ..... (name of country/countries)

— no cumulation applied ([3])

French version

L'exportateur des produits couverts par le présent document (autorisation douanière n° … ([1])) déclare que, sauf indication claire du contraire, ces produits ont l'origine préférentielle … ([2])).

— cumulation applied with ..... (name of country/countries)

— no cumulation applied ([3])

Croatian version

Izvoznik proizvoda obuhvaćenih ovom ispravom (carinsko ovlaštenje br. … ([1])) izjavljuje da su, osim ako je to drugačije izričito navedeno, ovi proizvodi … ([2]) preferencijalnog podrijetla.

— cumulation applied with ..... (name of the country/countries)

— no cumulation applied ([3])

Italian version

L'esportatore delle merci contemplate nel presente documento (autorizzazione doganale n. … ([1])) dichiara che, salvo indicazione contraria, le merci sono di origine preferenziale … ([2]).

— cumulation applied with ..... (name of country/countries)

— no cumulation applied ([3])

Latvian version

To produktu eksportētājs, kuri ietverti šajā dokumentā (muitas atļauja Nr. … ([1])), deklarē, ka, izņemot tur, kur ir citādi skaidri noteikts, šiem produktiem ir preferenciāla izcelsme … ([2]).

— cumulation applied with ..... (name of country/countries)

— no cumulation applied ([3])

Lithuanian version

Šiame dokumente išvardytų produktų eksportuotojas (muitinės liudijimo Nr … ([1])) deklaruoja, kad, jeigu kitaip nenurodyta, tai yra … ([2]) preferencinės kilmės produktai.

— cumulation applied with ..... (name of country/countries)

— no cumulation applied ([3])

Hungarian version

A jelen okmányban szereplő áruk exportőre (vámfelhatalmazási szám: … ([1])) kijelentem, hogy egyértelmű eltérő jelzés hiányában az áruk preferenciális … ([2]) származásúak.

— cumulation applied with ..... (name of country/countries)

— no cumulation applied ([3])

Maltese version

L-esportatur tal-prodotti koperti b'dan id-dokument (awtorizzazzjoni tad-dwana nru … ([1])) jiddikjara li, ħlief fejn indikat b'mod ċar li mhux hekk, dawn il-prodotti huma ta' oriġini preferenzjali … ([2]).

— cumulation applied with ..... (name of country/countries)

— o cumulation applied ([3])

Dutch version

De exporteur van de goederen waarop dit document van toepassing is (douanevergunning nr. … ([1])), verklaart dat, behoudens uitdrukkelijke andersluidende vermelding, deze goederen van preferentiële … oorsprong zijn ([2]).

— cumulation applied with ..... (name of country/countries)

— no cumulation applied ([3])

Polish version

Eksporter produktów objętych tym dokumentem (upoważnienie władz celnych nr … ([1])) deklaruje, że z wyjątkiem gdzie jest to wyraźnie określone, produkty te mają … ([2]) preferencyjne pochodzenie.

— cumulation applied with ..... (name of country/countries)

— no cumulation applied ([3])

Portuguese version

O exportador dos produtos abrangidos pelo presente documento (autorização aduaneira n.º … ([1])) declara que, salvo declaração expressa em contrário, estes produtos são de origem preferencial … ([2]).

— cumulation applied with ..... (name of country/countries)

— no cumulation applied ([3])

Romanian version

Exportatorul produselor ce fac obiectul acestui document (autorizația vamală nr. … ([1])) declară că, exceptând cazul în care în mod expres este indicat altfel, aceste produse sunt de origine preferențială … ([2]).

— cumulation applied with ..... (name of the country/countries)

— no cumulation applied ([3])

Slovenian version

Izvoznik blaga, zajetega s tem dokumentom (pooblastilo carinskih organov št … ([1])) izjavlja, da, razen če ni drugače jasno navedeno, ima to blago preferencialno poreklo … ([2]).

— cumulation applied with ..... (name of the country/countries)

— no cumulation applied ([3])

Slovak version

Vývozca výrobkov uvedených v tomto dokumente (číslo povolenia … ([1])) vyhlasuje, že okrem zreteľne označených, majú tieto výrobky preferenčný pôvod v … ([2]).

— cumulation applied with ..... (name of country/countries)

— no cumulation applied ([3])

Finnish version

Tässä asiakirjassa mainittujen tuotteiden viejä (tullin lupa n:o … ([1])) ilmoittaa, että nämä tuotteet ovat, ellei toisin ole selvästi merkitty, etuuskohteluun oikeutettuja … alkuperätuotteita ([2]).

— cumulation applied with ..... (name of country/countries)

— no cumulation applied ([3])

Swedish version

Exportören av de varor som omfattas av detta dokument (tullmyndighetens tillstånd nr. … ([1])) försäkrar att dessa varor, om inte annat tydligt markerats, har förmånsberättigande … ursprung ([2]).

— cumulation applied with ..... (name of country/countries)

— no cumulation applied ([3])

Arabic version

يصرح مصدر المنتجات التي تشملها هذه الوثيقة (التصريح الجمركي رقم .....([1])) باستثناء ما ينص بوضوح على خلاف ذلك، بأن هذه المنتجات من منشأ تفضيلي من .....([2]).

— cumulation applied with ..... (name of country/countries)

— no cumulation applied ([3])

..... ([4])

(Place and date)

.....

(Signature of exporter; in addition the name of the person signing the declaration has to be indicated in clear script)

([1]) When the origin declaration is made out by an approved exporter, the authorisation number of the approved exporter must be entered in this space. When the origin declaration is not made out by an approved exporter, the words in brackets shall be omitted or the space left blank.

([2]) Origin of products to be indicated. When the origin declaration relates, in whole or in part, to products originating in Ceuta and Melilla, the exporter must clearly indicate them in the document on which the declaration is made out, by means of the symbol 'CM'.

([3]) Complete and delete where necessary.

([4]) These indications may be omitted if the information is contained on the document itself.'.

CHAPTER II

TRANSITIONAL PROVISIONS

Article 4

Goods in transit

1. The provisions of the Agreement may be applied to goods exported from either Egypt to Croatia or from Croatia to Egypt, which comply with the provisions of Protocol 4 to the Agreement and that on the date of accession of Croatia are either *en route* or in temporary storage, in a customs warehouse or in a free zone in Egypt or in Croatia.

2. Preferential treatment may be granted in such cases, subject to the submission to the customs authorities of the importing country, within four months from the date of accession of Croatia, of a proof of origin issued retrospectively by the customs authorities of the exporting country.

CHAPTER III

FINAL AND GENERAL PROVISIONS

Article 5

Egypt undertakes that it shall neither make any claim, request or referral nor modify or withdraw any concession pursuant to Articles XXIV.6 and XXVIII of the GATT 1994 in relation to this enlargement of the Union.

Article 6

In due time after the initialling of this Protocol, the Union shall communicate to its Member States and Egypt, the Croatian language version of the Agreement. Subject to the entry into force of this Protocol, the language version referred to in the first sentence of this Article shall become authentic under the same conditions as the, Bulgarian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish Swedish and Arabic language versions of the Agreement.

Article 7

This Protocol and its Annex shall form an integral part of the Agreement.

Article 8

1. This Protocol shall be approved by the Council of the European Union on behalf of the Union and its Member States, and by Egypt, in accordance with their own procedures. The Contracting Parties shall notify each other of the completion of the procedures necessary for that purpose. The instruments of approval shall be deposited with the General Secretariat of the Council of the European Union.

2. This Protocol shall enter into force on the first day of the second month following the date on which all the Parties have notified each other of the completion of the procedures necessary for this purpose.

3. Pending the date of its entry into force, the Protocol shall apply provisionally with effect from 1 July 2013.

Article 9

This Protocol is drawn up in duplicate in Bulgarian, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish, Swedish and Arabic languages, each of these texts being equally authentic.

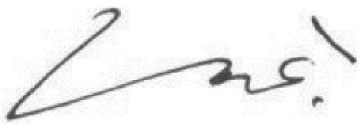
IN WITNESS WHEREOF, the undersigned Plenipotentiaries, duly authorised to this effect, have signed this Protocol.

Съставено в Брюксел на десети април през две хиляди и седемнадесета година.
Hecho en Bruselas, el diez de abril de dos mil diecisiete.
V Bruselu dne desátého dubna dva tisíce sedmnáct.
Udfærdiget i Bruxelles den tiende april to tusind og sytten.
Geschehen zu Brüssel am zehnten April zweitausendsiebzehn.
Kahe tuhande seitsmeteistkümnenda aasta aprillikuu kümnendal päeval Brüsselis.
Έγινε στις Βρυξέλλες, στις δέκα Απριλίου δύο χιλιάδες δεκαεπτά.
Done at Brussels on the tenth day of April in the year two thousand and seventeen.
Fait à Bruxelles, le dix avril deux mille dix-sept.
Sastavljeno u Bruxellesu desetog travnja godine dvije tisuće sedamnaeste.
Fatto a Bruxelles, addì dieci aprile duemiladiciassette.
Briselē, divi tūkstoši septiņpadsmitā gada desmitajā aprīlī.
Priimta Briuselyje du tūkstančiai septynioliktųjų metų balandžio dešimtą dieną.
Kelt Brüsszelben, a kétezer-tizenhetedik év április havának tizedik napján.
Magħmul fi Brussell, fl-għaxar jum ta' April fis-sena elfejn u sbatax.
Gedaan te Brussel, tien april tweeduizend zeventien.
Sporządzono w Brukseli dnia dziesiątego kwietnia roku dwa tysiące siedemnastego.
Feito em Bruxelas, em dez de abril de dois mil e dezassete.
Întocmit la Bruxelles la zece aprilie două mii șaptesprezece.
V Bruseli desiateho apríla dvetisícsedemnásť.
V Bruslju, dne desetega aprila leta dva tisoč sedemnajst.
Tehty Brysselissä kymmenentenä päivänä huhtikuuta vuonna kaksituhattaseitsemäntoista.
Som skedde i Bryssel den tionde april år tjugohundrasjutton.
تم في بروكسل في اليوم العاشر من شهر ابريل عام ألفين وسبعة عشر

За държавите-членки	За Европейския съюз
Por los Estados miembros	Por la Unión Europea
Za členské státy	Za Evropskou unii
For medlemsstaterne	For Den Europæiske Union
Für die Mitgliedstaaten	Für die Europäische Union
Liikmesriikide nimel	Euroopa Liidu nimel
Για τα κράτη μέλη	Για την Ευρωπαϊκή Ένωση
For the Member States	For the European Union
Pour les États membres	Pour l'Union européenne
Za države članice	Za Europsku uniju
Per gli Stati membri	Per l'Unione europea
Dalībvalstu vārdā –	Eiropas Savienības vārdā –
Valstybių narių vardu	Europos Sąjungos vardu
A tagállamok részéről	Az Európai Unió részéről
Għall-Istati Membri	Għall-Unjoni Ewropea
Voor de lidstaten	Voor de Europese Unie
W imieniu Państw Członkowskich	W imieniu Unii Europejskiej
Pelos Estados-Membros	Pela União Europeia
Pentru statele membre	Pentru Uniunea Europeană
Za členské štáty	Za Európsku úniu
Za države članice	Za Evropsko unijo
Jäsenvaltioiden puolesta	Euroopan unionin puolesta
För medlemsstaterna	För Europeiska unionen
عن الدول أعضاء الأتحاد الاوروبي	عن الجماعة الاوروبية

За Арабска република Египет
Por la República Árabe de Egipto
Za Egyptskou arabskou republiku
For Den Arabiske Republik Egypten
Für die Arabische Republik Ägypten
Egiptuse Araabia Vabariigi nimel
Για την Αραβική Δημοκρατία της Αιγύπτου
For the Arab Republic of Egypt
Pour la République arabe d'Égypte
Za Arapsku Republiku Egipat
Per la Repubblica araba d'Egitto
Ēģiptes Arābu Republikas vārdā –
Egipto Arabų Respublikos vardu
az Egyiptomi Arab Köztársaság részéről
Għar-Repubblika Għarbija tal-Eġittu
Voor de Arabische Republiek Egypte
W imieniu Arabskiej Republiki Egiptu
Pela República Árabe do Egipto
Pentru Republica Arabă Egipt
Za Egyptskú arabskú republiku
Za Arabsko republiko Egipt
Egyptin arabitasavallan puolesta
För Arabrepubliken Egypten

عن جمهورية مصر العربية



ANNEX

AGRICULTURAL PRODUCTS, PROCESSED AGRICULTURAL PRODUCTS AND FISH AND FISHERY PRODUCTS

MODIFICATIONS TO PROTOCOL 1 OF THE AGREEMENT CONCERNING THE ARRANGEMENTS APPLICABLE TO IMPORTS INTO THE EUROPEAN UNION OF AGRICULTURAL PRODUCTS, PROCESSED AGRICULTURAL PRODUCTS AND FISH AND FISHERY PRODUCTS ORIGINATING IN EGYPT

The concessions referred to in this Annex will replace, for the products of subheading 0810 10 00, the concessions currently applied in the framework of the Association Agreement (Protocol 1). For all products not referred to in this Annex the concessions currently applied remain unchanged.

CN Code	Description	Reduction of the MFN customs duty (%)	Tariff quota (tonnes net weight)	Reduction of the customs duty beyond the tariff quota (%)	Specific provisions
0810 10 00	Fresh strawberries, from 1 October to 30 April	100 %	10 000	—	
		100 %	94	—	Specific provisions in Protocol 1 paragraph 5 not applicable

COUNCIL DECISION (EU) 2017/769

of 25 April 2017

on the ratification and accession by Member States, in the interest of the European Union, to the Protocol of 2010 to the International Convention on Liability and Compensation for Damage in Connection with the Carriage of Hazardous and Noxious Substances by Sea, with the exception of the aspects related to judicial cooperation in civil matters

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 100(2), in conjunction with point (a)(v) of Article 218(6) thereof,

Having regard to the proposal from the European Commission,

Having regard to the consent of the European Parliament ([1]),

Whereas:

(1) The International Convention on Liability and Compensation for Damage in Connection with the Carriage of Hazardous and Noxious Substances by Sea, 1996 ('1996 HNS Convention') aims to ensure adequate, prompt and effective compensation of persons who suffer damage caused by spills of hazardous and noxious substances, when carried by sea. The 1996 HNS Convention filled a significant gap in the international regulation of liability in the context of maritime transport.

(2) In 2002, the Council adopted Decision 2002/971/EC ([2]). In accordance with that Decision, Member States were to take the necessary steps to ratify or accede to the 1996 HNS Convention, within a reasonable time and, if possible, before 30 June 2006. Four Member States have subsequently ratified that Convention. The 1996 HNS Convention has not entered into force.

(3) The 1996 HNS Convention has been amended by the Protocol of 2010 to the 1996 HNS Convention ('Protocol of 2010'). Pursuant to Article 2 and Article 18(1) of the Protocol of 2010, the 1996 HNS Convention and the Protocol of 2010 are to be read, interpreted and applied together as one, single instrument, as between the parties to the Protocol of 2010.

(4) A text consolidating the 1996 HNS Convention and the Protocol of 2010 ('2010 HNS Convention') was prepared by the International Maritime Organization ('IMO') Secretariat and approved by the IMO Legal Committee at its 98th meeting. The 2010 HNS Convention is not an instrument open to signature or ratification. The 2010 HNS Convention will take effect once the Protocol of 2010 enters into force in Member States.

(5) In accordance with Article 20(8) of the Protocol of 2010, the expression of consent by a State to be bound by the Protocol of 2010 nullifies any prior expression of consent by that State to be bound by the 1996 HNS Convention. As a result, States that are Contracting Parties to the 1996 HNS Convention will cease to be so the moment they express their consent to be bound by the Protocol of 2010 in accordance with Article 20, and in particular paragraphs (2), (3) and (4) thereof, of that Protocol.

(6) Directive 2004/35/EC of the European Parliament and of the Council ([3]) aims to prevent and remedy environmental damage caused by numerous occupational activities, including the transport by sea of dangerous goods. However, it does not apply to cases of personal injury, to damage to private property or to any economic loss, and does not affect any rights of compensation for such damage. The subject matter of that Directive and of the 2010 HNS Convention therefore partially overlap, but not to a large extent. Member States retain their competence for aspects of the 2010 HNS Convention which do not affect common rules.

([1]) Consent given on 5.4.2017 (not yet published in the Official Journal).

([2]) Council Decision 2002/971/EC of 18 November 2002 authorising the Member States, in the interest of the Community, to ratify or accede to the International Convention on Liability and Compensation for Damage in Connection with the Carriage of Hazardous and Noxious Substances by Sea, 1996 (the HNS Convention) (OJ L 337, 13.12.2002, p. 55).

([3]) Directive 2004/35/EC of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage (OJ L 143, 30.4.2004, p. 56).

(7) As was the case with its predecessor, the 2010 HNS Convention is particularly important for the interests of the Union and its Member States, as it provides for improved protection of the victims of damage in connection with the carriage of HNS by sea, including in the context of environmental damage, in line with the 1982 United Nations Convention on the Law of the Sea.

(8) In order for States to become Contracting Parties to the Protocol of 2010, and thereby to the 2010 HNS Convention, they have to submit to the Secretary-General of the IMO, at the same time as their instrument of consent, relevant data on the total quantities of contributing cargo under the 2010 HNS Convention ('HNS contributing cargo') during the preceding calendar year, in accordance with Article 20(4) thereof. For that purpose, States are required to set up a system for the reporting of HNS contributing cargo prior to expressing their consent to be bound by the Protocol of 2010.

(9) At its 100th meeting in 2013, the IMO Legal Committee endorsed Guidelines on the reporting of HNS contributing cargo, which were developed to facilitate the adoption by ratifying States of legislation on reporting prior to the entry into force of the Protocol of 2010 and to contribute to the global, uniform and effective implementation of the relevant requirements of the 2010 HNS Convention.

(10) In order to ensure legal certainty for all relevant stakeholders, Member States should inform each other and the Council and the Commission in an appropriate manner of their systems for the reporting of HNS contributing cargo. That information could be made available in an informal manner through existing channels, such as the Council preparatory bodies.

(11) The exchange of best practices among Member States on the setting up of the system for the reporting of HNS contributing cargo could facilitate the efforts of Member States in developing such a reporting system.

(12) As was the case with the 1996 HNS Convention, in the absence of a regional economic integration organisation ('REIO') clause only sovereign States may be party to the Protocol of 2010. Therefore, it is not possible for the Union to ratify or accede to the Protocol of 2010, and thereby to the 2010 HNS Convention.

(13) The ratification of the Protocol of 2010 by all Member States within a given timeframe should ensure a level playing field within the Union for all actors concerned by the application of the 2010 HNS Convention.

(14) Taking into account the international nature of the HNS regime, a global level playing field for all actors concerned by the application of the 2010 HNS Convention should be aimed for. For that reason, there is a need for global coverage of the Protocol of 2010.

(15) Member States should, therefore, be authorised to ratify or accede to, as appropriate, the Protocol of 2010 for the parts thereof falling under exclusive Union competence, with the exception of the aspects related to judicial cooperation in civil matters. The provisions of the 2010 HNS Convention falling within the competence conferred upon the Union in respect of judicial cooperation in civil matters are to be the subject of a Decision adopted in parallel to this Decision,

HAS ADOPTED THIS DECISION:

Article 1

Member States are hereby authorised, for the parts falling under the exclusive competence of the Union, to ratify or accede to, as appropriate, the Protocol of 2010 in the interest of the Union, with the exception of the aspects related to judicial cooperation in civil matters, and subject to the conditions laid down in this Decision.

Article 2

1. Member States shall endeavour to take the necessary steps to deposit the instruments of ratification of, or accession to, the Protocol of 2010 within a reasonable time and, if possible, by 6 May 2021.

2. Member States shall inform each other and the Council and the Commission in an appropriate manner when the system for the reporting of HNS contributing cargo becomes operational.

3. Member States shall seek to exchange best practices, in particular on the system for the reporting of HNS contributing cargo under the Protocol of 2010.

Article 3

When ratifying or acceding to the Protocol of 2010, Member States shall inform the Secretary-General of the International Maritime Organization in writing that such ratification or accession has taken place in accordance with this Decision and Council Decision (EU) 2017/770 ([1]).

Article 4

This Decision shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

Article 5

This Decision is addressed to the Member States in accordance with the Treaties.

Done at Luxembourg, 25 April 2017.

For the Council
The President
I. BORG

([1]) Council Decision (EU) 2017/770 of 25 April 2017 on the ratification and accession by Member States, in the interest of the European Union, to the Protocol of 2010 to the International Convention on Liability and Compensation for Damage in Connection with the Carriage of Hazardous and Noxious Substances by Sea, with regard to the aspects related to judicial cooperation in civil matters (see page 18 of this Official Journal).

COUNCIL DECISION (EU) 2017/770

of 25 April 2017

on the ratification and accession by Member States, in the interest of the European Union, to the Protocol of 2010 to the International Convention on Liability and Compensation for Damage in Connection with the Carriage of Hazardous and Noxious Substances by Sea, with regard to the aspects related to judicial cooperation in civil matters

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 81, in conjunction with point (a)(v) of Article 218(6) thereof,

Having regard to the proposal from the European Commission,

Having regard to the consent of the European Parliament [1],

Whereas:

(1) The International Convention on Liability and Compensation for Damage in Connection with the Carriage of Hazardous and Noxious Substances by Sea, 1996 ('1996 HNS Convention') aims to ensure adequate, prompt and effective compensation of persons who suffer damage caused by spills of hazardous and noxious substances, when carried by sea. The 1996 HNS Convention filled a significant gap in the international regulation of liability in the context of maritime transport.

(2) In 2002, the Council adopted Decision 2002/971/EC [2]. In accordance with that Decision, Member States were to take the necessary steps to ratify or accede to the 1996 HNS Convention, within a reasonable time and, if possible, before 30 June 2006. Four Member States have subsequently ratified that Convention. The 1996 HNS Convention has not entered into force.

(3) The 1996 HNS Convention has been amended by the Protocol of 2010 to the 1996 HNS Convention ('Protocol of 2010'). Pursuant to Article 2 and Article 18(1) of the Protocol of 2010, the 1996 HNS Convention and the Protocol of 2010 are to be read, interpreted and applied together as one, single instrument, as between the parties to the Protocol of 2010.

(4) A text consolidating the 1996 HNS Convention and the Protocol of 2010 ('2010 HNS Convention') was prepared by the International Maritime Organization ('IMO') Secretariat and approved by the IMO Legal Committee at its 98th meeting. The 2010 HNS Convention is not an instrument open to signature or ratification. The 2010 HNS Convention will take effect once the Protocol of 2010 enters into force in Member States.

(5) In accordance with Article 20(8) of the Protocol of 2010, the expression of consent by a State to be bound by the Protocol of 2010 nullifies any prior expression of consent by that State to be bound by the 1996 HNS Convention. As a result, States that are Contracting Parties to the 1996 HNS Convention will cease to be so the moment they express their consent to be bound by the Protocol of 2010 in accordance with Article 20, and in particular paragraphs (2), (3) and (4) thereof, of that Protocol.

(6) As was the case with its predecessor, the 2010 HNS Convention is particularly important for the interests of the Union and its Member States, as it provides for improved protection of the victims of damage in connection with the carriage of HNS by sea, including in the context of environmental damage, in line with the 1982 United Nations Convention on the Law of the Sea.

---

[1] Consent given on 5.4.2017.

[2] Council Decision 2002/971/EC of 18 November 2002 authorising the Member States, in the interest of the Community, to ratify or accede to the International Convention on Liability and Compensation for Damage in Connection with the Carriage of Hazardous and Noxious Substances by Sea, 1996 (the HNS Convention) (OJ L 337, 13.12.2002, p. 55).

(7) In order for States to become Contracting Parties to the Protocol of 2010, and thereby to the 2010 HNS Convention, they have to submit to the Secretary-General of the IMO, at the same time as their instrument of consent, relevant data on the total quantities of contributing cargo under the 2010 HNS Convention ('HNS contributing cargo') during the preceding calendar year, in accordance with Article 20(4) thereof. For that purpose, States are required to set up a system for the reporting of HNS contributing cargo prior to expressing their consent to be bound by the Protocol of 2010.

(8) Articles 38, 39 and 40 of the 2010 HNS Convention affect Union secondary legislation on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters, as laid down in Regulation (EU) No 1215/2012 of the European Parliament and of the Council [1].

(9) The Union therefore has exclusive competence in relation to Articles 38, 39 and 40 of the 2010 HNS Convention inasmuch as that Convention affects the rules laid down in Regulation (EU) No 1215/2012.

(10) The exchange of best practices among Member States on the setting up of the system for the reporting of HNS contributing cargo could facilitate the efforts of Member States in developing such a reporting system.

(11) As was the case with the 1996 HNS Convention, in the absence of a regional economic integration organisation ('REIO') clause only sovereign States may be party to the Protocol of 2010. Therefore, it is not possible for the Union to ratify or accede to the Protocol of 2010, and thereby to the 2010 HNS Convention.

(12) The ratification of the Protocol of 2010 by all Member States within a given timeframe should ensure a level playing field within the Union for all actors concerned by the application of the 2010 HNS Convention.

(13) Taking into account the international nature of the HNS regime, a global level playing field for all actors concerned by the application of the 2010 HNS Convention should be aimed for. For that reason, there is a need for global coverage of the Protocol of 2010.

(14) Member States should, therefore, be authorised to ratify or accede to, as appropriate, the Protocol of 2010 with regard to the aspects related to judicial cooperation in civil matters for which the Union has exclusive competence. The provisions of the 2010 HNS Convention falling within the competence conferred upon the Union other than the provisions related to judicial cooperation in civil matters are to be the subject of a Decision adopted in parallel to this Decision.

(15) When ratifying or acceding to the Protocol of 2010, Member States should make a declaration on the recognition and enforcement of judgments falling within the scope of the 2010 HNS Convention.

(16) The United Kingdom and Ireland are bound by Regulation (EU) No 1215/2012 and are therefore taking part in the adoption and application of this Decision.

(17) In accordance with Articles 1 and 2 of Protocol No 22 on the position of Denmark, annexed to the Treaty on European Union and to the Treaty on the Functioning of the European Union, Denmark is not taking part in the adoption of this Decision and is not bound by it or subject to its application,

HAS ADOPTED THIS DECISION:

Article 1

Member States are hereby authorised to ratify or accede to, as appropriate, the Protocol of 2010 in the interest of the Union with regard to the aspects related to judicial cooperation in civil matters for which the Union has exclusive competence, subject to the conditions laid down in this Decision.

[1] Regulation (EU) No 1215/2012 of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (OJ L 351, 20.12.2012, p. 1).

Article 2

1. Member States shall endeavour to take the necessary steps to deposit the instruments of ratification of, or accession to, the Protocol of 2010 within a reasonable time and, if possible, by 6 May 2021.

2. Member States shall inform each other and the Council and the Commission in an appropriate manner when the system for the reporting of HNS contributing cargo becomes operational.

3. Member States shall seek to exchange best practices, in particular on the system for the reporting of HNS contributing cargo under the Protocol of 2010.

Article 3

When ratifying or acceding to the Protocol of 2010, Member States shall also deposit the Declaration set out in the Annex to this Decision.

Article 4

This Decision shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

Article 5

This Decision is addressed to the Member States in accordance with the Treaties.

Done at Luxembourg, 25 April 2017.

For the Council
The President
I. BORG

ANNEX

Declaration to be deposited by Member States when ratifying or acceding to the Protocol of 2010, in accordance with Article 3:

'Judgments on matters covered by the Convention as amended by the Protocol of 2010, when given by a court of … [1], shall be recognised and enforced in … [2] in accordance with the relevant European Union rules on the subject [3].

Judgments on matters covered by the Convention as amended by the Protocol of 2010, when given by a court of the Kingdom of Denmark, shall be recognised and enforced in … [4] in accordance with the 2005 Agreement between the European Community and the Kingdom of Denmark on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters [5].

Judgments on matters covered by the Convention as amended by the Protocol of 2010, when given by a court of a third State bound by the Lugano Convention on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters of 30 October 2007 [6], shall be recognised and enforced in … [7] in accordance with that Convention.

---

[1] All Member States of the European Union, with the exception of the Member State making the Declaration and Denmark.
[2] The Member State making the Declaration.
[3] At present, these rules are laid down in Regulation (EU) No 1215/2012 of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (OJ L 351, 20.12.2012, p. 1).
[4] The Member State making the Declaration.
[5] OJ L 299, 16.11.2005, p. 62.
[6] OJ L 339, 21.12.2007, p. 3.
[7] The Member State making the Declaration.'.

REGULATIONS

COMMISSION REGULATION (EU) 2017/771

of 3 May 2017

amending Regulation (EC) No 152/2009 as regards the methods for the determination of the levels of dioxins and polychlorinated biphenyls

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules ([1]), and in particular Article 11(4) thereof,

Whereas:

(1) Commission Regulation (EC) No 152/2009 ([2]) includes methods for the determination of the levels of polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), dioxin-like polychlorinated biphenyls (PCBs) and non-dioxin-like PCBs in feed.

(2) EU reference laboratory for dioxins and PCBs in feed and food has provided evidence that analytical results for dioxins and PCBs in certain cases are not reliable when the performance criteria provided for in Part B of Annex V to Regulation (EC) No 152/2009 are not applied by laboratories performing the analysis of samples taken by feed business operators in accordance with Regulation (EC) No 183/2005 of the European Parliament and of the Council ([3]). It is therefore appropriate to make the application of the performance criteria for the analysis of samples obligatory.

(3) Given that the method of using a decision limit to ensure, with a certain probability, that an analytical result is above the maximum level, as provided for in Commission Decision 2002/657/EC ([4]), is no longer applied for the analysis of dioxins, furans and PCBs in feed, it is appropriate to delete that method and to keep only the method of the expanded uncertainty using the coverage factor of 2, which gives a level of confidence of approximately 95 %.

(4) Guidance documents for the measurement uncertainty and for the estimation of the Limit of Detection (LOD) and Limit of Quantification (LOQ) have been developed. It is appropriate to make reference to them.

(5) In line with the reporting requirements for bioanalytical screening methods provided for in Part B of Annex V to Regulation (EC) No 152/2009, it is appropriate to provide also for physico-chemical methods, to be used for screening, specific reporting requirements in Chapter II of that Part.

(6) Given that the analysis of dioxins, dioxin-like PCBs and non-dioxin-like PCBs are in most cases determined together, it is appropriate to align the performance criteria for the non-dioxin-like PCBs provided for in point 3.3 of Chapter III of Part B of Annex V to Regulation (EC) No 152/2009 to the performance criteria for dioxins and dioxin-like PCBs. This is a simplification without substantial changes in practice as for non-dioxin-like PCBs the relative intensity of qualifier ions compared to target ions is > 50 %.

([1]) OJ L 165, 30.4.2004, p. 1.
([2]) Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).
([3]) Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p. 1).
([4]) Commission Decision 2002/657/EC of 14 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results (OJ L 221, 17.8.2002, p. 8).

(7) Following experience gained, it is appropriate to adapt some technical specifications such as recoveries of isotope-labelled standards provided for in points 7.3 and 7.5 of Chapter III of Part B of Annex V to Regulation (EC) No 152/2009.

(8) Furthermore, there are several other minor modifications proposed to the current provisions to improve the consistency in the terminology used, requiring replacing the whole Part B of Annex V to Regulation (EC) No 152/2009 to maintain the readability of the text.

(9) Regulation (EC) No 152/2009 should therefore be amended accordingly.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Part B of Annex V to Regulation (EC) No 152/2009 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 3 May 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

In Annex V to Regulation (EC) No 152/2009, Part B 'DETERMINATION OF THE LEVELS OF DIOXINS (PCDD/PCDF) AND PCBs' is replaced by the following:

'B. DETERMINATION OF THE LEVELS OF DIOXINS (PCDD/PCDF) AND PCBs

CHAPTER I

Methods of sampling and interpretation of analytical results

1. **Scope and definitions**

The samples intended for the official control of the levels of polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), dioxin-like polychlorinated biphenyls (PCBs) ([1]) and non dioxin-like PCBs in feed shall be taken in accordance with the provisions of Annex I. The quantitative requirements in relation to the control of substances or products uniformly distributed throughout the feed as provided for in point 5.1. of Annex I shall be applied. Aggregate samples thus obtained shall be considered representative for the lots or sublots from which they are taken. Compliance with maximum levels laid down by Directive 2002/32/EC shall be established on the basis of the levels determined in the laboratory samples.

For the purposes of this Part B, the definitions laid down in Annex I to Commission Decision 2002/657/EC ([2]) shall apply.

([1]) Table of TEF (= toxic equivalency factors) for PCDDs, PCDFs and dioxin-like PCBs: WHO-TEFs for human risk assessment based on the conclusions of the World Health Organization (WHO) — International Programme on Chemical Safety (IPCS) expert meeting which was held in Geneva in June 2005 (Martin van den Berg et al., The 2005 World Health Organization Re-evaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-like Compounds. Toxicological Sciences 93(2), 223–241 (2006)).

Congener	TEF value	Congener	TEF value
Dibenzo-p-dioxins ("PCDDs") and Dibenzo-p-furans '("PCDFs")		"Dioxin-like" PCBs Non-ortho PCBs + Mono-ortho PCBs	
2,3,7,8-TCDD	1		
1,2,3,7,8-PeCDD	1	Non-ortho PCBs	
1,2,3,4,7,8-HxCDD	0,1	PCB 77	0,0001
1,2,3,6,7,8-HxCDD	0,1	PCB 81	0,0003
1,2,3,7,8,9-HxCDD	0,1	PCB 126	0,1
1,2,3,4,6,7,8-HpCDD	0,01	PCB 169	0,03
OCDD	0,0003	Mono-ortho PCBs	
2,3,7,8-TCDF	0,1	PCB 105	0,00003
1,2,3,7,8-PeCDF	0,03	PCB 114	0,00003
2,3,4,7,8-PeCDF	0,3	PCB 118	0,00003
1,2,3,4,7,8-HxCDF	0,1	PCB 123	0,00003
1,2,3,6,7,8-HxCDF	0,1	PCB 156	0,00003
1,2,3,7,8,9-HxCDF	0,1	PCB 157	0,00003
2,3,4,6,7,8-HxCDF	0,1	PCB 167	0,00003
1,2,3,4,6,7,8-HpCDF	0,01	PCB 189	0,00003
1,2,3,4,7,8,9-HpCDF	0,01		
OCDF	0,0003		

Abbreviations used: "T" = tetra; "Pe" = penta; "Hx" = hexa; "Hp" = hepta; "O" = octa; "CDD" = chlorodibenzodioxin; "CDF" = chlorodibenzofuran; "CB" = chlorobiphenyl.

([2]) Commission Decision 2002/657/EC of 14 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and interpretation of results (OJ L 221, 17.8.2002, p. 8).

In addition to those definitions, the following definitions shall apply for the purpose of this Part B:

"Screening methods" means methods used for selection of those samples with levels of PCDD/Fs and dioxin-like PCBs that exceed the maximum levels or the action thresholds. They shall allow a cost-effective high sample-throughput, thus increasing the chance to discover new incidents with high exposure and health risks to consumers. Screening methods shall be based on bioanalytical or GC-MS methods. Results from samples exceeding the cut-off value used to check compliance with the maximum level shall be verified by a full re-analysis from the original sample using a confirmatory method.

"Confirmatory methods" means methods that provide full or complementary information enabling the PCDD/Fs and dioxin-like PCBs to be identified and quantified unequivocally at the maximum or in case of need at the action threshold. Such methods utilize gas chromatography/high resolution mass spectrometry (GC-HRMS) or gas chromatography/tandem mass spectrometry (GC-MS/MS).

2. **Compliance of the lot or sublot with the maximum level**

2.1. *As regards non-dioxin-like PCBs*

The lot or sublot complies with the maximum level if the analytical result for the sum of PCB 28, PCB 52, PCB 101, PCB 138, PCB 153 and PCB 180 (hereafter referred to as non-dioxin-like PCBs) does not exceed the maximum level laid down by Directive 2002/32/EC, taking into account the expanded measurement uncertainty ([1]). The lot or sublot does not comply with the maximum level as laid down by Directive 2002/32/EC, if the mean of two upper-bound ([2]) analytical results obtained from duplicate analysis ([3]), taking into account the expanded measurement uncertainty, exceeds the maximum level beyond reasonable doubt, i.e. the analysed concentration after deduction of the expanded measurement uncertainty is used to assess compliance.

The expanded measurement uncertainty is calculated using a coverage factor of 2 which gives a level of confidence of approximately 95 %. A lot or sublot is non-compliant if the mean of the measured values minus the expanded uncertainty of the mean is above the maximum level.

The rules, mentioned in the paragraphs above under this point, shall apply for the analytical result obtained on the sample for official control. In case of analysis for defence or reference purposes, the national rules shall apply.

2.2. *As regards PCDD/Fs and dioxin-like PCBs*

The lot or sublot complies with the maximum level if the result of a single analysis

— performed by a screening method with a false-compliant rate below 5 %, indicates that the level does not exceed the respective maximum level of PCDD/Fs and the sum of PCDD/Fs and dioxin-like PCBs laid down by Directive 2002/32/EC,

— performed by a confirmatory method, does not exceed the respective maximum level of PCDD/Fs and the sum of PCDD/Fs and dioxin-like PCBs laid down by Directive 2002/32/EC, taking into account the expanded measurement uncertainty.

([1]) The principles described in the "Guidance Document on Measurement Uncertainty for Laboratories performing PCDD/F and PCB Analysis using Isotope Dilution Mass Spectrometry" (http://ec.europa.eu/food/safety/animal-feed_en) shall be followed when applicable.

([2]) The concept of "upper-bound" requires using the limit of quantification for the contribution of each non-quantified congener. The concept of "lower-bound" requires using zero for the contribution of each non-quantified congener. The concept of "medium-bound" requires using half of the limit of quantification calculating the contribution of each non-quantified congener.

([3]) Duplicate analysis: Separate analysis of the analytes of interest using a second aliquot of the same homogenized sample. In general, the requirements for duplicate analysis as provided for in Annex II, Chapter C, point 3 apply. However, for methods with the use of ^{13}C-labelled internal standard for the relevant analytes, the duplicate analysis is only necessary if the result of the first determination is not compliant. The duplicate analysis is necessary to exclude the possibility of internal cross-contamination or an accidental mix-up of samples. In case the analysis is performed in the course of a contamination incident, confirmation by duplicate analysis may be omitted in case the samples selected for analysis are through traceability linked to the contamination incident and the level found is significantly above the maximum level.

For screening assays a cut-off value shall be established for decisions on sample compliance with the respective maximum levels set for either PCDD/Fs, or for the sum of PCDD/Fs and dioxin-like PCBs.

The lot or sublot does not comply with the maximum level as laid down by Directive 2002/32/EC if the mean of two upper-bound ([1]) analytical results obtained from duplicate analysis ([2]) using a confirmatory method, taking into account the expanded measurement uncertainty, exceeds the maximum level beyond reasonable doubt, i.e. the analysed concentration after deduction of the expanded measurement uncertainty is used to assess compliance.

The expanded measurement uncertainty is calculated using a coverage factor of 2 which gives a level of confidence of approximately 95 %. A lot or sublot is non-compliant if the mean of the measured values minus the expanded uncertainty of the mean is above the maximum level.

The sum of the estimated expanded uncertainties of the separate analytical results of PCDD/Fs and dioxin-like PCBs shall be used for the sum of PCDD/Fs and dioxin-like PCBs.

The rules, mentioned in the paragraphs above under this point, shall apply for the analytical result obtained on the sample for official control. In case of analysis for defence or reference purposes, the national rules shall apply.

3. **Results exceeding action thresholds as laid down in Annex II to Directive 2002/32/EC**

Action thresholds serve as a tool for the selection of samples in those cases where it is necessary to identify a source of contamination and to take measures for its reduction or elimination. Screening methods shall establish the appropriate cut-off values for selection of those samples. Where significant efforts are necessary to identify a source and to reduce or eliminate the contamination, it is appropriate to confirm exceedance of the action thresholds by duplicate analysis using a confirmatory method and taking into account the expanded measurement uncertainty ([3]).

CHAPTER II

Sample preparation and requirements for methods of analysis used in offical control of the levels of dioxins (PCDD/Fs) and dioxin-like PCBs in feed

1. **Field of application**

The requirements set out in this Chapter shall be applied where feed is analysed for the official control of the levels of 2,3,7,8-substituted PCDD/Fs and dioxin-like PCBs and as regards sample preparation and analytical requirements for other regulatory purposes, which includes the controls performed by the feed business operator to ensure compliance with the provisions of Regulation (EC) No 183/2005 of the European Parliament and of the Council ([4]).

([1]) The concept of "upper-bound" requires using the limit of quantification for the contribution of each non-quantified congener to the Toxic Equivalent (TEQ). The concept of "lower-bound" requires using zero for the contribution of each non-quantified congener to the TEQ. The concept of "medium-bound" requires using half of the limit of quantification calculating the contribution of each non-quantified congener to the TEQ.

([2]) In general, the requirements for duplicate analysis as provided for in Annex II, Chapter C, point 2 apply. However, for confirmatory methods with the use of ^{13}C-labelled internal standard for the relevant analytes, the duplicate analysis is only necessary if the result of the first determination is not compliant. The duplicate analysis is necessary to exclude the possibility of internal cross-contamination or an accidental mix-up of samples. In case the analysis is performed in the course of a contamination incident, confirmation by duplicate analysis may be omitted in case the samples selected for analysis are through traceability linked to the contamination incident and the level found is significantly above the maximum level.

([3]) Identical explanation and requirements for duplicate analysis for control of action thresholds as in footnote 2 above for maximum levels.

([4]) Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p. 1).

Monitoring for the presence of PCDD/Fs and dioxin-like PCBs in feed may be performed with two different types of analytical methods:

(a) *Screening methods*

The goal of screening methods is to select those samples with levels of PCDD/Fs and dioxin-like PCBs that exceed the maximum levels or the action thresholds. Screening methods shall ensure cost-effective high sample-throughput, thus increasing the chance to discover new incidents with high exposure and health risks of consumers. Their application shall aim to avoid false-compliant results. They may comprise bioanalytical and GC-MS methods.

Screening methods compare the analytical result with a cut-off value, providing a yes/no-decision over the possible exceedance of the maximum level or action threshold. The concentration of PCDD/Fs and the sum of PCDD/Fs and dioxin-like PCBs in samples suspected to be non-compliant with the maximum level shall be determined or confirmed by a confirmatory method.

In addition, screening methods may give an indication of the levels of PCDD/Fs and dioxin-like PCBs present in the sample. In case of application of bioanalytical screening methods the result is expressed as Bioanalytical Equivalents (BEQ), whereas in case of application of physico-chemical GC-MS methods it is expressed as Toxic Equivalents (TEQ). The numerically indicated results of screening methods are suitable for demonstrating compliance or suspected noncompliance or exceedance of action thresholds and give an indication of the range of levels in case of follow-up by confirmatory methods. They are not suitable for purposes such as evaluation of background levels, estimation of intake, following of time trends in levels or re-evaluation of action thresholds and maximum levels.

(b) *Confirmatory methods*

Confirmatory methods allow the unequivocal identification and quantification of PCDD/Fs and dioxin-like PCBs present in a sample and provide full information on congener level. Therefore, those methods allow the control of maximum levels and action thresholds, including the confirmation of results obtained by screening methods. Furthermore, results may be used for other purposes such as determination of low background levels in feed monitoring, following of time trends, exposure assessment and building of a database for possible re-evaluation of action thresholds and maximum levels. They are also important for establishing congener patterns in order to identify the source of a possible contamination. Such methods utilise GC-HRMS. For confirming compliance or non-compliance with the maximum level, also GC-MS/MS can be used.

2. **Background**

For calculation of TEQ concentrations, the concentrations of the individual substances in a given sample shall be multiplied by their respective Toxic Equivalency Factor (TEF) (see footnote 1 of Chapter I) and subsequently summed to give the total concentration of dioxin-like compounds expressed as TEQs.

For the purposes of this Part B, the accepted specific limit of quantification of an individual congener means the lowest content of the analyte that can be measured with reasonable statistical certainty, fulfilling the identification criteria as described in internationally recognised standards, for example, in standard EN 16215:2012 (Animal feed — Determination of dioxins and dioxin-like PCBs by GC-HRMS and of indicator PCBs by GC-HRMS) and/or in EPA methods 1613 and 1668 as revised.

The limit of quantification of an individual congener may be identified as

(a) the concentration of an analyte in the extract of a sample which produces an instrumental response at two different ions to be monitored with a S/N (signal/noise) ratio of 3:1 for the less intensive raw data signal; or

(b) if for technical reasons the signal-to-noise calculation does not provide reliable results, the lowest concentration point on a calibration curve that gives an acceptable (≤ 30 %) and consistent (measured at least at the start and at the end of an analytical series of samples) deviation to the average relative response factor calculated for all points on the calibration curve in each series of samples. The limit of quantification (LOQ) is calculated from the lowest concentration point taking into account the recovery of internal standards and sample intake.

Bioanalytical screening methods will not give results at the congener level but merely an indication ([1]) of the TEQ level, expressed in BEQ to acknowledge the fact that not all compounds present in a sample extract that produce a response in the test may fulfill or meet all requirements of the TEQ-principle.

Screening and confirmatory methods may only be applied for control of a certain matrix if the methods are sensitive enough to detect levels reliably at the action threshold or maximum level.

3. **Quality assurance requirements**

3.1. Measures shall be taken to avoid cross-contamination at each stage of the sampling and analysis procedure.

3.2. The samples shall be stored and transported in glass, aluminum, polypropylene or polyethylene containers suitable for storage without any influence on the levels of PCDD/Fs and dioxin-like PCBs in the samples. Traces of paper dust shall be removed from the sample container.

3.3. The sample storage and transportation shall be performed in a way that maintains the integrity of the feed sample.

3.4. Insofar as relevant, each laboratory sample shall be finely grinded and mixed thoroughly using a process that has been demonstrated to achieve complete homogenisation (for example, ground to pass a 1 mm sieve). Samples shall be dried before grinding if the moisture content is too high.

3.5. Control of reagents, glassware and equipment for possible influence of TEQ- or BEQ-based results shall be carried out.

3.6. A blank analysis shall be performed by carrying out the entire analytical procedure omitting only the sample.

3.7. For bioanalytical methods, all glassware and solvents used in analysis shall be tested to be free of compounds that interfere with the detection of target compounds in the working range. Glassware shall be rinsed with solvents or heated at temperatures suitable to remove traces of PCDD/Fs, dioxin-like compounds and interfering compounds from its surface.

3.8. Sample quantity used for the extraction shall be sufficient to fulfill the requirements with respect to a sufficiently low working range including the concentrations of maximum levels or action threshold.

3.9. The specific sample preparation procedures used for the products under consideration shall follow internationally accepted guidelines.

4. **Requirements for laboratories**

4.1. In accordance with the provisions of Regulation (EC) No 882/2004, laboratories shall be accredited by a recognised body operating in accordance with ISO Guide 58 to ensure that they are applying analytical quality assurance. Laboratories shall be accredited following the EN ISO/IEC 17025 standard. The principles as described in the Technical Guidelines for the estimation of measurement uncertainty and limits of quantification for PCDD/F and PCB analysis shall be followed when applicable ([2])

([1]) Bioanalytical methods are not specific to those congeners included in the TEF-scheme. Other structurally related AhR-active compounds may be present in the sample extract which contribute to the overall response. Therefore, bioanalytical results cannot be an estimate but rather an indication of the TEQ level in the sample.

([2]) "Guidance Document on Measurement Uncertainty for Laboratories performing PCDD/F and PCB Analysis using Isotope Dilution Mass Spectrometry" (http://ec.europa.eu/food/safety/animal-feed_en), "Guidance Document on the Estimation of LOD and LOQ for Measurements in the Field of Contaminants in Feed and Food" (http://ec.europa.eu/food/safety/animal-feed_en).

4.2. Laboratory proficiency shall be proven by the continuous successful participation in inter-laboratory studies for the determination of PCDD/Fs and dioxin-like PCBs in relevant feed matrices and concentration ranges.

4.3. Laboratories applying screening methods for the routine control of samples shall establish a close cooperation with laboratories applying the confirmatory method, both for quality control and confirmation of the analytical result of suspected samples.

5. **Basic requirements to be met by analytical procedure for dioxins (PCDD/Fs) and dioxin-like PCBs**

5.1. *Low working range and limits of quantification*

For PCDD/Fs, detectable quantities shall be in the upper femtogram (10^{-15}g) range because of extreme toxicity of some of these compounds. For most PCB congeners a limit of quantification in the nanogram (10^{-9}g) range is already sufficient. For the measurement of the more toxic dioxin-like PCB congeners (in particular non-ortho-substituted congeners), the lower end of the working range shall reach the low picogram (10^{-12}g) levels. For all other PCB congeners a limit of quantification in the nanogram (10^{-9}g) range is sufficient.

5.2. *High selectivity (specificity)*

5.2.1. A distinction is required between PCDD/Fs and dioxin-like PCBs and a multitude of other, coextracted and possibly interfering compounds present at concentrations up to several orders of magnitude higher than those of the analytes of interest. For GC-MS methods, a differentiation among various congeners is required, such as between toxic (for example, the seventeen 2,3,7,8-substituted PCDD/Fs, and twelve dioxin-like PCBs) and other congeners.

5.2.2. Bioanalytical methods shall be able to detect the target compounds as the sum of PCDD/Fs, and/or dioxin-like PCBs. Sample clean-up shall aim at removing compounds causing false non-compliant results or compounds that may decrease the response, causing false compliant results.

5.3. *High accuracy (trueness and precision, bioassay apparent recovery)*

5.3.1. For GC-MS methods, the determination shall provide a valid estimate of the true concentration in a sample. High accuracy is required to avoid the rejection of a sample analysis result on the basis of poor reliability of the determined TEQ level. Accuracy is expressed as *trueness* (difference between the mean value measured for an analyte in a certified material and its certified value, expressed as a percentage of this value) and *precision* (RSD_R relative standard deviation calculated from results generated under reproducibility conditions).

5.3.2. For bioanalytical methods, the bioassay apparent recovery shall be determined. Bioassay apparent recovery means the BEQ level calculated from the TCDD or PCB 126 calibration curve corrected for the blank and then divided by the TEQ level determined by the confirmatory method. It aims at correcting factors like the loss of PCDD/Fs and dioxin-like compounds during the extraction and clean-up steps, co-extracted compounds increasing or decreasing the response (agonistic and antagonistic effects), the quality of the curve fit, or differences between the TEF values and the Relative Potency (REP) values. The bioassay apparent recovery is calculated from suitable reference samples with representative congener patterns around the level of interest.

5.4. *Validation in the range of maximum level and general quality control measures*

5.4.1. Laboratories shall demonstrate the performance of a method in the range of the maximum level, for example, 0,5x, 1x and 2x the maximum level with an acceptable coefficient of variation for repeated analysis, during the validation procedure and during routine analysis.

5.4.2. Regular blank controls and spiking experiments or analysis of control samples (preferably, if available, certified reference material) shall be performed as internal quality control measures. Quality control charts for blank controls, spiking experiments or analysis of control samples shall be recorded and checked to make sure the analytical performance is in accordance with the requirements.

5.5. *Limit of quantification*

5.5.1. For a bioanalytical screening method, the establishment of the limit of quantification (LOQ) is not an indispensable requirement but the method shall prove that it can differentiate between the blank and the cut-off value. When providing a BEQ level, a reporting level shall be established to deal with samples showing a response below this level. The reporting level shall be demonstrated to be different from procedure blank samples at least by a factor of three, with a response below the working range. It shall therefore be calculated from samples containing the target compounds around the required minimum level, and not from an S/N ratio or an assay blank.

5.5.2. The LOQ for a confirmatory method shall be about one fifth of the maximum level.

5.6. *Analytical criteria*

For reliable results from confirmatory or screening methods, the following criteria shall be met in the range of the maximum level for the TEQ or BEQ value, respectively, whether determined as total TEQ or total BEQ (as the sum of PCDD/Fs and dioxin-like PCBs) or separately for PCDD/Fs and dioxin-like PCBs:

	Screening with bioanalytical or physico-chemical methods	Confirmatory methods
False-compliant rate (*)	< 5 %	
Trueness		− 20 % to + 20 %
Repeatability (RSD_r)	< 20 %	
Intermediate precision (RSD_R)	< 25 %	< 15 %

(*) With respect to the maximum levels.

5.7. *Specific requirements for screening methods*

5.7.1. Both GC-MS and bioanalytical methods may be used for screening. For GC-MS methods the requirements laid down in point 6 shall be met. For cell based bioanalytical methods specific requirements are laid down in point 7.

5.7.2. Laboratories applying screening methods for the routine control of samples shall establish a close cooperation with laboratories applying the confirmatory method.

5.7.3. Performance verification of the screening method is required during routine analysis, by analytical quality control and on-going method validation. There shall be a continuous programme for the control of compliant results.

5.7.4. Check on possible suppression of the cell response and cytotoxicity:

20 % of the sample extracts shall be measured in routine screening without and with 2,3,7,8-TCDD added corresponding to the maximum level or action threshold, to check if the response is possibly suppressed by interfering substances present in the sample extract. The measured concentration of the spiked sample shall be compared to the sum of the concentration of the unspiked extract plus the spiking concentration. If this measured concentration is more than 25 % lower than the calculated (sum) concentration, this is an indication of potential signal suppression and the respective sample shall be submitted to GC-HRMS confirmatory analysis. Results shall be monitored in quality control charts.

5.7.5. Quality control on compliant samples:

Approximately 2 to 10 % of the compliant samples, depending on sample matrix and laboratory experience, shall be confirmed by GC/HRMS.

5.7.6. Determination of false-compliant rates from quality control data:

The rate of false-compliant results from screening of samples below and above the maximum level or the action threshold shall be determined. Actual false-compliant rates shall be below 5 %. When a minimum of 20 confirmed results per matrix/matrix group is available from the quality control of compliant samples, conclusions on the false compliant rate shall be drawn from this database. The results from samples analysed in ring trials or during contamination incidents, covering a concentration range up to for example 2x the maximum level (ML), may also be included in the minimum of 20 results for evaluation of the false-compliant rate. The samples shall cover most frequent congener patterns, representing various sources.

Although screening assays shall preferentially aim to detect samples exceeding the action threshold, the criterion for determining false-compliant rates is the maximum level, taking into account the expanded measurement uncertainty of the confirmatory method.

5.7.7. Potential non-compliant samples from screening shall always be verified by a full re-analysis of the original sample by a confirmatory method of analysis. These samples may also be used to evaluate the rate of false non-compliant results. For screening methods, the rate of false non-compliant results shall be the fraction of results confirmed to be compliant from confirmatory analysis, while in previous screening the sample has been declared to be potentially non-compliant. Evaluation of the advantages of the screening method shall be based on comparison of false-non-compliant samples with the total number of samples checked. This rate shall be low enough to make the use of a screening tool advantageous.

5.7.8. Under validation conditions, bioanalytical methods shall provide a valid indication of the TEQ level, calculated and expressed as BEQ.

Also for bioanalytical methods carried out under repeated conditions, the intra-laboratory RSD_r would typically be smaller than under reproducibility conditions(RSD_R)

6. SPECIFIC requirements for GC-MS methods to be complied with for screening or confirmatory purposes

6.1. *Acceptable differences between upper-bound and lower-bound WHO-TEQ results*

The difference between upper-bound level and lower-bound level shall not exceed 20 % for confirmation of exceedance of maximum level or in case of need of action thresholds.

6.2. *Control of recoveries*

6.2.1. Addition of ^{13}C-labelled 2,3,7,8-chlorine-substituted internal PCDD/F standards and of ^{13}C-labelled internal dioxin-like PCB standards shall be carried out at the very beginning of the analytical method e.g. prior to extraction in order to validate the analytical procedure. At least one congener for each of the tetra- to octa-chlorinated homologous groups for PCDD/Fs and at least one congener for each of the homologous groups for dioxin-like PCBs shall be added (alternatively, at least one congener for each mass spectrometric selected ion recording function used for monitoring PCDD/Fs and dioxin-like PCBs). In the case of confirmatory methods, all 17 ^{13}C-labelled 2,3,7,8-substituted internal PCDD/F standards and all 12 ^{13}C-labelled internal dioxin-like PCB standards shall be used.

6.2.2. Relative response factors shall also be determined for those congeners for which no ^{13}C-labelled analogue is added by using appropriate calibration solutions.

6.2.3. For feed of plant origin and feed of animal origin containing less than 10 % fat, the addition of the internal standards shall be mandatory prior to extraction. For feed of animal origin containing more than 10 % fat, the internal standards shall be added either before or after fat extraction. An appropriate validation of the extraction efficiency shall be carried out, depending on the stage at which internal standards are introduced.

6.2.4. Prior to GC-MS analysis, 1 or 2 recovery (surrogate) standard(s) shall be added.

6.2.5. Control of recovery is required. For confirmatory methods, the recoveries of the individual internal standards shall be in the range of 60 to 120 %. Lower or higher recoveries for individual congeners, in particular for some hepta- and octa- chlorinated dibenzo-p-dioxins and dibenzofurans, shall be acceptable on the condition that their contribution to the TEQ value does not exceed 10 % of the total TEQ value (based on sum of PCDD/F and dioxin-like PCBs). For GC-MS screening methods, the recoveries shall be in the range of 30 to 140 %.

6.3. *Removal of interfering substances*

— Separation of PCDD/Fs from interfering chlorinated compounds such as non-dioxin-like PCBs and chlorinated diphenyl ethers shall be carried out by suitable chromatographic techniques (preferably with a florisil, alumina and/or carbon column).

— Gas-chromatographic separation of isomers shall be < 25 % peak to peak between 1,2,3,4,7,8-HxCDF and 1,2,3,6,7,8-HxCDF.

6.4. *Calibration with standard curve*

The range of the calibration curve shall cover the relevant range of maximum level or action thresholds.

6.5. *Specific criteria for confirmatory methods*

— For GC-HRMS:

In HRMS, the resolution shall typically be greater than or equal to 10 000 for the entire mass range at 10 % valley.

Fulfilment of further identification and confirmation criteria as described in internationally recognised standards, for example, in standard EN 16215:2012 (Animal feed — Determination of dioxins and dioxin-like PCBs by GC-HRMS and of indicator PCBs by GC-HRMS) and/or in EPA methods 1613 and 1668 as revised.

— For GC-MS/MS:

Monitoring of at least 2 specific precursor ions, each with one specific corresponding transition product ion for all labelled and unlabelled analytes in the scope of analysis.

Maximum permitted tolerance of relative ion intensities of ± 15 % for selected transition product ions in comparison to calculated or measured values (average from calibration standards), applying identical MS/MS conditions, in particular collision energy and collision gas pressure, for each transition of an analyte.

Resolution for each quadrupole to be set equal to or better than unit mass resolution (unit mass resolution: sufficient resolution to separate two peaks one mass unit apart) in order to minimise possible interferences on the analytes of interest.

Fulfilment of the further criteria as described in internationally recognised standards, for example, in standard EN 16215:2012 (Animal feed — Determination of dioxins and dioxin-like PCBs by GC-HRMS and of indicator PCBs by GC-HRMS) and/or in EPA methods 1613 and 1668 as revised, except the obligation to use GC-HRMS.

7. **Specific requirements for bioanalytical methods**

Bioanalytical methods are methods based on the use of biological principles like cell-based assays, receptor-assays or immunoassays. This point 7 establishes requirements for bioanalytical methods in general.

A screening method in principle classifies a sample as compliant or suspected to be non-compliant. For this, the calculated BEQ level is compared to the cut-off value (see point 7.3). Samples below the cut-off value are declared compliant, samples equal or above the cut-off value are suspected to be non-compliant, requiring analysis by a confirmatory method. In practice, a BEQ level corresponding to two-thirds of the maximum level may serve as cut-off value provided that a false-compliant rate below 5 % and an acceptable rate for false non-compliant results are ensured. With separate maximum levels for PCDD/Fs and for the sum of PCDD/Fs and dioxin-like PCBs, checking compliance of samples without fractionation requires appropriate bioassay cut-off values for PCDD/Fs. For checking of samples exceeding the action thresholds, an appropriate percentage of the respective action threshold shall suit as cut-off value.

If an indicative level is expressed in BEQs, sample results shall be in the working range and shall exceed the reporting limit (see points 7.1.1 and 7.1.6).

7.1. *Evaluation of the test response*

7.1.1. General requirements

— When calculating the concentrations from a TCDD calibration curve, values at the higher end of the curve will show a high variation (high coefficient of variation (CV)). The working range is the area where this CV is smaller than 15 %. The lower end of the working range (reporting limit) shall be set at least by a factor of three above the procedure blanks. The upper end of the working range is usually represented by the EC_{70} value (70 % of maximal effective concentration), but lower if the CV is higher than 15 % in this range. The working range shall be established during validation. Cut-off values (see point 7.3) shall be well within the working range.

— Standard solutions and sample extracts shall be tested in triplicate or at least in duplicate. When using duplicates, a standard solution or a control extract tested in four to six wells divided over the plate shall produce a response or concentration (only possible in the working range) based on a CV < 15 %.

7.1.2. Calibration

7.1.2.1. Calibration with standard curve

— Levels in samples shall be estimated by comparison of the test response with a calibration curve of TCDD (or PCB 126 or a PCDD/PCDF/dioxin-like PCB standard mixture) to calculate the BEQ level in the extract and subsequently in the sample.

— Calibration curves shall contain 8 to 12 concentrations (at least in duplicates), with enough concentrations in the lower part of the curve (working range). Special attention shall be paid to the quality of the curve-fit in the working range. As such, the R^2 value is of little or no value in estimating the goodness of fit in non-linear regression. A better fit shall be achieved by minimising the difference between calculated and observed levels in the working range of the curve, for example by minimising the sum of squared residuals.

— The estimated level in the sample extract shall be subsequently corrected for the BEQ level calculated for a matrix or solvent blank sample (to account for impurities from solvents and chemicals used), and the apparent recovery (calculated from the BEQ level of suitable reference samples with representative congener patterns around the maximum level or action threshold). To perform a recovery correction, the apparent recovery shall be within the required range (see point 7.1.4). Reference samples used for recovery correction shall comply with the requirements laid down in point 7.2.

7.1.2.2. Calibration with reference samples

Alternatively, a calibration curve prepared from at least four reference samples (see point 7.2.4): one matrix blank, plus three reference samples at 0,5x, 1x and 2x the maximum level or action threshold may be used, eliminating the need to correct for blank and recovery if matrix properties of the reference samples match those of the unknown samples. In this case, the test response corresponding to two-thirds of the maximum level (see point 7.3) may be calculated directly from these samples and used as cut-off value. For checking of samples exceeding the action thresholds, an appropriate percentage of these action thresholds shall suit as cut-off value.

7.1.3. Separate determination of PCDD/Fs and dioxin-like PCBs

Extracts may be split into fractions containing PCDD/Fs and dioxin-like PCBs, allowing a separate indication of PCDD/Fs and dioxin-like PCB TEQ levels (in BEQ). A PCB 126 standard calibration curve shall preferentially be used to evaluate results for the fraction containing dioxin-like PCBs.

7.1.4. Bioassay apparent recoveries

The "bioassay apparent recovery" shall be calculated from suitable reference samples with representative congener patterns around the maximum level or action threshold and expressed as percentage of the BEQ level in comparison to the TEQ level. Depending on the type of assay and TEFs ([1]) used, the differences between TEF and REP factors for dioxin-like PCBs can cause low apparent recoveries for dioxin-like PCBs in comparison to PCDD/Fs. Therefore, if a separate determination of PCDD/Fs and dioxin-like PCBs is performed, bioassay apparent recoveries shall be: for dioxin-like PCBs 20 % to 60 %, for PCDD/Fs 50 % to 130 % (ranges apply for the TCDD calibration curve). As the contribution of dioxin-like PCBs to the sum of PCDD/Fs and dioxin-like PCBs can vary between different matrices and samples, bioassay apparent recoveries for the sum of PCDD/Fs and dioxin-like PCBs reflect these ranges and shall be between 30 % and 130 %. Any implication of substantially revised TEF values for the Union legislation for PCDD/Fs and dioxin-like PCBs requires the revision of these ranges.

([1]) Current requirements are based on the TEFs published in: M. Van den Berg et al, Toxicol Sci 93 (2), 223–241 (2006).

7.1.5. Control of recoveries for clean-up

The loss of compounds during the clean-up shall be checked during validation. A blank sample spiked with a mixture of the different congeners shall be submitted to clean-up (at least n = 3) and the recovery and variability checked by a confirmatory method. The recovery shall be within 60 % to 120 % especially for congeners contributing more than 10 % to the TEQ-level in various mixtures.

7.1.6. Reporting limit

When reporting BEQ levels, a reporting limit shall be determined from relevant matrix samples involving typical congener patterns, but not from the calibration curve of the standards due to low precision in the lower range of the curve. Effects from extraction and clean-up shall be taken into account. The reporting limit shall be set at least by a factor of three above the procedure blanks.

7.2. *Use of reference samples*

7.2.1. Reference samples shall represent sample matrix, congener patterns and concentration ranges for PCDD/Fs and dioxin-like PCBs around the maximum level or action threshold.

7.2.2. A matrix blank, and where it is not possible, a procedure blank, and a reference sample at the maximum level or action threshold shall be included in each test series. These samples shall be extracted and tested at the same time under identical conditions. The reference sample shall show a clearly elevated response in comparison to the blank sample, thus ensuring the suitability of the test. Those samples may be used for blank and recovery corrections.

7.2.3. Reference samples chosen to perform a recovery correction shall be representative for the test samples, meaning that congener patterns may not lead to an underestimation of levels.

7.2.4. Extra reference samples at e.g. 0,5x and 2x the maximum level or action threshold may be included to demonstrate the proper performance of the test in the range of interest for the control of the maximum level or action threshold. Combined, these samples may be used for calculating the BEQ levels in test samples (see point 7.1.2.2).

7.3. *Determination of cut-off values*

The relationship between bioanalytical results in BEQ and results from the confirmatory method in TEQ shall be established, for example by matrix-matched calibration experiments, involving reference samples spiked at 0, 0,5x, 1x and 2x the ML, with 6 repetitions on each level (n = 24). Correction factors (blank and recovery) may be estimated from this relationship but shall be checked in accordance with point 7.2.2.

Cut-off values shall be established for decisions over sample compliance with maximum levels or for the control of action thresholds, if relevant, with the respective maximum levels or action threshold set for either PCDD/Fs and dioxin-like PCBs alone, or for the sum of PCDD/Fs and dioxin-like PCBs. They are represented by the *lower* end-point of the distribution of bioanalytical results (corrected for blank and recovery) corresponding to the decision limit of the confirmatory method based on a 95 % level of confidence, implying a false-compliant rate < 5 %, and on a RSD_R < 25 %. The decision limit of the confirmatory method is the maximum level, taking into account the expanded measurement uncertainty.

The cut-off value (in BEQ) may be calculated in accordance with one of the approaches set out in points 7.3.1, 7.3.2 and 7.3.3. (see Figure 1).

7.3.1. Use of the *lower* band of the 95 % prediction interval at the decision limit of the confirmatory method:

$$\text{Cut-off value} = BEQ_{DL} - s_{y,x} \times t_{\alpha,f=m-2}\sqrt{1/n + 1/m + (x_i - \overline{x})^2/Q_{xx}}$$

with:

BEQ_{DL} BEQ corresponding to the decision limit of the confirmatory method, being the maximum level taking into account the expanded measurement uncertainty

$s_{y,x}$ residual standard deviation

$t_{\alpha,f=m-2}$ student factor (α = 5 %, f = degrees of freedom, single-sided)

m total number of calibration points (index j)

n number of repetitions on each level

x_i sample concentration (in TEQ) of calibration point i determined by a confirmatory method

$\overline{x}$ mean of the concentrations (in TEQ) of all calibration samples

$Q_{xx} = \sum_{j=1}^{m}(x_i - \overline{x})^2$ square sum parameter, i = index for calibration point i

7.3.2. Calculation from bioanalytical results (corrected for blank and recovery) of multiple analyses of samples (n ≥ 6) contaminated at the decision limit of the confirmatory method, as the *lower* endpoint of the data distribution at the corresponding mean BEQ value:

$$\text{Cut-off value} = BEQ_{DL} - 1{,}64 \times SD_R$$

with:

SD_R standard deviation of bioassay results at BEQ_{DL}, measured under within-laboratory reproducibility conditions

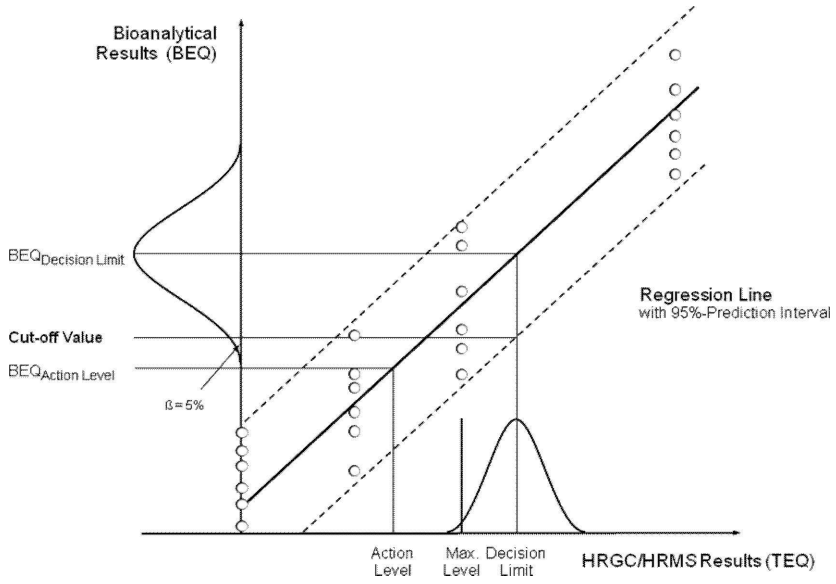
7.3.3. Calculation as mean value of bioanalytical results (in BEQ, corrected for blank and recovery) from multiple analysis of samples (n ≥ 6) contaminated at two-thirds of the maximum level or action threshold, based on the observation that this level will be around the cut-off value determined under point 7.3.1 or point 7.3.2:

Calculation of cut-off values based on a 95 % level of confidence implying a false-compliant rate < 5 %, and a RSD_R < 25 %:

(1) from the *lower* band of the 95 % prediction interval at the decision limit of the confirmatory method.

(2) from multiple analysis of samples (n ≥ 6) contaminated at the decision limit of the confirmatory method as the *lower* end-point of the data distribution (represented in the figure by a bell-shaped curve) at the corresponding mean BEQ value.

Figure 1



7.3.4. Restrictions to cut-off values

BEQ-based cut-off values calculated from the RSD_R achieved during validation using a limited number of samples with different matrix/congener patterns may be higher than the TEQ-based maximum levels or action thresholds due to a better precision than attainable in routine when an unknown spectrum of possible congener patterns has to be controlled. In such cases, cut-off values shall be calculated from an RSD_R = 25 %, or two-thirds of the maximum level or action threshold shall be preferred.

7.4. *Performance characteristics*

7.4.1. Since no internal standards can be used in bioanalytical methods, tests on the repeatability of bioanalytical methods shall be carried out to obtain information on the standard deviation within and between test series. Repeatability shall be below 20 % and intra-laboratory reproducibility shall be below 25 %. This shall be based on the calculated levels in BEQ after blank and recovery correction.

7.4.2. As part of the validation process, the test shall be shown to discriminate between a blank sample and a level at the cut-off value, allowing the identification of samples above the corresponding cut-off value (see point 7.1.2).

7.4.3. Target compounds, possible interferences and maximum tolerable blank levels shall be defined.

7.4.4. The percent standard deviation in the response or concentration calculated from the response (only possible in working range) of a triplicate determination of a sample extract may not be above 15 %.

7.4.5. The uncorrected results of the reference sample(s) expressed in BEQ (blank and at the maximum level or action threshold) shall be used for evaluation of the performance of the bioanalytical method over a constant time period.

7.4.6. Quality control charts for procedure blanks and each type of reference sample shall be recorded and checked to make sure the analytical performance is in accordance with the requirements, in particular for the procedure blanks with regard to the requested minimum difference to the lower end of the working range and for the reference samples with regard to within-laboratory reproducibility. Procedure blanks shall be controlled in a manner to avoid false-compliant results when subtracted.

7.4.7. The results from the confirmatory methods of suspected samples and 2 to 10 % of the compliant samples (minimum of 20 samples per matrix) shall be collected and used to evaluate the performance of the screening method and the relationship between BEQ and TEQ. This database may be used for the re-evaluation of cut-off values applicable to routine samples for the validated matrices.

7.4.8. Successful method performance may also be demonstrated by participation in ring trials. The results from samples analysed in ring trials, covering a concentration range up to e.g. 2 × maximum level, may be included in the evaluation of the false-compliant rate, if a laboratory is able to demonstrate its successful performance. The samples shall cover most frequent congener patterns, representing various sources.

7.4.9. During incidents, the cut-off values may be re-evaluated, reflecting the specific matrix and congener patterns of this single incident.

8. **Reporting of the results**

8.1. *Confirmatory methods*

8.1.1. The analytical results shall contain the levels of the individual PCDD/F and dioxin-like PCB congeners and TEQ-values shall be reported as lower-bound, upper-bound and medium-bound in order to include a maximum of information in the reporting of the results and thereby enabling the interpretation of the results according to specific requirements.

8.1.2. The report shall include the method used for extraction of PCDD/Fs and dioxin-like PCBs.

8.1.3. The recoveries of the individual internal standards shall be made available in case the recoveries are outside the range referred to in point 6.2.5, in case the maximum level is exceeded (in this case, the recoveries for one of the two duplicate analysis) and in other cases upon request.

8.1.4. As the expanded measurement uncertainty is to be taken into account when deciding about the compliance of a sample, this parameter shall be made available. Thus, analytical results shall be reported as x +/– U whereby x is the analytical result and U is the expanded measurement uncertainty using a coverage factor of 2 which gives a level of confidence of approximately 95 %. In the case of a separate determination of PCDD/Fs and dioxin-like-PCBs, the sum of the estimated expanded uncertainty of the separate analytical results of PCDD/Fs and dioxin-like PCBs shall be used for the sum of PCDD/Fs and dioxin-like PCBs.

8.1.5. The results shall be expressed in the same units and with at least the same number of significant figures as the maximum levels laid down by Directive 2002/32/EC

8.2. *Bioanalytical screening methods*

8.2.1. The result of the screening shall be expressed as “compliant” or “suspected to be non-compliant” (“suspected”).

8.2.2. In addition, an indicative result for PCDD/Fs and/or dioxin-like PCBs expressed in BEQ, and not TEQ, may be given.

8.2.3. Samples with a response below the reporting limit shall be expressed as “lower than the reporting limit”. Samples with a response above the working range shall be reported as “exceeding the working range” and the level corresponding to the upper end of the working range shall be given in BEQ.

8.2.4. For each type of sample matrix, the report shall mention the maximum level or action threshold on which the evaluation is based.

8.2.5. The report shall mention the type of the test applied, the basic test principle and the kind of calibration.

8.2.6. The report shall include the method used for extraction of PCDD/Fs and dioxin-like PCBs.

8.2.7. In case of samples suspected to be non-compliant, the report needs to include a note on the action to be taken. The concentration of PCDD/Fs and the sum of PCDD/Fs and dioxin-like PCBs in those samples with elevated levels has to be determined/confirmed by a confirmatory method.

8.2.8. Non-compliant results shall only be reported from confirmatory analysis.

8.3. *Physico-chemical screening methods*

8.3.1. The result of the screening shall be expressed as "compliant" or "suspected to be non-compliant" ("suspected").

8.3.2. For each type of sample matrix, the report shall mention the maximum level or action threshold on which the evaluation is based.

8.3.3. In addition, levels for individual PCDD/F and/or dioxin-like PCB congeners and TEQ-values reported as lower-bound, upper-bound and medium-bound may be given. The results shall be expressed in the same units and with at least the same number of significant figures as the maximum levels laid down by Directive 2002/32/EC.

8.3.4. The recoveries of the individual internal standards shall be made available in case the recoveries are outside the range referred to in point 6.2.5, in case the maximum level is exceeded (in this case, the recoveries for one of the two duplicate analysis) and in other cases upon request.

8.3.5. The report shall mention the GC-MS method applied.

8.3.6. The report shall include the method used for extraction of PCDD/Fs and dioxin-like PCBs.

8.3.7. In case of samples suspected to be non-compliant, the report needs to include a note on the action to be taken. The concentration of PCDD/Fs and the sum of PCDD/Fs and dioxin-like PCBs in those samples with elevated levels has to be determined/confirmed by a confirmatory method.

8.3.8. Non-compliance can only be decided after confirmatory analysis.

CHAPTER III

Sample preparation and requirements for methods of analysis used in offical control of the levels of non dioxin-like PCBs in feed

1. Field of application

The requirements set out in this Chapter shall be applied where feed is analysed for the official control of the levels of non-dioxin-like PCBs and as regards sample preparation and analytical requirements for other regulatory purposes, which includes the controls performed by the feed business operator to ensure compliance with the provisions of Regulation (EC) No 183/2005.

2. Applicable detection methods

Gas chromatography/Electron Capture Detection (GC-ECD), GC-LRMS, GC-MS/MS, GC-HRMS or equivalent methods.

3. **Identification and confirmation of analytes of interest**

3.1. Relative retention time in relation to internal standards or reference standards (acceptable deviation of +/– 0,25 %).

3.2. Gas chromatographic separation of the non-dioxin-like PCBs from interfering substances, especially co-eluting PCBs, in particular if levels of samples are in the range of legal limits and non-compliance is to be confirmed ([1]).

3.3. Requirements for GC-MS techniques

Monitoring of at least the following number of molecular ions or characteristic ions from the molecular cluster:

(a) two specific ions for HRMS;

(b) three specific ions for LRMS;

(c) two specific precursor ions, each with one specific corresponding transition product ion for for MS-MS.

Maximum permitted tolerances for abundance ratios for selected mass fragments:

Relative deviation of abundance ratio of selected mass fragments from theoretical abundance or calibration standard for target ion (most abundant ion monitored) and qualifier ion(s): ± 15 %

3.4. Requirements for GC-ECD techniques

Results exceeding the maximum level shall be confirmed with two GC columns with stationary phases of different polarity.

4. **Demonstration of performance of method**

The performance of the method shall be validated in the range of the maximum level (0,5 to 2 times the maximum level) with an acceptable coefficient of variation for repeated analysis (see requirements for intermediate precision in point (9).

5. **Limit of quantification**

The sum of the LOQs ([2]) of non-dioxin-like PCBs shall not be higher than one-third of the maximum level ([3]).

6. **Quality control**

Regular blank controls, analysis of spiked samples, quality control samples, participation in inter-laboratory studies on relevant matrices.

7. **Control of recoveries**

7.1. Suitable internal standards with physico-chemical properties comparable to analytes of interest shall be used.

([1]) Congeners often found to co-elute are for example PCB 28/31, PCB 52/69 and PCB 138/163/164. For GC-MS also possible interferences from fragments of higher chlorinated congeners shall be considered.

([2]) The principles as described in the "Guidance Document on the Estimation of LOD and LOQ for Measurements in the Field of Contaminants in Feed and Food" (http://ec.europa.eu/food/safety/animal-feed_en) shall be followed when applicable.

([3]) It is highly recommendable to have a lower contribution of the reagent blank level to the level of a contaminant in a sample. It is in the responsibility of the laboratory to control the variation of blank levels, in particular, if the blank levels are subtracted.

7.2. Addition of internal standards:

Addition to products (before extraction and clean-up process).

7.3. Requirements for methods using all six isotope-labelled non-dioxin-like PCB congeners

(a) results shall be corrected for recoveries of internal standards;

(b) recoveries of isotope-labelled internal standards shall be between 60 and 120 %;

(c) lower or higher recoveries for individual congeners with a contribution to the sum of non-dioxin-like PCBs below 10 % are acceptable.

7.4. Requirements for methods using not all six isotope-labelled internal standards or other internal standards:

(a) recovery of internal standard(s) shall be controlled for every sample;

(b) recoveries of internal standard(s) shall be between 60 and 120 %;

(c) results shall be corrected for recoveries of internal standards.

7.5. The recoveries of unlabelled congeners shall be checked by spiked samples or quality control samples with concentrations in the range of the maximum level. Recoveries for these congeners shall be considered acceptable, if they are between 60 and 120 %.

8. **Requirements for laboratories**

In accordance with the provisions of Regulation (EC) No 882/2004, laboratories shall be accredited by a recognised body operating in accordance with ISO Guide 58 to ensure that they are applying analytical quality assurance. Laboratories shall be accredited following the EN ISO/IEC 17025 standard. In addition, the principles as described in Technical Guidelines for the estimation of measurement uncertainty and limits of quantification for PCB analysis shall be followed when applicable ([1]).

9. **Performance characteristics: criteria for the sum of non-dioxin-like PCBs at the maximum level**

	Isotope dilution mass spectrometry ([1])	Other techniques
Trueness	− 20 to + 20 %	− 30 to + 30 %
Intermediate precision (RSD %)	≤ 15 %	≤ 20 %
Difference between upper and lower-bound calculation	≤ 20 %	≤ 20 %

([1]) Use of all six ^{13}C-labelled analogues as internal standards required.

10. **Reporting of the results**

10.1. The analytical results shall contain the levels of the individual non-dioxin-like PCBs and the sum of those PCB congenersreported as lower-bound, upper-bound and medium-bound in order to include a maximum of information in the reporting of the results and thereby enabling the interpretation of the results according to specific requirements.

([1]) Current requirements are based on the TEFs published in: M. Van den Berg et al, Toxicol Sci 93(2), 223–241 (2006).

10.2. The report shall include the method used for the extraction of PCBs.

10.3. The recoveries of the individual internal standards shall be made available in case the recoveries are outside the range referred to in point 7, in case the maximum level is exceeded and in other cases upon request.

10.4. As the expanded measurement uncertainty is to be taken into account when deciding about the compliance of a sample, that parameter shall also be made available. Thus, analytical results shall be reported as x +/– U whereby x is the analytical result and U is the expanded measurement uncertainty using a coverage factor of 2 which gives a level of confidence of approximately 95 %.

10.5. The results shall be expressed in the same units and with at least the same number of significant figures as the maximum levels laid down by Directive 2002/32/EC.'

COMMISSION IMPLEMENTING REGULATION (EU) 2017/772

of 3 May 2017

amending Implementing Regulation (EU) No 908/2014 as regards the list of measures for which certain information on beneficiaries is to be published

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 ([1]), and in particular Article 114 thereof,

Whereas:

(1) Pursuant to Article 111(1) of Regulation (EU) No 1306/2013, Member States have to publish information on the beneficiaries of the European Agricultural Guarantee Fund and the European Agricultural Fund for Rural Development, including, inter alia, the amount of the payment received for each measure financed by those Funds and the nature and the description of each measure.

(2) Article 57 of Commission Implementing Regulation (EU) No 908/2014 ([2]) provides for further details that have to be published in relation to those measures and refers to Annex XIII to that Regulation, which contains a list of the measures concerned.

(3) As a result of the Russian ban on the import of agricultural products and foodstuffs originating in the Union and a lower growth of the global demand for milk and milk products, notably as a result of the slowdown in export to China, the Commission has adopted measures necessary to address the market situation under Article 219(1) of Regulation (EU) No 1308/2013 of the European Parliament and of the Council ([3]) in the livestock sectors. Those measures are laid down in Commission Delegated Regulations (EU) 2015/1853 ([4]), (EU) 2016/1612 ([5]) and (EU) 2016/1613 ([6]). Those measures have been granted as measures supporting agricultural markets in accordance with Article 4(1)(a) of Regulation (EU) No 1306/2013 and apply to financial year 2016 or 2017, but they are not covered by the list in Annex XIII to Implementing Regulation (EU) No 908/2014. Therefore, it is appropriate to include them in that list.

(4) Implementing Regulation (EU) No 908/2014 should therefore be amended accordingly.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Committee on the Agricultural Funds,

HAS ADOPTED THIS REGULATION:

Article 1

In Annex XIII to Implementing Regulation (EU) No 908/2014, the following point 10 is added:

'10. The measures granted in the livestock sectors under Article 219(1) of Regulation (EU) No 1308/2013 as measures supporting agricultural markets in accordance with Article 4(1)(a) of Regulation (EU) No 1306/2013.'.

([1]) OJ L 347, 20.12.2013, p. 549.
([2]) Commission Implementing Regulation (EU) No 908/2014 of 6 August 2014 laying down rules for the application of Regulation (EU) No 1306/2013 of the European Parliament and of the Council with regard to paying agencies and other bodies, financial management, clearance of accounts, rules on checks, securities and transparency (OJ L 255, 28.8.2014, p. 59).
([3]) Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671).
([4]) Commission Delegated Regulation (EU) 2015/1853 of 15 October 2015 providing for temporary exceptional aid to farmers in the livestock sectors (OJ L 271, 16.10.2015, p. 25).
([5]) Commission Delegated Regulation (EU) 2016/1612 of 8 September 2016 providing aid for milk production reduction (OJ L 242, 9.9.2016, p. 4).
([6]) Commission Delegated Regulation (EU) 2016/1613 of 8 September 2016 providing for exceptional adjustment aid to milk producers and farmers in other livestock sectors (OJ L 242, 9.9.2016, p. 10).

Article 2

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 3 May 2017.

For the Commission

The President

Jean-Claude JUNCKER

COMMISSION IMPLEMENTING REGULATION (EU) 2017/773

of 3 May 2017

establishing the standard import values for determining the entry price of certain fruit and vegetables

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([1]),

Having regard to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors ([2]), and in particular Article 136(1) thereof,

Whereas:

(1) Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto.

(2) The standard import value is calculated each working day, in accordance with Article 136(1) of Implementing Regulation (EU) No 543/2011, taking into account variable daily data. Therefore this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 3 May 2017.

For the Commission,
On behalf of the President,
Jerzy PLEWA
Director-General
Directorate-General for Agriculture and Rural Development

([1]) OJ L 347, 20.12.2013, p. 671.
([2]) OJ L 157, 15.6.2011, p. 1.

ANNEX

Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	EG	288,4
	MA	90,1
	TR	118,3
	ZZ	165,6
0707 00 05	MA	79,4
	TR	142,5
	ZZ	111,0
0709 93 10	TR	138,1
	ZZ	138,1
0805 10 22, 0805 10 24, 0805 10 28	EG	54,3
	IL	80,7
	MA	57,7
	TR	65,5
	ZA	43,6
	ZZ	60,4
0805 50 10	TR	54,0
	ZZ	54,0
0808 10 80	AR	92,9
	BR	119,5
	CL	122,6
	NZ	140,7
	ZA	84,4
	ZZ	112,0

(1) Nomenclature of countries laid down by Commission Regulation (EU) No 1106/2012 of 27 November 2012 implementing Regulation (EC) No 471/2009 of the European Parliament and of the Council on Community statistics relating to external trade with non-member countries, as regards the update of the nomenclature of countries and territories (OJ L 328, 28.11.2012, p. 7). Code 'ZZ' stands for 'of other origin'.

DIRECTIVES

COMMISSION DIRECTIVE (EU) 2017/774

of 3 May 2017

amending, for the purpose of adopting specific limit values for chemicals used in toys, Appendix C to Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards phenol

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys ([1]), and in particular Article 46(2) thereof,

Whereas:

(1) In order to ensure a high level of protection of children against risks caused by chemical substances in toys, Directive 2009/48/EC establishes certain requirements with regard to chemical substances such as those classified as carcinogenic, mutagenic or toxic for reproduction (CMR) under Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([2]), allergenic fragrances and certain elements. In addition, Directive 2009/48/EC empowers the Commission to adopt specific limit values for chemicals used in toys which are intended for children under 36 months and in other toys intended to be placed in the mouth in order to ensure adequate protection in the case of toys involving a high degree of exposure. The adoption of such limit values takes the form of an inclusion in Appendix C to Annex II to Directive 2009/48/EC.

(2) For a number of chemicals, currently applicable limit values are either too high in the light of available scientific evidence or do not exist. Specific limit values should therefore be adopted for them, taking into account the packaging requirements for food as well as the differences between toys and food contact materials.

(3) In order to advise the European Commission in the preparation of legislative proposals and policy initiatives in the area of toy safety, the Commission established the Expert Group on Toys Safety. The mission of its subgroup 'Chemicals' is to provide such advice with regard to chemical substances which may be used in toys.

(4) Phenol (CAS number 108-95-2) is used as a monomer for phenolic resins in the manufacture of resin-bonded wood ([3]) for toys. The degradation of phenolic antioxidants in polymers can be a further source of phenol in toys ([4]). Phenol was identified in emissions from game consoles ([5]), in one of six analysed tents or tunnels for children ([6]) and in packaging film ([7]), it was tested in bath toys and other inflatable toys ([8]), and it was considered to be present in polyvinyl chloride (PVC) ([9]). Phenol could further be used as a preservative in water-based liquid toys such as bubble-blowing products or water-based liquid inks (e.g. felt-tipped marker pens) ([10]).

(5) In its deliberations on phenol the subgroup 'Chemicals' took European standards EN 71-9:2005+A1:2007, EN 71-10:2005 and EN 71-11:2005 as the basis. Those standards refer to the presence of phenol in toy materials (EN 71-9:2005+A1:2007) and provide specific methods of sample preparation (EN 71-10:2005) and measurement (EN 71-11:2005). EN 71-11:2005 repeats and details the limit values for phenol in toy materials set in EN 71-9:2005+A1:2007, namely 15 mg/l (migration limit) for phenol as a monomer and 10 mg/kg (content limit) for phenol as a preservative in liquid toy materials.

(6) The subgroup 'Chemicals' also took account of the recommendation of the Scientific Committee on Health and Environmental Risks (SCHER) that the migration limit value of 15 mg/l for phenol set out in the existing European standard be lowered at least by a factor of 2 in order to reach a Margin of Exposure of 100 that could be considered sufficiently large ([11]).

(7) The subgroup 'Chemicals' furthermore took account of the opinion of the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) at the European Food Safety Authority (EFSA), which reduced the tolerable daily intake (TDI) of phenol from 1,5 mg/kg body weight per day to 0,5 mg/kg body weight per day ([12]).

(8) Phenol is classified under Regulation (EC) No 1272/2008 as mutagenic category 2. According to point 5 of Part III of Annex II to Directive 2009/48/EC, mutagenic substances of category 2 such as phenol may be present in toys in concentrations equal to or smaller than the relevant concentration established for the classification of mixtures containing it, namely 1 %, which equals 10 000 mg/kg (content limit). Directive 2009/48/EC does not currently provide for a migration limit for phenol.

(9) In the light of the above, the subgroup 'Chemicals' recommended at its meetings of 26 March 2014 and 18 February 2015 that phenol be limited in toys to 5 mg/l (migration limit) when analysed in polymeric materials, and to a maximum concentration of 10 mg/kg (content limit) when analysed as a preservative, it being understood that 10 mg/kg (content limit) are a *de facto* use ban. Analyses should be carried out in accordance with European standards EN 71-10:2005 and EN 71-11:2005.

(10) While there is a generic migration limit for phenol as a monomer for use in certain food contact materials, the basic assumptions for deriving that migration limit are different from those for the migration limit for phenol as a monomer in toys. The use of phenol as a preservative is not regulated for food contact materials.

(11) In view of the above, Appendix C to Annex II to Directive 2009/48/EC should be amended to include a migration limit as well as a content limit for phenol in toys.

(12) The measures provided for in this Directive are in accordance with the opinion of the Committee established in Article 47 of Directive 2009/48/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

In Appendix C to Annex II to Directive 2009/48/EC, the following entry shall be added:

Substance	CAS No	Limit value
'Phenol	108-95-2	5 mg/l (migration limit) in polymeric materials in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005. 10 mg/kg (content limit) as a preservative in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005.'

Article 2

1. Member States shall adopt and publish, by 4 November 2018 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 4 November 2018.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 3 May 2017.

For the Commission

The President

Jean-Claude JUNCKER

(1) OJ L 170, 30.6.2009, p. 1.

(2) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

(3) E. Edmonds (2013) Occurrence of Phenol and Formaldehyde in Toys. Report commissioned by Toy Industries of Europe, p. 4.

(4) See footnote 3, pp. 5 and 8.

(5) Danish Environmental Protection Agency (EPA) (2003) Survey of chemical substances in consumer products Survey no. 32 — 2003. Emission and evaluation of chemical substances from selected electrical and electronic products, p. 47. http://eng.mst.dk/media/mst/69115/32.pdf

(6) Danish EPA (2004) Mapping of Chemical Substances in Consumer Products nr. 46, 2004. Release of chemical substances from tents and tunnels for children. http://eng.mst.dk/media/mst/69127/46.pdf

(7) Bundesinstitut für Risikobewertung (2009) Limit values for phenol in food-contact articles and toys are to be updated. Opinion No 038/2009, 18 August 2009. http://www.bfr.bund.de/cm/349/limit_values_for_phenol_in_food_contact_articles_and_toys_are_to_be_updated.pdf

(8) Voedsel en Waren Autoriteit (2004) Market Surveillances on Toy Safety. Report nr. ND04o063/01. https://www.nvwa.nl/binaries/nvwa/documenten/communicatie/inspectieresultaten/consument/2016m/market-surveillances-on-toy-safety/ND04o063-01_speelgoed.pdf

(9) Suortti T (1990) Determination of phenol in poly(vinyl chloride). J Chromatogr. 1990 May 16; 507:417-20. http://www.ncbi.nlm.nih.gov/pubmed/2380304

(10) CEN TC 52 (2002) Final report of the work of CEN/TC 52/WG 9 — Risk assessment. Contract BC/CEN/97/29.1.1. August 2002, p. 85.

(11) Scientific Committee on Health and Environmental Risks (SCHER), Opinion on 'CEN's response to the opinion of the CSTEE on the assessment of CEN report on the risk assessment of organic chemicals in toys', adopted on 29 May 2007, pp. 8 and 9.

(12) European Food Safety Authority (EFSA), Scientific Opinion on the toxicological evaluation of phenol, *EFSA Journal* 2013;11(4):3189 [44 pp]. http://www.efsa.europa.eu/en/efsajournal/pub/3189.htm

DECISIONS

COUNCIL DECISION (EU) 2017/775

of 25 April 2017

appointing an alternate member, proposed by the Republic of Finland, of the Committee of the Regions

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 305 thereof,

Having regard to the proposal of the Finnish Government,

Whereas:

(1) On 26 January 2015, 5 February 2015 and 23 June 2015, the Council adopted Decisions (EU) 2015/116 ([1]), 2015/190 ([2]) and 2015/994 ([3]) appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020.

(2) An alternate member's seat on the Committee of the Regions has become vacant following the end of the term of office of Ms Katri KULMUNI,

HAS ADOPTED THIS DECISION:

Article 1

The following is hereby appointed as an alternate member of the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2020:

— Ms Merja LAHTINEN, *Jämsän kaupunginvaltuuston jäsen*.

Article 2

This Decision shall enter into force on the date of its adoption.

Done at Luxembourg, 25 April 2017.

For the Council
The President
I. BORG

([1]) Council Decision (EU) 2015/116 of 26 January 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 20, 27.1.2015, p. 42).
([2]) Council Decision (EU) 2015/190 of 5 February 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 31, 7.2.2015, p. 25).
([3]) Council Decision (EU) 2015/994 of 23 June 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 159, 25.6.2015, p. 70).

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)

Publications Office of the European Union
2985 Luxembourg
LUXEMBOURG

EN