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⁽¹⁾ Text with EEA relevance

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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.

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2015/572

of 9 April 2015

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*.

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

⁽²⁾ OJ L 157, 15.6.2011, p. 1.

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

Done at Brussels, 9 April 2015.

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

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	AL	102,3
	MA	100,3
	TR	122,2
	ZZ	108,3
0707 00 05	MA	39,8
	MK	97,3
	TR	140,4
	ZZ	92,5
0709 93 10	MA	83,5
	TR	166,5
	ZZ	125,0
0805 10 20	CL	64,9
	EG	47,4
	IL	75,6
	MA	58,6
	TN	63,2
	TR	70,0
	ZZ	63,3
	ZZ	63,3
0805 50 10	TR	45,7
	ZZ	45,7
0808 10 80	BR	93,7
	CL	94,0
	MK	28,2
	US	253,0
	ZA	125,7
	ZZ	118,9
	ZZ	118,9
0808 30 90	AR	116,6
	CL	147,4
	CN	106,3
	ZA	157,3
	ZZ	131,9
	ZZ	131,9

⁽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 DELEGATED DIRECTIVE (EU) 2015/573

of 30 January 2015

amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in polyvinyl chloride sensors in in-vitro diagnostic medical devices

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment ⁽¹⁾, and in particular Article 5(1)(a) thereof,

Whereas:

- (1) Directive 2011/65/EU prohibits the use of lead in electrical and electronic equipment placed on the market.
- (2) Blood, body fluid and body gas analysers serve as a critical analytical instrument in many diagnostic and therapeutic procedures. Lead is required as a stabiliser in the processing of the PVC for the sensor cards. Although research of substitutes is ongoing, a suitable alternative is not yet available. The performance of tested alternatives both to lead in PVC and to PVC itself does not meet the specific technical requirements.
- (3) Both the substitution of lead in PVC sensor cards for in-vitro diagnostic medical devices for blood, body fluid and body gas analysis and the elimination of lead via substitution of PVC in these applications are technically impracticable.
- (4) The use of lead in PVC sensors for blood, body fluid and body gas analysis used in in-vitro diagnostic medical devices should therefore be exempted until 31 December 2018. In view of the innovation cycles for medical devices this is a short transition period which is unlikely to have adverse impacts on innovation.
- (5) Directive 2011/65/EU should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex IV to Directive 2011/65/EU is amended as set out in the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by the last day of the ninth month after entry into force at the latest. They shall forthwith communicate to the Commission the text of those provisions.

⁽¹⁾ OJ L 174, 1.7.2011, p. 88.

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, 30 January 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

In Annex IV to Directive 2011/65/EU, the following point 41 is added:

‘41. Lead as a thermal stabiliser in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases.

Expires on 31 December 2018.’

COMMISSION DELEGATED DIRECTIVE (EU) 2015/574**of 30 January 2015****amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for mercury in intravascular ultrasound imaging systems****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment ⁽¹⁾, and in particular Article 5(1)(a) thereof,

Whereas:

- (1) Directive 2011/65/EU prohibits the use of mercury in electrical and electronic equipment placed on the market.
- (2) Mercury is used in electric rotating connectors in medical devices for intravascular ultrasound imaging. Substitution of mercury or of the specific component would shorten product life or impair performance significantly.
- (3) Both the substitution of mercury in the connector and the elimination of mercury via substitution of the connector or the device are technically impracticable or have negative overall impacts due to an impact on patients' health.
- (4) The use of mercury in electric rotating connectors used in intravascular ultrasound imaging systems capable of high operating frequency modes of operation (> 50 MHz) should therefore be exempted until 30 June 2019. In view of the innovation cycles for medical devices this is a short transition period which is unlikely to have adverse impacts on innovation.
- (5) Directive 2011/65/EU should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex IV to Directive 2011/65/EU is amended as set out in the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by the last day of the ninth month after entry into force at the latest. They shall forthwith communicate to the Commission the text of those provisions.

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*.

⁽¹⁾ OJ L 174, 1.7.2011, p. 88.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 30 January 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

In Annex IV to Directive 2011/65/EU, the following point 42 is added:

'42. Mercury in electric rotating connectors used in intravascular ultrasound imaging systems capable of high operating frequency (> 50 MHz) modes of operation.

Expires on 30 June 2019.'

CORRIGENDA**Corrigendum to Commission Regulation (EU) 2015/552 of 7 April 2015 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 1,3-dichloropropene, bifenox, dimethenamid-P, prohexadione, tolylfluanid and trifluralin in or on certain products**

(Official Journal of the European Union L 92 of 8 April 2015)

On page 22, Article 2:

for:

'Article 2

Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were lawfully produced before 28 April 2015.'

read:

'Article 2

Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were lawfully produced before 28 October 2015.'

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