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Price: EUR 3

(<sup>1</sup>) 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.

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## II

(Non-legislative acts)

## REGULATIONS

## COMMISSION IMPLEMENTING REGULATION (EU) No 239/2014

of 12 March 2014

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 Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) <sup>(1)</sup>,

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 <sup>(2)</sup>, 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 multi-lateral 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, 12 March 2014.

*For the Commission,  
On behalf of the President,*

Jerzy PLEWA  
*Director-General for Agriculture and  
Rural Development*

<sup>(1)</sup> OJ L 299, 16.11.2007, p. 1.

<sup>(2)</sup> OJ L 157, 15.6.2011, p. 1.

## ANNEX

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

<i>(EUR/100 kg)</i>		
CN code	Third country code <sup>(1)</sup>	Standard import value
0702 00 00	MA	77,2
	TN	103,3
	TR	104,8
	ZZ	95,1
0707 00 05	MA	182,1
	TR	152,1
	ZZ	167,1
0709 91 00	EG	45,1
	ZZ	45,1
0709 93 10	MA	41,8
	TR	78,3
	ZZ	60,1
0805 10 20	EG	46,6
	IL	67,5
	MA	50,8
	TN	51,1
	TR	61,0
	ZZ	55,4
0805 50 10	TR	77,5
	ZZ	77,5
0808 10 80	CL	110,0
	CN	98,4
	MK	30,8
	US	207,8
	ZZ	111,8
0808 30 90	AR	102,4
	CL	159,0
	CN	68,3
	TR	158,2
	US	211,0
	ZA	95,8
	ZZ	132,5

<sup>(1)</sup> Nomenclature of countries laid down by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). Code 'ZZ' stands for 'of other origin'.

# DIRECTIVES

## COMMISSION DIRECTIVE 2014/39/EU

of 12 March 2014

amending Directive 2012/9/EU as regards the date for its transposition and the deadline for the end of the transitional period

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products <sup>(1)</sup>, and in particular Article 9(2) thereof,

Whereas:

- (1) Commission Directive 2012/9/EU <sup>(2)</sup> replaces Annex I to Directive 2001/37/EC, providing for new additional health warnings to be used on unit packets of tobacco products, as provided for in Article 5(2)(b) of Directive 2001/37/EC.
- (2) Directive 2012/9/EU sets 28 March 2014 as the deadline for its transposition by Member States and 28 March 2016 as the deadline for the end of the transitional period provided for in Article 3 of that Directive.
- (3) Commission Decision 2003/641/EC <sup>(3)</sup> establishes the rules on the use of colour photographs or other illustrations as health warnings on tobacco packages.
- (4) Commission Decision C(2005) 1452 of 26 May 2005 establishes the library of selected source documents containing colour photographs or other illustrations for each of the additional health warnings listed in Annex I to Directive 2001/37/EC.
- (5) Subsequent to the adoption of Directive 2012/9/EU, the Commission has launched studies for the development and testing of new colour photographs or other

illustrations for each of the additional health warnings specified in the Annex to Directive 2012/9/EU, replacing Annex I to Directive 2001/37/EC. These studies are not yet concluded.

- (6) Member States which require additional warnings in the form of colour photographs or other illustrations, as referred to in Article 5(3) of Directive 2001/37/EC need to have at their disposal the selected source documents sufficiently in advance in order to transpose Directive 2012/9/EU.
- (7) Given the complexity of the process of updating the library of selected source documents and amending Decision C(2005) 1452, there is a risk that the process will not have been concluded within a timeframe that would allow Member States sufficient time to comply with the deadline for transposition of Directive 2012/9/EU.
- (8) In order to ensure that Member States have adequate time it is appropriate to postpone the deadlines for the transposition of Directive 2012/9/EU and for the end of the transitional period provided for by that Directive.
- (9) The measures provided for in this Directive are in accordance with the opinion of the Committee set up by Article 10(1) of Directive 2001/37/EC,

HAS ADOPTED THIS DIRECTIVE:

### Article 1

Directive 2012/9/EU is amended as follows:

- (1) in Article 2(1) '28 March 2014' is replaced by '28 March 2016';
- (2) in Article 3 '28 March 2016' is replaced by '28 March 2018'.

### Article 2

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

<sup>(1)</sup> OJ L 194, 18.7.2001, p. 26.

<sup>(2)</sup> Commission Directive 2012/9/EU of 7 March 2012, amending Annex I to Directive 2001/37/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products (OJ L 69, 8.3.2012, p. 15).

<sup>(3)</sup> Commission Decision 2003/641/EC of 5 September 2003 on the use of colour photographs or other illustrations as health warnings on tobacco packages (OJ L 226, 10.9.2003, p. 24).

*Article 3*

This Directive is addressed to the Member States.

Done at Brussels, 12 March 2014.

*For the Commission*

*The President*

José Manuel BARROSO

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## DECISIONS

## COMMISSION IMPLEMENTING DECISION

of 11 March 2014

**rejecting the refusal of authorisations of biocidal products containing bromadiolone notified by Germany in accordance with Directive 98/8/EC of the European Parliament and of the Council***(notified under document C(2014) 1362)***(Text with EEA relevance)**

(2014/133/EU)

THE EUROPEAN COMMISSION,

Member States have subsequently authorised the contested products through mutual recognition.

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

- (3) The German competent authority for biocidal products received applications for mutual recognition of authorisations according to Article 4(1) of Directive 98/8/EC for the contested products.

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products <sup>(1)</sup>, and in particular Article 36(3) thereof,

- (4) Germany has notified the Commission, the other Member States and the applicants of its proposal to refuse the authorisations in accordance with Article 4(4) of Directive 98/8/EC, as Germany considers that the contested products do not meet the requirements of Article 5(1) of Directive 98/8/EC with regard to effects on human health.

Whereas:

- (1) Annex I to Directive 98/8/EC of the European Parliament and of the Council <sup>(2)</sup> contained the list of active substances approved at Union level for use in biocidal products. Commission Directive 2009/92/EC <sup>(3)</sup> added the active substance bromadiolone for use in products belonging to product-type 14, Rodenticides, as defined in Annex V to Directive 98/8/EC.

- (5) According to the notifications, Germany disagrees with the evaluation carried out by the United Kingdom regarding the dermal absorption value used in such evaluation (0,04 %). Germany considers this value as inappropriate according to OECD standards on *in vitro* dermal absorption methods <sup>(4)</sup> and pointed out that based on a more conservative value of 0,36 % as per these standards the assessment results in an unacceptable dermal exposure to bromadiolone for professional users.

- (2) In accordance with Article 8 of Directive 98/8/EC, the companies Pelgar International Limited and Unichem d.o.o. (the applicants) submitted applications to the United Kingdom for authorisation of biocidal products containing bromadiolone as a wax block formulation (the contested products). The United Kingdom authorised before 1 September 2013 the contested products for a number of uses including professional application in and around buildings and in sewers. A number of

- (6) For each notification, the Commission invited the other Member States and the applicants to submit comments to the notification in writing within 90 days in accordance with Article 27(1) of Directive 98/8/EC. Comments were submitted within that deadline by the United Kingdom, Belgium, Germany and one of the applicants. The notification was also discussed between Commission representatives and representatives of Member States' Competent Authorities for biocidal products in the meeting of the Product Authorisation and Mutual Recognition Facilitation Group of 14 May 2013.

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1.

<sup>(2)</sup> Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

<sup>(3)</sup> Commission Directive 2009/92/EC of 31 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include bromadiolone as an active substance in Annex I thereto (OJ L 201, 1.8.2009, p. 43).

<sup>(4)</sup> See OECD Guideline for the testing of chemicals 428 on skin absorption: *in vitro method*, available on the website [http://www.oecd-ilibrary.org/environment/test-no-428-skin-absorption-in-vitro-method\\_9789264071087-en](http://www.oecd-ilibrary.org/environment/test-no-428-skin-absorption-in-vitro-method_9789264071087-en)

- (7) From the abovementioned discussions and comments, it follows that the United Kingdom carried out the evaluation of the dermal absorption in a way which is compatible with the latest agreed EU guidance<sup>(1)</sup>, pursuant to which the possibility of reading across existing data from the active substance approval is accepted.
- (8) First, the United Kingdom used a dermal absorption value from a study considered as reliable in the context of the EU approval of the active substance bromadiolone, to which the applicants held the required letter of access from the data owner. Second, the dermal absorption study from which that value was obtained was carried out with a similar bait formulation to that of the contested products, as recommended by the abovementioned guidance.
- (9) Finally, the United Kingdom evaluated the product with the benefit of expert judgment to justify that the specific conditions of the study from which the dermal absorption value was obtained resembled more closely the actual exposure conditions for professional users loading wax blocks in bait stations. This approach is compatible with the abovementioned guidance and the common principles for the evaluation of dossiers for biocidal products as provided for by paragraph 12 of Annex VI to Regulation (EU) No 528/2012.
- (10) In the light of the above arguments, the Commission supports the conclusions of the assessment carried out by the United Kingdom and the other Member States having authorised the contested products through mutual recognition that they do not have unacceptable effects on human health, as required by Article 5(1) of Directive 98/8/EC. The Commission therefore considers

that the request by Germany to refuse the authorisations cannot be justified on the grounds put forward.

- (11) Regulation (EU) No 528/2012 shall apply to the contested products in accordance with the provisions of Article 92(2) of that Regulation. Since the legal basis for this Decision is Article 36(3) of that Regulation, this decision should be addressed to all Member States by virtue of Article 36(4) of that Regulation.
- (12) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

*Article 1*

The proposal by Germany to refuse the authorisations granted by the United Kingdom of the products mentioned in the Annex, is rejected.

*Article 2*

This Decision is addressed to all Member States.

Done at Brussels, 11 March 2014.

*For the Commission*  
Janez POTOČNIK  
*Member of the Commission*

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<sup>(1)</sup> See CA-July13-Doc.6.2.b — *Final on Approach to dermal absorption assessment for biocidal products authorisation*, available on the website <https://circabc.europa.eu/w/browse/884abd60-d8f9-48ad-8600-cd0bd5485cec>



## ANNEX

Products for which the proposal by Germany to refuse the authorisations granted by the United Kingdom, is rejected:

Product name	Application reference number in the Register for Biocidal Products in the United Kingdom	Application reference number in the Register for Biocidal Products in Germany	Applicant	Notification date	Other Member States where the contested products have been authorised through mutual recognition
Rodex Oktablok	2011/2309/7794/UK/AA/8845	2011/2309/7794/DE/MA/20435	Pelgar International Limited	8 April 2013	Lithuania, Cyprus, Denmark and Belgium
Ratimor Wax Blocks	2012/2249/12006/UK/AA/19026	2012/2249/12006/DE/MA/31827	Unichem d.o.o.	19 April 2013	Estonia, Poland, Malta, Latvia and Sweden





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