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Legislation

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Contents

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[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.

EN

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 469/2013

of 22 May 2013

concerning the authorisation of DL-methionine, DL-methionine sodium salt, hydroxy analogue of methionine, calcium salt of hydroxy analogue of methionine, isopropyl ester of hydroxy analogue of methionine, DL-methionine protected with copolymer vinylpyridine/styrene and DL-methionine protected with ethylcellulose as feed additives

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition [1], and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition [2].

(2) DL-methionine, DL-methionine sodium salt, hydroxy analogue of methionine, calcium salt of hydroxy analogue of methionine, isopropyl ester of methionine hydroxy analogue and DL-methionine technically pure protected with copolymer vinylpyridine/styrene were authorised without a time limit pursuant to Directive 82/471/EEC. These feed additives were subsequently entered in the European Union Register of feed additives as existing products, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of DL-methionine, DL-methionine sodium salt, hydroxy analogue of methionine and calcium salt of methionine hydroxy analogue as feed additives for all animal species and of isopropyl ester of methionine hydroxy analogue and DL-methionine technically pure protected with copolymer vinylpyridine/styrene as feed additives for dairy cows and, in accordance with Article 7 of that Regulation, for a change in the terms of the authorisation as regards the use of DL-methionine, DL-methionine sodium salt and the hydroxy analogue of methionine via drinking water. In addition, in accordance with Article 7 of that Regulation, the application contained the request for the authorisation of DL-methionine technically pure protected with ethylcellulose for ruminants. For all seven sources of methionine it was requested that those additives be classified in the additive category 'nutritional additives'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 6 March 2012 [3] that, under the proposed conditions of use, DL-methionine, DL-methionine sodium salt, hydroxy analogue of methionine, calcium salt of methionine hydroxy analogue, isopropyl ester of methionine hydroxy analogue, DL-methionine technically pure protected with copolymer vinylpyridine/styrene and DL-methionine technically pure protected with ethylcellulose do not have an adverse effect on animal health, human health or the environment, and that they are effective sources of methionine for protein synthesis in the respective target species. The Authority extrapolated this conclusion from dairy cows to all ruminants. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

[1] OJ L 268, 18.10.2003, p. 29.
[2] OJ L 213, 21.7.1982, p. 8.
[3] *EFSA Journal* 2012;10(3):2623.

(5) The assessment of DL-methionine, DL-methionine sodium salt, the hydroxy analogue of methionine, the calcium salt of methionine hydroxy analogue, the isopropyl ester of methionine hydroxy analogue, DL-methionine technically pure protected with copolymer vinylpyridine/styrene and DL-methionine technically pure protected with ethylcellulose shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied.

(6) The Authority recommends that the use of methionine should not be authorised in water for drinking. However, this recommendation refers rather to the farm management as it concerns the way to achieve the optimal protein supply of the animal including the prevention of protein surpluses. No maximum content for the methionine sources is proposed by the Authority. Thus, it is in the case of administration of methionine sources via drinking water appropriate to instruct the user to consider all different methionine sources in order to achieve an optimal supply with the essential amino acids without affecting the performance of the animals.

(7) The Authority recommends further, to avoid the combined supplementation of feed with hydroxy analogue of methionine and cystine/cysteine. However, the settings of the animal trials on which this recommendation is based are not considered to be tangible to fully justify such a measure.

(8) Accordingly, the use of these substances should be authorised as specified in the Annex to this Regulation.

(9) Since safety reasons do not require the immediate application of the modifications to the conditions of use for the already authorised sources of methionine, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(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

Authorisation

The substances specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues', are authorised as additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Transitional measures

The substances specified in the Annex that are authorised pursuant to Directive 82/471/EEC and feed containing these substances, which are produced and labelled before 12 December 2013 in accordance with the rules applicable before 12 June 2013 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 3

Entry into force

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, 22 May 2013.

For the Commission
The President
José Manuel BARROSO

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg/kg of complete feedingstuff with a moisture content of 12 %			
Category of nutritional additives. Functional group: amino acids, their salts and analogues									
3c301		DL-methionine, technically pure	*Additive composition* Methionine content: minimum 99 % *Characterisation of the active substance* IUPAC name: 2-amino-4-(methylthio)butanoic acid CAS number: 59-51-8 Chemical formula: $C_5H_{11}NO_2S$ *Analytical methods* (1) For the determination of methionine in the additives: — Ion exchange chromatography coupled with post-column derivatisation and photometric or fluorescence detection (HPLC-UV/FD) - ISO/DIS 17180. For the determination of methionine in premixtures, compound feed, feed materials and water: — Ion exchange chromatography coupled with post-column derivatisation and photometric detection (HPLC-UV) - Commission Regulation (EC) No 152/2009 (Annex III, F).	all animal species				1. DL-methionine, technically pure can be also used via water for drinking. 2. Declarations to be made on the labelling of the additive and premixtures: 'If the additive is administered via water for drinking protein excess should be avoided.'	12 June 2023
3c302		Sodium DL-methionine, liquid	*Additive composition* DL-Methionine content: minimum 40 % Sodium: minimum 6,2 % Water: maximum 53,8 %	all animal species				1. For user safety: breathing protection, safety glasses and gloves should be worn during handling.	12 June 2023

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg/kg of complete feedingstuff with a moisture content of 12 %			
			Characterisation of the active substance IUPAC name: 2-amino-4-(methylthio)butanoic acid sodium salt CAS number: 41863-30-3 Chemical formula: $(C_5H_{11}NO_2S)Na$ *Analytical methods* For the determination of methionine in the additives: — Ion exchange chromatography coupled with post-column derivatisation and photometric or fluorescence detection (HPLC-UV/FD) - ISO/DIS 17180. For the determination of methionine in premixtures, compound feed, feed materials and water: — Ion exchange chromatography coupled with post-column derivatisation and photometric detection (HPLC-UV) - Commission Regulation (EC) No 152/2009 (Annex III, F).					2. Sodium DL-methionine, liquid can be also used via water for drinking. 3. Declarations to be made on the labelling of the additive and premixtures: — DL-Methionine content, — 'If the additive is administered via water for drinking protein excess should be avoided.'	
3c303		DL-methionine protected with copolymer vinylpyridine/ styrene	*Additive composition* Preparation with DL-Methionine: minimum 74 % Stearic acid: maximum of 19 % Copolymer poly(2-vinylpyridine) co-styrene: maximum 3 % Ethylcellulose and sodium stearate: maximum 0,5 % *Characterisation of the active substance* IUPAC name: 2-amino-4-(methylthio)butanoic acid	Ruminants					12 June 2023

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg/kg of complete feedingstuff with a moisture content of 12 %			
			CAS number: 59-51-8 Chemical formula: $C_5H_{11}NO_2S$ *Analytical methods* (1) For the determination of methionine in the additives: — Ion exchange chromatography coupled with post-column derivatisation and photometric or fluorescence detection (HPLC-UV/FD) - ISO/DIS 17180. For the determination of methionine in premixtures, compound feed and feed materials: — Ion exchange chromatography coupled with post-column derivatisation and photometric detection (HPLC-UV) - Commission Regulation (EC) No 152/2009 (Annex III, F).						
3c304		DL-methionine protected with ethylcellulose	*Additive composition* Preparation with DL-Methionine: minimum 85 % Ethylcellulose: maximum 4 % Starch: maximum 8 % Sodium aluminium silicate: maximum 1,5 % Sodium stearate: maximum 1 % Water: maximum 2 % *Characterisation of the active substance* IUPAC name: 2-amino-4-(methylthio)butanoic acid CAS number: 59-51-8 Chemical formula: $C_5H_{11}NO_2S$	Ruminants					12 June 2023

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg/kg of complete feedingstuff with a moisture content of 12 %			
			Analytical methods (1) For the determination of methionine in the additives: — Ion exchange chromatography coupled with post-column derivatisation and photometric or fluorescence detection (HPLC-UV/FD) - ISO/DIS 17180. For the determination of methionine in premixtures, compound feed and feed materials: — Ion exchange chromatography coupled with post-column derivatisation and photometric detection (HPLC-UV) - Commission Regulation (EC) No 152/2009 (Annex III, F).						
3c307	—	Hydroxy analogue of methionine	*Additive composition* Hydroxy analogue of methionine: minimum 88 % Water: maximum 12 % *Characterisation of the active substance* IUPAC name: 2-hydroxy-4-(methylthio)butanoic acid CAS number 583-91-5 Chemical formula: $C_5H_{10}O_3S$ *Analytical methods* (1) For the determination of hydroxy analogue of methionine in the additive: — Titrimetry, potentiometric titration followed by oxidation reduction reaction. For the determination of hydroxy analogue of methionine in premixtures, compound feed, feed materials and water:	All animal species	—	—	—	1. For user safety: breathing protection, safety glasses and gloves should be worn during handling. 2. Hydroxy analogue of methionine can be also used via water for drinking. 3. Declarations to be made on the labelling of the additive and premixtures: — 'If the additive is administered via water for drinking protein excess should be avoided.' 4. Declarations to be made on the labelling of feed materials and compound feed in the listing of additives, if appropriate: — Name of the additive,	12 June 2023

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg/kg of complete feedingstuff with a moisture content of 12 %			
			— High-Performance Liquid Chromatography and photometric detection (HPLC-UV).					— Amount of the hydroxy analogue of methionine added.	
3c3108	—	Calcium salt of hydroxy analogue of methionine	*Additive composition* Hydroxy analogue of methionine: minimum 84 % Calcium: minimum 11,7 % Water: maximum 1 % *Characterisation of the active substance* IUPAC name 2-hydroxy-4-(methylthio)butanoic acid, calcium salt CAS number 4857-44-7 Chemical formula: $(C_5H_9O_3S)_2Ca$ *Analytical methods* (1) For the determination of hydroxy analogue of methionine in the additive: — Titrimetry, potentiometric titration followed by oxidation reduction reaction. For the determination of hydroxy analogue of methionine in premixtures, compound feed and feed materials: — High-Performance Liquid Chromatography and photometric detection (HPLC-UV).	All animal species	—	—	—	1. For user safety: breathing protection, safety glasses and gloves should be worn during handling. 2. Declarations to be made on the labelling of the additive and premixtures: — Hydroxy analogue of methionine content. 3. Declarations to be made on the labelling of feed materials and compound feed in the listing of additives, if appropriate: — Name of the additive, — Amount of the hydroxy analogue of methionine added.	12 June 2023
3c309	—	Isopropyl ester of hydroxy analogue of methionine	*Additive composition* Preparation of isopropyl ester of hydroxy analogue of methionine: minimum 95 % Water: maximum 0,5 %	Ruminants	—	—	—	1. Declarations to be made on the labelling of the additive and premixtures: — Content of hydroxy analogue of methionine	12 June 2023

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg/kg of complete feedingstuff with a moisture content of 12 %			
			Characterisation of the active substance IUPAC name isopropyl ester of 2-hydroxy-4-(methylthio)butanoic acid CAS number 57296-04-5 Chemical formula: $C_8H_{16}O_3S$ *Analytical method* For the determination of isopropyl ester of the hydroxy analogue of methionine in the feed: — High-Performance Liquid Chromatography and photometric detection (HPLC-UV).					2. Declarations to be made on the labelling of feed materials and compound feed in the listing of additives, if appropriate: — Name of the additive, — Amount of the hydroxy analogue of methionine added.	

([1]) Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/authorisation/evaluation_reports/Pages/index.aspx

COMMISSION IMPLEMENTING REGULATION (EU) No 470/2013

of 22 May 2013

opening a tariff quota for certain quantities of industrial sugar for the 2013/14 marketing year

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) [1], and in particular Article 142, in conjunction with Article 4 thereof,

Whereas:

(1) In order to ensure that the supply necessary for the production of the products referred to in Article 62(2) of Regulation (EC) No 1234/2007 is available at a price that corresponds to the world price, it is in the interest of the Union to suspend the import duties on sugar intended for the production of those products for the 2013/14 marketing year, for a quantity that would correspond to half of its industrial sugar needs.

(2) Commission Regulation (EC) No 891/2009 of 25 September 2009 opening and providing for the administration of certain Community tariff quotas in the sugar sector [2] provides for the administration of the tariff quotas for imports of sugar products under Article 142 of Regulation (EC) No 1234/2007 with order number 09.4390 (industrial import sugar). However, in accordance with Article 11 of Regulation (EC) No 891/2009 the quantities of those products for which import duties are to be suspended has to be determined by a separate legal act.

(3) The import quantities of industrial sugar for which no import duties should apply for the 2013/14 marketing year, need to be set accordingly.

(4) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for the Common Organisation of Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

The import duties for industrial sugar falling within CN 1701 and with order number 09.4390 shall be suspended for a quantity of 400 000 tonnes from 1 October 2013 to 30 September 2014.

Article 2

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

It shall apply from 1 October 2013.

It shall expire on 30 September 2014.

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

Done at Brussels, 22 May 2013.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 299, 16.11.2007, p. 1.
[2] OJ L 254, 26.9.2009, p. 82.

COMMISSION IMPLEMENTING REGULATION (EU) No 471/2013

of 22 May 2013

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) [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, 22 May 2013.

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

[1] OJ L 299, 16.11.2007, p. 1.
[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	AL	15,0
	MA	58,3
	TN	78,7
	TR	71,8
	ZZ	56,0
0707 00 05	AL	27,7
	MK	39,1
	TR	132,0
	ZZ	66,3
0709 93 10	TR	131,6
	ZZ	131,6
0805 10 20	EG	54,0
	IL	68,3
	MA	72,6
	ZZ	65,0
0805 50 10	AR	114,6
	EG	68,1
	TR	71,0
	ZA	110,2
	ZZ	91,0
0808 10 80	AR	157,2
	BR	97,4
	CL	127,8
	CN	90,2
	MK	46,1
	NZ	142,3
	US	200,4
	ZA	116,6
	ZZ	122,3

(1) 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'.

DECISIONS

COUNCIL IMPLEMENTING DECISION

of 21 May 2013

rejecting the proposal for a Council implementing regulation imposing a definitive anti-dumping duty on imports of certain polyethylene terephthalate originating in India, Taiwan and Thailand following an expiry review pursuant to Article 11(2) of Regulation (EC) No 1225/2009 and terminating the expiry review proceeding concerning imports of certain polyethylene terephthalate originating in Indonesia and Malaysia, in so far as the proposal would impose a definitive anti-dumping duty on imports of certain polyethylene terephthalate originating in India, Taiwan and Thailand

(2013/226/EU)

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Regulation (EC) No 1225/2009 of 30 November 2009 on protection against dumped imports from countries not members of the European Community [1], and in particular Articles 9(4) and 11(2) thereof,

Having regard to the proposal submitted by the European Commission, after consulting the Advisory Committee,

Whereas:

INTRODUCTION

(1) Anti-dumping measures against imports of polyethylene terephthalate (PET) originating in India, Indonesia, Malaysia, Taiwan and Thailand have been in force since 2000, having been renewed in 2007. In parallel, countervailing measures on PET from India have been in place since 2000, and trade defence measures are also in place on imports from China, Iran, Pakistan and UAE.

(2) The Expiry Review of these anti-dumping measures was initiated on 24 February 2012. An Expiry Review of the countervailing measures against imports of PET from India was also initiated on 24 February 2012. The Council has accepted the Commission's proposal to maintain these countervailing measures.

(3) According to Article 11(2) of Regulation (EC) No 1225/2009 (the Basic anti-dumping Regulation), measures will expire after a period unless expiry of a measure would be likely to lead to a continuation or recurrence of dumping and injury. Article 11(2) also says that the likelihood of recurrence may be indicated by evidence:

(a) of continued dumping and injury; or

(b) that the removal of injury is partly or solely due to the existence of measures; or

(c) that the circumstances of the exporters, or market conditions, are such that they would indicate the likelihood of further injurious dumping.

Finally, Article 11(2) says that conclusions are to be reached with due account taken of all relevant and duly documented evidence presented in relation to the question as to whether the expiry of measures would be likely, or unlikely, to lead to the continuation or recurrence of dumping and injury.

(4) The Council agrees that there is no likelihood that Indonesian or Malaysian exporting producers will resume exporting injurious quantities at dumped prices to the Union market in the short or medium term should measures be repealed.

(5) However, the Council view is that the case has not been made that the removal of anti-dumping measures against India, Taiwan and Thailand would be likely to lead to continuation or resumption of injurious dumping. It further concludes that the reimposition of measures would clearly be against the overall Union interest.

(6) The Council is of the opinion that 13 years has in this instance been enough to allow European industry to adapt to the global competition and recover substantially. In addition, the main export markets for PET are growing and the global demand for PET-packaged products is likely to expand further as the world economy recovers.

[1] OJ L 343, 22.12.2009, p. 51.

INJURY

(7) The Council's assessment, based on the evidence in the proposal, is that the EU industry is not currently suffering material injury.

RECURRENCE OF INJURY

(8) The Council has also examined whether the recurrence of material injury would be likely if the measures were allowed to lapse. The Council's assessment is that this would not be likely to happen. Productivity has increased in the period covered by the Expiry Review. EU industry consistently holds over 70 % of the EU market and prices, profitability, return on investment and cash flow figures are significantly improving. The trends show that the market developments cannot be regarded as temporary.

(9) These developments would allow EU producers to compete with the imports from the countries concerned without leading to recurrence of material injury. In addition, import prices have increased significantly during the last number of years and thus price pressure is diminishing.

(10) Imports from the countries concerned are not significant in terms of their share of the EU market (still below 4 % in RIP) and in relation to imports from other countries and EU producers sales. In addition, their prices are in line with those of the EU sales and the other imports. Further, according to the data presented, in terms of market shares the measures have been more beneficial to third country producers than the Union industry.

(11) The market shares of both Taiwan and Thailand are close to zero. Given that the volumes are so small, the reliability of claims about dumping are likely to be subject to a large margin of error.

(12) Where there are imports, import prices have been rising strongly. Indian prices increased 29 %, Taiwan prices increased 27 % and Thailand prices increased 32 % over the period considered. In addition, in all three cases, no price undercutting was found. The Council's assessment is that it is therefore not possible to justify a conclusion that these imports are causing injury. The Council's assessment is also that it has not been demonstrated that injurious dumping by imports from the countries concerned would be likely to recur once the measures lapsed.

(13) Although there is some overcapacity in the countries concerned, the Council is not persuaded that those unused capacities would be directed to the EU. Demand is growing in most of the major markets.

(14) The price level in the EU compared with other countries is higher than in other major markets because these long-lasting measures are in force. Without the measures prices would tend to normalise vis-à-vis other countries. Trade defence measures in third countries are unlikely to deflect significant trade towards the EU because these countries are not the world's main consumers of PET. No information has been provided on the existence or otherwise of trade defence measures in other major PET markets such as the US and Japan. Therefore the Council believes that although there could be an increase of imports after the lapse of the measures, this increase would not be significant.

(15) The Council's assessment is that no persuasive evidence has been provided on a number of factors which seem relevant to any assessment of whether removal of duties would lead to a resumption of injurious dumping. These include:

(a) Demand trends in third countries: in the case of Taiwan, for example, third country exports account for about 60 % of production capacity. This suggests that future demand trends in these countries are relevant to the assessment.

(b) Transport costs and other factors affecting profitability: if third country export markets are closer to the exporter than the EU market — East Asia is a significant market — this will affect transport costs and hence profitability of export sales and hence the relative attractiveness of the EU market.

(16) Other factors point to the likelihood that removal of measures will not lead to a resumption of dumping which causes material injury to the Union Industry. Continued anti-subsidy measures against India and anti-dumping measures against China and other countries will continue to provide some protection for the Union Industry. The past pattern of trade in this market also suggests that any rise in exports from India, Thailand and Taiwan could partly or wholly displace third country imports rather than EU production.

(17) The Council's assessment is that material injury is unlikely to recur if the measures are allowed to lapse. Therefore the Council finds that the criteria for continuing the measures according to Article 11(2) of the Basic Regulation are not met.

UNION INTEREST

(18) Article 21(1) of the Basic Regulation provides that a determination as to whether the Union interest calls for intervention is to be based on an appreciation of all the various interests taken as a whole.

(19) PET prices are determined by a number of factors, but it is clear the anti-dumping measures have increased the costs to the user industry. Many users are bottlers and SMEs operating on tight margins and they have been seriously affected by high PET prices in recent years because PET represents a decisive proportion of their production costs. The impact of the high costs has been biggest on smaller bottling companies who have

not been able to pass the increased prices on to retailers and final consumers due to low negotiating power. Many are heavily loss-making and have lost a significant number of employees. The proposal recognises the deteriorating situation of users and the fact that EU PET prices are higher than in other major markets. However, in the Council's opinion, it has not been demonstrated that the measures in question are not a contributing factor to the relatively high Union PET prices.

(20) The EU PET industry is now highly concentrated and increasingly vertically integrated. It is profitable and should be able to be internationally competitive.

(21) The accumulation of measures combined with the increasing integration of PET producers and PET-packaging companies in the EU creates a situation in which there is a lack of a level playing field for independent PET-packaging companies which are subject to PET at the highest prices worldwide (given the horizontal effect existing on PET prices), while their main competitors in third countries have access to PET at lower prices.

(22) PET users have very limited sources of supply outside the EU, because measures are also in force against imports originating in other third countries.

(23) The Council concludes that it is clearly not in the interest of the Union to extend the measures as the costs to importers, users and consumers are disproportionate to the benefits for the Union industry.

HAS ADOPTED THIS DECISION:

Article 1

The proposal for a Council implementing regulation imposing a definitive anti-dumping duty on imports of certain polyethylene terephtalate originating in India, Taiwan and Thailand following an expiry review pursuant to Article 11(2) of Regulation (EC) No 1225/2009 and terminating the expiry review proceeding concerning imports of certain polyethylene terephthalate originating in Indonesia and Malaysia is rejected, in so far as the proposal would impose a definitive anti-dumping duty on imports of certain polyethylene terephthalate originating in India, Taiwan and Thailand.

Article 2

The review proceeding concerning imports of polyethylene terephthalate having a viscosity number of 78 ml/g or higher, according to ISO standard 1628-5, currently falling within CN code 3907 60 20 and originating in India, Indonesia, Malaysia, Taiwan and Thailand is terminated.

Article 3

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

Done at Brussels, 21 May 2013.

For the Council
The President
E. GILMORE

COMMISSION DECISION

of 22 May 2013

terminating the anti-subsidy proceeding concerning imports of bicycles originating in the People's Republic of China

(2013/227/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 597/2009 of 11 June 2009 on protection against subsidised imports from countries not members of the European Community [1] ('the basic Regulation'), and in particular Article 14 thereof,

After consulting the Advisory Committee,

Whereas:

A. PROCEDURE

1. Initiation

(1) In April 2012 the European Commission ('the Commission') announced by a notice published in the *Official Journal of the European Union* [2] ('the Notice of initiation'), the initiation of an anti-subsidy proceeding with regard to imports into the Union of bicycles originating in the People's Republic of China ('the anti-subsidy proceeding').

(2) The anti-subsidy proceeding was initiated following a complaint lodged on 15 March 2012 by EBMA, the European Bicycles Manufacturers Association ('the complainant'), on behalf of Union producers representing more than 25 % of the total Union production of bicycles.

(3) The complaint contained prima facie evidence of subsidisation of the said product and of material injury resulting therefrom, which was considered sufficient to justify the initiation of a proceeding.

(4) The Commission officially advised the complainant, other known Union producers, Union producers associations, the known exporting producers in the People's Republic of China ('the PRC') and associations of exporting producers, the representatives of the PRC, known importers and associations of importers, known Union producers of bicycle parts and their associations and known users of the initiation of the proceeding and sent questionnaires. Interested parties were given the opportunity to make their views known in writing and to request a hearing within the time limit set in the Notice of initiation.

2. Parallel anti-dumping proceeding

(5) In March 2012 the Commission announced by a notice published in the *Official Journal of the European Union* [3] the initiation of an interim review of the anti-dumping measures concerning imports into the Union of bicycles originating in the PRC pursuant to Articles 11(3) and 13(4) of Council Regulation (EC) No 1225/2009 of 30 November 2009 on protection against dumped imports from countries not members of the European Community [4] ('the basic anti-dumping Regulation'). The investigation is ongoing.

3. Parallel anti-circumvention investigation

(6) In September 2012 by Commission Regulation (EU) No 875/2012 [5], the Commission initiated an investigation concerning the possible circumvention of anti-dumping measures imposed by Council Implementing Regulation (EU) No 990/2011 [6] on imports of bicycles originating in the PRC by imports of bicycles consigned from Indonesia, Malaysia, Sri Lanka and Tunisia, whether declared as originating in Indonesia, Malaysia, Sri Lanka and Tunisia or not, and making such imports subject to registration ('the anti-circumvention investigation').

(7) In November 2012 the Commission announced by a notice published in the *Official Journal of the European Union* [7] that the findings in the anti-circumvention investigation may be used in the anti-subsidy proceeding.

(8) The anti-circumvention investigation is still ongoing.

[1] OJ L 188, 18.7.2009, p. 93.
[2] OJ C 122, 27.4.2012, p. 9.
[3] OJ C 71, 9.3.2012, p. 10.
[4] OJ L 343, 22.12.2009, p. 51.
[5] OJ L 258, 26.9.2012, p. 21.
[6] OJ L 261, 6.10.2011, p. 2.
[7] OJ C 346, 14.11.2012, p. 7.

B. **WITHDRAWAL OF THE COMPLAINT AND TERMINATION OF THE PROCEEDING**

(9) By letter of 22 March 2013 addressed to the Commission, the complainant formally withdrew its complaint.

(10) In accordance with Article 14(1) of Regulation (EC) No 597/2009, when the complainant withdraws its complaint the proceeding may be terminated unless such termination would not be in the Union interest.

(11) The Commission considered that the present proceeding should be terminated since the respective anti-subsidy investigation had not brought to light any considerations showing that such termination would not be in the Union interest. Interested parties were informed accordingly and were given an opportunity to comment. However, no comments were received that would give a reason to reach a different conclusion.

(12) It was therefore concluded that the anti-subsidy proceeding concerning imports into the Union of bicycles originating in the PRC should be terminated without the imposition of measures,

HAS ADOPTED THIS DECISION:

Article 1

The anti-subsidy proceeding concerning imports into the Union of bicycles and other cycles (including delivery tricycles but excluding unicycles), not motorised, originating in the People's Republic of China and currently falling within CN codes 8712 00 30 and ex 8712 00 70 is hereby terminated.

Article 2

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

Done at Brussels, 22 May 2013.

For the Commission
The President
José Manuel BARROSO

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

DECISION No 1/2012 OF THE COMMITTEE ESTABLISHED UNDER THE AGREEMENT BETWEEN THE EUROPEAN COMMUNITY AND THE SWISS CONFEDERATION ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT

of 17 December 2012

on the inclusion in Annex 1 of a new Chapter 20 on explosives for civil use, the amendment of Chapter 3 on toys and the update of legal references listed in Annex 1

(2013/228/EU)

THE COMMITTEE,

Having regard to the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment ('the Agreement') and in particular Articles 10(4), 10(5) and 18(2) thereof;

Whereas:

(1) The Parties to the Agreement have agreed to modify Annex 1 to the Agreement to include a new chapter on explosives for civil use;

(2) The European Union has adopted a new Directive on the safety of toys [1] and Switzerland has amended its legislative, regulatory and administrative provisions deemed equivalent under Article 1(2) of the Agreement to the above mentioned European Union legislation;

(3) Chapter 3, Toys, of Annex 1 should be amended to reflect these developments;

(4) It is necessary to update certain legal references in the Annex to the Agreement;

(5) Article 10(5) of the Agreement provides that the Committee may, on a proposal from one of the Parties, modify the Annexes to the Agreement,

HAS DECIDED AS FOLLOWS:

1. Annex 1 to the Agreement is modified in order to include a new Chapter 20 on explosives for civil use (excluding ammunition) in accordance with the provisions set out in Attachment A annexed to this Decision.

2. Chapter 3, Toys, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment B annexed to this Decision.

3. Annex 1 on to the Agreement is amended in accordance with the provisions set out in Attachment C annexed to this Decision.

4. This Decision, done in duplicate, shall be signed by representatives of the Committee who are authorised to act on behalf of the Parties. This Decision shall be effective from the date of the later of these signatures.

Signed at Bern, 17 December 2012.
On behalf of the Swiss Confederation
Christophe PERRITAZ

Signed at Brussels, 12 December 2012.
On behalf of the European Union
Fernando PERREAU DE PINNINCK

[1] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1).

ATTACHMENT A

In Annex 1, Product Sectors, the following Chapter 20 on Explosives for civil use (excluding ammunition) shall be introduced:

'CHAPTER 20

EXPLOSIVES FOR CIVIL USE

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1 paragraph 2

European Union	1.	Council Directive 93/15/EEC of 5 April 1993 on the harmonisation of the provisions relating to the placing on the market and supervision of explosives for civil uses (in the version of OJ L 121, 15.5.1993, p. 20, corrected in OJ L 79, 7.4.1995, p. 34 (ES, DA, DE, EL, EN, FR, IT, NL, PT, FI, SV) and in OJ L 59, 1.3.2006, p. 43 (DE) ([1]), hereinafter referred to as "Directive 93/15/EEC"
	2.	Commission Directive 2008/43/EC of 4 April 2008 setting up, pursuant to Council Directive 93/15/EEC, a system for the identification and traceability of explosives for civil uses (OJ L 94, 5.4.2008, p. 8), as amended by Commission Directive 2012/4/EU (OJ L 50, 23.2.2012, p. 18), hereinafter referred to as "Directive 2008/43/EC"
	3.	Commission Decision 2004/388/EC of 15 April 2004 on an Intra-Community transfer of explosives document (OJ L 120, 24.4.2004, p. 43), as amended by Commission Decision 2010/347/EU (OJ L 155, 22.6.2010, p. 54), hereinafter referred to as "Decision 2004/388/EC"
Switzerland	100.	Federal Act of 25 March 1977 on explosive substances (Explosives Act) as last amended on 12 June 2009 (RO *2010* 2617)
	101.	Ordinance of 27 November 2000 on explosives (Explosives Ordinance), as last amended on 21.09.2012 (RO *2012* 5315)

SECTION II

Conformity assessment bodies

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

SECTION III

Designating authorities

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the designating authorities notified by the Parties.

SECTION IV

Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies, the designating authorities shall comply with the general principles contained in Annex 2 to this Agreement and the assessment criteria set out in Article 6(2) of Directive 93/15/EEC and its Annex III.

SECTION V

Supplementary provisions

1. *Identification of products*

Both Parties shall ensure that undertakings in the explosives sector which manufacture or import explosives or assemble detonators shall mark explosives and each smallest packaging unit with a unique identification. Where an explosive is subject to further manufacturing processes, manufacturers shall not be required to mark the explosive with a new unique identification unless the original unique identification is no longer marked in compliance with Directive 2008/43/EC and/or the Explosives Ordinance.

([1]) This Chapter shall not apply to explosives intended for use, in accordance with national law, by the armed forces or the police, to pyrotechnical articles and to ammunition.

The unique identification shall comprise the components prescribed in the Annex to Directive 2008/43/EC and Annex 14 to the Explosives Ordinance and shall be mutually recognised by both parties.

Each undertaking in the explosives sector and/or manufacturer shall be attributed a three-digit code by the Member State's or Swiss national authority where it is established. This three-digit code shall be mutually recognised by both Parties if the manufacturing site or the manufacturer is located in the territory of one of the Parties.

2. *Provisions governing the supervision of transfers between the European Union and Switzerland*

1. Explosives covered by this Chapter may be transferred between the European Union and Switzerland only in accordance with the following paragraphs.

2. Controls performed pursuant to European Union law or national law in the event of transfers of the explosives governed by section V.2 shall solely be performed as part of the normal control procedures applied in a non-discriminatory fashion throughout the territory of the European Union or Switzerland.

3. Approval to transfer explosives shall be obtained by the consignee from the recipient competent authority. The competent authority shall verify that the consignee is legally authorised to acquire explosives and that he is in possession of the necessary licenses or authorisations. The person responsible for the transfer must notify the competent authorities of the transit Member State or Member States or Switzerland of movements of explosives through this or these States or Switzerland, whose approval shall be required.

4. Where a Member State or Switzerland considers that there is a problem regarding the verification of the entitlement to acquire explosives referred to in paragraph 3, that Member State or Switzerland shall forward the available information on the subject to the European Commission which will put the matter before the Committee provided for in Article 13 of Directive 93/15/EEC without delay. The European Commission shall inform Switzerland accordingly through the Committee established under Article 10 of this Agreement.

5. Where the recipient competent authority approves a transfer, it shall issue to the consignee a document which includes all the information referred to in paragraph 7. Such a document must accompany the explosives until they arrive at their stated destination. It must be produced at the request of the relevant competent authorities. A copy of this document shall be retained by the consignee who shall present it for examination by the recipient competent authority, at the latter's request.

6. Where the competent authority of a Member State or Switzerland considers that special security requirements such as those referred to in paragraph 5 are unnecessary, explosives can be transferred on their territory or part thereof without prior provision of information within the meaning of paragraph 7. The recipient competent authority shall then grant an approval for a fixed period and liable to suspension or withdrawal at any time on the basis of a reasoned justification. The document referred to in paragraph 5, which must accompany the explosives until they arrive at their destination, shall refer solely to the abovementioned approval.

7. Where transfers of explosives must be specially supervised in order to comply with special security requirements in the territory or part of the territory of a Member State or Switzerland, prior to the transfer the following information shall be provided by the consignee to the recipient competent authority:

— the names and addresses of the operators concerned; this information must be detailed enough to enable the operators to be contacted and confirmation to be obtained that the persons in question are legally entitled to receive the consignment,

— the number and quantity of the explosives being transferred,

— a full description of the explosive in question and of the means of identification, including the United Nations identification number,

— where the explosives are to be placed on the market, information on compliance with conditions for placing on the market,

— the means of transfer and the itinerary,

— the expected dates of departure and arrival,

— where necessary, the precise points of entry to and exit from Member States or Switzerland.

Recipient competent authorities shall examine the conditions under which the transfer may take place, with particular regard to the special security requirements. If the special security requirements are satisfied, approval for the transfer shall be granted. In the event of transit through the territory of other Member States or Switzerland, those States or Switzerland shall likewise examine and approve, in the same conditions, the particulars concerning the transfer.

8. Without prejudice to the normal checks which the country of departure shall carry out in its territory, at the request of the competent authorities concerned, the consignees and the operators concerned in the explosives sector shall forward to the authorities of the country of departure and to those of country of transit all relevant information they possess concerning the transfer of explosives.

9. No supplier may transfer explosives unless the consignee has obtained the necessary authorisations for the transfer in accordance with the provisions of paragraphs 3, 5, 6 and 7.

10. For the purposes of implementing paragraph 4, where a measure provided for in Article 13 of Directive 93/15/EEC is adopted regarding products from Swiss undertakings in the explosives sector and/or Swiss manufacturers, it shall be communicated immediately to the Committee established under Article 10 of this Agreement.

    If Switzerland disagrees with this measure, the application of the measure shall be deferred for three months from the date of communication. The Committee established under Article 10 of this Agreement shall hold consultations with a view to reaching a settlement. If a settlement is not reached within the period referred to in this paragraph, either Party may suspend the chapter in part or in full.

11. For the purposes of implementing paragraphs 5 and 6, the provisions of Decision 2004/388/EC shall apply.

3. *Information exchange*

In accordance with the general provisions of this Agreement, the Member States and Switzerland shall keep at each other's disposal any relevant information needed to ensure a proper implementation of Directive 2008/43/EC.

4. *Location of the manufacturer*

For the purpose of this Chapter, it shall be sufficient that the undertaking in the explosives sector, the manufacturer, an authorised representative or, where neither of these is present, the person responsible for placing the product on the market, is established in the territory of one of the Parties.'

ATTACHMENT B

In Annex 1, Product Sectors, Chapter 3, Toys should be deleted and replaced by the following:

'CHAPTER 3

TOYS

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union	1. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1, as last amended by Commission Directive 2012/7/EU (OJ L 64, 3.3.2012, p. 7) (hereinafter referred to as "Directive 2009/48/EC")
Switzerland	100. Federal Law of 9 October 1992 on foodstuffs and commodities (RO 1995 1469) as last amended on 9 November 2011 (RO 2011 5227)
	101. Ordinance of 23 November 2005 on foodstuffs and commodities (RO 2005 5451) as last amended on 22 August 2012 (RO 2012 4713)
	102. Ordinance of the Federal Department of Home Affairs (FDHA) of 15 August 2012 on the safety of toys (RO 2012 4717)
	103. Ordinance of the FDHA of 23 November 2005 on the enforcement of foodstuff legislation (RO 2005 6555) as last amended on 15 August 2012 (RO 2012 4855)
	104. Ordinance of 17 June 1996 on the Swiss accreditation system and on the designation of test laboratories and conformity assessment bodies (RO 1996 1904), as last amended on 1 June 2012 (RO 2012 2887)

SECTION II

Conformity assessment bodies

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

SECTION III

Designating authorities

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the designating authorities notified by the Parties.

SECTION IV

Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies, the designating authorities shall comply with the general principles contained in Annex 2 to this Agreement and with Article 24 of Directive 2009/48/EC.

SECTION V

Supplementary provisions

1. *Exchange of information concerning the certificate of conformity and the technical documentation*

The market surveillance authorities of the Member States or Switzerland may, on reasoned request, ask for the technical documentation, or a translation of parts thereof from a manufacturer based in the territory of either Switzerland or a Member State. The market surveillance authorities of the Member states and Switzerland may request from a Swiss or a European Union-based manufacturer the relevant part of the technical documentation into an official language of the requesting authority or in English.

When a market surveillance authority requests the technical documentation or a translation of parts thereof from a manufacturer, it may set a deadline for receipt of 30 days, unless a shorter deadline is justified in the case of serious and immediate risk.

If the manufacturer based on the territory of either Switzerland or a Member State does not comply with this provision, the market surveillance authority may require it to have a test performed by a designated body at its own expense within a specified period in order to verify compliance with the harmonised standards and essential requirements.

2. *Information requests to designated bodies*

The market surveillance authorities of the Member States and of Switzerland may request a designated body in Switzerland or in a Member State to provide information relating to any type examination certificate which that body has issued or withdrawn, or which relates to any refusal to issue such a certificate, including the test reports and technical documentation.

3. *Information obligations of designated bodies*

In accordance with Article 36(2) of Directive 2009/48/EC, designated bodies shall provide the other bodies designated under this Agreement which carry out similar conformity assessment activities covering the same toys with relevant information on issues relating to negative and, on request, positive conformity assessment results.

4. *Exchange of experience*

Swiss national authorities may take part in the exchange of experience between the Member States' national authorities responsible for the notification procedure referred to in Article 37 of Directive 2009/48/EC.

5. *Coordination of designated bodies*

Designated Swiss conformity assessment bodies may take part in the coordination and cooperation mechanisms and sectoral groups or groups of notified bodies provided for in Article 38 of Directive 2009/48/EC, directly or by means of designated representatives.

6. *Market access*

Importers based in the European union or Switzerland shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the toy or, when that is not possible, on its packaging or in a document accompanying the toy.

The Parties mutually recognise this indication of the coordinates of the manufacturer and importer, registered trade name or registered trade mark and the address at which they can be contacted, which must be mentioned as above. For the purpose of this specific obligation, "importer" shall mean any natural or legal person established within the territory of either the European Union or Switzerland who places a toy from a third country on the European Union or on the Swiss market.

7. *Harmonised standards*

Switzerland recognises harmonised standards conferring a presumption of conformity with the legislation referred to in Section 1 of this Chapter. Where Switzerland considers that compliance with a harmonised standard does not entirely satisfy the requirements which are set out in the legislation listed in Section I, it shall bring the matter before the Committee and give its reasons.

The Committee shall consider the case and may ask the European Union to act in accordance with the procedure provided for in Article 14 of Directive 2009/48/EC. The Committee shall be informed of the result of the procedure.

8. *Procedure for dealing with toys presenting a non-compliance that is not restricted to their national territory* [1]

Pursuant to Article 12(4) of this Agreement, in cases where the market surveillance authorities of a Member State or Switzerland have taken action or have sufficient reasons to believe that a toy covered by Section I of the present Chapter presents a risk to the health or safety of persons, and if they consider that the non-compliance is not restricted to their national territory, they shall inform each other and the European Commission immediately of:

— the results of the evaluation they have carried out and of the actions which they have required the relevant economic operator to take;

— provisional measures taken to prohibit or restrict the toy being made available on their national market, to withdraw the toy from that market or to recall it when the relevant economic operator does not take adequate corrective action. This includes the details set out in Article 42(5) of Directive 2009/48/EC.

[1] This procedure does not imply an obligation of the European Union to grant Switzerland access to the Community Rapid Information System ('RAPEX') under Article 12(4) of Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002, p. 4).

The market surveillance authorities of the Member States or Switzerland other than the one initiating this procedure shall inform without delay the European Commission and the other national authorities of any measures adopted and of any additional information at their disposal relating to the non-compliance of the toy concerned.

The Parties shall ensure that appropriate restrictive measures in respect of the toy concerned, such as withdrawal of the toy from their market, are taken without delay.

9. *Safeguard procedure in case of objections against national measures*

Should it disagree with the notified national measure, Switzerland or a Member State shall inform the European Commission of its objections.

Where, on completion of the procedure set out in paragraph 8 above, objections are raised by a Member State or Switzerland against a measure taken by Switzerland or a Member State respectively, or where the European Commission considers a national measure to be non-compliant with the legislation referred to in this Chapter, the European Commission shall without delay enter into consultation with the Member States, Switzerland and the relevant economic operator or operators and shall evaluate the national measure in order to determine if it is justified or not.

In case of an agreement between the Parties on the results of their investigations, the Member States and Switzerland shall take the measures necessary to ensure that appropriate restrictive measures are taken in respect of the toy concerned, such as the withdrawal of the toy from their market, without delay.

In case of a disagreement between the Parties on the results of their investigations, the issue will be forwarded to the Committee, which may decide to have an expert study carried out.

Where the Committee considers that the measure is:

(a) unjustified, the national authority of the Member State or Switzerland which took the measure shall withdraw it;

(b) justified, the Parties shall take the measures necessary to ensure that the non-compliant toy is withdrawn from their market.'

ATTACHMENT C

Amendments to Annex 1

Chapter 1 (Machinery)

In Section I, Legislative regulatory and administrative provisions, Provisions covered by Article 1(2), the reference to Swiss provisions should be deleted and replaced by the following text:

'Switzerland	100. Federal Law of 12 June 2009 on product safety (RO 2010 2573)
	101. Ordinance of 19 May 2010 on product safety (RO 2010 2583)
	102. Ordinance of 2 April 2008 on the safety of machinery (RO 2008 1785), as last amended on 20 April 2011 (RO 2011 1755)'

Chapter 7 (Radio Equipment and Telecommunications Terminal Equipment)

In Section I, Legislative, regulatory and administrative provisions, Provisions covered by Article 1(2), the reference to Swiss provisions should be deleted and replaced by the following text:

'Switzerland	100. Federal Law of 30 April 1997 on Telecommunications (LTC); (RO 1997 2187), as last amended on 12 June 2009 (RO 2010 2617)
	101. Ordinance of 14 June 2002 on Telecommunications Equipment (OIT); (RO 2002 2086), as last amended on 18 November 2009 (RO 2009 6243)
	102. Ordinance of 14 June 2002 of the Federal Office of Communications (OFCOM) on Telecommunications Equipment; (RO 2002 2111), as last amended on 13 August 2012 (RO 2012 4337)
	103. Annex 1 to the OFCOM Ordinance on Telecommunications Equipment (RO 2002 2115), as last amended on 21 November 2005 (RO 2005 5139)
	104. List of technical standards published in the Feuille Fédérale with titles and references, as last amended on 1st May 2012 (FF 2012 4380)
	105. Ordinance of 9 March 2007 on Telecommunication Services (RO 2007 945), as last amended on 9 December 2011 (RO 2012 367)'

Chapter 12 (Motor vehicles)

Section I, Legislative regulatory and administrative provisions should be deleted and replaced by the following:

'SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union	1. Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive) (OJ L 263, 9.10.2007, p. 1), as last amended by Commission Regulation (EU) No 65/2012 of 24 January 2012 (OJ L 28, 31.1.2012, p. 24), and taking into account the acts listed in Annex IV of Directive 2007/46/EC, as amended until 2 March 2012 and amendments to the aforementioned Annex respectively to acts listed therein, accepted according to the procedure described in Section V, paragraph 1 (hereinafter together referred to as Framework Directive 2007/46/EC)
Switzerland	100. Ordinance of 19 June 1995 relating to the technical requirements for power-driven transportation vehicles and their trailers (RO 1995 4145), as amended until 2 March 2012 (RO 2012 1909) and taking into account amendments accepted according to the procedure described in Section V, paragraph 1
	101. Ordinance of 19 June 1995 relating to the type appro-val of road vehicles (RO 1995 3997), as amended until 11 June 2010 (RO 2010 2749) and taking into account amendments accepted according to the procedure described in Section V, paragraph 1'

Chapter 13 (Agricultural and Forestry Tractors)

Section I, Legislative regulatory and administrative provisions should be deleted and replaced by the following:

'SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union	1. Council Directive 76/432/EEC of 6 April 1976 on the approximation of the laws of the Member States relating to the braking devices of wheeled agricultural or forestry tractors, as last amended by Directive 97/54/EC of the European Parliament and of the Council of 23 September 1997 (OJ L 277, 10.10.1997, p. 24)
	2. Council Directive 76/763/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to passenger seats for wheeled agricultural or forestry tractors, as last amended by Commission Directive 2010/52/EU of 11 August 2010 (OJ L 213, 13.8.2010, p. 37)
	3. Council Directive 77/537/EEC of 28 June 1977 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of pollutants from diesel engines for use in wheeled agricultural or forestry tractors, as last amended by Directive 97/54/EC of the European Parliament and of the Council of 23 September 1997 (OJ L 277, 10.10.1997, p. 24)
	4. Council Directive 78/764/EEC of 25 July 1978 on the approximation of the laws of the Member States relating to the driver's seat on wheeled agricultural or forestry tractors, as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJ L 363, 20.12.2006, p. 81)
	5. Council Directive 80/720/EEC of 24 June 1980 on the approximation of the laws of the Member States relating to the operating space, access to the driving position and the doors and windows of wheeled agricultural or forestry tractors, as last amended by Commission Directive 2010/62/EU of 8 September 2010 (OJ L 238, 9.9.2010, p.7)
	6. Council Directive 86/297/EEC of 26 May 1986 on the approximation of the laws of the Member States relating to the power take-offs of tractors and their protection, as last amended by Commission Directive 2012/24/EU of 8 October 2012 (OJ L 274, 9.10.2012, p. 24)
	7. Council Directive 86/298/EEC of 26 May 1986 on rear-mounted roll-over protection structures of narrow-track wheeled agricultural and forestry tractors, as last amended by Commission Directive 2010/22/EU of 15 March 2010 (OJ L 91, 10.4.2010, p. 1)
	8. Council Directive 86/415/EEC of 24 July 1986 on the installation, location, operation and identification of the controls of wheeled agricultural or forestry tractors, as last amended by Commission Directive 2010/22/EU of 15 March 2010 (OJ L 91, 10.4.2010, p. 1)
	9. Council Directive 87/402/EEC of 25 June 1987 on roll-over protection structures mounted in front of the driver's seat on narrow-track wheeled agricultural and forestry tractors, as last amended by Commission Directive 2010/22/EU of 15 March 2010 (OJ L 91, 10.4.2010, p. 1)
	10. Directive 2000/25/EC of the European Parliament and of the Council of 22 May 2000 on action to be taken against the emission of gaseous and particulate pollutants by engines intended to power agricultural or forestry tractors and amending Council Directive 74/150/EEC as last amended by Directive 2011/87/EU of the European Parliament and of the Council of 16 November 2011 (OJ L 301, 18.11.2011, p. 1)
	11. Directive 2003/37/EC of the European Parliament and of the Council of 26 May 2003 on type approval of agricultural or forestry tractors, their trailers and interchangeable towed machinery, together with their systems, components and separate technical units and repealing Directive 74/150/EEC, as last amended by Commission Directive 2010/62/EU of 8 September 2010 (OJ L 238, 9.9. 2010, p. 7)
	12. Directive 2008/2/EC of the European Parliament and of the Council of 15 January 2008 on the field of vision and windscreen wipers for wheeled agricultural or forestry tractors (codified version) (OJ L 24, 29.1.2008, p. 30)

13. Directive 2009/57/EC of the European Parliament and of the Council of 13 July 2009 relating to the roll-over protection structures of wheeled agricultural or forestry tractors (codified version) (OJ L 261, 3.10.2009, p. 1)

14. Directive 2009/58/EC of the European Parliament and of the Council of 13 July 2009 on the coupling device and the reverse of wheeled agricultural or forestry tractors (codified version) (OJ L 198, 30.7.2009, p. 4)

15. Directive 2009/59/EC of the European Parliament and of the Council of 13 July 2009 on rear-view mirrors for wheeled agricultural or forestry tractors (codified version) (OJ L 198, 30.7.2009, p. 9)

16. Directive 2009/60/EC of the European Parliament and of the Council of 13 July 2009 on the maximum design speed of and load platforms for wheeled agricultural or forestry tractors (codified version) as last amended by Commission Directive 2010/62/EU of 8 September 2010 (OJ L 238, 9.9.2010, p. 7)

17. Directive 2009/61/EC of the European Parliament and of the Council of 13 July 2009 relating to the installation of lighting and light signalling devices on wheeled agricultural and forestry tractors (codified version) (OJ L 203, 5.8.2009, p. 19)

18. Directive 2009/63/EC of the European Parliament and of the Council of 13 July 2009 on certain parts and characteristics of wheeled agricultural or forestry tractors (codified version) (OJ L 214, 19.8.2009, p. 23)

19. Directive 2009/64/EC of the European Parliament and of the Council of 13 July 2009 on the suppression of radio interference produced by agricultural or forestry tractors (electromagnetic compatibility) (codified version) (OJ L 216, 20. 8.2009, p. 1)

20. Directive 2009/66/EC of the European Parliament and of the Council of 13 July 2009 on the steering equipment of wheeled agricultural or forestry tractors (codified version) (OJ L 201, 1.8.2009, p. 11)

21. Directive 2009/68/EC of the European Parliament and of the Council of 13 July 2009 on the component type-approval of lighting and light-signalling devices on wheeled agricultural or forestry tractors (codified version) (OJ L 203, 5.8.2009, p. 52)

22. Directive 2009/75/EC of the European Parliament and of the Council of 13 July 2009 on roll-over protection structures of wheeled agricultural or forestry tractors (static testing) (codified version) (OJ L 261, 3.10.2009, p. 40)

23. Directive 2009/76/EC of the European Parliament and of the Council of 13 July 2009 relating to the driver-perceived noise level of wheeled agricultural or forestry tractors (codified version) (OJ L 201, 1.8.2009, p. 18)

24. Directive 2009/144/EC of the European Parliament and of the Council of 30 November 2009 on certain components and characteristics of wheeled agricultural or forestry tractors (codified version), as last amended by Commission Directive 2010/62/EU of 8 September 2010 (OJ L 238, 9.9.2010, p. 7)

Switzerland

100. Ordinance of 19 June 1995 relating to the technical requirements for agricultural tractors (RO 1995 4171), as last amended on 2 March 2012 (RO 2012 1915)

101. Ordinance of 19 June 1995 relating to the type approval of road vehicles (RO 1995 3997), as last amended on 11 June 2010 (RO 2010 2749)'

Chapter 14 (Good Laboratory Practice, GLP)

In Section I, Legislative regulatory and administrative provisions, Provisions covered by Article 1(2), the reference to Swiss provisions should be deleted and replaced by the following text:

'Switzerland

100. Federal law of 7 October 1983 on the protection of the environment (RO 1984 1122), as last amended on 19 March 2010 (RO 2010 3233)

101. Federal law of 15 December 2000 on protection against dangerous substances and preparations (RO 2004 4763), as last amended on 17 June 2005 (RO 2006 2197)

102. Ordinance of 18 May 2005 on protection against dangerous substances and preparations (RO 2005 2721), as last amended on 10 November 2010 (RO 2010 5223)

103. Ordinance of 18 May 2005 on the authorisation of plant protection products (RO 2005 3035), as last amended on 17 June 2011 (RO 2011 2927)

104. Federal law of 15 December 2000 on medicinal products and medical devices (RO 2001 2790), as last amended on 12 January 2011 (RO 2011 725)

105. Ordinance of 17 October 2001 on medicinal products (RO 2001 3420), as last amended on 8 September 2010 (RO 2010 4039)'

Chapter 15 (Medicinal products GMP Inspection and batch certification)

Section I, Legislative regulatory and administrative provisions should be deleted and replaced by the following:

'SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union

1. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1), as last amended by Regulation (EU) No 1027/2012 of the European Parliament and of the Council of 25 October 2012 amending Regulation (EC) No 726/2004 as regards pharmacovigilance (OJ L 316, 14.11.2012, p. 38)

2. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as last amended by Directive 2012/26/EU of the European Parliament and of the Council amending Directive 2001/83/EC as regards pharmacovigilance (OJ L 299, 27.10.2012, p. 1)

3. Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33, 8.2.2003, p. 30), as last amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny — Part Four (OJ L 188, 18.7.2009, p. 14)

4. Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1) as last amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny — Part Four (OJ L 188, 18.7.2009, p. 14)

5. Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (OJ L 262, 14.10.2003, p. 22)

6. Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products (OJ L 228, 17.8.1991, p. 70)

7. Guidelines on Good Distribution Practice of medicinal products for human use (OJ C 63, 1.3.1994, p. 4) (published on website of the European Commission)

8. EudraLex Volume 4 — Medicinal Products for Human and Veterinary Use: EU Guidelines to Good Manufacturing Practice (published on website of the European Commission)

9. Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34)

10. Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (OJ L 91, 9.4.2005, p. 13)

	11. Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (OJ L 174, 1.7.2011, p. 74)
Switzerland	100. Federal Act of 15 December 2000 on medicinal products and medical devices (RO 2001 2790), as last amended on 12 January 2011 (RO 2011 725)
	101. Ordinance of 17 October 2001 on the establishment of licences (RO 2001 3399), as last amended on 25 May 2011 (RO 2011 2561)
	102. Ordinance of the Swiss Agency for Therapeutic Products of 9 November 2001 on the requirements for the marketing authorisation of medicinal products (RO 2001 3437), as last amended on 7 September 2012 (RO 2012 5651)
	103. Ordinance of 17 October 2001 on clinical trials of pharmaceutical products (RO 2001 3511), as last amended on 9 May 2012 (RO 2012 2777)'

DECLARATION FROM THE EUROPEAN COMMISSION

In order to ensure the effective implementation of Chapter 3, Toys, and in accordance with the Council Declaration on Swiss attendance of committees [1], the European Commission will consult Swiss experts in the preparatory stage of draft measures to be submitted subsequently to the Committee established by Article 47(1) of Directive 2009/48/EC.

[1] OJ L 114, 30.4.2002, p. 429.

NOTICE TO READERS

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