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COVER NOTE

from:	European Commission
date of receipt:	28 February 2012
to:	General Secretariat of the Council of the European Union
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Subject:	Draft Commission Regulation (EU) amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

Delegations will find attached Commission document D016833/03.

Encl.: D016833/03

EUROPEAN COMMISSION

Brussels, XXX
D016833/03
[…](2011) XXX draft

COMMISSION REGULATION (EU) No …/..

of XXX

amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

(Text with EEA relevance)

COMMISSION REGULATION (EU) No …/..

of XXX

amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

(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 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006[1], and in particular Article 37(5) thereof,

Whereas:

(1) Part 3 of Annex VI to Regulation (EC) No 1272/2008 contains two lists of harmonised classification and labelling of hazardous substances. Table 3.1 lists the harmonised classification and labelling of hazardous substances based on the criteria set out in Parts 2 to 5 of Annex I to Regulation (EC) No 1272/2008. Table 3.2 lists the harmonised classification and labelling of hazardous substances based on the criteria set out in Annex VI to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances[2]. Those two lists need to be amended to include updated classifications for substances already subject to those harmonised classifications and to include new harmonised classifications.

(2) The Committee for Risk Assessment of the European Chemicals Agency (ECHA) has issued opinions on proposals for harmonised classification and labelling of substances which had been submitted to ECHA pursuant to Article 37 of Regulation (EC) No 1272/2008. Based on those opinions, as well as on the comments received from the parties concerned, it is appropriate to amend Annex VI to Regulation (EC) No 1272/2008 in order to harmonise the classification and labelling of certain substances.

(3) The harmonised classifications set out in Part 3 of Annex VI to Regulation (EC) No 1272/2008, as amended by this Regulation, should not apply immediately, as a certain period of time will be necessary to allow operators to adapt the labelling and

[1] OJ L 353, 31.12.2008, p. 1.
[2] OJ 196, 16.8.1967, p. 1.

packaging of substances and mixtures to the new classifications and to sell existing stocks. In addition, a certain period of time will be necessary to allow operators to comply with the registration obligations resulting from the new harmonised classifications for substances classified as carcinogenic, mutagenic or toxic to reproduction, categories 1A and 1B (Table 3.1) and categories 1 and 2 (Table 3.2), or as very toxic to aquatic organisms which may cause long term effects in the aquatic environment, in particular with those set out in Article 23 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[3].

(4) In line with the transitional provisions of Regulation (EC) No 1272/2008 which allow the application of the new provisions at an earlier stage on a voluntary basis, suppliers should have the possibility of applying the harmonised classifications set out in Part 3 of Annex VI to Regulation (EC) No 1272/2008, as amended by this Regulation, and of adapting the labelling and packaging accordingly on a voluntary basis before 1 December 2013.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended as follows:

(1) Table 3.1 is amended as follows:

(a) The entries corresponding to the entries set out in Annex I are replaced by the entries set out in that Annex;

(b) The entries set out in Annex II are inserted in accordance with the order of the entries set out in Table 3.1.

(2) Table 3.2 is amended as follows:

(a) The entries corresponding to the entries set out in Annex III are replaced by the entries set out in that Annex;

(b) The entries set out in Annex IV are inserted in accordance with the order of the entries set out in Table 3.2.

[3] OJ L 136, 29.5.2007, p. 3.

Article 2

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

2. Article 1 shall apply from 1 December 2013.

3. The harmonised classifications set out in Part 3 of Annex VI to Regulation (EC) No 1272/2008, as amended by this Regulation, may be applied before 1 December 2013.

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

Done at Brussels,

For the Commission
The President
José Manuel BARROSO

ANNEX I

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard Statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
"009-016-00-2	trisodium hexafluoroaluminate [1] trisodium hexafluoroaluminate (cryolite) [2]	237-410-6 [1] 239-148-8 [2]	13775-53-6 [1] 15096-52-3 [2]	STOT RE 1 Acute Tox. 4 Aquatic Chronic 2	H372 H332 H411	GHS07 GHS08 GHS09 Dgr	H372 H332 H411			
603-012-00-X	2-ethoxyethanol; ethylene glycol monoethyl ether	203-804-1	110-80-5	Flam. Liq. 3 Repr. 1B Acute Tox. 3 Acute Tox. 4	H226 H360FD H331 H302	GHS02 GHS08 GHS06 Dgr	H226 H360FD H331 H302			
603-025-00-0	tetrahydrofuran	203-726-8	109-99-9	Flam. Liq. 2 Carc. 2 Eye Irrit. 2 STOT SE 3	H225 H351 H319 H335	GHS02 GHS07 GHS08 Dgr	H225 H351 H319 H335	EUH019	STOT SE 3; H335: C ≥ 25% Eye Irrit.2; H319: C ≥ 25%	
613-016-00-3	fuberidazole (ISO); 2-(2-furyl)-1*H*-benzimidazole	223-404-0	3878-19-1	Carc. 2 Acute Tox. 4 STOT RE 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H351 H302 H373 (heart) H317 H400 H410	GHS07 GHS08 GHS09 Wng	H351 H302 H373 (heart) H317 H410		M = 1	

617-001-00-2	di-*tert*-butyl peroxide	203-733-6	110-05-4	Org. Perox. E Flam. Liq. 2 Muta. 2	H242 H225 H341	GHS02 GHS08 Dgr	H242 H225 H341"			

ANNEX II

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard Statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
"015-199-00-X	tris[2-chloro-1-chloromethyl)ethyl] phosphate	237-159-2	13674-87-8	Carc. 2	H351	GSH08 Wng	H351			
015-200-00-3	indium phosphide	244-959-5	22398-80-7	Carc. 1B Repr. 2 STOT RE 1	H350 H361f H372 (lungs)	GHS08 Dgr	H350 H361f H372 (lungs)		STOT RE 1; H372: C ≥0,1% Carc 1B; H350: C ≥0,01% STOT RE 2; H373: 0,01% ≤ C < 0,1%	
015-201-00-9	trixylyl phosphate	246-677-8	25155-23-1	Repr. 1B	H360F	GHS08 Dgr	H360F			
015-202-00-4	tris(nonylphenyl) phosphite	247-759-6	26523-78-4	Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H317 H400 H410	GHS07 GHS09 Wng	H317 H410			

015-203-00-X	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	278-355-8	75980-60-8	Repr. 2	H361f (causing atrophy of the testes)	GHS08 Wng	H361f (causing atrophy of the testes)			
602-109-00-4	Hexabromocyclododecane [1] 1,2,5,6,9,10-hexabromocyclododecane [2]	247-148-4 [1] 221-695-9[2]	25637-99-4[1] 3194-55-6[2]	Repr. 2 Lact.	H361 H362	GHS08 Wng	H361 H362			
606-143-00-0	abamectin (combination of avermectin B1a and avermectin B1b) (ISO) [1] avermectin B1a (purity ≥80%); [2]	_ [1] 265-610-3 [2]	71751-41-2 [1] 65195-55-3 [2]	Repr. 2 Acute Tox. 2 Acute Tox. 1 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H361d H300 H330 H372 (nervous system) H400 H410	GHS06 GHS08 GHS09 Dgr	H361d H300 H330 H372 (nervous system) H410		STOT RE 1; H372: C ≥ 5% STOT RE 2; H373: 0,5% ≤C<5% M =10 000	
606-144-00-6	acequinocyl (ISO); 3-dodecyl-1,4-dioxo-1,4-dihydronaphthalen-2-yl acetate	_	57960-19-7	Skin Sens. 1 STOT SE 1 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H317 H370 (lung) (inhalation) H373 (blood system) H400 H410	GHS07 GHS08 GHS09 Dgr	H317 H370 (lung) (inhalation) H373 (blood system) H410		M = 1000	
607-698-00-1	4-*tert*-butylbenzoic acid	202-696-3	98-73-7	Repr. 1B STOT RE 1 Acute Tox. 4	H360F H372 H302	GHS07 GHS08 Dgr	H360F H372 H302			

612-281-00-2	leucomalachite green; N,N,N',N'-tetramethyl-4,4'-benzylidenedianiline	204-961-9	129-73-7	Carc. 2 Muta. 2	H351 H341	GHS08 Wng	H351 H341			
616-205-00-9	Metazachlor (ISO); 2-chloro-N-(2,6-dimethylphenyl)-N-(1H-pyrazol-1-ylmethyl)acetamide	266-583-0	67129-08-2	Skin Sens. 1B Carc. 2 Aquatic Acute 1 Aquatic Chronic 1	H317 H351 H400 H410	GHS07 GHS08 GHS09 Wng	H317 H351 H410		M = 100 M = 100"	

ANNEX III

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
"009-016-00-2	trisodium hexafluoroaluminate [1] trisodium hexafluoroaluminate (cryolite) [2]	237-410-6 [1] 239-148-8 [2]	13775-53-6 [1] 15096-52-3 [2]	Xn; R20 T; R48/23/25 N; R51-53	T; N R: 20-48/23/25-51/53 S: (1/2-)22-37-45-61		
603-012-00-X	2-ethoxyethanol; ethylene glycol monoethyl ether	203-804-1	110-80-5	R10 Repr. Cat. 2; R60-61 Xn; R20/22	T R: 60-61-10-20/22 S: 53-45		E
603-025-00-0	tetrahydrofuran	203-726-8	109-99-9	F; R11-19 Carc. Cat. 3; R40 Xi; R36/37	F; Xn R: 11-19-40-36/37 S: (2-)(13-)16-29-33-36-37(-46)	Xi; R36/37: C ≥ 25%	
613-016-00-3	fuberidazole (ISO); 2-(2-furyl)-1*H*-benzimidazole	223-404-0	3878-19-1	Carc. Cat. 3; R40 Xn; R48/22 Xn; R22 Xi; R43 N; R50-53	Xn; N R: 40-48/22-22-43-50/53 S: (2)-22-36/37-60-61	N; R50-53: C≥ 25% N; R51-53: 2,5 % ≤ C < 25 % R52-53: 0,25 % ≤ C < 2,5 %	
617-001-00-2	di-*tert*-butyl peroxide	203-733-6	110-05-4	O; R7 F; R11 Muta. Cat. 3, R68	O; F; Xn R: 7-11-68 S: (2-)3/7-14-16-23-36/37/39		

ANNEX IV

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
"015-199-00-X	tris[2-chloro-1-chloromethyl)ethyl] phosphate	237-159-2	13674-87-8	Carc. Cat. 3; R40	Xn R: 40 S: (2-)36/37		
015-200-00-3	indium phosphide	244-959-5	22398-80-7	Carc. Cat. 2; R45 Repr. Cat. 3; R62 T; R48/23	T R: 45–48/23–62 S: 45- 53	T; R48/23: C ≥0,1% Carc Cat 2; R45: C ≥0,01% Xn; R48/20: 0,01%≤ C < 0,1%	E
015-201-00-9	trixylyl phosphate	246-677-8	25155-23-1	Repr. Cat. 2; R60	T R: 60 S: 53-45		
015-202-00-4	tris(nonylphenyl) phosphite	247-759-6	26523-78-4	Xi; R43 N; R50-53	Xi; N R: 43-50/53 S: 24-37-60-61		
015-203-00-X	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	278-355-8	75980-60-8	Repr. Cat. 3; R62	Xn R: 62 S: (2)-22-36/37.		

602-109-00-4	Hexabromocyclododecane [1] 1,2,5,6,9,10-hexabromocyclododecane [2]	247-148-4 [1] 221-695-9[2]	25637-99-4[1] 3194-55-6[2]	Repr. Cat. 3; R63 R64	Xn R: 63-64 S: 36/37-53		
606-143-00-0	abamectin (combination of avermectin B1a and avermectin B1b) (ISO) [1] avermectin B1a (purity ≥80%); [2]	_ [1] 265-610-3 [2]	71751-41-2 [1] 65195-55-3 [2]	Repr. Cat. 3; R63 T+; R26/28 T ; R48/23/25 N; R50-53	T+; N R: 63-26/28-48/23/25-50/53 S: 28-36/37-45-60-61	T; R48/23: C ≥ 5% Xn; R48/20: 0,5% ≤ C <5% N; R50-53: C ≥ 0,0025% N; R51-53: 0,00025% ≤ C <0,0025% R52-53: 0,000025% ≤ C<0,00025%	
606-144-00-6	acequinocyl (ISO); 3-dodecyl-1,4-dioxo-1,4-dihydronaphthalen-2-yl acetate	_	57960-19-7	T; R39/23 Xi; R43 N; R50-53	T; N R: 39/23-43-50/53, S: (2-)24-37-38-60-61	N; R50-53: C ≥ 0,025% N; R51-53: 0,0025% ≤ C < 0,025% R52-53: 0,00025% ≤ C < 0,0025%	
607-698-00-1	4-*tert*-butylbenzoic acid	202-696-3	98-73-7	Repr. Cat. 2; R60 T; R48/23/24/25 Xn; R22	T R: 60-22-48/23/24/25 S: 53-45		E
612-281-00-2	leucomalachite green N,N,N',N'-tetramethyl-4,4'-benzylidenedianiline	204-961-9	129-73-7	Carc. Cat. 3; R40 Muta. Cat. 3; R68	Xn R: 40-68 S: (2-)36/37		
616-205-00-9	Metazachlor (ISO); 2-chloro-N-(2,6-dimethylphenyl)-N-(1H-pyrazol-1-ylmethyl)acetamide	266-583-0	67129-08-2	R43 Carc. Cat. 3; R40 N; R50-53	Xn; N R: 40-43-50/53 S: (2-)36-37-60-61	N; R50-53: C ≥ 0,25% N; R51-53: 0,025% ≤ C < 0,25% R52-53: 0,0025% ≤ C < 0,025%"	