



EUROPEAN COMMISSION

ENVIRONMENT DIRECTORATE-GENERAL
Water, Marine Environment & Chemicals
Chemicals, Biocides and Nanomaterials

ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL
Resources Based, Manufacturing and Consumer Goods Industries
REACH
Chemicals Industry

Brussels, 1 March 2013
Doc. **CA/3/2013**

12th Meeting of Competent Authorities for REACH and CLP 13 – 14 March 2013

- Concerns:** 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 (6th ATP)
- Agenda Point:** 12
- Action Requested:** Comments should be sent before CARACAL meeting to sylvain.bintein@ec.europa.eu and roberto.scazzola@ec.europa.eu or provided during CARACAL meeting.



Brussels, **XXX**
[...](2013) **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 1907/2006¹, 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 substances².
- (2) Proposals for new or updated harmonised classification and labelling of certain substances have been submitted to the European Chemicals Agency (ECHA) pursuant to Article 37 of Regulation (EC) No 1272/2008. Based on the opinions on those proposals issued by the Committee for Risk Assessment of ECHA, as well as on the comments received from the parties concerned, it is appropriate to introduce, remove or update harmonised classification and labelling of certain substances by amending Annex VI to that Regulation.
- (3) Compliance with the new harmonised classifications should not be required immediately, as a certain period of time will be necessary to allow operators to adapt the labelling and 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)

¹ OJ L 353, 31.12.2008, p. 1.

² OJ 196, 16.8.1967, p. 1.

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/EC³.

- (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 new harmonised classifications and of adapting the labelling and packaging accordingly on a voluntary basis before the deadline for compliance.
- (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 set out in Annex VI to Regulation (EC) No 1272/2008 corresponding to the entries set out in Annex I to this Regulation are replaced by the entries set out in Annex I to this Regulation;
- (b) The entries set out in Annex II to this Regulation are inserted in accordance with the order of the entries set out in Table 3.1;
- (c) The entry set out in Annex III to this Regulation is deleted from Table 3.1;

(2) Table 3.2 is amended as follows:

- (a) The entries set out in Annex VI to Regulation (EC) No 1272/2008 corresponding to the entries set out in Annex IV to this Regulation are replaced by the entries set out in Annex IV to this Regulation;
- (b) The entries set out in Annex V to this Regulation are inserted in accordance with the order of the entries set out in Table 3.2;
- (c) The entry set out in Annex III to this Regulation is deleted from Table 3.2.

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 April 2015.

³ OJ L 136, 29.5.2007, p. 3.

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 the date referred to in paragraph 2.

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)		
006-086-00-6	fenoxycarb (ISO); ethyl [2-(4-phenoxyphenoxy)ethyl]carbamate	276-696-7	72490-01-8	Carc. 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H400 H410	GHS08 GHS09 Wng	H351 H410		M =1 M =10000	
015-154-00-4	ethephon; 2-chloroethylphosphonic acid	240-718-3	16672-87-0	Acute Tox. 3 Acute Tox. 4 Acute Tox. 4 Skin Corr. 1C Aquatic Chronic 2	H311 H332 H302 H314 H411	GHS06 GHS05 GHS09 Dgr	H311 H332 H302 H314 H411	EUH071		
015-192-00-1	tetrakis(2,6-dimethylphenyl)- <i>m</i> -phenylene biphosphate	432-770-2	139189-30-3	Skin Sens. 1	H317	GHS07 Wng	H317			
601-023-00-4	ethylbenzene	202-849-4	100-41-4	Flam. Liq. 2 Acute Tox. 4* STOT RE 2 Asp. Tox. 1	H225 H332 H373 (hearing organs) H304	GHS02 GHS07 GHS08 Dgr	H225 H332 H373 (hearing organs) H304			
601-026-00-0	styrene	202-851-5	100-42-5	Flam. Liq. 3 Repr. 2	H226 H361d	GHS02 GHS08	H226 H361d		*	D

				Acute Tox. 4* STOT RE 1 Skin Irrit. 2 Eye Irrit. 2	H332 H372 (hearing organs) H315 H319	GHS07 GHS08 Dgr	H332 H372 (hearing organs) H315 H319			
603-061-00-7	tetrahydro-2-furylmethanol; tetrahydrofurfuryl alcohol	202-625-6	97-99-4	Repr. 1B Eye Irrit. 2	H360Df H319	GHS08 GHS07 Dgr	H360Df H319			
605-001-00-5	formaldehyde	200-001-8	50-00-0	Carc. 1B Muta. 2 Acute Tox. 3* Acute Tox. 3* Acute Tox. 3* Skin Corr. 1B Skin Sens. 1	H350 H341 H301 H311 H331 H314 H317	GHS08 GHS06 GHS05 Dgr	H350 H341 H301 H311 H331 H314 H317	* Skin Corr. 1B; H314: C ≥ 25 % Skin Irrit. 2; H315: 5 % ≤ C < 25 % Eye Irrit. 2; H319: 5 % ≤ C < 25 % STOT SE 3; H335: C ≥ 5 % Skin Sens. 1; H317: C ≥ 0,2 %	B, D	
616-035-00-5	cymoxanil (ISO); 2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino)acetamide	261-043-0	57966-95-7	Repr. 2 Acute Tox. 4 STOT RE 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H361fd H302 H373 (blood, thymus) H317 H400 H410	GHS08 GHS07 GHS09 Wng	H361fd H302 H373 (blood, thymus) H317 H410	M =1 M =1		

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)		
050-028-00-2	2-ethylhexyl 10-ethyl-4,4-dimethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate	260-829-0	57583-35-4	Repr. 2 Acute Tox. 4 STOT RE 1 Skin Sens. 1A	H361d H302 H372 (nervous system, immune system) H317	GHS08 GHS07 Dgr	H361d H302 H372 (nervous system, immune system) H317			
050-029-00-8	dimethyltin dichloride	212-039-2	753-73-1	Repr. 2 Acute Tox. 2 Acute Tox. 3 Acute Tox. 3 STOT RE 1 Skin Corr. 1	H361d H330 H301 H311 H372 (nervous system, immune system) H314	GHS08 GHS06 GHS05 Dgr	H361d H330 H301 H311 H372 (nervous system, immune system) H314	EUH071		
601-088-00-9	4-vinylcyclohexene	202-848-9	100-40-3	Carc. 2	H351	GHS08 Wng	H351			

601-089-00-4	muscalure; cis-tricos-9-ene	248-505-7	27519-02-4	Skin Sens. 1B	H317	GHS07 Wng	H317			
604-090-00-8	4-tert-butylphenol	202-679-0	98-54-4	Repr. 2 Skin Irrit. 2 Eye Dam. 1	H361f H315 H318	GHS08 GHS05 Dgr	H361f H315 H318			
604-091-00-3	etofenprox (ISO); 2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzyl ether	407-980-2	80844-07-1	Lact. Aquatic Acute 1 Aquatic Chronic 1	H362 H400 H410	GHS09 Wng	H362 H410		M =100 M =1000	
606-146-00-7	tralkoxydim (ISO); 2-[(1E)-N-ethoxypropanimidoyl]-3-hydroxy-5-mesitylcyclohex-2-en-1-one	-	87820-88-0	Carc. 2 Acute Tox. 4 Aquatic Chronic 2	H351 H302 H411	GHS08 GHS07 GHS09 Wng	H351 H302 H411			
606-147-00-2	cycloxydim (ISO); 2-(N-ethoxybutanimidoyl)-3-hydroxy-5-(tetrahydro-2H-thiopyran-3-yl)cyclohex-2-en-1-one	405-230-9	101205-02-1	Repr. 2	H361d	GHS08 Wng	H361d			
607-705-00-8	benzoic acid	200-618-2	65-85-0	STOT RE 1 Skin. Irrit. 2 Eye Dam. 1	H372 (lungs) (inhalation) H315 H318	GHS08 GHS05 Dgr	H372 (lungs) (inhalation) H315 H318			
607-706-00-3	methyl 2,5-dichlorobenzoate	220-815-7	2905-69-3	Acute Tox. 4 STOT SE 3 Aquatic Chronic 2	H302 H336 H411	GHS07 GHS09 Wng	H302 H336 H411			
612-287-00-5	fluazinam (ISO) ; 3-chloro-N-[3-chloro-2,6-dinitro-4-(trifluoromethyl)phenyl]-5-(trifluoromethyl)pyridin-2-amine	-	79622-59-6	Repr. 2 Acute Tox. 4	H361d H332	GHS08 GHS07	H361d H332			

				Eye Dam. 1 Skin Sens. 1A Aquatic Acute 1 Aquatic Chronic 1	H318 H317 H400 H410	GHS05 GHS09 Dgr	H318 H317 H410		M =10 M =10	
613-317-00-X	penconazole (ISO); 1-[2-(2,4-dichlorophenyl)pentyl]-1H-1,2,4-triazole	266-275-6	66246-88-6	Repr. 2 Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1	H361d H302 H400 H410	GHS08 GHS07 GHS09 Wng	H361d H302 H410		M =1 M =1	
613-318-00-5	fenpyrazamine (ISO); S-allyl 5-amino-2-isopropyl-4-(2-methylphenyl)-3-oxo-2,3-dihydro-1H-pyrazole-1-carbothioate	-	473798-59-3	Aquatic Chronic 2	H411	GHS09	H411			
616-212-00-7	3-iodo-2-propynyl butylcarbamate; 3-iodoprop-2-yn-1-yl butylcarbamate	259-627-5	55406-53-6	Acute Tox. 3 Acute Tox. 4 STOT RE1 Eye Dam. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H331 H302 H372 (larynx) H318 H317 H400 H410	GHS06 GHS08 GHS05 GHS09 Dgr	H331 H302 H372 (larynx) H318 H317 H410		M =10 M =1	

ANNEX III

The entry in Table 3.1 and Table 3.2 with the Index number: 015-188-00-X is deleted.

ANNEX IV

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
006-086-00-6	fenoxycarb (ISO); (ethyl [2-(4-phenoxyphenoxy)ethyl]carbamate	276-696-7	72490-01-8	Carc. Cat. 3; R40 N; R50-53	Xn; N R: 40-50/53 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 %	
015-154-00-4	ethephon; 2-chloroethylphosphonic acid	240-718-3	16672-87-0	C; R34 Xn; R20/21/22 N; R51-53	C; N R: 20/21/22-34-51/53 S: (1/2)-26-36/37/38-45-61	Xi; R37: 5 % < C < 10 %	
015-192-00-1	tetrakis(2,6-dimethylphenyl)-m-phenylene biphosphate	432-770-2	139189-30-3	R43	Xi R: 43 S: (2-)24-37		
601-023-00-4	ethylbenzene	202-849-4	100-41-4	F; R11 Xn; R20-R48/20-65	F; Xn R: 11-20-48/20-65 S: (2-)16-24/25-29-62		
601-026-00-0	styrene	202-851-5	100-42-5	Repr. Cat. 3; R63 Xn; R20-R48/20 Xi; R36/38 R10	Xn R: 10-20-36/38-48-63 S: (2-)23-36/37-45-53	Xn; R20: C ≥ 12,5 % Xi; R36/38: C ≥ 12,5 %	D
603-061-00-7	tetrahydro-2-furylmethanol; tetrahydrofurfuryl alcohol	202-625-6	97-99-4	Repr. Cat. 2; R61 Repr. Cat. 3; R62	T R: 36-61-62	Xi; R36/37/38: C ≥ 10 %	

				Xi; R36	S: 2-36/37/39-46		
605-001-00-5	formaldehyde	200-001-8	50-00-0	Carc. Cat. 2; R45 Muta. Cat. 3; R68 T; R23/24/25 C; R34 Xi; R43	T R: 23/24/25-34-43-45-68 S: (1/2-)26-36/37/39-45-51	T; R23/24/25: C $\geq$ 25 % Xn; R20/21/22: 5 % $\leq$ C < 25 % C; R34: C $\geq$ 25 % Xi; R36/37/38: 5 % $\leq$ C < 25 % R43: C $\geq$ 0,2 %	B, D
616-035-00-5	cymoxanil (ISO); 2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino)acetamide	261-043-0	57966-95-7	Repr. Cat. 3; R62-63 Xn; R22-48/22 R43 N; R50-53	Xn; N R : 22-43-48/22-62-63-50/53 S : (2-)36/37-46-60-61	N; R50-53: C $\geq$ 25 % N; R51-/53: 2,5 % $\leq$ C < 25 % R52-53: 0,25 % $\leq$ C < 2,5 %	

ANNEX V

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
050-028-00-2	2-ethylhexyl 10-ethyl-4,4-dimethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate	260-829-0	57583-35-4	Repr. Cat. 3; R63 T; 48/25 Xn; R22 R43	T R: 22-43-48/25-63 S: (1/2-)36/37-45-46		
050-029-00-8	dimethyltin dichloride	212-039-2	753-73-1	Repr. Cat. 3; R63 T+; R26 T; R24/25-48/25 C; R34	T+ R: 24/25-26-34-48/25-63 S: (1/2-)26-28-36/37-39-45-63		
601-088-00-9	4-vinylcyclohexene	202-848-9	100-40-3	Carc. Cat. 3; R40	Xn R: 40 S: 36/37		
601-089-00-4	muscalure; cis-tricos-9-ene	248-505-7	27519-02-4	R43	Xi R: 43 S: (2-)24-37		
604-090-00-8	4-tert-butylphenol	202-679-0	98-54-4	Repr. Cat. 3; R62 Xi; R38-41	Xn R: 38-41-62 S: (2-)26-36/37-39-46		
604-091-00-3	etofenprox (ISO); 2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzyl ether	407-980-2	80844-07-1	R64 N; R50-53	N R: 50/53-64	N; R50-53: C ≥ 0,25 % N; R51-53: 0,025	

					S: 60-61	% ≤ C < 0,25 % R52-53: 0,0025 % ≤ C < 0,025 %	
606-146-00-7	tralkoxydim (ISO); 2-[(1E)-N-ethoxypropanimidoyl]-3-hydroxy-5-mesitylcyclohex-2-en-1-one	–	87820-88-0	Carc. Cat. 3; R40 Xn; R22 N; R51-53	Xn; N R: 22-40-51/53 S: 36/37-60-61	N; R51-53: C ≥ 25 % R52-53: 2,5 % ≤ C < 25 %	
606-147-00-2	cycloxydim (ISO); 2-(N-ethoxybutanimidoyl)-3-hydroxy-5-(tetrahydro-2H-thiopyran-3-yl)cyclohex-2-en-1-one	405-230-9	101205-02-1	F; R11 Repr. Cat. 3	F; Xn R: 11-63 S: 2-16-36/37-46		
607-705-00-8	benzoic acid	200-618-2	65-85-0	T; R48/20 Xi; R38-41	T R: 38-41-48/20 S: (1/2-)26-39-45-63		
607-706-00-3	methyl 2,5-dichlorobenzoate	220-815-7	2905-69-3	Xn; R22 N; R51-53	Xn; N R: 22-51/53 S: (2)-60-61		
612-287-00-5	fluazinam (ISO); 3-chloro-N-[3-chloro-2,6-dinitro-4-(trifluoromethyl)phenyl]-5-(trifluoromethyl)pyridin-2-amine	–	79622-59-6	Repr. Cat. 3; R63 Xn; R20 Xi; R41 R43 N; R50-53	Xn; N R: 20-41-43-50/53-63 S: (2-)26-36/37-39-46-60-61	N; R50-53: C ≥ 2,5 % N; R51-53: 0,25 % ≤ C < 2,5 % R52-53: 0,025 % ≤ C < 0,25 %	
613-317-00-X	penconazole (ISO); 1-[2-(2,4-dichlorophenyl)pentyl]-1H-1,2,4-triazole	266-275-6	66246-88-6	Repr. Cat. 3; R63 Xn; R22 N; R50-53	Xn; N R: 22-50/53-63 S: (2)-36/37-46-60-61	N; R50-53: C ≥ 25 % N; R51-53: 2,5 % ≤ C < 25 % R52-53: 0,25 % ≤ C < 2,5 %	

613-318-00-5	fenpyrazamine (ISO); S-allyl 5-amino-2-isopropyl-4-(2-methylphenyl)-3-oxo-2,3-dihydro-1H-pyrazole-1-carbothioate	-	473798-59-3	N; R51-53	N R: 51/53 S: 60-61		
616-212-00-7	3-iodo-2-propynyl butylcarbamate; 3-iodoprop-2-yn-1-yl butylcarbamate	259-627-5	55406-53-6	T; R23-48/23 Xn; R22 Xi; R41 R43 N; R50	T; N R: 22-23-41-43-48/23-50 S: (1/2-)24-26-37-39-45-61-63	N; R50: C ≥ 2,5 %	