

## I

(Acts whose publication is obligatory)

**COMMISSION REGULATION (EC) No 1048/2005**

of 13 June 2005

**amending Regulation (EC) No 2032/2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market**

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market <sup>(1)</sup>, and in particular Article 16(2) thereof,

Whereas:

(1) Article 4 of Commission Regulation (EC) No 2032/2003 <sup>(2)</sup> lays down that, from the date of entry into force, any existing active substance not listed in Annex I to that Regulation is to be considered as not having been placed on the market for biocidal purposes before 14 May 2000. As a consequence biocidal products containing active substances not listed in Annex I may no longer be placed on the market, unless inclusion into Annex I or IA to Directive 98/8/EC is applied for in accordance with Article 11 of that Directive, and provisional authorisation has been received in accordance with Article 15(2) of that Directive. However, a limited number of active substances have been detected by the Member States which were not identified or notified before the time limit laid down in Commission Regulations (EC) No 1896/2000 <sup>(3)</sup> and (EC) No 1687/2002 <sup>(4)</sup> although there is evidence they were contained in biocidal products placed on the market before 14 May 2000. Some of these active substances are important from a socioeconomic perspective or for protection of public health. It is therefore appropriate to draw up a further list of active substances that should be allowed to remain on the market until 1 September 2006.

<sup>(1)</sup> OJ L 123, 24.4.1998, p. 1. Directive as amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

<sup>(2)</sup> OJ L 307, 24.11.2003, p. 1.

<sup>(3)</sup> OJ L 228, 8.9.2000, p. 6. Regulation as amended by Regulation (EC) No 2032/2003.

<sup>(4)</sup> OJ L 258, 26.9.2002, p. 15.

(2) Certain substances not included in Annex II to Regulation (EC) No 2032/2003 are applied in uses for which Member States claim that there is evidence demonstrating the essential need for reasons of health, safety, and protection of cultural heritage, or the use is critical for the functioning of society in the absence of technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment or health. It is therefore appropriate to introduce a system for applying for an extension of the period for marketing of biocidal products containing those substances. Such extensions should only be granted for the requesting Member States if the requests are justified, continued use does not give rise to concerns for human health and the environment, and, where appropriate, alternatives are being developed. The extension should only be allowed until 14 May 2010 at the latest.

(3) In accordance with Article 4(2) of Regulation (EC) No 2032/2003, placing on the market of biocidal products containing active substances not notified, or not notified for the appropriate product types, has to stop on 1 September 2006 at the latest. For certain substances or substance/product type combinations that have so far not been notified, there is now an interest by economic operators to prepare complete dossiers in view of their inclusion into Annex I or IA to Directive 98/8/EC. It is therefore appropriate, to introduce the possibility to prolong the marketing deadline for biocidal products containing such substances, in the product type concerned, provided interested operators submit complete dossiers well before 1 September 2006. If these dossiers are accepted, an extension of the period for placing those products on the market in the product types concerned should be allowed until the end of the evaluation of the complete dossiers, which should take place in parallel with the evaluation of the notified substances for the product types concerned.

Active substances for private area and public health area disinfectants and other biocidal products			Rapporteur Member State
Name (EINECS and/or others)	EC number	CAS number	
1-[[2-(2,4-Dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole/Propiconazole	262-104-4	60207-90-1	FI
Chlorocresol	200-431-6	59-50-7	FR
Glyoxal	203-474-9	107-22-2	FR
m-Cresol	203-577-9	108-39-4	FR
Phthalaldehyde	211-402-2	643-79-8	FR
Hydroxyl-2-pyridone	212-506-0	822-89-9	FR
Copper	231-159-6	7440-50-8	FR
Copper sulphate	231-847-6	7758-98-7	FR
Sodium p-chloro-m-cresolate	239-825-8	15733-22-9	FR
Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6)	Mixture	55965-84-9	FR
Monohydrochloride of polymer of N, N <sup>m</sup> -1,6-hexanediybis[N'-cyanoguanidine] (EINECS 240-032-4) and hexamethylenediamine (EINECS 240-679-6)/Polyhexamethylene biguanide (monomer: 1,5-bis(trimethylen)guanylguanidinium monohydrochloride)	Polymer	27083-27-8	FR
Oligo-(2-(2-ethoxy)ethoxyethyl guanidinium chloride)	Polymer	374572-91-5	FR
Poly-(hexamethylenediamine guanidinium chloride)	Polymer	57028-96-3	FR
Polyhexamethylene biguanide	Polymer	91403-50-8	FR
Peroxyoctanoic acid		33734-57-5	FR
1,3-Bis(hydroxymethyl)urea	205-444-0	140-95-4	HU
2-Butanone, peroxide	215-661-2	1338-23-4	HU
Tar acids, polyalkylphenol fraction	284-893-4	84989-05-9	HU
Reaction product of dimethyl adipate, dimethyl glutarate, dimethyl succinate with hydrogen peroxide/Perestane	432-790-1		HU
Silver-zinc-aluminium-boronphosphate oxide, silver- and zinc-containing glass/Glass	Not yet allocated	398477-47-9	HU