

COMMISSION REGULATION (EC) No 565/2006**of 6 April 2006****imposing testing and information requirements on the importers or manufacturers of certain priority substances in accordance with Council Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of risks of existing substances ⁽¹⁾, and in particular Articles 10(2) thereof,

Whereas:

- (1) The rapporteurs designated by the Member States in accordance with Article 10(1) of Regulation (EEC) No 793/93 have evaluated the information submitted by the manufacturers and importers in respect of certain priority substances. After consultation of those manufacturers and importers, the rapporteurs have determined that it is necessary for the purposes of the risk evaluation to require those manufacturers and importers to submit further information and carry out further testing.
- (2) The information needed to evaluate the substances in question is not available from former manufacturers or importers. The manufacturers and importers have checked that tests on animals cannot be replaced or limited by using other methods.
- (3) It is therefore appropriate to request manufacturers and importers of priority substances to submit further infor-

mation and carry out further testing of those substances. The protocols submitted by the rapporteurs to the Commission should be used for performing those tests.

- (4) The provisions of this Regulation are in accordance with the opinion of the Committee established pursuant to Article 15 of Regulation (EEC) No 793/93,

HAS ADOPTED THIS REGULATION:

Article 1

The manufacturers and importers of the substances listed in the Annex, who have submitted information in accordance with the requirements of Articles 3, 4, 7 and 9 of Regulation (EEC) No 793/93, shall provide the information and perform the tests indicated in the Annex and shall deliver the results to the relevant rapporteurs.

The tests shall be performed according to the protocols specified by the rapporteurs.

The results shall be delivered within the time limits laid down in the Annex.

Article 2

This Regulation shall enter into force on the 20th day following 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, 6 April 2006.

For the Commission

Stavros DIMAS

Member of the Commission

⁽¹⁾ OJ L 84, 5.4.1993, p. 1. Regulation as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

ANNEX

No	Einecs No	CAS No	Substance name	Rapporteur	Testing/Information requirements	Time limit from the date of entry into force of this Regulation
1	214-604-9	1163-19-5	Bis(pentabromophenyl)ether ⁽¹⁾	UK/F	Developmental neurotoxicity study in rats or mice	24 months
					Suitable human bio-monitoring programme, including breast milk and blood, and the need for a trend analysis over a certain period	Annual reporting over a period of 10 years
					Environmental monitoring programme including birds, sewage sludge, sediment, and air to establish time trends for the substance and its more toxic and bioaccumulative degradation products over a period of ten years	Annual reporting over a period of 10 years
2	237-158-7	13674-84-5	Tris(2-chloro-1-methylethyl) phosphate ⁽²⁾	UK/IRL	Data on releases and use pattern of certain life cycle stages	3 months
3	237-159-2	13674-87-8	Tris[2-chloro-1-(chloromethyl) ethyl] phosphate ⁽²⁾	UK/IRL	Data on releases and use pattern of certain life cycle stages	3 months
					Sediment-water <i>Chironomid</i> toxicity test using spiked sediment (OECD 218)	6 months
					Sediment-water <i>Lumbriculus</i> toxicity test using spiked sediment	6 months
					Sediment-water <i>Hyallella</i> toxicity test using spiked sediment	6 months
4	253-760-2	38051-10-4	2,2-Bis(chloromethyl) trimethylene bis (bis(2-chloroethyl) phosphate ⁽²⁾	UK/IRL	Data on releases and use pattern of certain life cycle stages	3 months
5	231-111-4 232-104-9 222-068-2 231-743-0 236-068-5	7440-02-0 7786-81-4 3333-67-3 7718-54-9 13138-45-9	Nickel ⁽³⁾ Nickel sulphate ⁽³⁾ Nickel carbonate ⁽²⁾ Nickel dichloride ⁽²⁾ Nickel dinitrate ⁽²⁾	DK	Information on ecotoxicity and bioavailability of nickel in laboratory studies	3 months
					Information on ecotoxicity, fate and bioavailability from field studies	6 months
					Information on toxicity of nickel in various soil types	6 months
					Development and validation of a chronic Biotic Ligand Model for <i>Rainbow trout</i>	3 months
					Development and validation of a chronic Biotic Ligand Model for algae and invertebrates	3 months
					Exposure information for derivation of PEC _{local} and PEC _{regional}	6 months
					Monitoring data of European surface waters	6 months
	232-104-9	7786-81-4	Nickel sulphate ⁽³⁾		Two-year oral carcinogenicity study with nickel sulphate in rats (OECD 451 — B32)	30 months
	231-111-4	7440-02-0	Nickel ⁽³⁾		Two-year inhalation carcinogenicity study with elemental nickel metal powder in rat (OECD 451 — B32)	30 months

No	Einecs No	CAS No	Substance name	Rapporteur	Testing/Information requirements	Time limit from the date of entry into force of this Regulation
6	221-221-0	3033-77-0	2,3-Epoxypropyltrimethyl ammonium chloride ⁽³⁾	FIN	Simulation test Aerobic sewage treatment, Activated sludge units (OECD 303A)	6 months
					Environmental exposure information	3 months
7	222-048-3	3327-22-8	(3-Chloro-2-hydroxypropyl) trimethyl ammonium chloride ⁽³⁾	FIN	Simulation test Aerobic sewage treatment, Activated sludge units (OECD 303A)	6 months
					Environmental exposure information	3 months
8	202-453-1	95-80-7	4-Methyl-m-phenylene-diamine ⁽¹⁾	D	Sediment-water <i>Lumbriculus</i> toxicity test using spiked sediment	6 months

⁽¹⁾ Substance listed in the Annex to Commission Regulation (EC) No 1179/94 (OJ L 131, 26.5.1994, p. 3; priority list 1).

⁽²⁾ Substance listed in the Annex to Commission Regulation (EC) No 2364/2000 (OJ L 273, 23.10.2000, p. 5; priority list 4).

⁽³⁾ Substance listed in the Annex to Commission Regulation (EC) No 143/97 (OJ L 25, 27.1.1997, p. 13; priority list 3).