COMMISSION REGULATION (EC) No 642/2005

of 27 April 2005

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 Article 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 information 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 twentieth 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, 27 April 2005.

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	201-245-8	80-05-7	4,4′-Isopropylidenediphenol (1)	UK	Long-term fish endocrine effects study with investigation of effects on sperm development	18 months
					Long-term toxicity study with an appropriate freshwater snail species	18 months
					2 generation study with 4,4′-isopropylidenediphenol in mice according to OECD 416 (with some specific modifications)	39 months
2	203-545-4	108-05-4	Vinyl acetate (2)	D	Further data on pattern of polymerisation facilities and information on exhaust air purification techniques for representative facilities	6 months
3	202-627-7	98-01-1	2-Furaldehyde (3)	NL	Long-term toxicity test with fish	6 months
					Long-term toxicity test with daphnia	6 months
4	201-622-7	85-68-7	Benzyl butyl phthalate (1)	N	Data about releases into the Wupper from all sources	12 months
					Plant fumigation test	12 months
					Long-term fish study on reproductive and endocrine effects	12 months
					Monitoring study on local air concentrations near flooring production sites and sealant formulation plants	12 months
5	201-329-4	81-15-2	5-Tert-butyl-2,4,6-trinitro-m-xylene (1)	NL	Biodegradation simulation test for determination of half-life in marine environment	18 months
6	200-663-8	67-66-3	Chloroform (3)	F	Environmental exposure information for production and uses	6 months
					Two long-term toxicity tests on sediment organisms	6 months
					Toxicity tests on micro-organisms: — tests on activated sludge for production sites — nitrification inhibition test — test on the inhibition of methanogenic bacteria	6 months
7	202-974-4	101-77-9	4,4′-Methylenedianiline (2)	D	Long-term toxicity test on sediment organisms (*Chironomus spec.*)	6 months
					Long-term toxicity test on sediment organisms (*Hyalella azteca*)	6 months

No	Einecs No	CAS No	Substance name	Rapporteur	Testing/information requirements	Time limit from the date of entry into force of this Regulation
8	231-152-8 215-146-2	7440-43-9 1306-19-0	Cadmium (1) Cadmium oxide (1)	B	Ecotoxicity tests under very low water hardness conditions	12 months
					Validation of applicability of SEM/AVS concept (bioavailability in sediment compartment)	12 months
9	231-668-3	7681-52-9	Sodium hypochlorite (3)	IT	Whole effluent assessment	9 months
10	247-148-4	25637-99-4	Hexabromocyclododecane (3)	S	Biodegradation simulation test providing valid half-lives as well as identification of metabolites	8 months
11	201-236-9	79-94-7	Tetrabromobisphenol-A (4)	UK	Clarification of use pattern	9 months
					Long term toxicity test with *Chironomus riparius* in sediment	9 months
					Long term toxicity test with *Chironomus riparius* in water	9 months
					Toxicity study with molluscs	9 months
					Investigation of degradation to bisphenol-A in sediment	9 months
12	287-476-5	85535-84-8	Alkanes, C_{10-13}, chloro (SCCPs) (2)	UK	Environmental exposure information on emissions	3 months
					Biodegradation simulation test to determine half-life in the marine environment	18 months

(1) Substance listed in the Annex to Commission Regulation (EC) No 143/97 (OJ L 25, 28.1.1997, p. 13; priority list No 3).
(2) Substance listed in the Annex to Commission Regulation (EC) No 1179/94 (OJ L 131, 26.5.1994, p. 3; priority list No 1).
(3) Substance listed in the Annex to Commission Regulation (EC) No 2268/95 (OJ L 231, 28.9.1995, p. 18; priority list No 2).
(4) Substance listed in the Annex to Commission Regulation (EC) No 2364/2000 (OJ L 273, 26.10.2000, p. 5; priority list No 4).