COMMISSION REGULATION (EC) No 506/2007

of 8 May 2007

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 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, 8 May 2007.

For the Commission Stavros DIMAS Member of the Commission

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.	237-158-7	13674-84-5	Tris(2-chloro-1-methylethyl) phosphate (TCPP)	IE/UK	— 2-generation study — fertility effects (OECD 416-B35)	24 months
					— In vivo Comet assay in rat liver	12 months
					In vitro percutaneous absorption of radiolabelled TCPP through human skin (OECD 428)	12 months
2.	237-159-2	13674-87-8	Tris[2-chloro-1-(chloro-methyl)ethyl] phosphate (TDCP)	IE/UK	— Sorption/desorption study (modified OECD 106 test)	6 months
3.	253-760-2	38051-10-4	2,2-Bis(chloromethyl) trimethylene bis(bis(2- chloroethyl)phosphate	IE/UK	— 2-generation study — fertility effects (OECD 416-B35)	24 months
			(V6)		In vitro percutaneous absorption of radiolabelled V6 through human skin (OECD 428)	12 months
4.	202-679-0	98-54-4	4-Tert-butylphenol	NO	Endocrine effects study with fish (draft OECD ext. ELS test)	18 months
5.	202-411-2	95-33-0	N-cyclohexylben- zothiazole-2-sulphe- namide	DE	Measured data from road border soils and surface waters receiving runoff from roads. The degradation products to be measured are 2-mercaptobenzothiazole, benzothiazole, 2-benzothiazolone, 2-methylthiobenzothiazole and 2-methylbenzothiazole	4 years
					Measured data on landfill leachate. The degradation products to be measured are 2-mercaptobenzothiazole, benzothiazole, 2-benzothiazolone, 2-methylthiobenzothiazole and 2-methylbenzothiazole	4 years
					Use and exposure information on tyre recycling, especially on tyre shredding facilities, on sport grounds using recycled tyre material and on other similar open uses of recycled tyres	4 years
6.	233-118-8	10039-54-0	Bis(hydroxylammonium) sulphate	DE	— Daphnia magna reproduction test (OECD 211)	3 months
					Exposure information from production and processing	3 months
					Literature data on/or an Activated sludge respiration inhibition test (OECD 209)	3 months

No	Einecs No	CAS No	Substance name	Rapporteur	Testing/Information requirements	Time limit from the date of entry into force of this Regulation
7.	201-245-8	80-05-7	4,4'-isopropylidenedi- phenol	UK	— Terrestrial plants growth test (OECD 208)	6 months
			Promot		— Enchytraeid reproduction test (OECD 220)	6 months
					Reproduction test with a suitable springtail species	6 months
8.	266-028-2	65996-93-2	Pitch, coal tar, high temp.	NL	— STP sludge inhibition test (OECD 209 — C11)	3 months