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)

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.

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EC) No 506/2007. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

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

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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-(chloromethyl)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 (V6)	IE/UK	— 2-generation study — fertility effects (OECD 416-B35)	24 months

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					— *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-cyclohexylbenzothiazole-2-sulphenamide	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-	4 years