# COMMISSION REGULATION (EC) No 2161/1999

## of 12 October 1999

## imposing further testing requirements on the importers or manufacturers of a certain priority substance as foreseen under Council Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances

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 the risks of existing substances [1] and in particular Article 10(2) thereof,

(1) Whereas Article 10 of Regulation (EEC) No 793/93 foresees that the Member State 'Rapporteur' for a given substance shall be responsible for evaluating the information submitted by the manufacturer(s) or importer(s) and for identifying, after consultation of the producers or importers concerned whether for the purposes of the risk evaluation it is necessary to require the above manufacturers or importers to submit further information or to carry out further testing;

(2) Whereas the Commission has been informed by one Member State Rapporteur of the need to impose on the importers or manufacturers of a certain priority substance undergoing risk evaluation activities a request for further testing within certain time limits;

(3) Whereas Article 12 of Regulation (EEC) No 793/93 foresees that in the case of a substance produced or imported as such or in a preparation by several manufacturers/importers, the further testing may be performed by one manufacturer/importer acting on behalf of the other manufacturers/importers concerned who shall make reference to the tests carried out and shall make a fair and equitable contribution to the cost;

(4) Whereas 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*

1. The manufacturer(s) and importer(s), referred to in Article 10(1) of Regulation (EEC) No 793/93, of the substance listed in the Annex to the present Regulation, shall perform the test there indicated and shall deliver the relevant results to the Member State Rapporteur.

2. These results shall be delivered within the time limits also indicated in the Annex (calculated from the date of entry into force of this Regulation).

*Article 2*

This Regulation shall enter into force on the third day following its publication in the *Official Journal of the European Communities*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 12 October 1999.

*For the Commission*

Margot WALLSTRÖM

*Member of the Commission*

[1] OJ L 84, 5.4.1993, p. 1.

*ANNEX*

| | Einecs No | CAS No | Substance name | Rapporteur | Testing requirements | Months |
|---|---|---|---|---|---|---|
| 1 | 263-125-1 | 61790-33-8 | Amines, tallow alkyl (1) | D | OECD TG 421 (2) | 6 |

(1) Substance listed in the Annex to Commission Regulation (EC) No 2268/95 (OJ L 231, 28.9.1995, p. 18)

(2) *OECD's Guideline for the testing of chemicals — Section 4 health effects* TG No 421: 'Reproduction/developmental toxicity screening test' (Original guideline adopted 27 July 1995)