II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 9 December 1991

establishing the conditions governing the notification of chemical substances existing on the market of the former German Democratic Republic prior to 18 September 1981 which do not appear on the inventory provided for in Article 13 of Directive 67/548/EEC

(Only the German text is authentic)

(92/3/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 90/660/EEC of 4 December 1990 on the transitional measures applicable in Germany with regard to certain Community provisions relating to the protection of the environment, in connection with the internal market [1],

Whereas Article 1 (2) of Directive 90/660/EEC provides that the Federal Republic of Germany shall take the measures necessary to ensure that substances and preparations which do not comply with Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances [2], as last amended by Directive 90/517/EEC [3], are not placed on the territory of the Community other than the territory of the former German Democratic Republic; whereas any substance which does not appear on the inventory provided for in Article 13 of Directive 67/548/EEC (European inventory of existing commercial chemical substances — Einecs [4]) must be notified in accordance with the provisions of that Directive; whereas the conditions governing the notification of substances existing on the market of the former German Democratic Republic prior to 18 September 1981 which do not appear on the inventory shall be laid down by the Commission;

Whereas any derogations from Community law provided for in connection with regard to the specific situation existing in the territory of the former German Democratic Republic must be temporary and cause the least possible disturbance to the functioning of the common market and must also reflect the high standard of protection for man and the environment achieved in the Community;

Whereas it seems, therefore, to be appropriate to subject chemical substances existing on the market of the former German Democratic Republic prior to 18 September 1981 which do not appear on the inventory to a simplified notification procedure with certain minimum requirements, similar to Article 6 (1) of Directive 67/548/EEC,

HAS ADOPTED THIS DECISION:

Article 1

This Decision concerns the conditions governing the notification of substances existing on the market of the former German Democratic Republic prior to 18 September 1981 which do not appear on the inventory provided for in Article 13 of Directive 67/548/EEC.

Article 2

Substances covered by this Decision are those which do not appear on the inventory provided for in Article 13 of Directive 67/548/EEC for which proof can be furnished to the satisfaction of the German competent authorities

[1] OJ No L 353, 17. 12. 1990, p. 79.
[2] OJ No 196, 16. 8. 1967, p. 1.
[3] OJ No L 287, 19. 10. 1990, p. 37.
[4] OJ No C 146A, 15. 6. 1990, p. 1.

established pursuant to Article 7 (1) of Directive 67/548/EEC, that they existed on the market in the territory of the former German Democratic Republic prior to 18 September 1981.

Article 3

For all substances defined in Article 2 the provisions of Directive 67/548/EEC are applicable unless otherwise specified.

Article 4

1. Manufacturers or importers of substances defined in Article 2, which are situated in the territory of the former German Democratic Republic and have to notify the substance, have to submit to the German competent authorities a provisional notification as soon as possible, but not later than 31 March 1992. The provisional notification shall include :

(a) a declaration concerning the unfavourable effects of the substance in terms of the various foreseeable uses ;

(b) the proposed classification and labelling of the substance in accordance with Directive 67/548/EEC ;

(c) proposals for any recommended precautions relating to the safe use of the substance ;

(d) a technical dossier supplying the information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may entail for man and the environment, and containing all available relevant data for this purpose.

2. The technical dossier referred to in Article 4 (1) (d) shall contain as a minimum the information and results of the studies referred to in Annex VII, Section 1 and 2, Section 3 points 3.1, 3.2, 3.6, 3.8, 3.9 and 3.10, and Section 4 points 4.1.1, 4.1.5 and 4.1.6 of Directive 67/548/EEC ; in addition, it shall contain a mutagenicity test, in which the substance should be examined in a bacteriological (reverse mutation) test with and without metabolic activation. Where information and results of studies additional to these minimal requirements are available they shall also be submitted ; this includes also studies referred to in Annex VIII of Directive 67/548/EEC. The results of studies shall be submitted together with a detailed and full description of the studies conducted and of the methods used or a bibliographical reference to them. Studies which have been initiated before 3 October 1990 and which have not been carried out in accordance with the methods laid down in Annex V of Directive 67/548/EEC and the principles of good laboratory practice provided for in Directive 87/18/EEC (1), may be accepted, if the data are adequate for the purpose of risk assessment.

(1) OJ No L 15, 17. 1. 1987, p. 29.

3. Substances defined in Article 2 which have not been provisionally notified according to paragraph 1 and 2 may not be placed on the market in the territory of the former German Democratic Republic after 31 March 1992.

Article 5

The German competent authorities shall examine the conformity of the data submitted in provisional notifications in order to assess compliance with the requirements of Article 4 (1) and (2). They shall send without delay copies of the provisional notification dossiers or summaries thereof to the Commission, which the Commission shall forward to the other Member States. The information will be exchanged according to Article 10 (1) of Directive 67/548/EEC.

Article 6

1. The German competent authorities shall evaluate the data submitted in provisional notifications and examined in accordance with Article 5, and shall where necessary decide, on a case by case basis and in consultation with the Commission, what additional data are required to complete the notification dossier.

2. The decision on additional data requirements has to be taken in view of the overall aim of Directive 67/548/EEC to assess the potential risks to man and the environment of chemical substances. It has to take into account in particular the available data, the intended use, and the tonnages of the substance to be marketed. The additional data shall not exceed those required pursuant to Article 6 (1) of Directive 67/548/EEC.

3. Decisions on additional information and testing requirements shall be communicated to the notifiers without undue delay.

4. The data required additionally have to be submitted to the German competent authorities by a date to be determined by them on a case by case basis, but not later than 12 months after the date on which the additional information and testing requirements were communicated to the notifier.

Article 7

1. Upon receipt of the additional data submitted in conformity with Article 6 the German competent authorities shall decide in consultation with the Commission whether the notification is finally accepted and communicate their decision to the notifier.

2. After a decision has been taken to accept a notification, the German competent authorities shall send without delay copies of the completed notification dossiers or summaries thereof to the Commission, which the Commission shall forward to the other Member States. The information shall be exchanged according to Article 10 of Directive 67/548/EEC.

Article 8

1. Substances which have been provisionally notified in accordance with Article 4 (1) and (2) and have been examined in accordance with Article 5 may be placed on the market of the Community, provided their label bears, in addition to the provisional label derived from the classification based on the tests already carried out, the warning: 'Caution — substance not yet fully tested'.

2. Substances shall no longer be placed on the market of the Community according to paragraph 1, if:

(a) additional data required according to Article 6 have not been submitted within the deadline; or

(b) the German competent authorities have decided not to accept the notification dossier according to Article 7 (1) and have communicated this decision to the notifier.

Article 9

Substances for which the notification dossier has been accepted in accordance with Article 7 (1) of this Decision will be considered as notified pursuant to Article 6 (1) of Directive 67/548/EEC. These substances shall be subject to the same obligations as other substances notified pursuant to Article 6 (1) of Directive 67/548/EEC, particularly with respect to additional information or studies.

Article 10

This Decision shall enter into force on 9 December 1991.

Article 11

This Decision is addressed to the Federal Republic of Germany.

Done at Brussels, 9 December 1991.

For the Commission

Carlo RIPA DI MEANA

Member of the Commission