

COMMISSION DECISION

of 7 December 1999

adopting measures prohibiting the placing on the market of toys and childcare articles intended to be placed in the mouth by children under three years of age made of soft PVC containing one or more of the substances di-iso-nonyl phthalate (DINP), di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), di-iso-decyl phthalate (DIDP), di-n-octyl phthalate (DNOP), and butylbenzyl phthalate (BBP)

(notified under document number C(1999) 4436)

(Text with EEA relevance)

(1999/815/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 92/59/EEC of 29 June 1992 on general product safety ⁽¹⁾, and in particular Article 9 thereof,

Whereas:

- (1) Pursuant to Article 3 of Directive 92/59/EEC, producers are obliged to place only safe products on the market; the Directive stresses in particular the need to ensure a high level of protection of the health and safety of children;
- (2) Article 9 of the Directive provides that the Commission may, under certain conditions and in conformity with the procedure set out in the Directive, adopt a decision requiring Member States to take temporary measures to prevent, restrict or submit to particular conditions the placing on the market of a product, or requiring its withdrawal from the market, if it presents a serious and immediate risk to the health and safety of consumers;
- (3) The Commission may adopt such a decision with regard to a product which, in accordance with information provided by a Member State, presents a serious and immediate risk and in respect of which one or more Member States have adopted measures entailing restrictions on the marketing of the product or requiring its withdrawal from the market;
- (4) Such a decision is subject to the conditions that Member States differ on the adoption of measures to deal with the risk in question; that the risk cannot be dealt with in a manner compatible with the urgency of the case under the other procedures laid down by the specific Community legislation applicable to the product or category of products concerned; that the risk can be eliminated effectively only by adopting appropriate measures applicable at Community level, in order to ensure the protection of the health and safety of consumers and the proper functioning of the internal market;
- (5) The Danish authorities have informed the Commission, in four notifications presented in April and July 1997 under Article 8 of Directive 92/59/EEC, of the serious and immediate risk presented by certain soft PVC teething rings containing the phthalates DINP, DEHP, DBP, DIDP, DNOP and BBP;
- (6) The Spanish authorities have informed the Commission, in a notification presented in the same framework in February 1998, of the risk presented by a soft PVC imitation fruit containing the phthalate DINP, intended for children;
- (7) The Greek authorities adopted on 15 January 1999 measures concerning the withdrawal from the market of soft PVC childcare articles intended for teething by infants and the prohibition of the import and marketing of certain soft PVC toys intended for children under the age of three years;
- (8) The Austrian authorities adopted on 4 August 1998 a law prohibiting toys containing phthalates; intended for children of less than three years of age, which are, under normal and foreseeable conditions of use, sucked, chewed or otherwise frequently placed in the mouth;
- (9) The Danish authorities issued on 15 March 1999 a Statutory Order prohibiting the production, import and marketing of childcare articles intended or likely to be placed in mouth, and of toys, and products which must be expected to be used as toys by children under the age of three years, or parts thereof, containing more than 0,05 % of phthalates;
- (10) The Swedish authorities adopted on 10 June 1999, a measure prohibiting the marketing and sale of phthalate-containing toys and childcare articles intended for children under three years of age and which can be put in the mouth;
- (11) The Finnish authorities adopted on 23 September 1999, a Resolution of the Council of State prohibiting childcare articles and toys which can be put into the mouth by children under three years of age which are made of soft PVC and contain more than 0,05 % by weight of DINP, DEHP, DBP, DIDP, DNOP or BBP;

⁽¹⁾ OJ L 228, 11.8.1992, p. 24.

- (12) The Italian authorities adopted on 30 September 1999 a measure prohibiting the marketing of soft plastic toys for children under three years of age intended or likely to be put in the mouth, containing more than 0,05 % of DINP, DIDP, DEHP, DBP, DNOP or BBP; in addition the Italian authorities notified the Commission on 14 June 1999 within the framework of Directive 98/34/EC of the European Parliament and of the Council ⁽¹⁾ as last amended by Directive 98/48/EC ⁽²⁾, of a draft measure prohibiting the use of four phthalates (DIDP, DEHP, DINP, DBP) in plastic materials and elastomers and restricting the use of certain other phthalates to a maximum of 5 % by weight in childcare articles;
- (13) The French authorities adopted on 5 July 1999 a measure suspending the marketing, production, import and export and ordering a withdrawal of certain toys and childcare articles intended for placing in the mouth by children under 36 months in soft PVC containing DINP, DIDP, DEHP, DBP, DNOP and BBP; they have in addition notified the Commission within the framework of Directive 98/34/EC of a draft measure prohibiting the use of DINP, DIDP, DEHP, DBP, DNOP and BBP in toys and childcare articles intended for placing in the mouth by children under three years of age;
- (14) The German authorities notified the Commission on 24 August 1999 within the framework of Directive 98/34/EC of a draft measure prohibiting the marketing, production and import of teething rings and certain plastic toys for children up to three years of age entirely or partly made of plastic materials, of which the plastic parts are intended or can be foreseen to be put in the mouth, containing more than 0,1 % of any phthalates;
- (15) All the abovementioned notifications and measures relate to the risks associated with exposure of children to phthalates and concern childcare products and/or toys made of soft PVC containing certain phthalates which are intended or likely to be placed in the mouth by young children;
- (16) The Commission adopted, on 1 July 1998 recommendation 98/485/EC ⁽³⁾ on phthalates in certain childcare articles and toys, on the basis of the scientific knowledge then available, inviting Member States to monitor the level of phthalate migration from the products in question, taking into account the opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) of 24 April 1998, and to take the measures required to ensure a high level of child health protection;
- (17) The Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE), consulted by the Commission, in its opinion on phthalates in toys of 27 November 1998, taking into account the results of the most recent relevant studies, has confirmed that there are grounds for concern with the low safety margins as regards the exposure of children to the phthalate DEHP and DINP, in connection with the use of certain toys and childcare articles made of soft PVC containing these substances;
- (18) The SCTEE has come to this conclusion on the basis, *inter alia*, of adverse effects of DINP for liver and kidney and testicular damage caused by DEHP observed in laboratory tests; it therefore appears that under certain conditions these substances may have serious adverse health effects:
- (19) In the light of the SCTEE opinion, the Commission considers that young children who use certain toys and childcare articles which are placed in the mouth, made of phthalate-containing soft PVC, may be subject to daily levels of exposure to DINP and DEHP higher than the levels deemed to be safe;
- (20) The SCTEE found the release of the other phthalates (DNOP, DIDP, BBP and DBP) to be low and to present no risk under current conditions of use. The Committee observed that a larger release would occur if they were used as plasticisers in higher concentrations;
- (21) The Commission considers that, should the use of DNOP, DIDP, BBP and DBP be allowed to replace DINP and DEHP, as a consequence of the prohibition of these two substances as plasticisers in the products in question, the exposure of children to them would increase and consequently the risk would be higher. Therefore, the Commission, adopting a precautionary approach, considers that this Decision should also apply to them;
- (22) Young children are also exposed to phthalates from sources other than PVC toys and childcare articles, but the level of exposure due to these sources cannot, according to the SCTEE opinion, be quantified because of lack of sufficient data; the existence of such additional exposure should however be taken into account in managing the risks in question;
- (23) Although the serious effects mentioned above do not become manifest until some time after exposure, the risk associated with the products in question is an immediate one because it is directly associated with exposure to the phthalates; such products, following the normal period of use by a child, may lead to significant exposure with serious effects later in life;
- (24) Therefore, the Commission considers that toys and childcare articles for young children made of soft PVC containing phthalates are liable to present a serious and immediate risk to health;

⁽¹⁾ OJ L 204, 21.7.1998, p. 37.

⁽²⁾ OJ L 217, 5.8.1998, p. 18.

⁽³⁾ OJ L 217, 5.8.1998, p. 35.

- (25) The products which pose the abovementioned risks are toys and childcare articles which are intended to be placed in the mouth by young children and are made of soft PVC containing one or more of the phthalates in question, because they are expected to be placed in the mouth for periods long enough and in a way liable to give rise to daily phthalate-extraction above the levels deemed to be safe; this Decision concerns, taken into account the nature of the risk, both products produced in the Community and imported products;
- (26) Denmark, Austria, Greece, Finland, Sweden, Italy, France and Germany have decided to submit the products belonging to the category in question to restrictive measures with different scope, aimed at eliminating the use of phthalates in this application; the Commission has ascertained, that Member States differ on the adoption of measures to deal with the risk in question;
- (27) Because of the differences between Member States and between the scope of the measures taken by certain Member States, a Community measure is necessary to eliminate the risk and effectively ensure a consistent high level of protection of child health and the proper functioning of the internal market;
- (28) Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations ⁽¹⁾, as last amended by Directive 1999/77/EC ⁽²⁾ applies to dangerous substances and preparations, but does not yet contain provisions concerning phthalates; Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys ⁽³⁾, as last amended by Directive 93/68/EEC ⁽⁴⁾, as regards dangerous substances refers to the relevant Community legislation relating to certain categories of products or to the prohibition, restriction of use or labelling of certain dangerous substances and preparations; it does not apply to childcare articles and does not provide for an emergency procedure;
- (29) The Danish authorities requested the Commission on 15 April 1998 to adopt a decision introducing restrictive measures in relation to the products in question, in compliance with Article 9 of Directive 92/59/FEC;
- (30) The European Parliament, in its resolution on a consumer policy action plan, adopted on 4 May 1999, has called on the Commission to take steps in removing phthalates from PVC toys intended for babies and young children ⁽⁵⁾;
- (31) The SCTEE, consulted by the Commission, has concluded in its opinion of 28 September 1999 on TNO, LGC and United States CPSC reports on phthalate-migration test validation that none of the phthalate-migration test methods which have been subject to validation attempts is currently suitable for control purposes;
- (32) In the absence of a test method of phthalate migration that has been validated and standardised at Community level, it is not currently feasible to guarantee a consistently high level of child health protection by laying down limits on the migration of these substances from the toys and childcare articles in question, and to ensure standard and non-discriminatory application of these limits; furthermore it is at present very difficult to establish phthalate migration limits which take account of the contribution to phthalate child exposure from sources other than PVC toys and childcare articles;
- (33) The scientific evidence on phthalate migration-test methods mentioned above, which has been made available recently, has shown that Recommendation 98/485/EC is not sufficient to ensure a consistent high level of child health protection; it is now urgent to prohibit rapidly the placing on the market of toys and childcare articles intended to be placed in the mouth by children under three years, because it has now become evident that there is no other effective control measure currently available for regulatory purposes;
- (34) The Commission has presented a proposal for an amendment to Directive 76/769/EEC on restrictions on the marketing and use of dangerous substances and preparations prohibiting, the use of DINP, DEHP, DIDP; DNOP, DBP and BBP in toys and childcare articles made of soft PVC and intended to be put in the mouth by children under the age of three. Furthermore, the placing on the market of such products is not allowed if they contain the mentioned phthalates; the proposal aims, in addition, at ensuring that other toys and childcare articles of soft PVC intended for children under the age of three and which could be put in the mouth should bear a label in order to ensure that the children do not put them in the mouth;
- (35) In order to ensure a consistent high level of child health protection throughout the EU, in the period preceding the adoption by the European Parliament and the Council of the proposed Directive and its implementation by the Member States, and given that toys and childcare articles of soft PVC containing phthalates intended for placing in the mouth by children under three years of age present a serious and immediate risk, it is necessary to prohibit immediately their placing on the market;

⁽¹⁾ OJ L 262, 27.9.1976, p. 201.

⁽²⁾ OJ L 207, 6.8.1999, p. 18.

⁽³⁾ OJ L 187, 16.7.1988, p. 1.

⁽⁴⁾ OJ L 220, 30.8.1993, p. 1.

⁽⁵⁾ OJ C 279, 1.10.1999, p. 86.

- (36) All the relevant phthalates must be covered by this Decision in order to eliminate those which are presently used and prevent use of the others which pose comparable risks for child health;
- (37) This Decision should eliminate the deliberate use of the relevant phthalates as plasticizers in the products in question, while acknowledging the possibility of their presence at a trace level of up to 0,1 % by weight which is considered a level allowing for non-intended impurities not giving rise to concern for child health;
- (38) The duration of the validity of this Decision is limited to three months; period of validity may be prolonged if necessary;
- (39) Pursuant to Article 11(3) of Directive 92/59/EEC Member States shall take all necessary measures to implement the decision adopted within less than 10 days;
- (40) The measures provided for in this Decision are in accordance with the opinion of the Emergencies Committee,

HAS ADOPTED THIS DECISION:

Article 1

This Decision shall apply to toys and childcare articles:

- made of, or in part made of; soft PVC containing more than 0,1 % by weight of one or more of the following substances:
 - di-isononyl phthalate (DINP) CAS No 28553-12-0 Einecs No 249-079-5,
 - di(2-ethylhexyl) phthalate (DEHP) CAS No 117-81-7 Einecs No 204-211-0,
 - di-n-octyl phthalate (DNOP) CAS No 117-84-0 Einecs No 204-214-7,
 - di-iso-decyl phthalate (DIDP) CAS No 26761-40-0 Einecs No 247-977-1,

- butyl benzyl phthalate (BBP) CAS No 85-68-7 Einecs No 201-622-7,
 - dibutyl phthalate (DBP) CAS No 84-74-2 Einecs No 201-557-4,
- intended to be placed in the mouth by children of less than three years of age.

Article 2

For the purposes of this Decision:

- a 'toy' shall mean any product designed or clearly intended for use in play by children,
- childcare article shall mean any product intended to facilitate sleep, relaxation, the feeding of children, or sucking on the part of children.

Article 3

Member States shall prohibit the placing on the market of the toys and childcare articles referred to in Article 1.

Article 4

Member States shall take the measures necessary to comply with this Decision within less than 10 days of its notification. They shall forthwith inform the Commission thereof.

Article 5

This Decision shall be applicable until 8 March 2000.

Article 6

This Decision is addressed to the Member States.

Done at Brussels, 7 December 1999.

For the Commission

David BYRNE

Member of the Commission