

Opinion of the Economic and Social Committee on the 'Proposal for a Directive of the European Parliament and of the Council amending for the 22nd time Directive 76/769/EEC 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 (phthalates) and amending Council Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys'

(2000/C 117/12)

On 29 February 2000, the Council decided to consult the Economic and Social Committee, under Article 95 of the Treaty establishing the European Community, on the above-mentioned proposal.

The Section for the Single Market, Production and Consumption, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 15 February 2000. The rapporteur was Mrs Williams.

At its 370th plenary session on 1 and 2 March 2000 (meeting of 1 March), the Economic and Social Committee adopted the following opinion by 27 votes to twenty-one, with eight abstentions.

1. Introduction

1.1. First and foremost, the present proposal relates to the high level of protection of health and safety of consumers endorsed in the EU Treaty and continuing now in the Amsterdam Treaty under Article 153. The Commission proposes to ban the use of six toxic phthalates in certain products for babies and small children — the weakest and most vulnerable consumers. It sets out a twenty-second amendment to the existing Directive on dangerous substances⁽¹⁾ and adds a separate amendment to the Directive on toy safety⁽²⁾.

1.2. Nevertheless, the proposal has wide-ranging general implications. It is concerned with the following major issues or subjects:

1.2.1. the harmonisation of practices and the establishment of uniform rules in both the Internal Market and the 'candidate' countries;

1.2.2. the interaction with other Directives, such as the use of emergency procedures outlined in Article 9 of the General Product Safety Directive (GPSD)⁽³⁾;

1.2.3. the validity of test methods used to ascertain the level of release of phthalates;

1.2.4. pressures from environmental groups on a subject bound to arouse emotion as well as practical considerations;

1.2.5. the growing emphasis on risk assessment procedures and the use of the precautionary principle.

1.2.5.1. The relevance of the precautionary principle in particular must be highlighted. This is a relatively new procedure described in a recent Communication from the Commission⁽⁴⁾, and this is only the third time it has been invoked. The procedure enables the Commission to take preventive action where evidence is 'insufficient, inconclusive or uncertain' but where failure to act would result in excessive risk to public health or the environment (as in the case of dioxins in Belgian food). The central principle is that when there is a potential threat, risk assessment studies should be carried out; nevertheless, the results do not have to be conclusive for action to be taken. 'The absence of scientific proof ... should not be used to justify inaction.'

2. Background information

2.1. What are phthalates?

Six phthalates, itemised in an Annex, are the subject of the present proposal. They are long established chemicals which are added to hard plastic (like polyvinyl chloride — PVC) to soften it. The softened plastic can then be used to make products for babies and small children under thirty-six months such as teething rings, dummies, rattles and some toys such as bathtime ducks. The commonest phthalate in use for products such as teething rings has been di-'isononyl' phthalate (DINP). Some phthalates can also occur naturally in foods such as bananas.

2.2. What are the problems with phthalates?

Phthalates are not bound into the PVC and can over time migrate or leach. Tests on rats show that phthalates can cause hormonal disturbances as well as cancer with consequent damage to liver, kidneys and testicles. The particular risk is to babies and small children who chew and suck over prolonged

(1) Directive 76/769/EEC, OJ L 262, 27.9.1976, p. 201.

(2) Directive 88/378/EEC, OJ L 187, 16.7.1988, p. 1.

(3) Directive 92/59/EEC, OJ L 228, 11.8.1992, p. 24.

(4) COM(2000) 1 final of 2.2.2000.

periods. Their chewing action can break down the plastic which accelerates the release of phthalates and its consequent migration into their saliva. Moreover, an Acceptable Daily Intake (ADI) tolerable in an adult is not tolerable in a baby because of its lower body weight. Phthalates may be cumulative and can be absorbed by the baby from other sources e.g. through breast milk.

2.2.1. Therefore there has been a strong call from certain Member States for a ban on phthalates in products for infants, which resulted in a Recommendation in July 1998⁽¹⁾ (rather than the emergency ban Commissioner Bonino would have wished). There has also been pressure from environmental groups for a ban as part of a broader campaign for the removal of all PVC products. The Scientific Committee on Toxicology, Ecotoxicology and the Environment produced its Opinion in Autumn 1999.

2.2.2. The Commission, through the emergency procedures in the GPSD, has received the agreement of Member States to a temporary and interim ban of the six phthalates on the grounds that they pose a serious risk to child health. This measure came into effect on 19 December 1999.

2.2.3. This present proposal deals with the amendment of legislation in the longer term.

3. General Comments: the Committee's view

3.1. First, the Committee supports the Commission's immediate ban on phthalates in certain childcare products and accordingly Article 1 of the proposed Directive.

3.1.1. Since the ban is an interim and temporary measure to be reviewed on 8 March, the Committee asks what future transitional procedures are to be followed.

3.1.2. The Committee realises that the Commission had two choices: either to impose a ban or to rely on stringent tests for maximum release limits against which checks could be instituted. Since such test methods for phthalates are still uncertain, unreliable and unable to be reproduced in view of the difficulty in simulating the sucking and chewing action of a baby, the Committee accepts the Commission's decision invoking the Precautionary Principle. Moreover, it points out that alternatives which may be developed could present new doubts and uncertainties and accordingly calls for much further research.

3.2. Secondly, regarding future action, the Committee questions the Commission's procedure (outlined in Article 2) for dealing with products which can be put in the mouth although not intended for that purpose. The Commission intends to deal with the risks inherent in such items — predominantly toys where the length of sucking/chewing time is less — via labelling which will provide warnings to parents and other carers of small children.

3.2.1. The Committee emphasises the practical difficulties in formulating any form of cautionary words which can reasonably cover the huge range of children's products involved, particularly if such words have to appear on the product as well as on the packaging in several languages.

4. Specific comments

4.1. Article 1

The Committee accepts this Article as the only possibility under present circumstances with the general reservations already expressed. There are the following additional points to be raised:

4.1.1. The Committee regrets that the final amendment to the legislation on the marketing of dangerous products can only be applied several years from now 'for procedural reasons' but notes that the bridging mechanisms to be put in place must continue to ensure the safety of babies and young children.

4.1.2. The Committee points out the particular problem of controlling the supply of items handed down in families and used by children in different age groups. It also notes the problem of childcare products sold second hand (e.g. in charity shops).

4.1.3. The Committee stresses the importance of enforcement (with Europe-wide co-ordination) by responsible authorities, bearing in mind the problems of those countries where there is not always a single authority.

4.1.4. The Committee emphasises the need for constant and effective monitoring of the ban, with special market surveillance for products imported from third and third-world countries.

4.1.5. The Committee stresses the need for effective communication with parents and all those responsible for childcare on the subject of product safety in general and on phthalates in particular, with special consideration given to the extension of Helpline telephone numbers provided on packaging by some manufacturers. It also calls for sensitive, non-authoritarian education, starting at an early age, relating to the care and behaviour of babies and small children.

⁽¹⁾ Recommendation 98/485/EC, OJ L 217, 5.8.1998, p. 35.

4.2. Article 2

The Committee points out that the severity of these warnings is such that they are effectively a ban. The suggested wording of such labels, moreover, is difficult and fails to communicate adequately.

Nevertheless, if such labelling is finally accepted as an appropriate measure, then the Committee makes the following comments.

4.2.1. It is not enough for any warning to be legible and indelible. It must also be understandable.

4.2.2. The Committee questions the practicality — both in design and manufacture — of applying permanent warning labels to small items intended for children, particularly if a range of languages is involved.

4.3. Since the risk inherent in sucking or chewing a toy intermittently is slight, then the Committee recommends for the time being that the proposed cautionary labelling on actual

products should be dropped in the light of the difficulties it would cause. Warnings should appear on packaging where size permits. The precautionary principle invoked states that measures based on the precautionary principle must be proportionate to the risk which is to be limited or eliminated.

5. Conclusion

5.1. The Committee reiterates the over-riding importance of safety, particularly where children are concerned, and supports the Commission's efforts in introducing the current ban. It remains concerned, however, that the validity of present test methods to ascertain the level of release of phthalates is still uncertain, and that alternative materials provide new doubts. It accordingly calls for much further research.

5.2. The Committee accepts that the Commission in Article 2 is indicating its belief in parents' right to information by providing stringent warnings on both packaging and actual childcare items. If the Commission persists in enforcing these warnings, both their language and practicality of communication must be taken into account.

Brussels, 1 March 2000.

The President
of the Economic and Social Committee
Beatrice RANGONI MACHIAVELLI
