

## COMMISSION DECISION

of 28 May 2009

## amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of organostannic compounds for the purpose of adapting its Annex I to technical progress

(notified under document number C(2009) 4084)

(Text with EEA relevance)

(2009/425/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Committee on Health and Environmental Risks (SCHER) in its opinion of 30 November 2006 <sup>(5)</sup>.

Having regard to the Treaty establishing the European Community,

Having regard to 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 the restrictions on the marketing and use of dangerous substances and preparations <sup>(1)</sup>, and in particular Article 2a thereof,

Whereas:

- (1) Tri-substituted organostannic compounds were previously widely used in antifouling paints on ships. However, such paints were found to pose risks for aquatic organisms through endocrine disruptive effects. The use of organostannic compounds, also known as organotin compounds, in antifouling paints was therefore restricted in Directive 76/769/EEC, and in Regulation (EC) No 782/2003 of the European Parliament and of the Council of 14 April 2003 on the prohibition of organotin compounds on ships <sup>(2)</sup>. Furthermore, tri-substituted organostannic compounds may no longer be used as biocides under Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market <sup>(3)</sup>. However articles treated with such biocides may still be imported into the Community.
- (2) Di-substituted organostannic compounds, including in particular dibutyltin compounds (DBT) and dioctyltin compounds (DOT), are widely used in consumer articles where they function either as a stabilizer or as a catalyst.
- (3) The use of organostannic compounds in consumer articles has been found to pose a risk to human health, particularly for children. The specific risks to the health of children and adults from various consumer articles have been identified in a risk assessment <sup>(4)</sup>, and have been confirmed by the Commission's Scientific

- (4) Although di-substituted and tri-substituted organostannic compounds have the same adverse health effect, namely immunotoxicity via the thymus gland, and act in a cumulative way, the potency of the tri-substituted compounds (such as TBT and TPT) is greater than that of the di-substituted compounds (DOT and DBT). Furthermore, tri-substituted organostannic compounds being emitted from articles for either consumer or professional use could have adverse effects on the environment — in particular on aquatic organisms. More severe restrictions should therefore be imposed on articles containing tri-substituted organostannic compounds.
- (5) Certain DBT compounds (dibutyltin dichloride, CAS: 683-18-1, and dibutyltin hydrogen borate, CAS: 75113-37-0) will soon be classified in the framework of Council Directive 67/548/EEC <sup>(6)</sup> as toxic to reproduction, category 2, and it will subsequently be prohibited to sell the substances and mixtures containing them to consumers <sup>(7)</sup>. More severe restrictions should therefore be imposed on articles containing DBT compounds, allowing for continued use for an additional period of time only where no suitable alternatives are available such as catalysts in RTV-1 and RTV-2 sealants, paints and coatings, or PVC stabilisers in certain products (for example coated fabrics, PVC profiles) to allow the development of suitable alternatives, or where the articles concerned are already regulated by other more specific legislation.
- (6) Exposure to DOT compounds is highest from certain specific consumer articles such as printed textiles, gloves, footwear, wall and floor coverings, female hygiene products, nappies, and two-component silicone moulds.
- (7) Despite the availability of alternatives for most uses to be restricted, certain producers of articles containing DOT and DBT will need time to adapt, and an appropriate transition period should be therefore foreseen for these applications.

<sup>(1)</sup> OJ L 262, 27.9.1976, p. 201.

<sup>(2)</sup> OJ L 115, 9.5.2003, p. 1.

<sup>(3)</sup> OJ L 123, 24.4.1998, p. 1.

<sup>(4)</sup> Risk assessment studies on targeted consumer applications of certain organotin compounds. RPA study finalised in September 2005. [http://ec.europa.eu/enterprise/chemicals/studies\\_en.htm](http://ec.europa.eu/enterprise/chemicals/studies_en.htm)

<sup>(5)</sup> [http://ec.europa.eu/health/ph\\_risk/committees/04\\_scher/scher\\_opinions\\_en.htm](http://ec.europa.eu/health/ph_risk/committees/04_scher/scher_opinions_en.htm)

<sup>(6)</sup> OJ 196, 16.8.1967, p. 1.

<sup>(7)</sup> In accordance with entries 29, 30 and 31 of Directive 76/769/EEC.

- (8) Directive 76/769/EEC should therefore be amended accordingly.
- (9) This Decision is without prejudice to the Community legislation laying down minimum requirements for the protection of workers, such as Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work <sup>(1)</sup> and individual Directives based thereon, in particular Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (codified version) <sup>(2)</sup> and Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) <sup>(3)</sup>.
- (10) The measures provided for in this Decision are in accordance with the opinion of the Committee on the

adaptation to technical progress of the Directives for the elimination of technical barriers to trade in dangerous substances and preparations,

HAS ADOPTED THIS DECISION:

*Article 1*

Annex I to Directive 76/769/EEC is amended in accordance with the Annex to this Decision.

*Article 2*

This Decision is addressed to the Member States.

Done at Brussels, 28 May 2009.

*For the Commission*

Günter VERHEUGEN

*Vice-President*

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<sup>(1)</sup> OJ L 183, 29.6.1989, p. 1.

<sup>(2)</sup> OJ L 158, 30.4.2004, p. 50; corrected by OJ L 229, 29.6.2004, p. 23.

<sup>(3)</sup> OJ L 131, 5.5.1998, p. 11.

## ANNEX

The following paragraphs are added to Entry 21, 'Organostannic compounds', of Annex I to Directive 76/769/EEC:

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4. Tri-substituted organostannic compounds
- (a) Tri-substituted organostannic compounds such as tributyltin (TBT) compounds and triphenyltin (TPT) compounds shall not be used after 1 July 2010 in articles where the concentration in the article, or part thereof, is greater than the equivalent of 0,1 % by weight of tin.
  - (b) Articles not complying with paragraph 4(a) shall not be placed on the market after 1 July 2010, except for articles that were already in use in the Community before that date.
5. Dibutyltin (DBT) compounds
- (a) Dibutyltin (DBT) compounds shall not be used after 1 January 2012 in mixtures and articles for supply to the general public where the concentration in the mixture or the article, or part thereof, is greater than the equivalent of 0,1 % by weight of tin.
  - (b) Articles and mixtures not complying with paragraph 5(a) shall not be placed on the market after 1 January 2012, except for articles that were already in use in the Community before that date.
  - (c) By way of derogation, paragraphs 5(a) and (b) shall not apply until 1 January 2015 to the following articles and mixtures for supply to the general public:
    - one-component and two-component room temperature vulcanisation sealants (RTV-1 and RTV-2 sealants) and adhesives,
    - paints and coatings containing DBT compounds as catalysts when applied on articles,
    - soft polyvinyl chloride (PVC) profiles whether by themselves or coextruded with hard PVC,
    - fabrics coated with PVC containing DBT compounds as stabilisers when intended for outdoor applications,
    - outdoor rainwater pipes, gutters and fittings, as well as covering material for roofing and façades.
  - (d) By way of derogation, paragraphs 5(a) and (b) shall not apply to materials and articles regulated under Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food (\*).
6. Dioctyltin (DOT) compounds
- (a) Dioctyltin (DOT) compounds shall not be used after 1 January 2012 in the following articles for supply to, or use by, the general public, where the concentration in the article, or part thereof, is greater than the equivalent of 0,1 % by weight of tin:
    - textile articles intended to come into contact with the skin,
    - gloves,
    - footwear or part of footwear intended to come into contact with the skin,
    - wall and floor coverings,
    - childcare articles,
    - female hygiene products,
    - nappies,
    - two-component room temperature vulcanisation moulding kits (RTV-2 moulding kits),
  - (b) Articles not complying with paragraph 6(a) shall not be placed on the market after 1 January 2012, except for articles that were already in use in the Community before that date.
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(\* ) OJ L 338, 13.11.2004, p. 4.