

**Opinion of the European Economic and Social Committee on the 'Proposal for a Directive of the European Parliament and of the Council relating to restrictions on the marketing and use of toluene and trichlorobenzene (twenty-eighth amendment of Council Directive 76/769/EEC)'**

(COM(2004) 320 final - 2004/0111 (COD))

(2005/C 120/02)

On 11 May 2004, the Council decided to consult the European Economic and Social Committee, under Article 95 of the Treaty establishing the European Community, on the abovementioned 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 6 October 2004. The rapporteur was Mr Sears.

At its plenary session of 27 and 28 October 2004 (meeting of 27 October), the European Economic and Social Committee adopted the following opinion by 165 votes to 1, with 5 abstentions:

## 1. Introduction

1.1 'Existing' substances are substances deemed to have been on the European Community market between 1 January 1971 and 18 September 1981. 100,195 such substances were identified and listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) published in the Official Journal in 1990<sup>(1)</sup>. Substances placed on the market after 18 September 1981 are defined to be 'new' and require pre-marketing notification under the relevant European Union legislation.

1.2 Risks to human health and the environment of these existing substances have been routinely assessed under Council Regulation (EEC) 793/93<sup>(2)</sup>. To date, four priority lists for assessment have been established, for implementation by the competent authorities in Member States. The last of these was dated 25 October 2000<sup>(3)</sup>. These identified 141 substances where some risk might be expected either due to their specific structures and known or anticipated biochemical interactions, or where their high production volumes (HPV) gave rise to concern.

1.3 Member States assess each substance at all stages of manufacture and use for both hazard and exposure to determine whether or not there are indeed risks to health and the environment and if there are, what risk reduction measures might be required. If it is determined that, despite being on a priority list for assessment, there are no or very low risks in any actual or planned use, control measures are either not required or are likely to be low in both impact and benefit.

1.4 Completed Risk Assessment Reports (RARs) from the Member States have in turn been evaluated by the Scientific Committee on Toxicity, Ecotoxicity and the Environment

(CSTEE). If the CSTEE agrees with the conclusions and supports the overall assessment process, risk reduction measures, if required, can be proposed as amendments to Annex 1 of the Council Directive on the marketing and use of certain dangerous substances and preparations 76/769/EEC<sup>(4)</sup>. The present proposal is the twenty-eighth such amendment.

1.5 The two substances (toluene and trichlorobenzene) referred to in the proposal have been assessed in accordance with the above procedure. Both were included in the second list of priority substances published as Commission Regulation EC 2268/95 of 27 September 1995<sup>(5)</sup>. Both were awarded to Denmark for the process of assessment. The CSTEE substantially agreed with and supported the subsequent RARs in Opinions delivered at its 24<sup>th</sup> and 25<sup>th</sup> plenary meetings on 12 June 2001 and 20 July 2001 respectively.

1.6 This proposal sets out risk reduction measures for the two substances to be implemented by Member States within eighteen months of the entry into force of the Directive. The Commission published the proposal on 28 April 2004. After following due procedures, and if agreement can be reached on any changes required, it should take effect in Member States by no later than June 2006.

## 2. Summary of the Commission's proposal

2.1 The proposal seeks to protect human health and the environment, as well as establishing (or preserving) the Internal Market for these two substances. It is believed that this can be done at little or no cost as uses in the specified applications have already declined and alternative products are believed to be readily available.

<sup>(1)</sup> OJ C 146A of 15.6.1990

<sup>(2)</sup> OJ L 84 of 5.4.1993

<sup>(3)</sup> OJ L 273 of 26.10.2000

<sup>(4)</sup> OJ L 262 of 27.9.1976

<sup>(5)</sup> OJ L 231 of 28.9.1995

2.2 In the case of toluene, recognised as a versatile HPV substance used as an essential raw material for chemical synthesis and as a solvent in many industrial and consumer applications, restrictions are to be placed on any use above 0,1 % by mass in adhesives and spray paints for sale to the general public. This does not apply to any industrial applications and is intended to protect consumer health.

2.3 In the case of trichlorobenzene, with a more limited use as an intermediate for certain herbicides and as a process solvent in closed systems, restrictions are to be placed on any use above 0,1 % by mass in any use except as an intermediate. This restricts any possible sales to the general public and provides additional protection to health in the work place.

2.4 The two products to which this amendment applies are defined by their CAS Numbers 108-88-3 120-82-1 in the Annex to the proposal. Restrictions on usage will be added to Annex 1 of Directive 76/769/EEC.

2.5 Member States will have one year to publish laws necessary to comply with this Directive, with the controls to be effective within a further six months. This will be from the date of entry into force of this proposal, after consulting, as required by Article 95 of the Treaty, the European Economic and Social Committee (EESC) and following the Co-decision Procedure with the European Parliament.

### 3. General comments

3.1 As with the twenty-sixth amendment of Council Directive 76/769/EEC (restrictions on the marketing and use of nonylphenol, nonylphenol ethoxylates and cement) <sup>(1)</sup>, on which the EESC delivered its Opinion in March 2003 <sup>(2)</sup>, this proposal deals with unrelated substances which, for clarity, will be discussed separately. (The intervening twenty-seventh amendment on polycyclic aromatic hydrocarbons in extender oils and tyres has been published but is still under review.)

### 4. Toluene

4.1 Toluene is a clear colourless liquid with a distinctive smell. Also known as methyl benzene, it has the second, after benzene, most simple aromatic structure – a six-member carbon ring with a one member (alkyl) carbon chain attached. It occurs naturally in crude oil, in some plants and trees, and in

emissions from volcanoes and forest fires, and can be deliberately manufactured in very large quantities from coal or crude oil.

4.2 According to industry sources, worldwide capacity and production levels for deliberately produced toluene in 2002 were 20 million tonnes and 14 million tonnes respectively. 75 % of this capacity is located in the US, Asia and Japan. The CSTEE Opinion quotes EU production in 1995 at 2,6 million tonnes. Much larger quantities result from the routine manufacture of gasoline and contribute to overall exposures; these are not included in these totals <sup>(3)</sup>.

4.3 Toluene is used primarily as the raw material in closed systems for the deliberate manufacture of benzene, urethane foams and other chemical products, and, in much smaller quantities, as a solvent carrier in paints, inks, adhesives, pharmaceutical products and cosmetics. Its effects on human health and the environment have been widely studied and generally accepted by all those concerned. There is a clear need to minimise any unnecessary actual or theoretical uncontrolled exposure, in particular where alternative products, with similar solvating power, exist.

4.4 The two end uses specified in this proposal fall into this latter category. The usage of toluene as the solvent for adhesives and spray paints for sale to the general public is neither necessary nor supported by its manufacturers in Europe. Actual sales are currently believed to be low or nil to these two end uses. This is therefore a largely precautionary measure, with little anticipated effect on manufacturers' costs or on consumers' choice or health.

4.5 The EESC recognises that the prime requirement is to ensure that toluene can be safely handled in large quantities in closed systems in the work place. This proposal ensures that members of the general public, outside of a controlled work environment, will be adequately protected, both now and in the future, from unnecessary exposure. The EESC therefore supports this part of the proposal.

### 5. Trichlorobenzene

5.1 The situation for trichlorobenzene differs significantly from the above and some amendments and clarifications are required to the proposal.

<sup>(1)</sup> OJ L 178 of 17.7.2003

<sup>(2)</sup> OJ C 133 of 6.6.2003

<sup>(3)</sup> Data from the APA (Aromatics Producers Association), a member of CEFIC (European Chemical Industry Council)

5.2 'Trichlorobenzene' is a deliberately made chemical which does not occur in nature, other than by the degradation of other chlorinated aromatic compounds. There are three different isomers, depending on the location of the chlorine atoms around the six-member carbon ring. Each has (marginally) different physical properties and biochemical interactions, for instance as measured by their LD50 values. Each has a different CAS and EINECS Number. In addition there is an entry in both CAS and EINECS registers for 'trichlorobenzene' in general. All are commercially available in the US and elsewhere. 1,3,5-Trichlorobenzene is no longer believed to be manufactured in Europe. Details of the listings are as follows (1):

|                      |              |              |              |              |
|----------------------|--------------|--------------|--------------|--------------|
| EINECS Number        | 201-757-1    | 204-428-0    | 203-686-6    | 234-413-4    |
| CAS Number           | 87-61-6      | 120-82-1     | 108-70-3     | 12002-48-1   |
| Isomer               | 1,2,3-       | 1,2,4-       | 1,3,5-       | -            |
| Form                 | White flakes | Clear liquid | White flakes | Clear liquid |
| Melting Point ° C    | 52-55        | 17           | 63-65        | -            |
| Oral, rat LD50 mg/kg | 1830         | 756          | 800          | -            |
| UN Number            | 2811         | 2321         | 2811         | -            |

5.3 The RAR and CSTEE Opinion refer specifically to 1,2,4-Trichlorobenzene, with EINECS and CAS Numbers as above. The present proposal confirms this single CAS Number (and therefore the one isomer that has been studied) in the Annex – but not in the title or text.

5.4 The different isomers are manufactured to high degrees of purity as intermediates in closed systems for the synthesis of certain herbicides, pesticides, dyes and other specialist chemicals. Where the specific isomeric structure is less important, a mixture of isomers can be used in closed systems as a solvent carrier for dyes or as process regulators or heat transfer media, in sprays as a corrosion inhibitor and in metal working fluids.

5.5 In the EU (and elsewhere) the prime usage is of 1,2,4-Trichlorobenzene (1,2,4-TCB), in varying degrees of purity. Production is believed to have declined steadily since the 1980s. Data presented to the OSPAR Commission for the protection of the marine environment estimated 1994 production of 1,2,4-TCB as being between 7-10 thousand tonnes; 1,2,3-TCB as less than 2 thousand tonnes; and 1,3,5-TCB as less than 200 tonnes (2). In June 2000 OSPAR added all three isomers as individual entries to its list of Hazardous Substances for Priority Action. The CSTEE Opinion of July 2001 also quotes 7 thousand tonnes production in Europe in 1994/95. Production levels have continued to decline and are currently believed to be around half these levels, with the greater part being for export (3).

5.6 At present there is believed to be only one remaining producer in the EU/OSPAR region. Sales are said to be

restricted to the isomers 1,2,4-TCB and 1,2,3-TCB for use only as intermediates, with this being confirmed in pre-delivery written use statements from each customer.

5.7 A limited number of other closed system uses are known and recognised by the Commission and CSTEE, for instance as process solvents with no release to the external environment. As this proposal is intended to allow essential manufacture but severely restrict emissions due to open use, it would seem reasonable to add this to the permitted uses in the Annex to this proposal.

5.8 The EESC believes that, subject to the specific points made above, this proposal should provide increased protection in the work place and remove altogether any risks of exposure outside the work place. Manufacturers and users of trichlorobenzene and of competing products seem to have largely anticipated this proposal. There should, therefore, be only minor impacts on manufacturers' and users' costs. The EESC therefore supports this part of the proposal.

## 6. Specific comments

6.1 The EESC notes, as above, that this proposal has to be based on the relevant RAR and CSTEE Opinion and therefore has to refer solely to 1,2,4-TCB. This should be made clear in the title and text. Happily the effect of the restrictions on usage will remain the same, as this isomer is the principal constituent of mixed-isomer TCBS previously sold for use in solvents or sprays.

(1) European Chemicals Bureau Website (<http://ecb.jrc.it>)

(2) Data from Eurochlor, a member of CEFIC.

(3) CSTEE opinions are available at the DG SANCO website.

6.2 Other closed system uses should be permitted, by the addition of the words 'or in other closed systems where no release to the environment is possible' at the conclusion of the relevant restriction.

6.3 As with previous amendments to Council Directive 76/769/EEC, the EESC regrets the linking of unrelated products in a single text which may require specific and continuing amendments to match external realities. This does not support good, timely and effective governance. If it follows from resource limitations during this final and critical stage of agreeing specific risk reduction measures, these limitations should be overcome as quickly as possible.

6.4 The EESC notes that the last list of priority substances for assessment was published in October 2000. The EESC regrets that this approach seems to have been abandoned long before other procedures such as REACH can be implemented. This loss of momentum is regretted.

6.5 The EESC notes the key role played by the CSTEE in the past and trusts that adequate provision has been made for continuing this role in the future, despite the recently announced changes to the structure and responsibilities of the scientific committees.

6.6 The EESC shares the generally expressed concerns over the time taken to evaluate substances under the present system. For these two products close to 11 years will have elapsed before the legislation comes into effect. Five years of this will be after the CSTEE pronounced the RARs to be satisfactory. When the legislation does come into force, there will be virtually no costs – or measurable health or environmental benefits – for anyone concerned. In the absence of further information, it is impossible to say whether this is good (i.e., the market has adapted under pressure of the continuing risk assessments) or bad (the process has achieved very little, at considerable cost to all concerned) – or how to make any desired improvements.

6.7 The EESC therefore believes that, as a complement to other proposals such as REACH and to ensure that they will indeed improve rather than detract from the existing processes, reasons for the slow progress should be evaluated without further delay. This should be in parallel with other studies now in progress to measure impacts, costs and benefits for all the stakeholders in these processes designed to benefit health and the environment, within the framework of a successful and competitive knowledge-based European economy.

Brussels, 27 October 2004.

The President  
of the European Economic and Social Committee  
Anne-Marie SIGMUND

---