Scientific Committees

Scientific Committee on Toxicity, Ecotoxicity and the Environment

Outcome of discussions

Opinion on a study commissioned by Directorate General III (Industry) of the European Commission on Recent Assessments of the Hazards and Risks Posed by Asbestos and Substitute Fibres, and Recent Regulation of Fibres World-Wide (Environmental Resources Management, Oxford) (opinion expressed on 9 February 1998)

CSTEE position on Human Health Risks from Chrysotile

The ERM Report provides no new evidence which indicates that a change in the risk assessment for chrysotile is appropriate.

There is a very substantial body of historic information on chrysotile, albeit at high exposure levels. Neither epidemiology data nor the animal data is sufficient to identify the nature of the dose response relationship at the low doses which reflect current exposure in Europe. Consequently, it is not possible to be certain whether or not there is a true threshold dose for lung carcinogenesis or mesothelioma. It may be appropriate in the absence of definitive information to assume that there is no safe dose of chrysotile.

For the substitute materials, with the exception of vitreous fibres, there is no significant epidemiology base to judge the human health risks. Currently this reliance has to be placed on a combination of animal toxicology and fibre durability. These data are by no means comprehensive and does not allow the assumption that a threshold level can be legitimately applied to them; hence the conclusion that specific substitute materials pose a substantially lower risk to human health, particularly public health, than the current use of chrysotile, is not well founded although it might eventually prove to be correct.

The SCTEE recommends :

i) A proper evaluation of public, occupational and para-occupational health risks posed by the candidate substitutes for the permitted application of chrysotile.

ii) An assessment of current public and para-occupational levels of exposure to chrysotile.

iii) In judging alternatives to chrysotile, environmental impacts of substituted materials should be taken into consideration.

Appendix

Comments on the ERM Report

1. Background

At the plenary meeting of 17 November 1997 the CSTEE Secretariat gave the information that a request for an opinion on chrysotile asbestos would be submitted to the CSTEE. A Working Group, hereafter called *'the group'*, was set up within the CSTEE with a view to later address this subject when precise terms of reference would be available.

On 16 December 1997 CSTEE members were sent a note and a copy of the report, hereafter called *'the ERM report'*, under reference. They were also formally informed that the CSTEE was being asked to peer-review it according to the terms of reference in the mentioned note and to further send comments to the appointed chairman of the group.

Other relevant recent documents made available to the group were:

a) a draft copy of the IPCS report for the Environmental Health Criteria Document on Chrysotile Asbestos. This document – dated July 1996 – is confidential; to the best of the CSTEE's knowledge, it has not been published yet.

b) a commentary (dated 6 September 1997) on the draft ERM report (dated June 1997). This critical review has been prepared by G.W. Gibbs, J.M.G. Davis, J. Dunnigan and R.P. Nolan. The Governments of Canada and Quebec participated in commissioning it and it was formally made available to the chairman of the group through the Canadian Embassy in Rome.

2. Terms of Reference

The terms of reference for this opinion request addressed to the CSTEE, as indicated by Directorate General III of the European Commission, were the following:

(i) *Are the conclusions of the study justified?*

(ii) *As a secondary issue, the CSTEE may also wish to comment on the general quality of the study.*

3. Comments on the conclusions of the study on chrysotile asbestos

3.1 It is the CSTEE's view that the seven points spelled out at the bottom of page 61 and the top of page 62 of the ERM report reflect current knowledge and are acceptable.

3.2 Nevertheless, the statements that *'no threshold level of exposure has been identified below which chrysotile does not pose carcinogenic risks'* and that *'further data are needed to confirm (that the risks of exposure to chrysotile to concentrations below one f/ml are very small)'* require some specifications.

In fact, a threshold implies the demonstration that an effect does not occur at or under a given dose level. The unequivocal demonstration (i.e. identification) of a *'negative'* is tantamount to impossible. Even in the case of large, well-designed and well-conducted epidemiological or toxicological studies, the probability of a statistical error of the second type cannot be reduced to zero. However, circumstances can occur in which a huge bulk of good scientific information consistently provides convincing suggestion of lack of effect.

This is more than semantics. In the ERM report the statements are not complemented by an indication of the hypothetical conditions in which the authors would consider a threshold to be identified. Do or do not the authors agree with the concept of *'practical threshold'* which has been put forward by the British Health and Safety Executive? How many and which type of *'further data'* would confirm that concentrations below one f/ml entail negligible risks? In the absence of this indication, these two

concluding statements of the report may sound more ritual than scientific.

3.3 It must be stressed that conclusions – if any – on the ability of chrysotile to produce mesothelioma do not necessarily apply to the frequent circumstance of exposure to chrysotile contaminated with an amphibole asbestos (usually tremolite).

4. Comments on the conclusions of the report on substitute fibres

4.1 The statement (page 62) that '*The main fibrous alternatives to chrysotile asbestos, in its residual applications, are polyvinylalcohol fibre, cellulose and para-aramid fibre*' is not complemented by adequate (and evaluable) information on the technical performance of these materials, which render them '*main alternatives*'.

4.2 In the same page, ERM acknowledges that little research has been carried out on hazards and risks posed by candidate substitutes to chrysotile, other than MMMFs (it is remarkable, for instance, that no carcinogenicity experimental study on polivinylalcohol fibre was identified). Nevertheless, it is concluded that '*... it would appear that each of these types of fibre is likely to pose less of a risk ... than chrysotile*'. In fact, the report provides no criteria for comparing hazards (i.e. the potential to produce harm) and risks (at the same level of technical performance) of chrysotile, MMMFs and other substitute fibres.

4.3 With regard to durability of fibres, it should be pointed out that predictability of hazard of *in vivo* (as well as *in vitro*) biopersistence assays is well below the corresponding predictability of conventional toxicological tests. In the ERM report, the statement (page E3) that a '*quantitative relationship between durability and tumorigenic capacity in animals ... is currently being developed*' is at least premature (it also ignores effects other than cancer).

5. Comments on the general quality of the ERM report

Major concerns on the ERM report include the following.

5.1 It is based on materials '*submitted by Member States*' which were considered to be relevant. There is no indication of criteria used to ensure exhaustivity and relevance of these materials. In addition this has led to a preponderance of non-scientific material and submissions by interest groups in the list of references.

5.2 No active and systematic effort has been made in order to trace the available scientific literature.

5.3 It is based on reviews prepared by others. Some of them – admittedly – are of high quality and were produced by reputable agencies. Nevertheless, ERM did not develop (or, at least, did not specify) its own criteria for a systematic critical evaluation of the methods and the design of the toxicological and epidemiological studies which – in the long run – form the basis of its conclusions. This has led to much heterogeneity of the sources of information that has been included in the report.

5.4 In many points of the text, of the conclusions and of the executive summary, it is unclear whether remarks refer to any type of asbestos under any circumstance, or specifically to chrysotile. For example, in the executive summary, under '*level of exposure*' (bottom of page E4), the risk for occupants of dwellings in the construction of which asbestos-containing materials were used is considered to be negligible. To the best of our knowledge, this is probably true in the case of chrysotile-containing materials that are in a good state of repair, but does not apply to dwellings built with waste materials from any cement asbestos factory.

5.5 The ERM report lacks balance also in the sense that it is assumed that asbestos substitutes should

produce the same harmful consequences of asbestos. In fact physico-chemical properties (e.g. solubility) of substitutes may well underlie other effects. Thus, each candidate substitute requires full toxicological evaluation (In this respect information on cellulose fibres is highly unsatisfactory).

5.6 In addition to the question of *'banning'* asbestos and to the recommendation to use *'safer'* substitutes (and apart from the discussion on the *'threshold'* or *'non-threshold'* model), the important aim is to reduce exposure to any potential hazard to its lowest possible level and to inform users.

European Voice

NEWS

Scientists fail to clarify rules for asbestos

By Simon Coss

EUROPEAN Commission plans to introduce EU-wide rules on the use of asbestos appear to have run into trouble.

A committee of scientific experts met last week to discuss the drawing up of a definitive list of circumstances in which the substance , recognised to be carcinogenic, could be used or sold.

But Commission officials say the conclusions of that meeting were too vague. "The scientists met last week but their answer was unclear," said Jochen Kubosch, spokesman for Industry Commissioner Martin Bangemann.

Eight EU member states (Italy, France, Germany, Denmark, Sweden, the Netherlands and Finland) have already banned the use of asbestos. Belgium announced earlier this month that it would soon follow suit.

Six countries (Ireland the UK, Spain, Portugal, Greece and Austria) still import asbestos for various controlled products.

The Commission wants to harmonise regulations to assist firms operating in more than one EU member state.

"Our basic approach will either be to propose a general ban with a set of exemptions, or to say use in certain circumstances will be allowed with an annexe setting out detailed criteria," said Kubosch.

Asbestos was used as a fireproofing agent until 1980, and was regularly sprayed on to the superstructures of new buildings. One of them was the Commission's old Berlaymont headquarters, which is currently shrouded in protective sheeting while the substance is removed.

It also has other uses, for instance in brake linings for trucks and aircraft and as a sealing agent in machinery operating at extremely high temperatures.

Officials at the European Advisory Council of the Asbestos International Association argue that the use of asbestos in such specific circumstances should be allowed until viable alternatives have been found.

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