AIA NORTH AMERICA

NEWS & NOTES

a monthly publication

February 27, 1998

COMMENTARY ON OPINION GIVEN BY A SCIENTIFIC COMMITTEE ON A STUDY AFFECTING ASBESTOS IN EUROPE

In Dec. 1997, the Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) of the Directorate General XXIV, European Commission, received a mandate to peer review the report of a study commissioned by Directorate General III, EC, (Industry). The report is entitled, "Recent Assessments of the Hazards and Risks Posed by Asbesetos and Substitute Fibres Worldwide," and was prepared by the consulting firm of Environmental Resources Management (ERM), Oxford, United Kingdom. A complete copy of the opinion given by the DG XXIV SCTEE is appended in the news clip section of this newsletter.

The terms of references set by the Directorate General III for an opinion from the SCTEE were the following:

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

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

An important point came out from the opinion of the SCTEE in their "Outcome of discussions": the question of the existence of a demonstrated threshold of exposure to chrysotile below which the lung cancer risk is zero. The authors of the ERM report state: *"no threshold of exposure has been identified below which chrysotile does not pose carcinogenic risks."*

For the SCTEE, this statement appears to be more "ritual than scientific." And the reason, the SCTEE explains, is that **"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 effect is tantamount to impossible".** But the SCTEE hastens to add that given this inherent impossibility to prove a negative, there may well be a **"practical threshold"**, such as would be suggested when **"a huge bulk of good scientific information consistently provides convincing suggestion of a lack of effect."**

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Put differently, this would be the situation when repeated observations of large cohorts, followed over several decades consistenly provide lack of evidence of measurable effects (i.e. excess lung cancer) at low exposure levels. For exposure to chrysotile asbestos, data available from the longest follow-up (several decades) of the largest cohort of chrysotile workers (11,000 subjects) ever studied, indicate that indeed there are exposure levels to chrysotile (300 mpcf.years) below which there is no measurable excess lung cancer risks. This was repeatedly confirmed in the studies published on the Quebec chrysotile miners and millers **(Liddell FDK, McDonald AD and McDonald JC. Ann Occup Hyg 41:13-35 (1997)** - The 1891-1920 Birth Cohort of Quebec Chrysotile Miners and Millers: Development from 1904 and Mortality to 1992

It should be noted that the existence of a demonstrated threshold, or of a "practical threshold" not only applies to exposure to chrysotile asbestos, but to all suspected carcinogens. Indeed, regarding the substitute fibrous materials, the SCTEE states that *"the data presently available are by no means comprehensive and does not allow the assumption that a threshold level can be legitimately applied; hence, the conclusions 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..."* In other words, if, for reasons mentioned above, there is no demonstrated evidence of a threshold for chrysotile exposure at current levels, there is no evidence for the substitute materials either.

It follows that if regulations leading to a ban were to apply to all "no-demonstrated-threshold" substances, they should apply not only to chrysotile but also to all substitute materials for which, according to the SCTEE, "there is no significant epidemiological base to judge the human health risk." Thus, for these substances as well as for chrysotile, the sensible regulatory approach is to determine at what exposure level a "practical threshold" is reached, and set the permissible exposure levels accordingly.

With regards to the ERM's conclusions on substitute fibres, the SCTEE takes issue with the ERM's contention that three fibrous materials (poyvinylalcohol, cellulose and paramid fibres) are the main alternatives to chrysotile, without giving any evaluable information on the technical performance of these materials. Most importantly, the SCTEE does not accept the conclusion reached by ERM to the effect that "...it would appear that these types of fibres are likely to pose less of a risk...than chrysotile," while at the same time recognizing that little research has been carried out

on hazards and risks posed by candidate substitutes. The SCTEE notes that the ERM study offers no criteria for comparing hazards (i.e. the potential to cause harm) and risks (at the same level of technical performance) of chrysotile and other substitute fibres.

It is for these reasons that 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.

In summary, it is the opinion of the members of the SCTEE that, rather than entertaining endless discussions on "threshold" and "non-threshold" models, the important aim is to reduce exposure to any potential hazard to its lowest possible level and to inform users.

This commentary was prepared by Dr. Jacques Dunnigan, Contacts/J.D., Katevale, Quebec, Canada.

INDUSTRY GROUPS PRAISE BILL SUBSTITUTE ADDRESSING ADMINISTRATION'S CONCERNS

Industry groups praised new regulatory reform bill language released Feb. 4 that seeks to address concerns by the Clinton administration and public interest groups over an earlier regulatory reform effort that stalled in the Senate in 1997. The new language, intended as a substitute for the Regulatory Improvement Act (S 981) sponsored by Sens. Fred Thompson (R-Tenn) and Carl Levin (D-Mich), addresses concerns about the bill's provisions on risk assessment and judicial reviews of agency actions, incorporates a savings clause sought by the administration, and eliminates an advisory committee that was to review agency rules.

"This is not about less regulation," Thompson, who chairs the Senate

Governmental Affairs Committee, said at a Feb. 4 press conference to release the language. "We are giving people the right to peer over government officials' shoulders to see what they're doing and how they're doing it." Levin said the substitute language "makes it explicitly clear" that the bill cannot be used to override existing health, safety, and environmental standards, or to use cost-benefit analysis and risk assessment to dictate the outcome of a rule. The Business Roundtable and another industry group, Alliance USA, expressed satisfaction with the bill and urged quick committee approval. However, Gary Bass, executive director of OMB Watch, a consumer watchdog group, said the new language did not appear to be much different from the previous bill and he still would have a hard time supporting it.

The main features of the bill are requirements that regulatory agencies perform risk assessments and cost-benefit analyses on all new major rules, which are those that have an economic impact of $100 million of more. While the concepts in the bill are not new, the substitute amendment makes several changes.

Among other things, it would:

Modify cost-benefit analysis provisions "to make absolutely clear that the agency determination is a disclosure requirement" and does not dictate the outcome of the rule;

Change the principles for risk assessment so they are less prescriptive to agencies and more accommodating when addressing non-carcinogenic risks; and

Change the definition of substitution risk to require that it mean a "significant" increased risk instead of any increased risk.

A "savings clause" was added to affirm that "nothing in the bill is intended to supersede any requirement for rulemaking or opportunity for judicial review applicable under any other Federal law," according to a summary of changes to S 981. The savings clause was pushed by the Clinton administration at a Sept. 12, 1997, hearing on the regulatory reform bill(27 OSHR 536).