is estimated to be 3 excess deaths per 1,000 workers.

Additionally, OSHA estimated the risk (i.e., the predicted incidence) of asbestosis morbidity at the existing permissible exposure level of 2 f/cc. OSHA's best estimate is based on the results of a high-quality study of the incidence of compensable (certified) asbestosis at an asbestos-cement factory (Ex. 84-240). Based on cumulative exposure data and assuming a linear model, OSHA estimates that the incidence of asbestosis is 50 cases per 1,000 workers exposed for 45 years to 2 f/cc.

In the April notice, OSHA characterized the basis for determining that a significant risk exists at the 2 f/cc level as being "particularly strong" (49 FR 14120). This assessment was based on the reliance on occupational epidemiological studies for the quantitative risk assessment, the high quality of the scientific data, the consistent estimates of dose-response among the various studies used, and the appropriateness of the models and methods employed in the risk assessment. Review of the record evidence submitted since publication of the April notice has served to reinforce OSHA's confidence in the data and analysis underlying the determination that a significant risk exists at the existing permissible exposure level for asbestos.

Regarding the quality of the data, several commenters stated that the health evidence for asbestos-related disease is far more convincing, due to the quality and number of human studies available, than are health effects data for any other hazardous substance. This point was emphasized at the informal hearing by Dr. Nicholson under cross-examination by Ms. Seminario of the AFL-CIO:

> Seminario: Would you say that [the data for asbestos] . . . is generally better and more complete than . . . [for other toxic substances]?
>
> Nicholson: I don't even think there's a comparison. The data for asbestos are so much more extensive than those of other toxic substances in the workplace. It's a wide divergence.
>
> Seminario: . . . Basically, you have asbestos with a lot of studies and a lot of information, and a great number of workers included as subjects in those studies . . . compared to less complete data for other toxic substances?
>
> Nicholson: Yes.
>
> Seminario: . . . [I]t really is a much more complete data base for conducting risk assessment and making estimates [of risk] than you would have for any other substance?
>
> Nicholson: Yes, it is
>
> Seminario: . . . [I]n conducting risk assessments, in many cases, those risk assessments will be based not on epidemiologic studies, but, indeed, on animal studies. Is that correct?
>
> Nicholson: Often, that may be our only recourse, in other studies. . . . [I]f one reviews the [International] Agency for Research on Cancer Monographs] . . . volumes 1-29 that have evaluated human carcinogens, they have only deemed 18 agents or work processes to have sufficient data for which one could . . . establish carcinogenicity [in humans], let alone provide quantitative risk assessments in hypothetical circumstances. So our human data are very scanty for most agents (Tr. 6/19 pp. 134-135).

Similarly, Dr. Hans Weill commented that ". . . we know of no other occupational disease for which more complete exposure-response data are available from human population studies" (Ex. 99, p. 30). In its post-hearing submission, Organization Resources Counselors, Inc. stated that "[a]sbestos is a proven carcinogen of long standing. Volumes of scientific work attest to the fact that asbestos produces both lung cancer and mesothelioma" (Ex. 127-A, p. 2). These comments, and the evidence contained in the record on health effects from asbestos exposure (see Section IV) reaffirm OSHA's belief that the data used in the quantitative risk assessment are of unusually high quality.

A review of the rulemaking record has also strengthened OSHA's belief that it used the most appropriate models to calculate the risk. To estimate the risk for lung cancer, OSHA used a linear dose-response model based on evidence found in several epidemiologic studies that examined lung cancer mortality in relation to cumulative asbestos exposure (Exs. 84-43, 84-59, 84-35), and on the use of a linear model by several other investigators (Exs. 85-22, 84-216, 84-243, 82-2, 84-180, 84-256, 321). For mesothelioma, OSHA used an absolute risk model, which has been used or suggested by a number of other authors to estimate the risk of mesothelioma (Exs. 84-252, 84-385, 84-342, 84-87, 132, 84-138). In response to record comments submitted after publication of the April notice, OSHA revised the individual potency factors for lung cancer (K_L) and mesothelioma (K_M) for some of these epidemiological studies (see Section V of this preamble). These adjustments had little effect on the overall K_L of 0.01 and K_M of 1×10^{-8} originally proposed by OSHA for the combined data sets. OSHA believes that this finding reflects the reasonableness of the risk estimates for lung cancer and mesothelioma set forth in the April notice.

The first element established by the Supreme Court's Benzene decision (*IUD v. API* 448 U.S.) for determining the significance of risk of material impairment—that a significant risk existed at the existing permissible exposure limit of 2 f/cc—is thus clearly and decisively established by OSHA's risk assessment and by the insidious nature of asbestos-related disease. In making a determination that this risk is significant, OSHA relies, in part, upon the Supreme Court's indication of when a reasonable person might consider a risk significant and take steps to decrease that risk. OSHA finds, as indicated by the risk assessment, that the existing standard of 2 f/cc would permit an excess cancer mortality risk of 64 deaths per 1,000 employees and an estimated asbestosis incidence of 50 cases per 1,000 employees exposed for a working lifetime; this excess risk must be considered significant and unacceptable using virtually any reasonable basis for making such a determination. OSHA also finds that the excess risk of cancer mortality resulting from 20 years of exposure to asbestos (44 excess deaths/1,000 workers) is also significant. As pointed out in the April notice (49 FR 14120), the risk from asbestos exposure at the 2 f/cc level has also been acknowledged as being unacceptable by other governments. (Exs. 84-378, 84-379). The level of risk estimated by OSHA at the existing permissible exposure limit is also comparable to the estimated risks for other toxic substances that OSHA has regulated or proposed to regulate in the past.

In accordance with the second element of the Supreme Court's Benzene decision on the determination of significant risk, OSHA has determined that reducing the permissible exposure limit for asbestos to 0.2 f/cc is reasonably necessary to reduce the cancer mortality risk from exposure to asbestos. OSHA's risk assessment shows that lowering the permissible exposure limit from 2 f/cc to 0.2 f/cc reduces the asbestos related cancer mortality risk from lifetime exposure from 64 deaths per 1,000 workers to 6.7 deaths per 1,000 workers; this corresponds to a 90 percent reduction in the risk. The asbestos-related cancer risk is also reduced by 90 percent, from 44 deaths to 4.5 deaths per 1,000 employees, for a 20-year exposure duration. It is estimated that the incidence of asbestosis for workers exposed for a working lifetime under the new standard will fall by 90 percent, from 50 cases to 5 cases per 1,000 employees. As these figures show,

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