for Disease Control and Prevention. This request was published for public comment in the **Federal Register** (August 18, 1994, 58 FR 44098).

During the September 9–10, 1993, meeting, the Recombinant DNA Advisory Committee recommended by consensus that the current classification of etiological agents described in the Biosafety in Microbiological and Biomedical Laboratories, 3rd edition, May 1993, U.S. Department of Health and Human Services, should be endorsed by the Committee. The Committee retains the option to adopt any modification to the CDC listing. The Committee recommended that the revised Appendix B, Classification of Microorganisms on the Basis of Hazard, submitted by Dr. Fleming should not be adopted until the Committee receives letters of concurrence from both the Centers for Disease Control and Prevention and the NIH Division of Safety.

In a telephone call on October 20, 1994, Dr. Fleming stated that Appendix B, Classification of Microorganisms on the Basis of Hazard, would be reviewed by experts from the Centers for Disease Control and Prevention and the American Society for Microbiology. The revised Appendix B was submitted to the Recombinant DNA Advisory Committee December 1–2, 1994, meeting for review and discussion. During the December 1994 meeting, the Committee recommended publishing the revised Appendix B in the **Federal Register** for public comment, with further review of this proposal and possible approval during the March 6–7, 1995, meeting.

The proposed Appendix B reads as follows:

Appendix B. Classification of Etiologic Agents and Oncogenic Viruses on the Basis of Risk (See Appendix B–VI–A)

Agents evaluated by the Centers for Disease Control (CDC) and the National Institutes of Health (NIH) and published in the Morbidity and Mortality Weekly Report, or in a revision of the CDC/NIH ''Biosafety in Microbiological and Biomedical Research Laboratories'' (BMBL), as agent summary statements shall automatically be added to this list. Revisions to lists of agents provided by the Subcommittee on Arbovirus Laboratory Safety (SALS) as taken from the BMBL (see Appendix B–VI–D) and provided here in Tables 3–6 shall be incorporated into this list. Appendix B shall undergo an annual review for the Office of Recombinant DNA Activities (ORDA) by a special committee of the American Society for Microbiology (ASM) to ensure that all such updates have been incorporated. Additions or corrections to this list may also occur following a review by ORDA, the RAC, and/or by recommendation of the CDC.

Appendix B–I. Points To Consider in Using Appendix B and in Assessing the Risk of Handling Microorganisms

Appendix B is not to be used to replace a thorough assessment of the risk of working with a particular biohazardous agent. However, the information can be used to establish an initial, qualitative assessment of the risk of handling an agent. Such information would be appropriate for initial estimates of the design of facilities needed for the use of such agents or the requirements for their transport. Much of the information in the previous version of Appendix B, based upon a 1974 publication of the Centers for Disease Control (see Appendix B–VI–C), is updated and retained in this revision. Information on agent risk assessments found in the ''Agent Summary Statements'' of the CDC/NIH publication ''Biosafety in Microbiological and Biomedical Laboratories'' (See Appendix B–VI–D), information from the American Public Health Association publication, ''Control of Communicable Diseases of Man'' (See Appendix B–VI–B) and input from a special committee of the American Society for Microbiology provided additional information for the revised list of four risk groups found in Appendix B. The definition of each risk group and the relationship of the four risk groups to four biosafety levels (BL) is found in Tables 1 and 2 from the Laboratory Biosafety Manual of the World Health Organization (See Appendix B–VI–E). As a general principle, the greater the hazard posed by the microorganism, the higher the risk group placement. Use of the term ''risk group'' is recommended by the World Health Organization and is used here to indicate the result of a qualitative risk assessment based upon agent characteristics as described below. Risk Group designations are currently used in Canada for human and animal pathogens, and in the member nations of the European Union, which list only human pathogens in the Directive for protection of workers from exposure to biohazardous agents.

Specific strains of many species may fall into either a more or a less hazardous risk group depending upon the genetic background and natural history of the strain. Information on the parent or wild-type strain is used for the qualitative risk assessment list in Appendix B. Further information on a specific strain is to be used by the Principal Investigator or supervisor for a quantitative risk assessment.

In assessing the risk of working with a specific strain, the following criteria should be considered: any organism directly isolated from a human or animal should be treated as a potentially pathogenic organism until proven otherwise; specific strains that are known to be more hazardous than the parent strain, such as those resistant to a limited number of drugs used for treatment, may need to be handled at a higher containment level than the parent strain. On the other hand, specific strains of Risk Group 2 microorganisms that are known to have minimal hazard risk to humans may be classified within Risk Group 1 and handled at BL1. Certain attenuated strains that are commonly used for live vaccines and specific attenuated strains with an extensive history of safe laboratory use without harmful effect may be placed in a lower risk group than the parent organism, as done by the CDC (See Appendices B–VI–C through –D). Where a strain is attenuated or has lost known virulence factors (i.e., genes) and is to be used as a product or part of a product or for prophylactic/therapeutic purposes, then the containment required by the classification of the parent strain need not apply when used for such purpose.

Appendix B–I–A. The list of biohazardous agents in Appendix B is meant to be based on the effect of a biological agent on a healthy worker. No account is taken of particular effects on those whose susceptibility may be affected by one or other reasons such as preexisting disease, medication, compromised immunity, pregnancy or breast feeding. Additional risk to workers should be considered as a part of the required (quantitative) risk assessment which takes into account the potential interactions of the agent-host-activity. Only agents known to infect humans are meant to be included in Appendix B. Lists of restricted animal pathogens, included in BMBL and previously included in Appendix B, should be obtained by contacting the USDA, Animal and Plant Health Inspection Service (APHIS).

Appendix B–I–B. Genetically modified organisms are not specifically covered by this list. The determination of the risk of a recombinant organism is a part of the required quantitative risk assessment of the specific strain to be carried out by the Principal Investigator/supervisor.

Appendix B–I–C. For agents where more than one species is known to be pathogenic for man, this appendix may include the genus name as well as