

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Recombinant DNA Research: Actions Under the Guidelines

AGENCY: National Institutes of Health (NIH), PHS, DHHS.

ACTION: Notice of Actions Under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).

SUMMARY: This notice sets forth actions to be taken by the Director, National Institutes of Health (NIH), under the NIH Guidelines for Research Involving Recombinant DNA Molecules (59 FR 34496, amended 59 FR 40170, 60 FR 20726, 61 FR 1482, 61 FR 10004, 62 FR 4782).

FOR FURTHER INFORMATION CONTACT: Background documentation and additional information can be obtained from the Office of Recombinant DNA Activities (ORDA), National Institutes of Health, MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892-7010, Phone 301-496-9838, FAX 301-496-9839. The ORDA web site is located at <http://www.nih.gov/od/orda> for further information about the office.

SUPPLEMENTARY INFORMATION: Today's action is being promulgated under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines). The proposed actions were published for comment in the **Federal Register** of February 14, 1997 (62 FR 7108), and reviewed by the NIH Recombinant DNA Advisory Committee (RAC) at its meeting on March 6, 1997.

I. Background Information and Decisions on Actions Under the NIH Guidelines

In a letter dated December 2, 1995, Dr. Kenneth I. Berns (President), Dr. Gail Cassel (Chair, Public and Scientific Affairs Board), and Dr. Diane O. Fleming (Chair, Subcommittee on Laboratory Safety) of the American Society for Microbiology (ASM) requested that Equine morbillivirus, Sabia, and Flexal be added to Appendix B of the NIH Guidelines. The Centers for Diseases Control and Prevention (CDC) has developed a list of select agents identified as potential weapons for biological terrorism. These select agents are subject to Federal regulation 42 CFR Part 72, published by CDC on October 24, 1996, in the **Federal Register** (61 FR 55190). This regulation promulgates the final rule of additional requirements for facilities transferring or receiving select

agents. Most of the biological agents in the select agents list are already included in Appendix B except these three agents requested for inclusion by ASM. In a letter dated December 20, 1996, ORDA asked Dr. Flemming to clarify the proper Risk Group classification of these three viruses. In her letter dated February 3, 1997, Dr. Fleming stated that Flexal virus should be listed as a Risk Group 3 agent based on the classification recommended in the CDC/NIH publication entitled: Biosafety in Microbiological and Biomedical Laboratories, 3rd Edition, 1993. Sabia virus and Equine morbillivirus have not been formally classified in this publication. Dr. Fleming stated that she has consulted with Dr. Michael P. Kiley, Chairman of the Subcommittee on Arboviral Laboratory Safety (SALS) of the American Society for Tropical Medicine and Hygiene, with regard to the proper Risk Group classification of these two viruses. Dr. Kiley recommended that Sabia and Equine morbillivirus should be classified as Risk Group 4 agents. Risk Group 4 agents are handled under Biosafety Level 4 physical containment, because they are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not available.

The ASM request was reviewed by Brian R. Murphy, M.D., Head, Respiratory Viruses Section, NIH, and Stephen E. Straus, M.D., Chief, Laboratory of Clinical Investigation, NIH. Dr. Murphy presented his review and Dr. Straus' written review at the March 6-7, 1997, RAC meeting. Dr. Murphy and Dr. Straus concurred with the ASM request with regard to the classification of these three viruses.

The RAC deliberated the issue at the March 6-7, 1997, RAC meeting. A motion was made by the RAC to amend: (1) Appendix B-III-D, Risk Group 3 (RG3)—Viruses and Prions, to include Flexal, an arenavirus, and (2) Appendix B-IV-D, Risk Group 4 (RG4)—Viral Agents, to include Sabia, an arenavirus, and Equine morbillivirus, a paramyxovirus. The motion passed by a vote of 8 in favor, 0 opposed, and no abstentions.

I accept the RAC recommendations, and the NIH Guidelines will be amended accordingly.

II. Summary of Actions

A. Appendix B-III-D, Risk Group 3 (RG3)—Viruses and Prions, will be amended to include Flexal, an arenavirus.

B. Appendix B-IV-D, Risk Group 4 (RG4)—Viral Agents, will be amended

to include Sabia, an arenavirus, and Equine morbillivirus, a paramyxovirus.

OMB's "Mandatory Information Requirements for Federal Assistance Program Announcements" (45 FR 39592) requires a statement concerning the official government programs contained in the Catalog of Federal Domestic Assistance. Normally NIH lists in its announcements the number and title of affected individual programs for the guidance of the public. Because the guidance in this notice covers virtually every NIH and Federal research program in which DNA recombinant molecule techniques could be used, it has been determined not to be cost effective or in the public interest to attempt to list these programs. Such a list would likely require several additional pages. In addition, NIH could not be certain that every Federal program would be included as many Federal agencies, as well as private organizations, both national and international, have elected to follow the NIH Guidelines. In lieu of the individual program listing, NIH invites readers to direct questions to the information address above about whether individual programs listed in the Catalog of Federal Domestic Assistance are affected.

Dated: September 30, 1997.

Harold Varmus,

Director, National Institutes of Health.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Availability of the Assessment Plan: Grant Calumet River, Indiana Harbor Ship Canal, Indiana Harbor and Associated Lake Michigan Environments

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: Notice is given that the document titled "Assessment Plan for the Natural Resource Damage Assessment of the Grand Calumet River, Indiana Harbor Ship Canal, Indiana Harbor and Associated Lake Michigan Environments" ("The Plan") will be available for public review and comment on the date of publication in the **Federal Register**. The U.S. Department of the Interior, and The State of Indiana ("trustees") are trustees for natural resources considered in this assessment, pursuant to subpart G of the National Oil and Hazardous Substances Pollution Contingency Plan. 40 CFR