



the University of Alabama in Birmingham / UNIVERSITY STATION / BIRMINGHAM, ALABAMA 35294

the Medical Center / DEPARTMENT OF MICROBIOLOGY

May 20, 1977

Dr. Maxine F. Singer
Laboratory of Biochemistry and Metabolism
National Institutes of Health
Bethesda, MD 20014

Dear Maxine,

At the May 14-15, 1977 meeting of the NIH Recombinant DNA Molecule Program Advisory Committee various revisions were proposed in the 1976 version of the NIH Guidelines for Recombinant DNA Molecule Research. The Advisory Committee will meet again toward the end of June to complete its revision of the Guidelines and to review changes already made. One of the major issues under consideration was a redefinition of the types of recombinant DNA molecule activities to be regulated by these guidelines. As most of you are aware, the legislative bills introduced by Senator Edward Kennedy and by Congressman Paul Rogers both exempt certain recombinant DNA molecule experiments from the regulation. The NIH Advisory Committee also considered this issue and drafted appropriate definitions and statement of intent as to which experiments are or are not included. A copy of the proposed first paragraph of the Guidelines is enclosed for your information.

The second sentence includes a definition of recombinant DNA molecules much as it was given in the 1976 version of the Guidelines. The third sentence defines "novel recombinant DNAs" as arising from the joining of segments of any DNA from different species that are not known to exchange chromosomal DNA by natural physiological processes and indicates that the Guidelines will pertain only to these novel recombinant DNAs. The fourth sentence provides a clarification so that it is clear that formation of recombinant DNAs between viral, extrachromosomal or chromosomal DNAs are excluded from the Guidelines when all components are known to replicate in the prokaryotic host organism used to propagate the recombinant DNA. The fifth sentence, however, states an exception and specifies that certain types of recombinant DNAs that might not be novel that are formed between a eukaryotic viral DNA and eukaryotic DNA are included under the Guidelines. The last sentence indicates that it is the responsibility of the Director of NIH to establish a list of the types of recombinant DNA molecules that are excluded from the Guidelines.

I would very much appreciate any comments you have on these definitions and provisions so that the NIH Advisory Committee at their June meeting can make any necessary changes. It should be evident that the purpose of these statements is to exclude those experiments which most would agree have no risk associated with them. This

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exclusion would undoubtedly eliminate 75% of the paperwork associated with grant submissions, filling out of Memoranda of Understanding and Agreement and activities of institutional biohazards committees.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Roy Curtiss III', with a long, sweeping vertical stroke extending downwards from the end of the signature.

Roy Curtiss III

RCIII:kb

cc: William J. Gartland
Members, NIH Recombinant DNA Molecule Program Advisory Committee