Appendix A: Chronology

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Key

<table>
<thead>
<tr>
<th>Color</th>
<th>Description</th>
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<tbody>
<tr>
<td>Green</td>
<td>major developments in scientists’ collective discussions of recombinant DNA research</td>
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<tr>
<td>Blue</td>
<td>national government regulations of recombinant DNA research</td>
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<tr>
<td>Purple</td>
<td>international standards relevant to conduct of recombinant DNA research</td>
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1950

Further studies confirm double helix structure of DNA

1953


1960

continued research opens up possibility of creating recombinant DNA (rDNA) by combining genetic material from different organisms to produce offspring with desired traits.

1968-1971

gradual tightening of lab safety standards among researchers working with viruses.

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1969  

1970-71  
Discussion of safety of Paul Berg’s proposed experiment involving insertion of monkey virus SV-40 into E. coli bacteria to see if it were possible to use tumor cells to determine whether genes from lower (less complex) organisms can function in higher (more complex) ones.

1971  
Founding of first “biotech” company, Cetus Corporation.

1972  
Nov.  Andrew Lewis Jr. asks superiors at National Institutes of Allergy and Infectious Diseases for guidance on how to handle requests for samples of the Adenovirus-SV40 hybrids he has been working on in his lab.

1973  
Jan.  100 scientists from around the USA meet at Asilomar Conference Center in Pacific Grove, California to assess risks of doing research with viruses. Results published as Biohazards in Biological Research.

Jun.  Gordon Conference on Nucleic Acids includes session on biohazards and laboratory handling of biohazardous materials.

Sep.  Science publishes letter from Maxine Singer and Dieter Söll calling on National Academy of Sciences to establish an expert committee to address biohazard issues of rDNA experiments.

1974  
Apr.  National Academy of Sciences supports informal meeting of researchers discussing biohazard problems.

Jun.  Statement on suspending rDNA research pending assessment of safety inspired by the April meeting published in Science, Nature, and the Proceedings of the National Academy of Science. This outlines rationale for moratorium and asks the National Academy of Science to appoint a committee to develop recommendations regarding safe laboratory practices for rDNA research.

National Academy agrees to convene an international conference of scientists to assess the biohazards involved in rDNA research.

Oct.  US Department of Health, Education and Welfare charters the Recombinant DNA Molecule Advisory Panel (name later shortened to Recombinant DNA Advisory Committee)
1975


Feb.  Conference on Recombinant DNA held at the Asilomar Conference Grounds in Pacific Grove, California develops consensus guidelines for safe experimentation with recombinant DNA technology. Its 153 participants include 50 scientists from outside the USA.

First meeting of NIH Recombinant DNA Advisory Committee

Feb.-Mar.  Press coverage of Asilomar Conference includes considerable discussion of real or possible hazards giving prominence to nightmare scenarios of “super” versions of disease-causing viruses or bacteria and invasive life forms that crowd out natural varieties of plants or animals.

Apr.  US Senate Subcommittee on Health holds public hearings on scientific research and the public interest. One session is devoted to genetic engineering and the Asilomar Conference.

May  Second meeting of NIH Recombinant DNA Advisory Committee works on framing guidelines.


Jul.  Third meeting of NIH Recombinant DNA Advisory Committee in Woods Hole, Massachusetts; produces and circulates draft guidelines.

Aug.  49 of the biologists attending a bacteriophage workshop at Cold Spring Harbor sign a joint letter criticizing the Woods Hole draft as diluting the safety standards agreed at the Asilomar Conference.

Dec.  Fourth meeting of NIH Recombinant DNA Advisory Committee held in La Jolla, California with a large audience present; agrees on revised guidelines stricter than those proposed by NIH in November.

1976

Feb.  Meeting of NIH Director’s Advisory Committee discussing the draft rDNA guidelines open to public comment.

Jun.  US government issues regulations regarding conduct of rDNA research.

Canadian government publishes draft report on rDNA guidelines.
Jun.-Jul.  City of Cambridge (Mass) public hearings on conduct of rDNA research.

Aug.  


NIH issues draft environmental impact statement on its rDNA guidelines.

Sep.  Joint oversight hearings in US Senate on implementation of the NIH guidelines by the Subcommittee on Health of the Committee on Labor and Public Welfare and the Subcommittee on Administrative Practice and Procedure of the Committee on the Judiciary.

1977

Jan.-Dec.  Height of Congressional interest in developing legislation to govern rDNA work. Several proposed laws submitted but none is adopted.

Feb.  City of Cambridge adopts ordinance adding city guidelines and a city biohazards committee to oversee them.

Jun.  NIH RAC informed of lawsuit by citizen of Frederick, Maryland asking court to block polyoma risk experiments until NIH prepares a full environmental impact statement as required under the National Environmental Policy Act.

Invitation-only workshop at Falmouth, MA concludes that E. coli K12 carrying recombinant DNA, is infectious to humans but cannot trigger an epidemic while the hazards of particular proposed experiments with it.


Oct.  NIH publishes Final Environmental Impact Statement on rDNA research.

1977-81

Local or state rules on rDNA research adopted in 5 cities and 2 states (New York and Maryland).

1977

Sep.  American Society for Microbiology’s Council Policy Committee adopts a resolution outlining “nine principles” that should guide any US legislation on rDNA research.

Dec.  Revised US regulations tighten restrictions on large-scale rDNA experiments but drops restrictions on experiments with organisms that naturally exchange DNA with E. coli on grounds these are not hazardous.
1978

Genentech, Biogen, and Genex join Cetus as leaders in the emerging biotechnology industry; major drug companies are establishing their own development teams or hiring biotech firms to develop products for them.

Feb. Ascot Workshop (US-European MB Organization joint workshop) on assessing risks of rDNA experiments involving the genomes of animal, plant, and insect viruses.

Mar. NSF, NIH, and USA Department of Agriculture workshop on risk assessment of agricultural pathogens.

Spring Dr. Sydney Brenner (UK Medical Research Council Laboratory in Cambridge) writes paper for the UK Genetic Manipulation Advisory Group (British equivalent of NIH’s RAC) suggesting a more analytical framework for assessing the potential hazards of different classes of rDNA experiments.

Jul. NIH published proposed revised rDNA research guidelines with Environmental Impact Statement.

Sep. Department of Health, Education and Welfare holds public comment meeting on draft revised guidelines.

Fall Court rules in favor of allowing the polyoma risk experiments.

Dec. US regulations amended to relax some of the containment rules.

Membership of RAC increased to 25 and composition altered to include 1/3 nonscientists; more information to be given to the public.

Food and Drug Administration requires rDNA studies it funds to comply with NIH Guidelines

US Food and Drug Administration issues notice of intention to propose rDNA regulations.

1979

Apr. Wye Conference on risks and benefits of rDNA research held at Wye Agricultural College, England; co-sponsored by the International Council of Scientific Unions’ Committee on Genetic Research (COGENE) and the Royal Society.

1980

Jan. Revised NIH Guidelines for rDNA research allow most experiments to be done under P1 (minimal) containment conditions.

Also established program of voluntary compliance with guidelines by laboratories not receiving NIH funding.
Press coverage begins emphasizing the potential benefits of rDNA technology in medical research and treatment of disease.

**Apr.** NIH publishes recommendations regarding physical containment measures for large-scale uses of organisms having rDNA. These are not made part of the guidelines but are endorsed by the NIH Division of Lab Safety.

**Jun.** Biogen researchers announce that they have successfully produced bacteria that release interferon, a hitherto scarce antiviral substance existing in animals and humans, opening up possibilities of more effective treatments of viral diseases and cancer.

**1981 Sep.** NIH RAC recommends making the guidelines for rDNA research a voluntary code of practice. The more general rules regulating biohazards and workplace safety continue to apply.