

Information on International Guidelines for Recombinant DNA

The following information is based largely on international surveys undertaken by The Committee on Genetic Experimentation of the International Council of Scientific Unions reported as of July 1979.¹

I. Nations that had established guidelines for conduct of rDNA research or were using the guidelines of other nations:

| | |
|-----------------------------|----------------|
| Australia | Italy |
| Belgium | Japan |
| Brazil | Mexico |
| Bulgaria | Netherlands |
| Canada | New Zealand |
| Czechoslovakia | Norway |
| Denmark | Poland |
| German Democratic Republic | South Africa |
| Federal Republic of Germany | Sweden |
| Finland | Switzerland |
| France | Taiwan |
| Hungary | United Kingdom |
| Israel | United States |
| | U.S.S.R. |
| | Yugoslavia |

II. Nations that had not established guidelines or had not responded with updated information:

| Country | Yes | No |
|-----------|-----|----|
| Austria | X | |
| Ghana | X | |
| India | X | |
| Iran | X | |
| Jamaica | | X |
| Korea | | X |
| Nigeria | | X |
| Singapore | | X |
| Sri Lanka | | X |
| Sudan | | X |
| Turkey | X | |

III. Nations that had drafted their own guidelines:

| | |
|-----------------------------|----------------|
| Canada | Japan |
| Federal Republic of Germany | United Kingdom |

¹Report to COGENE VIII of the working group on Recombinant DNA Guidelines, May 1980.

| | |
|---------|---------------|
| Germany | United States |
| France | U.S.S.R. |
| Italy | |

IV. Nations that had modified the guidelines of other, indicated, countries:

| | |
|--|-------------------------------|
| Australia (UK, U. S.) | Mexico (U. S.) |
| Belgium (UK, U. S.) | Netherlands (U. S.) |
| Brazil (U. S.) | New Zealand |
| Bulgaria (U. S. S. R., U. S.) | Norway (U. S.) |
| Czechoslovakia (U. S. S. R., U. S., Fed. Rep. Ger.) | Poland (U. S.) |
| Denmark (UK) | South Africa (U. S.) |
| East German Democratic Republic (UK, U. S., Netherlands) | Sweden (U.S) |
| Finland (U.S. mainly) | Switzerland (U. S.) |
| Hungary (U. S.) | Taiwan (U. S., UK) |
| | Yugoslavia |
| | (European Science Foundation) |

V. Nations in which entirely voluntary guidelines have been adopted:

Finland

VI. Nations with guidelines that are enforceable through control of research funding:

| | |
|--|-----------------------------|
| Australia ^a | Japan |
| Canada | Netherlands |
| Czechoslovakia | Norway |
| Denmark | South Africa |
| Federal Republic of Germany ^b | Sweden |
| France | Switzerland |
| German Democratic Republic | Taiwan ^c |
| | United Kingdom ^d |
| | United States |

^aSubmissions may be made directly to the Academy of Science or through a granting agency. In the latter case, it is a requirement for the applicant to observe the recommendations of the Academy's Standing Committee if the agency makes a grant for the work. Otherwise, the guidelines are voluntary with the worker required to make an annual report on progress, or more frequently if conditions of the experiment (such as volumes) are changed appreciably.

^bControl through Academy of Sciences and Ministry of Health.
^cSeveral research organizations require receivers of grants to apply the guidelines until their own national guidelines are completed.

^dThe Netherlands Organization for the Advancement of Pure Research will only subsidize projects which have been given the committee's consent. Waiting for approval from National Advisory Committee.

Notification of proposals to MAUR became compulsory August 1978. In addition, funding bodies require, as a condition of funding, MAUR's advice to be sought and followed.

VII. Nations in which guidelines are legally enforceable:

- Hungary
U.S.S.R.
Finland. “At present, the guidelines are entirely voluntary, but in the near future, the intention is to include them in the law of infectious diseases when they will become legally enforceable.”
South Africa. “At present the guidelines are not legally enforceable. They will only become so if regulations under the existing Health Act of 1977 and the Animal Diseases and Parasites Act of 1956 are promulgated; and none are intended at present.”
United Kingdom “The regulation to notify GMAG does not strictly mean that the Williams Guidelines themselves are legally enforceable. But, under the Health and Safety at Work Act (within which the Regulations were introduced), it is expected that account will be taken of the relevant Codes of Practice and the advice given by GMAG.”

VIII. Nations in which observance of the guidelines is monitored by a nationally-directed mechanism:

- | | |
|----------------------------|----------------|
| Australia | Norway |
| Czechoslovakia | South Africa |
| German Democratic Republic | Sweden |
| France | United Kingdom |
| Hungary | United States |
| Japan | U.S.S.R. |
| | Yugoslavia |

IX. Nations in which a license or other authorization for recombinant DNA activity is granted:

- to an institution: U.S.S.R.
—to an individual laboratory: Hungary, Czechoslovakia
—to an individual scientist: Australia, Canada, German Democratic Republic, Federal Republic of Germany, Finland, France, Japan, Norway, South Africa, Sweden, United Kingdom”, United States and U.S.S.R.
Netherlands: “There are gentlemen’s agreements, signed by the individual scientist, the institution and the Committee.” The reports of the Committee also recommend legislation that will require registration of research projects in this field and make binding the guidelines and supervision of their observance. (Report of *the Committee in Charge of*

the Control on Genetic Manipulation, Amsterdam, March 1977, p. 54.)

- Bulgaria, Switzerland: None of the above.
Taiwan: No response.

⁴The Group advises on proposals from individual workers, but consider them in the context of information about the ‘centre’ in which the work is to go on.”

X. Nations in which special provisions for agriculture and/or industrial research and applications have been made:

- Czechoslovakia. “10 liter maximum volume of the culture containing recombinant DNA”
German Democratic Republic. “The GDR Guidelines will be compulsory for industrial and agricultural applications. 10-liter maximum deviations may be allowed by the Minister of Health if suggested by the Committee.”
Federal Republic of Germany “Specification of containment of plants”
France “Industry, maximum volume of cell culture is set at 10 liters”
Norway “The Guidelines cover both agriculture and industry. Application of recombinant DNA research outside an approved laboratory is prohibited. Otherwise the Committee follows the NIH Guidelines.”
United Kingdom “Agriculture, industry; see Williams Report, paragraphs 1.3, 2.7, 5.13 and appendix II, section 34.”
United States “Agriculture. NIH Guidelines provide containment levels for cloning total plant DNA, plant virus DNA and plant organelle DNA in E. coli K-12, and provide general guidance for the use of plant host-vector systems. 10 liter maximum. A proposed Supplement to the Guidelines for voluntary compliance by the private sector is under consideration by RAC. Development of a monograph for large-scale applications has been proposed.”
U.S.S.R. “Guidelines are compulsory for industrial and agricultural applications. 10 liter maximum. Deviation is allowed by the Recombinant DNA Commission.”
Other respondents, No

XI. Number of laboratories currently engaged in recombinant DNA activities:

| Country | Any labs? | How many? |
|---------------------------------------|------------------|----------------|
| Australia | yes | 16 |
| Austria | no ^a | |
| Belgium | yes ^a | 6 |
| Brazil | yes | 5 |
| Bulgaria | yes ^a | no response |
| Canada | yes | 10-15 |
| Czechoslovakia | yes | 3 |
| Denmark | yes ^a | several |
| German Democratic Republic | yes | 5 |
| Federal Republic of Germany | yes | 10-20 |
| Finland | yes | 3(3-4 planned) |
| France | yes ^a | 12 |
| Ghana | n o ^a | |
| Hungary | yes ^a | 1-2 |
| India | n o ^a | |
| Iran | n o ^a | |
| Israel | yes ^a | 1 |
| Jamaica | n o ^a | |
| Japan | yes | 35 |
| Korea | n o ^a | |
| Netherlands | yes | 7 |
| New Zealand | yes | 2 |
| Nigeria | no | |
| Norway | yes | not stated |
| Philippines | n o ^a | |
| Poland | yes ^a | 3 |
| Singapore | n o ^a | |
| South Africa | yes ^a | 3 |
| Sri Lanka | n o ^a | |
| Sudan | n o ^a | |
| Sweden | yes ^a | 2 |
| Switzerland | yes ^a | 18 |
| Taiwan | yes | 2 |
| Turkey | n o ^a | |
| United Kingdom | yes | 45 |
| United States | yes ^a | 50 |
| U.S.S.R | yes ^a | 6 |
| Yugoslavia | yes ^b | 4 |

^abased on replies from previous Questionnaires.
^bin preparation.

XII. Countries in which specific training for workers and safety officers in recombinant DNA activities is required by the guidelines:

| Country | Yes | No | Other |
|---------------------------------------|----------------|----------------|---------------|
| Australia | | | ^a |
| Bulgaria | X | | |
| Canada | | X | |
| Czechoslovakia | | x ^a | |
| German Democratic Republic | x ^c | | |
| Federal Republic of Germany | x ^a | | |
| Finland | | X | |
| France | X | | |
| Hungary | | X | |
| Japan | | X | |
| Netherlands | x ^a | | |
| Norway | | x ^a | |
| South Africa | X | | |
| Sweden | | X | |
| Switzerland | | | “recommended” |
| Taiwan | | | “recommended” |
| United Kingdom | X ^e | | |
| United States | | x ⁿ | |
| U.S.S.R | X | | |
| Yugoslavia | | | no response |

Other respondents: no or no response to question.

Australia: “Require expertise through Biosafety committee.”
 Czechoslovakia: “specific training is recommended.”
 German Democratic Republic: “Training courses are organized by the Committees in cooperation with Akademie fur rzliche fortbildung der DR.”
 Federal Republic of Germany: “Experience as required by workers on the control of communicable diseases.”
 Netherlands: “The scientists should be trained in microbiology.”
 Norway: The Committee certifies training and expertise of personnel are adequate. ”
 United Kingdom: “Details of training are required; the employer is legally obliged to provide suitable training.”
 United States: “specific training not required. However, local biohazards committees are required to certify to the IHT that the training and expertise of the personnel are adequate.”

XIII. Countries in which the guidelines are applicable only to biological agents containing recombinant DNA, or also cover the recombinant DNA molecules themselves:

| Country | Only to biological agents | Also recombinant DNA molecules |
|---------------------------------------|---------------------------|--------------------------------|
| Australia | | X |
| Bulgaria | | |
| Canada | (a) | (a) |
| Czechoslovakia . . | | X |
| German | | |
| Democratic Republic | X | |
| Federal Republic of Germany | X | |
| Finland | | X |
| France | X | |
| Japan | X | |
| Netherlands | | X |
| New Zealand | | X |
| Norway | | X |
| South Africa | | X |
| Sweden | | X |
| Switzerland | | X |
| Taiwan | X | |
| United Kingdom . . | | X |
| United States | | X ^b |
| U. S. S. R. | | X |

^aGuidelines apply to oral but containment is not required for naked DNA.
^bOnly [guidelines apply to recombinant DNA experiments that are not exempt under Section I-E of the Guidelines. Recombinant DNA molecules that are not in organisms or viruses are exempt from the Guidelines (I-E-1).”

XIV. Groups/Committees responsible for carrying out monitoring of containment procedures:

| Country | Group |
|---------------------------------------|---|
| Australia | Institutional Biosafety Committees. |
| Bulgaria | National Committee |
| Canada | “University and Medical Research Council Biohazards Committees” |
| Czechoslovakia . . . | “Under consideration of the National Institutes of Public Health.” |
| German | |
| Democratic Republic | “Monitoring is carried out by local Biosafety Officers, who are representatives of the Committee in their institutions. ” |
| Federal Republic of Germany | Officers for Biological Safety monitor the health of employees |

| | |
|------------------------|--|
| France | and compliance at laboratories; ZKBS (Zentrale Commission fur die biologische Sicherheit) has overall responsibility. |
| Hungary. | “Local safety committees” |
| Hungary. | “National Institutes of Public Health” |
| Japan | “Principal Investigator and Safety Officer” |
| Netherlands | “Site Inspection Commission” |
| New Zealand | “Local controlling Committees are charged with monitoring observance of Guidelines. Biological Safety Officers are appointed to take immediate responsibility.” |
| Norway | “Physical containment: Norwegian National Institute of Public Health. Biological containment: Committee. ” |
| South Africa | “Above P3, Biosafety Committee of Institute involved and SAGENE. Below P3, SAGENE only.” |
| Sweden | Not applicable. |
| Switzerland | “At the responsibility of either the individual investigator or a local biohazards committee.” |
| Taiwan | No response |
| United Kingdom . . | The Health and Safety Executive |
| United States | “Observance of containment is to be monitored by biohazards committees located in institutions in which the research is conducted. Effectiveness of containment procedures is to be monitored by the principal investigator who is to report problems to the NIH.” |
| U. S. S. R. | “Local biosafety commission, State Sanitary Inspection control group of Recombinant DNA Commission. |

xv. Countries in which the guidelines apply to all gene combinations instructed by cell-free methods, or only to molecules containing combinations of genes from different species:

| Country | All gene combinations instructed by cell-free methods | Molecules containing combinations of genes from different species |
|--------------------------------------|---|---|
| Australia. | | X |
| Canada. | X | |
| Czechoslovakia. . . | | X |
| German Democratic Republic. | X | |
| Federal Republic of Germany. | | X ^a |
| Finland. | X | |
| France | X | |
| Japan | | X |
| Netherlands | | X ^b |
| New Zealand. | X | |
| Norway | X | |
| South Africa | | X |
| Sweden. | | X |
| Switzerland | X | |
| Taiwan. | | ∅ |
| United Kingdom . . | | ∅ ^c |
| United States | | ∅ |
| U. S. S. R.. | X | |

^aFederal Republic of Germany self-cloning experiments involving non-pathogenic donors and hosts shall be reported to ZKBS.

^bNetherlands: "The definition of recombinant DNA has recently been modified and includes the insertion of chemically synthesized DNA molecules into a vector."

^cUnited Kingdom "The group's [provision] interpretation of their written remit is that they are concerned with work involving genetic manipulation, defined for these purposes as: the formation of new combinations of heritable materials via the insertion of nucleic acid molecules, produced by whatever means outside the cell, into any virus, bacterial plasmid, or other vector system; so as to allow their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation."

XVI. Countries in which the guidelines restrict the intentional dissemination into the environment of biological agents containing recombinant DNA:

All respondents . . . Yes^a

Australia. Not explicitly so

German

Democratic

Republic "Exceptions have to be discussed by the Committee and require special permission by the Minister of Health."

New Zealand. . . . "Yes, with the approval of the National Committee."

United Kingdom . . "The question has not arisen."

Other respondents No

Are there any circumstances under which such dissemination can be carried out?

XVII. Countries in which the guidelines are restricted to recombinant DNA activities or also cover other areas of genetic experimentation:

| Country | Recombinant DNA activities | Other areas of genetic experimentation |
|--------------------------------------|----------------------------|--|
| Australia. | X ^a | |
| Bulgaria | X | |
| Canada | | X ^b |
| Czechoslovakia. . . | X | |
| German Democratic Republic | X | |
| Federal Republic of Germany. | X | |
| Finland. | X | |
| France | X | |
| Hungary. | X | |
| Japan | X | |
| Netherlands | X | |
| New Zealand. | | X ^c |
| Norway | X | |
| South Africa. | | X ^d |
| Sweden. | X | |
| Switzerland | X | |
| United Kingdom . . | X | |
| United States | X | |
| U. S. S. R.. | X | |

^aAt present, the terms of reference of the Academy Committee refer only to *in vitro* experiments (i.e., the use of restriction enzymes and bases). An *Ad hoc* Academy Committee is about to investigate *in vivo* experimentation, with the following terms of reference:

1. Examine whether, other than by using the technique of *in vitro* recombinant DNA construction, new hybrid nucleic acid molecules can be produced that are potentially dangerous to humans, animals, or plants.

In so doing, the committee should give particular attention to the following possibilities:

—The use of mixed infections involving human or animal viruses, or the use of bacteria or fungi.

—The introduction of foreign DNA into plants and the production of new plant pathogens.

2. Consider whether there are certain classes of viral pathogens (e.g., polio) on which experimentation should not be carried out unless a special need is demonstrated."

^bwork with animal viruses and cells"

^cie. cell fusion with approval of National Committee"

^dOther closely related areas are also covered."

XVIII. Countries in which the recombinant DNA advisory committee includes public representatives as well as scientists:

| Country | Yes | No |
|--------------------------------------|-----|----|
| Australia | | X |
| Bulgaria | | X |
| Canada | X | |
| Czechoslovakia. . . | | X |
| Denmark | | X |
| German Democratic Republic | X | |
| Federal Republic of Germany. . . | X | |
| Finland. | X | |
| France | X | |
| Hungary. | | X |
| Italy | | X |
| Japan | X | |
| Netherlands | | X |
| New Zealand. | | X |
| Norway | | X |
| South Africa | X | |
| Sweden. | X | |
| Switzerland | X | |
| Taiwan. | | X |
| United Kingdom | X | |
| United States | X | |
| U. S. S. R. | | X |

Composition of DNA advisory committees is as follows:

| | |
|--------------------------------------|---|
| Australia. | 8 scientists |
| Canada | 5 laymen (1 lawyer, 1 businessman, 3 generalists); 6 scientists (2 M.D.s, 3 virologists/cancer specialists, 1 recombinant DNA specialist) |
| Czechoslovakia. . . | 6 members representing molecular biology, genetics, microbiology, medicine |
| Denmark | 9 scientists and administrative representatives. |
| German Democratic Republic | 3 geneticists, 1 biochemist, 2 bacteriologists, 2 virologist, 1 jurist, 1 representative of trade union of GDR. |
| Federal Republic of Germany. | 4 experts working in the field of recombinant DNA research; 4 experts who, though not working in the field of recombinant DNA |

research, possess specific knowledge in the implementation of safety measures in biological research work, particularly however in microbiology, cytobiology, or hygiene and, in addition, 4 outstanding individuals, for example from the trade unions, industry, and the research-promoting organizations.

| | |
|------------------------|--|
| Finland. | 27 members: 6 molecular biology, 3 genetics, 3 microbiology, 1 virology, 1 plant physiology, 3 infectious diseases, 3 epidemiology, 2 enteric bacteria, 1 cell cultures, 3 public health, 1 occupational health. |
| France | 13 members, 4 observers, 1 secretary |
| Hungary. | Scientists |
| Italy | 8 molecular biologists, 4 microbiologists, 1 civil servant (Health Ministry). |
| Japan | (Combines both Steering Committee and Advisory Group): 7 recombinant DNA scientists, 7 scientists in other fields, 6 specialists in medicine and biohazards, 2 lawyers, 2 specialists in physical containment, 3 public representatives. |
| Netherlands | 14 scientists representing genetics, molecular biology, bacteriology, virology, botany, medicine, ethics and social aspects of health and health-care. To be added: a committee composed of scientists and representatives of industry and trade unions. |
| New Zealand. | 1 molecular biologist, 1 microbial geneticist, 1 virologist, 1 botanist (molecular biologist), 1 human geneticist (medically qualified). |
| Norway | 3 biochemists, 2 medicine, 1 veterinary medicine, 1 lawyer, 1 artist. |
| South Africa | One each from: Council for Scientific and Industrial Research, Medical Research Council, Department of Health, Department of Agricultural Technical Services. Three from universities, public and legal professions. |
| Sweden. | No response |

Switzerland ... , . 12 members representing medicine, microbiology, molecular biology, antibiotics, industry, university management, and 7 governmental departmental assessors.

United States Molecular biology: 6, Molecular Genetics: 5, Ethics: 3, Microbiology: 2, Plant Genetics: 2, Law: 2, Environmental Concerns, Laboratory Technician, Infectious Diseases, Occupational Health, Education: 1 each.

U. S. S. R.. ..8 scientists

Yugoslavia3 geneticists