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November 14, 1992

The Honorable Hubert Curien
Minister of Research and Technology
1, rue Descartes
75231 Paris Cedex 05, France

Dear Dr. Curien:

At the last meeting of our Carnegie group, it was agreed to exchange information on the regulation of biotechnology in each country.

Now I am enclosing with this letter "Guidelines for Recombinant DNA Experiment", which has been translated into English recently. I hope it would be of use to you.

I am looking forward to seeing you again in December in France.

Sincerely yours,

Wataru Mori

Wataru Mori
Member of
Council for Science and Technology

Guidelines for
Recombinant DNA Experiment

August 27, 1979

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Prime Minister

Guidelines for
Recombinant DNA Experiment

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PART I. General

Chapter 1. General Rules

Item 1. Objective

Objective of this guideline is to define basic conditions required to ensure safety for recombinant DNA and related experiments, thereby to promote recombinant DNA researches.

Item 2. Definition

This guideline shall be interpreted with the following understanding of terms:

1. "Recombinant DNA molecule" means a DNA prepared by combining in vitro a DNA that can duplicate in a living cell (vector) and an alien DNA.
2. "Recombinant DNA experiment" means an experiment aiming at duplication of a donated DNA by transferring a recombinant DNA molecule into living cells, or an experiment using living cells to which recombinant DNA molecule(s) is introduced (except for those cases in which living cells having the gene composition identical to the DNA-introduced cell exist in nature).
3. "Related experiment" means a recombinant DNA experiment in which donated DNAs are introduced directly into living cells without using vector and the donated DNAs are duplicated for the purpose of differentiation.
4. "Recombinant organism" means a living cell to which recombinant DNA(s) has been introduced as a result of recombinant DNA

experiments.

5. "Host" means a living cell to which recombinant DNA(s) is to be introduced by recombinant DNA experiments.

6. "Vector" means a DNA which carries donated DNA(s) to the host in a DNA recombination experiment.

7. "Host-vector system" means a combination of a host and a vector.

8. "DNA donor" means the cell or the organism to provide the DNA that is to be introduced into the vector. In case that a DNA synthesized with an RNA as template, the term means the cell or organism that provides the RNA.

9. "Large-scale culture experiment" means a recombinant DNA experiment performed in a scale larger than 20L.

10. "Recombinant animal" means an animal prepared by one of the following experiments (including fertilized egg, embryo, fetus, grown organism or its part. Same in the following):

- a. an experiment using animal as host in a recombinant DNA experiment

- b. an experiment to inoculate an animal with a recombinant DNA

- c. an experiment using animal prepared by the above experiments

11. "Recombinant plant" means a plant prepared by one of the following experiments (including pollen, spore, seed, or other part of grown plant. Including differentiated cultured cells and cells grown for the purpose of organ differentiation. Same in the following):

- a. an experiment using plant as host in a recombinant DNA experiment

- b. an experiment to inoculate a plant with a recombinant DNA
- c. an experiment using plant prepared by the above experiments
12. "Laboratory" means a room where the recombinant DNA experiments are performed.
13. "Experiment area" means an area consisting of rooms and corridors which are isolated from other areas by entrance area to control entrance and exit.
14. "Special experiment area" means an air-tight sealed area in the experiment area, equipped with life-supporting apparatuses.
15. "Non-closed system area" means a certain area of greenhouse or net room of non-closed structures, serving the purpose of safety evaluation prior to experiments in outdoor isolated experiment areas.
16. "Outdoor isolated experiment area" means a certain area of isolated farmland, serving the purpose of safety evaluation.
17. "Safety cabinet" means a box-shaped apparatus, listed in Table 1, which is designed to contain polluting aerosols produced by the experiments conducted within.
18. "Laboratory worker" means a person engaged in recombinant DNA experiments.
19. "Laboratory supervisor" means one of the laboratory workers to be responsible for conducting individual experiments.
20. "Founder of research institution" means the minister of the ministry, the head of local community, or the representative of the company to which the research institution belongs.

Item 3. Safety ensurance for recombinant DNA experiments

Recombinant DNA experiments or related experiments("experiments")

in the following) must be conducted under proper safety ensurance measures generally employed in microorganism laboratories, incorporating proper combinations of physical/biological containment measures as necessitated by the safety evaluation of the experiment. Large-scale culture experiments must be conducted in a facility equipped with large scale apparatuses equivalent to those with containment structures. However, large-scale culture experiments with recombinant organisms that have been confirmed for their biological safety can be conducted in a facility equipped with large scale apparatuses equivalent to properly equipped facilities.

Management of breeding/culture of recombinant animals/plants must be conducted as described in this guideline.

Item 4. Responsibility of laboratory workers

The laboratory workers must be aware of the necessity of safety ensurance measures in the experiments, actually taking those measures, and must have been thoroughly trained with expertise in standard methods and practices in microbiological experiments.

Item 5. Responsibility of heads of institutions

The head of the institution must continually strive for safety of experiments through organizational or other possible measures in the institution.

Item 6. Procedures for ensuring the safety experiments

Those experiments for which standards of containment are given in this guideline must be conducted according to those standards.

Those experiments for which this guideline gives no standards must be provided with standards according to safety verification as

necessitated. In case that experiments are required for safety evaluation to provide additional standards, or for obtaining special scientific knowledge, they shall be conducted under the guidance of the Government.

These experiments are classified as follows:

(1) Non-standard experiment

Those experiments, for which this guideline gives no standard of containment, conducted under governmental guidance after approval of the experimental plan by the director of the institution.

The period of approval for a non-standard experiment is three years.

(2) Standard experiment

1) Institution-authorized experiment

Those experiments, for which this guideline gives standard of containment, requiring prior approval of the plan by the director of the institution.

2) Institution-notified experiment

Those experiments, for which this guideline gives standard of containment, requiring prior notification approval of the plan to the director of the institution.

Non-standard experiments and institution-notified experiments must be reviewed by the Safety Committee (tentative name), a body independent from the involved institution.

Chapter 2. Methods of Containment

Section 1. Physical Containment

Item 1. Purpose of physical containment

The purpose of physical containment is to prevent transmission to laboratory workers and diffusion to outer world of recombinant organisms, through containing the organisms within the facility or apparatuses.

Item 2. Physical containment for experiments handling not more than 20 liters of culture

Physical containment for below-20 liter scale experiment is composed of three elements, i.e., containment facilities, laboratory design, and experiment rules. The containment is classified into four levels of P1, P2, P3, and P4.

(1) P1 level

1) Design of facility and laboratory

The laboratory must be equipped and designed to a level similar to a regular microbiological laboratory.

2) Experiment rules

① Keep windows and doors of the laboratory closed during experiments.

② The bench must be sterilized after work every day, and every time of inadvertent spills during experiment.

③ All waste materials arisen from experimental organisms must be sterilized before disposal. Contaminated instruments must be sterilized before cleaning for reuse or disposal.

- ④ Use of mechanical pipettes is recommended.
- ⑤ Eating, drinking, smoking or food storage are not permitted in the laboratory.
- ⑥ Wash hands after handling of recombinant organisms and before leaving the laboratory.
- ⑦ Take care to minimize generation of aerosols throughout all procedures.
- ⑧ When decontamination is to be done outside of the laboratory, the contaminated materials must be conveyed in a sturdy and tightly sealed container.
- ⑨ Control insects and rodents in the laboratory.
- ⑩ Use of syringes must be avoided as long as other means are available.
- ⑪ The laboratory must be kept clean and tidy.
- ⑫ Clothing for experiments must be chosen according to the direction of laboratory supervisor.
- ⑬ Other directions by laboratory supervisor must be followed.

(2) P2 level

1) Containment facilities

Treatment of recombinant organisms with apparatuses which are liable to generate large amounts of aerosols, such as blender, freeze-drier, ultrasonic homogenizer, or centrifuge, must be performed under necessary precautions to prevent leakage of aerosols to outside. Use of safety cabinet (See Table 1.) is recommended. The performance of cabinet should be tested as required.

2) Design of laboratory

The laboratory must be built in a building that has high-pressure autoclave to treat contaminated matters and waste materials.

3) Experiment rules

① Keep windows and doors of the laboratory closed during experiments.

② The bench and safety cabinet must be sterilized after work every day, and every time of inadvertent spills during experiment.

③ All waste materials including recombinant organisms must be sterilized before disposal. Contaminated instruments must be sterilized before cleaning for reuse or disposal.

④ Mechanical pipettes must be used.

⑤ Eating, drinking, smoking or food storage are not permitted in the laboratory.

⑥ Wash hands after handling of recombinant organisms and before leaving the laboratory.

⑦ Take care to minimize generation of aerosols throughout all procedures.

⑧ When decontamination is to be done outside the laboratory, the contaminated materials must be conveyed in a sturdy and tightly sealed container.

⑨ Control insects and rodents in the laboratory.

⑩ Use of syringes must be avoided as long as other means are available.

⑪ Workers must wear lab coats in the laboratory, and take these off when leaving the laboratory.

⑫ Those who are unaware of the nature of the experiment being

conducted must not be allowed to enter the laboratory without permission of the laboratory supervisor.

⑬ During experiments, post a sign of "P2 experiment under way" on the outside of the entrance.

Put same signs on freezers and refrigerators to keep recombinant organisms.

⑭ The laboratory must be kept clean and tidy.

⑮ HEPA filter of safety cabinet must be decontaminated through vapor sterilization with 10 g/m³ formaldehyde, before its replacement and inspection.

⑯ When another experiment classified under P1 category is conducted simultaneously in the same laboratory, the areas for these experiments must be strictly separated from each other.

⑰ Other directions by laboratory supervisor must be followed.

(3) P3 level

1) Facility of containment

① Treatment of recombinant organisms must be performed in a sealed safety cabinet where manipulation or use of equipments that can produce aerosols are allowed, except for specially designed aerosol-tight apparatuses.

② The safety cabinet must be installed in such a way to facilitate periodical inspection, exchange of HEPA filter, or formaldehyde sterilization, without moving the cabinet. The safety cabinet must be tested for:

- a. speed and flux of air flow
- b. performance of HEPA filter

c. air tightness

immediately after installation, and subsequently, for a. and b. more than once a year.

2) Design of laboratory

① The experiment area must be specified, including an entrance area with doors on the front and back sides, which cannot be opened simultaneously, and a changing room.

② The experiment area must be equipped with a high-pressure autoclave to treat contaminated matters and waste materials.

③ The floor, the wall, and the ceiling of the experiment area must be of structure and materials suited for cleaning and vapor sterilization.

④ The laboratory and its main exit must be equipped with a hand washer that can be activated by leg, elbow, or automatic sensor.

⑤ Windows of experiment area must have air-tight structure.

⑥ Doors of experiment area must have self-closing functions.

⑦ The vacuum line for experiment must be independent from other vacuum systems. Its inlets must be equipped with filter or trap of sterilizing solution.

⑧ The experiment area must be equipped with a ventilation system. This system must be designed so as to make air flow from the entrance area toward the experiment area. Exhaust from the experiment area must be released after filtration or other necessary treatment.

3) Experiment rules

① Keep doors of the laboratory closed during experiments.

② The bench and the safety cabinet must be sterilized after work every day, and every time of inadvertent spills during experiment.

③ All waste materials including recombinant organisms must be sterilized before disposal. Contaminated instruments must be sterilized before cleaning for reuse or disposal.

④ Mechanical pipettes must be used.

⑤ Eating, drinking, smoking or food storage are not permitted in the experiment area.

⑥ Wash hands after handling of recombinant organisms and before leaving the experiment area.

⑦ Take care to minimize generation of aerosols throughout all procedures.

⑧ When decontamination is to be done outside the laboratory, the contaminated materials must be conveyed in a sturdy and tightly sealed container.

⑨ Control insects and rodents in the experiment area.

⑩ Use of syringes must be avoided as long as other means are available.

⑪ In the experiment area, workers must wear lab coats with long sleeves and no front buttons, and must take these off when leaving the area.

The coats must be sterilized before laundering.

⑫ Entrance to and exit from the experiment area must be made through the entrance area. Outsider unaware of the nature of the experiment being conducted must not be allowed in the laboratory without permission of the laboratory supervisor.

⑬ During experiments, post a sign of "P3 experiment under way" on the wall of the laboratory and the outside of the entrance area.

Put same signs on freezers and refrigerators to keep recombinant organisms.

⑭ The experiment area must be kept clean and tidy, and unnecessary items must be kept out of the area.

⑮ HEPA filter of the safety cabinet must be decontaminated through vapor sterilization with 10 g/m³ formaldehyde, immediately before replacement, at its periodical replacement and at the time of change in the experimental program.

⑯ Sample must be handled with protecting gloves, which must be removed and sterilized after operation, with precaution not to contaminate other items.

⑰ Other experiments classified below P2 category must not be conducted simultaneously in the same laboratory.

⑱ Other directions by the laboratory supervisor must be followed.

(4) P4 level

1) Containment facilities

① Use a Class III safety cabinet to handle recombinant organisms. A Class I or Class II safety cabinet may be used only in case that the experiment is conducted in a special experiment area and the workers are wearing one-piece coats ventilated by life-supporting system and kept above-atmospheric pressure.

② The safety cabinet must be installed in such a way to facilitate periodical inspection, exchange of HEPA filter, or formaldehyde sterilization, without moving the cabinet. The safety

cabinet must be tested for:

- a. speed and flux of air flow (excluding Class III)
- b. performance of HEPA filter
- c. air tightness

immediately after installation, and subsequently, for a. and b. more than once a year.

2) Design of laboratory

① The experiment area must be specified as an entire building or a part thereof that is clearly separated from other areas, and it must be possible to restrict accessibility for persons who are not laboratory workers.

② The entrance area must have doors on the front and back sides, which can not be opened simultaneously, and must have changing room and shower room.

③ Personnel entering the experiment area to deliver samples or other supplies without changing their clothes must go through an entrance area, which has ultraviolet irradiation and front- and back doors that cannot be opened simultaneously.

④ The floor, the wall and the ceiling of the experiment area must be designed to facilitate cleaning and vapor sterilization and to prevent entering of insects and rodents; the area also must be capable of properly containing vaporized sterilizing agents at a constant pressure. This does not necessitate air tightness.

⑤ The laboratory and its main exit must be equipped with a hand washer that can be activated by leg, elbow, or automatic sensor.

⑥ Doors of the experiment area must have self-closing functions.

⑦ When a centralized vacuum line is provided, it must be dedicated to the experiment area, and equipped with HEPA filters at each vacuum terminal and as close as possible to inspection valves. These HEPA filters must be installed so as to be readily sterilized and exchanged.

⑧ Water and gas plumbing for the experimental area must be equipped with back-flush checkers.

⑨ The experiment area must be equipped with two-doored, pass-through type high-pressure autoclave ("autoclave" in the following) to sterilize items to be removed from the experiment area.

⑩ For removing samples or other items that are not suited to thermal sterilization, the experiment area must be equipped with a complete immerse-and-pass-through vessel ("immersing vessel" in the following) containing sterilizing agent, or vapor sterilization room with front and back doors that cannot be opened simultaneously ("vapor sterilization room" in the following).

⑪ The experiment area must be equipped with dedicated air supply/exhaust system. This system must be designed to supply air in the direction from low- to high-hazard area, maintaining pressure difference between successive areas. It must be designed to prevent backward flows. It must also be equipped with alarm system to warn failures and malfunction of the system.

⑫ Recycled air in each room must be cleaned with HEPA filter.

⑬ Exhaust from the experiment area must be filtered with HEPA filter and released avoiding to reach nearby buildings and

air-intakes. These HEPA filters must be installed to facilitate in-place sterilization and after-exchange performance test.

⑭ Processed exhaust from the Class III safety cabinet must be released to outside. Processed exhaust from the Class I or Class II safety cabinet may be released to experiment areas. When this exhaust is released through exhaust system dedicated to experiment area, the systems must be integrated so as not to disturb ventilation balances in experiment areas.

⑮ The special experiment area designated in the experiment area must meet the following requirements:

a. Life-supporting system must be equipped with alarm system and emergency air reservoir.

b. The entrance must be equipped with air-tight door for air-locking.

c. A chemical-agent shower room must be provided to remove contaminants on clothes at the time of dismissal.

d. Exhaust from this area must be doubly treated with HEPA filters.

e. Exhaust ventilator must have a backup for security.

f. Emergency power supply, lighting, and communication means must be provided.

g. Pressure of the area must be always lower than surrounding areas.

h. Autoclaves must be provided to sterilize wastes removed from the area.

3) Experiment rules

① Keep doors of the laboratory closed during experiments.

② The experiment desk and the safety cabinet must be sterilized after work every day, and every time of inadvertent spills during experiment.

③ All waste materials including recombinant organisms must be sterilized before disposal. Contaminated instruments must be sterilized before cleaning for reuse or disposal.

④ Mechanical pipettes must be used.

⑤ Eating, drinking, smoking or food storage are not permitted in the experiment area.

⑥ Wash hands after handling recombinant organisms and before leaving the experiment area.

⑦ Take care to minimize generation of aerosols throughout all procedures.

⑧ When a living specimen is removed from the Class III safety cabinet or from the experiment area, it must be kept in a sturdy and leak-free container and must be passed through immersing-type or vapor-phase sterilization chamber.

Same for when the Class III safety cabinet is used.

⑨ A sample or an item, other than a living specimen, to be removed from the Class III safety cabinet or experiment area must be sterilized by autoclave; items susceptible to heat or steam can be treated by immersion vat or vapor sterilization. Same procedure applies to introduction of sample or item into the Class III safety cabinet.

⑩ Control insects and rodents in the experiment area.

⑪ Use of syringes must be avoided as long as other means are available.

⑫ Experiment area must be kept accessible only to laboratory workers and safety checking personnel.

⑬ Entering and exiting of experiment area are done through the entrance area equipped with a shower.

⑭ A worker must wear a full set of experimental wears consisting of underwears, pants, shirts, jacket, shoes, cap, gloves, etc. On exiting the worker must take off and place all these items in collecting chest before entering the shower room.

⑮ All freezers and refrigerators containing recombinant organisms must bear internationally established signs of biological hazard.

⑯ The experiment area must be kept clean and tidy, and unnecessary items must be kept out of the area.

⑰ HEPA filter of the safety cabinet must be decontaminated through vapor sterilization with 10 g/m³ formaldehyde, immediately before replacement, at its periodical replacement and at the time of change in the experimental program.

⑱ Waste water from safety cabinet and laboratory sinks must be sterilized by heating. Waste water from shower and hand washing sinks must be sterilized by physical or chemical means.

⑲ Other experiment classified below P3 category must not be conducted simultaneously in the same laboratory.

⑳ Other directions by laboratory supervisor must be followed.

Item 3. Physical containment for large-scale culture experiment

Rules for physical containment of large-scale culture experiments consists of containment facility, design, and experimental guideline. They are classified into three levels, LS-C, LS-1, and LS-2, according to the level of containment.

(1) LS-C level

1) Facility and design of containment

① Fermenters and other instruments must be kept in well-maintained conditions.

② Exhaust gas from fermenter for recombinant organisms must be processed by a system that is designed to minimize release of recombinant organisms.

2) Experiment rules

① All solid and liquid wastes from large-scale culture experiments must be inactivated after completion of experiments and before disposal of wastes. The effectiveness of the inactivation procedure must be verified for the host used in the large-scale culture experiments.

② Inoculation of culture medium with recombinant organisms or sampling of recombinant organisms from the culture must be done with proper caution to minimize contamination of outer surfaces of the fermenter.

③ Transfer of recombinant organisms from fermenter to other instruments must be done with proper caution to minimize contamination with recombinant organisms.

④ Area for large-scale culture experiments ("Large-scale culture experiment area" in the following) must be kept clean. Proper measures must be taken to control insects and rodents.

⑤ Fermenter or other apparatuses in which a large-scale culture experiment is under way must be indicated as "LS-C level large-scale experiment under way".

⑥ Clothing for large-scale culture experiment must be specified by the laboratory supervisor.

⑦ Other directions by the laboratory supervisor must be followed.

(2) LS-1 level

1) Facility and design of containment

① The fermenter must be designed to prevent release of recombinant organisms and to facilitate interior sterilization without opening the vessel. The fermenter must be tested for airtightness immediately after installation and annually.

② Instruments that are prone to generate aerosols in processing recombinant organisms, such as blender, lyophilizer, ultrasonic homogenizer, or centrifuge, must be placed in containing safety cabinet or equivalent means ("safety cabinet" in the following). The said rule, however, shall not apply when the instruments are inherently designed to prevent release of aerosols. The safety cabinet must be tested for performance at the time of installation and regularly once a year.

③ Fermenter for recombinant organisms must be designed so that all exhaust gas is released through sterilizing filter or other

sterilizing means("sterilizing filter" in the following). The filter must be tested at the time of installation and once a year thereafter.

④ Any modification and replacement of parts of instruments related to containment functions must be followed by tests of related parts for air-tightness and performances.

2) Experiment rules

① Large-scale culture experiment area must be specified.

② All contaminated apparatuses and instruments, including fermenters, and waste materials generated by recombinant organisms in large-scale culture experiments must be sterilized after completion of large-scale culture experiments and before disposal. The effectiveness of sterilization procedures must be verified beforehand for the host used in the large-scale culture experiment.

③ Use of mechanical pipette is recommended.

④ Eating, drinking, smoking or food storage are not permitted in the experiment area.

⑤ Wash hands after handling recombinant organisms and before leaving the large-scale culture experiment area.

⑥ Take care to minimize generation of aerosols throughout all procedures.

⑦ Inoculation of culture medium with recombinant organisms or sampling of recombinant organisms from the culture must be done with proper caution to minimize contamination of outer surfaces of the fermenter. Any contamination must be immediately removed.

⑧ Transfer of recombinant organisms from fermenter to other

fermenter or sealed vessels or instruments must be done by using sturdily and tightly sealed container. The transfer operation must be done while preventing contamination of outer surfaces of the container. Any contamination must be removed immediately.

⑨ Culture medium containing recombinant organisms must not be taken out from fermenter without sterilization, except for the procedure is done in a safety cabinet, or by the conditions of ⑦ or ⑧. The effectiveness of the sterilization procedure must be verified beforehand for the host for the large-scale culture experiment.

⑩ When decontamination is to be done outside the large-scale culture experiment area, the contaminated materials must be conveyed from the large-scale culture experiment area in a sturdy and tightly sealed container.

⑪ Large-scale culture experiment area must be treated for proper procedures to control insects and rodents.

⑫ The large-scale culture experiment area must be indicated as "LS-1 level large-scale experiment under way".

Freezers and refrigerators containing recombinant organisms must be similarly indicated.

⑬ Clothing for the large-scale culture experiment must be chosen under direction of the laboratory supervisor.

⑭ Tightness of sealing must be checked at least once a day during the course of the large-scale culture experiment.

⑮ Sterilizing filters for the safety cabinet or other instruments must be sterilized prior to replacement and at the time

of periodical inspections.

⑮ When other experiment classified as P1 category is conducted simultaneously, the areas must be clearly specified and separated carefully.

⑯ Other directions by the laboratory supervisor must be followed.

(3) LS-2 level

1) Facility and design of containment

① The fermenter must be designed to prevent release of recombinant organisms and to facilitate interior sterilization without opening the vessel. In particular, parts subjected to direct contact with fermenter, such as revolving seals or tubings, must be designed with adequate precaution to prevent leaks of recombinant organisms. The fermenter must be tested for air-tightness immediately after installation and each time of the large-scale culture experiment.

② Instruments that are prone to generate aerosols in processing recombinant organisms, such as blender, lyophilizer, ultrasonic homogenizer, or centrifuge, must be placed in a Class-II safety cabinet or equivalent means ("Class-II safety cabinet" in the following). The said rule, however, shall not apply when the instruments are inherently designed to prevent release of aerosols.

③ Fermenter for recombinant organisms must be designed so that all exhaust gas is released through sterilizing filter (with a microbe removing performance better or equivalent to HEPA filter) or other sterilizing means ("sterilizing filter" in the following).

The filters must be tested at the time of installation and regularly once a year thereafter.

④ The class II safety cabinet must be installed to facilitate periodical inspection, replacement of sterilizing filters and formaldehyde vapor sterilization without moving the cabinet.

The class-II safety cabinet must be tested for a) - c) at the time of installation, and for a) and b) periodically at least once a year.

a) Air flow speed and flux test

b) Performance test of sterilizing filter

c) Air tightness test

⑤ Containment apparatuses, including fermenters, instruments attached therewith, or the class-II safety cabinet, must be equipped with means to monitor air-tightness of the apparatus during large-scale culture experiments.

⑥ All apparatuses and instruments must be numbered serially and put under strict controls. These numbers must be described in all related records including inspection and operation records.

⑦ Laboratory must be located in a building equipped with autoclave to sterilize contaminated items and waste materials.

⑧ Any modification and replacement of parts of instruments related to containment functions must be followed by tests of related parts for air-tightness and performances.

2) Experiment rules

① Keep windows of the laboratory closed during large-scale culture experiments. Opening of doors should be minimized.

② All contaminated apparatuses and instruments, including

fermenters, and waste materials generated by recombinant organisms in large-scale culture experiments must be sterilized after completion of large-scale culture experiments and before disposal. The effectiveness of the sterilization procedures must be verified beforehand for the host used in the large-scale culture experiment.

③ Mechanical pipettes must be used.

④ Eating, drinking, smoking or food storage are not permitted in the experiment area.

⑤ Wash hands after handling recombinant organisms and before leaving the laboratory.

⑥ Take care to minimize generation of aerosols throughout all procedures.

⑦ Inoculation of culture medium with recombinant organisms or sampling of recombinant organisms from the culture must be done with proper caution to minimize contamination of outer surfaces of the fermenter. Any contamination must be immediately removed.

⑧ Transfer of recombinant organisms from fermenter to other fermenter or sealed vessels or instruments must be done by using sturdily and tightly sealed container. The transfer operation must be done while preventing contamination of outer surfaces of the container. Any contamination must be removed immediately.

⑨ Culture medium containing recombinant organisms must not be taken out from fermenter without sterilization, except for the procedure is done in a Class-II safety cabinet, or by conditions of ⑦ or ⑧. The effectiveness of the sterilization procedure must be verified beforehand for the host for large-scale culture

experiments.

⑩ When decontamination is to be done outside of the laboratory, the contaminated materials must be conveyed from the laboratory in a sturdily and tightly sealed container.

⑪ Laboratory area must be treated for proper procedures to control insects and rodents.

⑫ The worker must wear clothes as specified for large-scale culture experiments; the clothes must be taken off at the time of dismissal.

⑬ Those who are unaware of the nature of the experiment being conducted must not be allowed in the laboratory without permission of the laboratory supervisor.

⑭ During large-scale culture experiments, post a sign of "LS-2 level experiment under way" on the outside of entrance.

Put same signs on freezers and refrigerators to keep recombinant organisms.

⑮ Laboratory must be kept clean, tidy, and free of unnecessary items.

⑯ Containment apparatuses, including fermenters, instruments attached therewith, or the class-II safety cabinet, must be continually monitored during large-scale culture experiments.

⑰ Sterilizing filters for the class-II safety cabinet and other apparatuses must be decontaminated by one-hour, 10 g/m³ formaldehyde vapor treatment or other means.

⑱ When other large-scale culture experiments classified as P1, P2 or LS-1 category is conducted simultaneously, the area must be

clearly specified and separated carefully.

⑯ Other directions by the laboratory supervisor must be followed.

<Table 1> Standard for safety cabinet and HEPA filter.

Class I

Usage	For handling microbe or pathogenic bacteria of low or medium level hazard, when clean air is not required for operating area.
Structure and specification	Having front opening and exhaust opening. Air flow entering through the front opening prevents release of aerosols. Exhaust is treated by HEPA filter and released to outside of cabinet. Average air flow speed (air flux per unit opening area) must be more than 0.40 m/s.

Class II

Usage	For handling microbe or pathogenic bacteria of low or medium level hazard, when clean air is required for operating area. Type A is for regular biological studies; Type B is for handling small amounts of hazardous chemicals, radioactive materials, gaseous substances which cannot be efficiently trapped by HEPA filter.
Structure	Having front opening and exhaust opening. Air flow entering through the front opening prevents release of aerosols and a laminar flow of clean air is supplied through HEPA filter. Exhaust is treated by HEPA filter and released to outside of cabinet. The structure having contaminated positive-pressure plenum contacting the outer-wall is not recommended for Type A. Type B must have a duct to lead exhaust to outside of the room.

Specification

Air-tightness

When cabinet is pressurized with air to 50 mm water, loss of pressure after 30 minutes must be less than 10%, or leak must not be detected by applying soap water or leak detecting agent to all joints and welded parts of cabinet (Leak of halogen must be less than 5×10^{-7} cc/sec for the type having positive plenum contacting outer wall.)

Safety test for operators

When $5 - 10 \times 10^8$ cfu (colony forming unit) of Bicillus subtilis spore suspension is sprayed for test, the number of colony trapped by 4 impingers must be less than 10. The number of colony on slit sampler within 5-15 min after starting test must be less than 5 for each test. Three consecutive tests must be cleared.

Sample protection test

When $5 - 10 \times 10^6$ cfu of Bicillus subtilis spore suspension is sprayed for test, the number of colony trapped on agar plates (10 cm petri dishes are placed as many as possible. Same in the following.) must be less than 5. Three consecutive tests must be cleared.

Cross contamination test

When $5 - 10 \times 10^4$ cfu of Bicillus subtilis spore suspension is sprayed for test, the number of colony trapped on agar plates displaced from the wall by more than 355 mm must be less than 2 in total. Three consecutive tests for each of left side and right side must be cleared.

Blowing speed

Wind speed measured by lattice with a pitch smaller than 15 cm must be within $\pm 20\%$ of averaged value. For cabinet designed to provide graduated wind speed, the test must be made for each area specified by the manufacturer.

Inlet air speed

Average inlet air speed from front opening must be more than 0.40 m/s (0.50 m/s for Type B).

Wind generator

When pressure loss by filter is increased by 20%, the loss in the air flux from wind generator must be less than 25% without adjusting its rotation.

Direction of air flow

Flow profile is visually examined by using smoke generator. Smoke must be moving smoothly downward at various positions between right and

	left walls for the following levels: 100 mm$\pm$10 mm above the lower edge of front panel; position of splitting downward laminar air flow into front and back air intake in the operating space; 150 mm$\pm$20 mm above the lower edge of front panel; 20-30 mm inside of front panel. There must be no parts where smoke does not move or moves upward. There must not be leaks of smoke. When scanned at 30 mm to 40 mm high on the outside of front opening, smoke that has once entered the cabinet must not be released from the cabinet or let in to the working room. Temperature rise The difference between room temperature and inner temperature of cabinet must be less than 8°C after 4 hours of continuous operation. Noise level Noise level must be below 67 dBA. Illumination Average illumination must be between 600 and 1200 lux. Vibration Amplitude of vibration in three perpendicular directions must be less than 5 μmRMS. Liquid holding pan Liquid holding pan must have a structure for easy cleaning, with a capacity of more than 4 liters.
Consideration about cleaning and sterilization	Surfaces that are prone to be contaminated with liquids and splashes must be suited for cleaning without using tools. Corners of workbench and working space must be rounded. Cabinet must have structure to allow formaldehyde vapor sterilization without moving the unit. Front opening and exhaust outlets must have structure to allow sealing with metal plate, plastic sheet, or sticking tape. For ease of cleaning, bottom of cabinet must be elevated from the floor by more than 80 mm, or it must be tightly fixed onto the floor or base.
Inspection	Various changes, such as clogging of HEPA filter, can occur that affect the performance after start of operation. For securing safety operations, after-installation and annual inspections are recommended.

Class III

Usage	For handling microbe or pathogenic bacteria of high-level hazard.
Structure and specification	Sealed cabinet with air intake through front opening and outlet through exhaust opening, both being processed by HEPA filter. Exhaust must be release to outside after doubly filtered by HEPA filter, or by going through incinerating sterilizer. Working space must have negative pressure (more than 15 mm water) relative to working room. Operation gloves, autoclave or sterilizing vat for introduction and removal of samples and instruments must be provided.

HEPA filter for safety cabinet

Performance	When test aerosol is applied to primary side of filter, passing rate for each supposed compartment(secondary-to-primary ratio of aerosol concentration) must be lower than 0.01%. When scanning test was conducted by using relative concentration meter or particle counter with intake flow rate of 28.3 l/min at a condition of nearly constant flow rate, passing rate for ca. 0.3 μ m aerosol particles must be less than 0.01%. Use an aluminum separator. Preferably equipped with a differential pressure gauge to indicate pressure loss at HEPA filter.
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Section 2. Biological containment

Item 1. Purpose of biological containment, and other matters

1 The concept of biological containment for experiments (excluding those experiments in which use nonviral hosts are used, all virus-derived DNAs have solely expression-controlling functions as promoters or terminators, and no infectious viruses are produced.

"experiments using virus etc." in the following.) involving viruses (viruses, viroids of eukaryotes excepting fungi, and protozoa of vertebrates. Same in the following.) is to ensure safety of experiments by keeping high biological safety of recombinant organisms through the use of: a host-vector system composed of a host that is viable only under special incubation conditions and a vector that is transferable only to specially prepared experimental cells, thus preventing transmission and diffusion of recombinant organisms to environment; or host-vector systems for which high biological safety has been established.

2 Safety for experiments other than virus experiments ("experiments using cultured cell etc." in the following), which is considered to be inherently safer than experiments using virus etc. in terms of transmissibility, is ensured by considering the biological properties of DNA donor used in recombinant DNA preparation, and by examining biological properties of constituent elements of host-vector system.

3 To attain the purpose of biological containment, the laboratory worker must continually and vigorously examine that the used hosts and vectors meet the conditions of biological containment.

Item 2. Level of biological containment

1 Experiments using virus etc.

The level of biological containment for experiments using virus etc. is defined as B1 and B2, depending on the level of biological safety of host-vector system. (A host-vector system belonging to B1 or B2 level is called "authorized host-vector system", Same in the following.)

(1) B1 level

A B1 level host-vector system is either; host-vector system composed of a host with low viability in natural conditions and a vector with high dependency on host, thus being not readily transferable to other cells; or host-vector system that has been demonstrated, on basis of genetic/physiological properties or ecological behavior under natural conditions, to have high biological safety for human or other organisms. The host-vector systems listed in Table 2(1) belong to B1 level.

(2) B2 level

A B2 level host-vector system is host-vector system to meet the criteria for B1 level, and composed of a host with especially low viability in natural conditions and a vector with especially high dependency on host, thus being effectively prevented from transmission and diffusion into environment. The host-vector systems listed in Table 2(2) belong to B2 level.

Those host-vector systems (excluding the systems generating infectious viruses) using cultured cells (excluding those for

differentiation) of animals or plants designated as high-safety host under the guidance of the Government can be treated as B2 level host-vector systems.

Standard for containment of recombinant organisms is defined by combining safety evaluations based on biological properties of host-vector systems and DNA donors.

Exceptionally, DNAs prepared from cells, cloned DNAs, or chemically synthesized DNAs for which function, size, and structure are well understood are regarded as having high safety. The containment standard can be lowered for these DNAs.

<Table 2> Authorized host-vector system

(1) B1 level host-vector system

a.	EK1 (The host-vector system composed of <u>Escherichia coli</u> K12 strain, which is genetically and physiologically well understood, nontoxic, and poorly viable under natural conditions and its induced strain) as host, and plasmid or bacteriophage as vector that are inconjugatable and not transferable to other bacteria. The host must not have conjugatable plasmids or conventionally introduced bacteriophages.
b.	SC1 (The host-vector system composed of laboratory-maintained strain of yeast, <u>Saccharomyces cerevisiae</u> , as host, and plasmid or minichromosome as vector.)
c.	BS1 (The host-vector system composed of an induced strain of <u>Bacillus subtilis</u> Marburg 168 which has mutation of multi-nutritional requirement for amino acids or nucleic acid bases as host, and plasmid or bacteriophage that is inconjugatable and not transferable to other bacteria.)
d.	The host-vector system composed of animal or plant cells (excluding those for differentiation) as host (excluding those cases to produce infectious viruses).

(2) B2 level host-vector system

a. EK2 (Those systems belonging to EK1, and composed of a genetically defective host, listed in the left column below, which has very low viability except under special incubating conditions and a highly host-dependent vector, listed in the right column, which has very low transferability to other cells. The system must have a survival ratio for recombinant cell, of 10 parts per billion after 24 h of incubation except for special conditions.)

HOST	VECTOR
λ 1776	pSC101 pCR1 pMB9 pBR313 pBR322 pBR325 pBR327 pDH24 pGL101 Ylp1 YEp2 YEp4 Ylp5 YEp6 YRp7 YEp20 YEp21 YEp24 Ylp26 Ylp27 Ylp28 Ylp29 Ylp30 Ylp31 Ylp32 Ylp33 pKY2662 pKY2738 pKY2800
DP50 sup F	λ WES λ B λ gtAL0 λ B Charon21A

<u>E. coli</u> K12	λ gtvJZ-B
DP50 DP50 sup F	Charon3A Charon4A Charon16A Charon23A Charon24A

2 Experiments using cultured cell etc.

(1) The biological properties of host-vector systems and DNA donors used in experiments using cultured cell etc. must be evaluated in terms of the following aspects.

- ① Pathogenicity
- ② Toxigenicity
- ③ Parasitism, Fixability
- ④ Carcinogenicity
- ⑤ Resistance to chemicals
- ⑥ Influences on metabolism
- ⑦ Influences on ecological system
- ⑧ Host dependency
- ⑨ Transmittability

Based on these criteria, the containment levels are classified as in Safety Evaluation Classification Table (Attached Table 1-3).

(2) Standard of containment method for recombinant organisms in experiment using cultured cell etc. must be determined by safety evaluation of the highest required containment level of involved host-vector system or DNA donor. Also, safety consideration for transmittability must be made separately.

On the other hand, DNAs prepared from cells, cloned DNAs, or chemically synthesized DNAs with known function, size and structure are evaluated as having higher safety, and lower standards of containment can be applied.

Chapter 3. Handling of recombinant organisms

Item 1. Storage of recombinant organisms

1 Sample or waste containing recombinant organisms must be clearly indicated as "Recombinant organisms" and stored safely in a laboratory, experiment area, or large-scale culture experiment area that meets the conditions of containment required for experiments using recombinant organisms.

Freezers or refrigerators storing sample or waste containing recombinant organisms must be indicated as "Recombinant organisms stored".

2 The laboratory supervisor must keep and store the record of sample and waste containing recombinant organisms. However, the experiment record suffices instead of sample/waste record for experiments involving only those recombinant organisms that require P2 or lower physical containment.

3 The above rules apply to experiments using animals, plants, or cultured cells (differentiation purpose only); additional rules for these experiments will be described in Part II.

Item 2. Transportation of recombinant organisms

1 Transportation of sample or waste containing recombinant organisms requiring P2- or lower physical containment to outside of laboratory or experiment area must be done in a tight and leak-free container which is sealed in the laboratory.

2 Transportation of sample or waste containing recombinant

organisms requiring P3- or higher physical containment to out side of laboratory or experiment area must be done as in 1 above, and special measures must be taken to prevent release of contents in case of failure of container. Container or package must be clearly indicated as "Handle with care" in red ink.

Mailing of such a container or package is subject to the following rules: Japan Postal Service Code, Section 8, Item 3; International Postal Service Code, Sections 68 and 69; and, International Postage Treaty, Acting Rule, Sections 119 and 120.

3 The laboratory supervisor must keep and store the record of name, amount, destination (names of institution and responsible individual). However, the experiment record suffices instead of transportation record for experiments involving only those recombinant organisms that require P2 or lower physical containment.

4 In the case of large-scale culture experiment, LS-C level physical containment or transportation of samples or wastes containing recombinant organisms used in Part II, Chapter 2, Section 2, Item 2 (2) ② from the large-scale culture experiment area must be done in the same manner for the case requiring lower than P2-level physical containment. Samples or wastes containing recombinant organisms used in LS-1 or LS-2 level must be handled in the same manner for the case requiring P3 level physical containment.

5 Experiments using animals, plants or cultured cells (only those for the purpose of differentiation) as host shall be described in

Part II, in addition to the rules described above.

Chapter 4. Training and health care

Item 1. Training

Laboratory supervisors or heads of institutions must provide laboratory workers thorough instruction of the guideline and conduct educational training regarding the following items.

- (1) Safe handling of microbes according to the level of their possible hazard.
- (2) Knowledge and expertise about physical containment.
- (3) Knowledge and expertise about biological containment.
- (4) Knowledge about hazard of experiment to be conducted.
- (5) Knowledge about emergency response (Special care must be taken for chemical sterilization in case of leaks of medium in large-scale culture experiments.)

Item 2. Health care

1 The head of institution must provide experimenters regular health checks before starting experiment and every period thereafter shorter than one year.

2 The head of institution must provide reviews on prophylactic remedies for laboratory workers handling pathogenic microbes, and provide them with antibiotics, vaccines, or serum as necessitated. In addition, special health check must be provided in every less than six months after starting experiment.

3 When experiment is conducted in experiment area at or over the P3 level, the head of institution must collect samples of serum of laboratory workers before starting experiment, and store them at least two years after completion of experiment.

4 In case of possible infections in experiment areas, the head of institution must conduct immediate health check and other necessary measures.

5 Heads of institutions must take and keep records of health checks.

6 Heads of institutions must provide immediate investigation and necessary measures in one or more of the following case arise for laboratory workers or when being informed of incidents described in(7)

(1) When recombinant organisms are inadvertently swallowed or inhaled.

(2) Skin contact with recombinant organisms.

(3) Attendance to significant contamination of laboratory, experiment area or large-scale culture experiment area with recombinant organisms.

7 Laboratory workers must pay continuous attention to his/her state of health. Laboratory workers must inform the head of the institution of any physical irregularities serious or long-term diseases. Any individual who had opportunity to learn the said conditions of others has the same duty.

Chapter 5. Organization for safety ensurance of experiments

Item 1. Laboratory worker

Laboratory workers must be highly aware of the importance of safeguards for the experiment in planning and implementation of experiments, and must have sufficient knowledge and expertise in standard techniques and special procedures involved in the experiment regarding microbes.

Item 2. Laboratory supervisor

The laboratory supervisor must be an individual with thorough knowledge of this guideline, knowledge and expertise to prevent biological incidents and related knowledge and expertise, to conduct the following duties:

- 1 To follow this guideline strictly in planning and implementing experiments and provide proper management and direction in close cooperation with the safety officer.
- 2 To provide laboratory workers with training described in the preceding chapter, Item 1.
- 3 To submit the plans for non-standard or institution-authorized experiments to the head of institution. Same for alteration in experiment plans.
- 4 To submit the plans of institution-notified experiments beforehand to the head of institution. Same for alteration in experiment plans.
- 5 To take other necessary measures for ensuring safety of

experiments.

Item 3. Head of institution

The head of institution is responsible for safety for experiment conducted by laboratory workers, bearing the following responsibility:

1 To appoint members of the safety committee (tentative) and the safety officer (tentative).

2 To provide health control measures for laboratory workers, described in the preceding chapter, Item 2, according to recommendations by the safety committee.

3 To maintain the following records for large-scale culture experiments for more than five years after conducting the experiment. These records must be submitted to the Government on request.

(1) Document showing ground of authorization of the large-scale culture experiment with regard to this guideline.

(2) Record of reviews by the safety committee.

(3) Document regarding safety measures in experimental facilities, methods, and results.

4 To approve or not approve non-standard experiments after review by the safety committee and under guidance by the government.

5 To approve or not approve institution-authorized experiments after review by the safety committee.

6 To accept notifications of experimental plans for institution-notified experiments.

7 To accept experiment completion reports and notifications on

storage facilities and persons in charge for storage of recombinant organisms.

8 To conduct other necessary safety measures.

Item 4. Safety committee

1 The institution must have a safety committee(tentative).

2 The safety committee must be composed of experts of various disciplines who can provide professional knowledge, expertise, and decision-making.

3 The safety committee must respond to requirements by the head of the institution about the following matters:

(1) compliance of experiment plans to this guideline

(2) training and health control measures for experiment

(3) emergency response

(4) other safety measures.

4 The safety committee can require reports from the laboratory supervisor or the safety officer as necessitated.

Item 5. Safety officer

1 Appoint a safety director to assist the head of institution (tentative).

2 The safety officer must have full knowledge of this guideline, and general and specific knowledge/expertise for preventing biological incidents. The person must conduct the following duties:

(1) to monitor compliance of experiments to this guideline

(2) to give advice and instruction to the laboratory supervisor

(3) to provide other services required for safety activities.

3 The safety officer must be in close contact with the safety committee in the course of conducting duties and submit reports on necessary items to the committee.

Item 6. Founder of Institution

The founder of institution must provide advice and instruction to the head of institution with regard to experimental safety.

PART II. Specific Rules

Chapter 1. Category of Experiments

Experiments are classified into the following categories with regard to the type of organisms:

1 Experiments using cultured cells etc.

(1) Experiments using microbes or cultured cells as host

Experiments using microbes (including rickettsiae and chlamydia but excluding viruses. Same in the following.) or cultured cells (excluding those for differentiation purposes) as host. This category does not include experiments using virus-derived DNAs (except for those having expression-controlling functions only, such as promoters and terminators, and not producing infectious viruses)

(2) Experiments using animals or plants as host

Experiments using animals, plants or cultured cells (only those for differentiation purposes) as host. This excludes those experiments involving virus-derived DNAs (except for those having expression-controlling functions only such as promoters or terminators, and not producing infectious viruses).

2 Experiments using viruses etc.

Experiments using viruses etc. (except for experiments in which all virus-derived DNAs have expression-controlling functions only such as promoters or terminators, and not producing infectious viruses).

Category of experiment		Host-vector system		DNA donor
		Host	Vector	
Experiments using cultured cells etc.	Experiments using microbes or cultured cells as host	Microbes (including rickettsiae and chlamydia and excluding viruses (excluding viruses of non-fungi eukaryotes, viroids, and protozoa of vertebrates. Same in the following.)) and cultured cells (only those not intended for differentiation)	DNAs of nonviral origins and those DNAs of viral origins having expression-controlling functions only such as promoters and terminators, and not producing infectious viruses.	
	Experiments using animals or plants as host	Animal, plant and cultured cells (only those for differentiation purposes).		
Experiments using viruses etc.		Experiments using viruses etc. (excluding those experiments using nonviral hosts in which all DNAs of viral origin have expression controlling functions only such as promoters and terminators, and not generate infectious viruses).		

Chapter 2. Experiments using microbes or cultured cell as host

Those experiments using microbes or cultured cells (only those for non-differentiation purposes) as host must be conducted properly according to this guideline.

Section 1. Definitions of non-standard and standard experiments

Item 1. Non-standard experiment

Those experiments using microbes or cultured cells as host and meeting one or more conditions described below are referred to as non-standard experiments.

- (1) Experiments using microbes that are not identified species and are not confirmed non-pathogenicity.
- (2) Experiments using DNAs having expression-controlling functions only such as promoters and terminators, not producing infectious viruses, and derived from DNA donors listed in Attached Table 2-(4) or Attached Table 3-(4) .
- (3) Experiments using hosts or vectors listed in Attached Table 1-(1).
- (4) Cloning experiments of genes that can generate protein toxic to vertebrates.
- (5) Large-scale culture experiments, excluding the following experiments, which correspond to P1 or P2 level containment in less than 20-liter scale, and use recombinant organisms composed of host-vector system and cell-derived, cloned or chemically synthesized DNAs with known function, size and structure, having useful functions such as production of useful proteins.

• Experiments which use recombinant organisms composed of host-vector system listed in the left column of Table 3 and cell-derived, cloned or chemically synthesized DNAs in Attached Table 1-(3) with known function, size and structure, having useful functions such as production of useful proteins.

(6) Experiments involving environmental release of recombinant organisms.

Item 2. Institution-authorized experiment

Experiments other than non-standard experiments and institution-notified experiments are treated as institution-authorized experiments.

Item 3. Institution-notified experiment

Experiments using EK1, BS1, SC1 or EK2 as host-vector system and using plants or the organisms listed in Attached Table 1-(3) as DNA donor are treated as institution-notified experiments (except for those described in Item 1 above).

Section 2. Standard for containment method according to safety evaluation of experiments

Item 1. Basic concepts in safety evaluation of experiments

(1) Experiments must be conducted under proper measures to ensure safety, based on common standard procedures in microbiological laboratories, and under planning for proper physical containment according to biological safety evaluation of the involved recombinant organisms.

(2) Experiments using authorized host-vector system are regarded as

having higher safety level than those using other host-vector systems.

Experiments using host-vector system of EK1, BS1, SC1, or EK2 are regarded as having especially high safety level for recombinant organisms.

Also, when DNAs listed in the center column of Table 3 or those which is derived from DNA donors that are confirmed of having same safety evaluation thereof is introduced into a host-vector system listed in the left column of Table 3, safety evaluation for the recombinant body is considered to be as high as in the experiment described above.

(3) Safety for large-scale culture experiments must be secured as described above and additionally by using well-equipped experimental facilities using various tightly containing apparatuses such as large-scale fermenters. However, large-scale culture experiments using recombinant organisms that have been confirmed especially high safety levels can be conducted in a facility having well-maintained large scale fermenters or equivalent facilities.

Item 2. Standard for containment method according to

biological safety evaluation of recombinant organisms

(1) Experiments of 20-liter or smaller scale

Safety classification for cells used as host-vector system or DNA donor is given in Attached Table 1. Standard containment methods for recombinant organisms shall be determined by safety evaluation of the constituent thereof requiring the highest level of

containment.

For DNAs derived from viruses etc. (having expression-controlling function only such as promoter or terminator, and not generating infectious viruses), safety classification for used viruses etc. shall be those given in Attached Tables 2 and 3.

(2) Large-scale culture experiments

1) DNAs to be used in large-scale culture experiments must be limited to cell-derived DNAs, cloned DNAs, or chemically synthesized DNAs that have known function, size and structure, and are known to have certain utility such as production of useful proteins.

2) When the experiment requiring P1 level physical containment, performed at below-20-liter scale, is to be performed at above-20-liter scale, LS-1 level physical containment shall apply. Also, when the experiment requiring P2 level physical containment when performed at below-20-liter scale is to be performed at above-20-liter scale, LS-2 level physical containment shall apply.

3) However, those experiments which use recombinant organisms with confirmed high level of biological safety can be conducted according to the following rules under the guidance of the government:

① physical containment of LS-C level

② special physical containment method other than physical containment levels described in Part 1, Chapter 2, Section 1, Item 3.

(3) Exception to containment level for DNA donor

When DNA donor is chosen from cell-derived DNAs, cloned DNAs, or chemically synthesized DNAs that have known function, size and

structure, the containment level for experiment can be lowered through review by the Safety Committee for the following criteria:

- ① pathogenicity
- ② production of toxic substances
- ③ carcinogenicity
- ④ transmittability

Section 3. Transfer and handling of recombinant organisms after completion of experiments

Item 1. Transfer of recombinant organisms.

The recombinant body can be transferred to other research institutions. The institution to receive the recombinant organisms must follow the procedure described in Part I, Chapter 1, Item 6.

Item 2. Handling of recombinant organisms after completion of experiments

After completion of experiment, The recombinant organisms must be inactivated and disposed. However, when other experiments are to be conducted by using the same recombinant organisms, it can be stored by notifying the institution director of the completion of the first experiment, location and person in charge of storage of the recombinant organisms. Further storage of the recombinant organisms derived from non-standard experiment or continuation of experiment using thereof must follow, in addition to the above rules, the guidance of the Government.

<Table 3> Host-vector systems that are particularly safe only
in case of using selected types of DNA donors

Host-vector system	DNA donor	Physical containment level for experiment
Host-vector system composed of the following bacteria as host and plasmids of bacteriophages as vector <u>Acetobacter aceti</u> <u>Acetobacter liquefaciens</u> <u>Acetobacter pasteurianus</u> <u>Bacillus amyloliquefaciens</u> <u>Bacillus brevis</u> <u>Bacillus stearothermophilus</u> <u>Bacillus subtilis</u> (Other than BS-1 series) o <u>Brevibacterium flavum</u> o <u>Brevibacterium lactofermentum</u> <u>Corynebacterium ammoniagenes</u> <u>Corynebacterium glutamicum</u> o <u>Corynebacterium herculis</u> <u>Escherichia coli</u> (B strain) <u>Gluconobacter oxydans</u> <u>Lactobacillus helveticus</u> <u>Pseudomonas putida</u> <u>Streptococcus cremoris</u> <u>Streptococcus lactis</u> <u>Streptococcus thermophilus</u> <u>Streptomyces coelicolor</u> <u>Streptomyces griseus</u>	Those described in Attached Table 1-(3)	P1

- o <u>Streptomyces kasugaensis</u> - o <u>Streptomyces lividans</u> <u>Streptomyces parvullus</u>		
Host-vector system composed of the following eukaryotes as host and plasmids or minichromosomes as vector <u>Acremonium chrysogenum</u> <u>Aspergillus oryzae</u> <u>Aspergillus sojae</u> <u>Neurospora crassa</u> <u>Pichia pastoris</u> <u>Saccharomycopsis lipolytica</u> <u>Schizosaccharomyces pombe</u> <u>Trichoderma viride</u> <u>Zygosaccharomyces rouxii</u>	Those described in Attached Table 1-(3).	P1

The circle o mark shows conventionally used names.

<Table 4-1> Level of containment in experiments using microbe or cultured cell (below 201 scale)

DNA donor		Animal	Plant	Attached	Attached	Attached
Host-vector system		(P2)	(P1)	Table 1-(1) (P3)	Table 1-(2) (P2)	Table 1-(3) (P1)
EK2 series		P1	Institution notified experiment (P1)	P2	P1	Institution notified experiment (P1)
EK1 series, SC1 series, BS1 series		P2	Institution notified experiment (P1)	P3	P2	Institution notified experiment (P1)
Host-vector system listed in the left column of Table 3		P2	P1	P3	P2	P1
Cultured cell(host) (excepting those for differentiation purposes)	Attached Table 1-(1) [vector]	Non-standard experiment	Non-standard experiment	Non-standard experiment	Non-standard experiment	Non-standard experiment
	Attached Table 1-(2) [vector]	P2	P2	P3	P2	P2
	Attached Table 1-(3) [vector]	P2	P1	P3	P2	P1
Those using Attached Table 1-(1) as either host or vector		Non-standard experiment	Non-standard experiment	Non-standard experiment	Non-standard experiment	Non-standard experiment
Those using Attached Table 1-(2) as either host or vector (excepting those using Attached Table 1-(1))		P2	P2	P3	P2	P2
Host-vector system composed solely of Attached Table 1-(3)		P2	P1	P3	P2	P1

- Experiment using microbe which are not identified to species and not confirmed of nonpathogenicity is classified as non-standard experiment.
- Those with containment level description only are institution-authorized experiments.
- When all DNAs derived from viruses or other organisms have promoter or terminator function only and do not generated infectious virus particles, Attached Table 1 is substituted by Attached Table 2 or Attached Table 3.

<Table 4-2> Level of containment in experiments using microbe or cultured cell
(large-scale culture experiment)

DNA donor		Animal	Plant	Attached Table 1-(1)	Attached Table 1-(2)	Attached Table 1-(3)
Host-vector system		(P2)	(P1)	(P3)	(P2)	(P1)
EK2 series		LS-1	LS-1	LS-2	LS-1	LS-1
EK1 series, SC1 series, BS1 series		LS-2	LS-1	Non-standard experiment	LS-2	LS-1
Host-vector system listed in the left column of Table 3		Non-standard experiment	Non-standard experiment	Non-standard experiment	Non-standard experiment	LS-1
Cultured cell(host) (excepting those for different- iation purposes)	Attached Table 1-(1) [vector]	Non-standard experiment	Non-standard experiment	Non-standard experiment	Non-standard experiment	Non-standard experiment
	Attached Table 1-(2) [vector]	LS-2	LS-2	Non-standard experiment	LS-2	LS-2
	Attached Table 1-(3) [vector]	LS-2	LS-1	Non-standard experiment	LS-2	LS-1
Those using Attached Table 1-(1) as either host or vector		Non-standard experiment	Non-standard experiment	Non-standard experiment	Non-standard experiment	Non-standard experiment
Those using Attached Table 1-(2) as either host or vector (excepting those using Attached Table 1-(1))		Non-standard experiment	Non-standard experiment	Non-standard experiment	Non-standard experiment	Non-standard experiment
Host-vector system composed solely of Attached Table 1-(3)		Non-standard experiment	Non-standard experiment	Non-standard experiment	Non-standard experiment	Non-standard experiment

- DNA derived from DNA donor must be those having specific useful functions as described in the text.
- Experiment using microbe which are not identified to species and not confirmed of nonpathogenicity is classified as non-standard experiment.
- Those with containment level description only are institution-authorized experiments.
- When all DNAs derived from viruses or other organisms have promoter or terminator function only and do not generated infectious virus particles, Attached Table 1 is substituted by Attached Table 2 or Attached Table 3.

Chapter 3. Experiments using animals or plants as host

1. Experiments using animals or cultured cells (differentiation purposes only) as host

Experiments using animals or cultured cells (differentiation purposes only) as host (denoted as "experiments using animals as host" in the following) must be conducted under proper precaution by following this guideline. Also, the following regulations must be followed: "Animal protection and management act" (1973, Law No. 105), "Standard for breeding and management of animals for biological experiments" (1980, Ordinance of Prime Minister's Office, No. 6), and other related laws.

Section 1. Non-standard and standard experiments

Item 1. Non-standard experiment

Experiments which use animals and fall under one of the following are classified as non-standard experiment:

- (1) Experiments using microbes that are not identified species and are not confirmed non-pathogenicity.
- (2) Experiments using DNAs having expression-controlling functions only such as promoter or terminator, not generating infectious virus particles, and derived from DNA donors listed in Attached Table 2-(4) or Attached Table 3-(4).
- (3) Experiments using those listed in Attached Table 1-(1) as vector.
- (4) Experiments producing toxic proteins to vertebrates.
- (5) Experiments in which animals are inoculated with recombinant

organisms prepared by non-standard experiments.

(6) Experiments in which recombinant animals are kept in unclosed areas or isolated outdoor experiment areas.

(7) Experiments using recombinant animals prepared in foreign countries.

Item 2. Institution-authorized experiment

All experiments other than non-standard experiments are Institution-authorized experiments.

Section 2. Standard for containment method according to safety evaluation of experiments

Item 1. Basic concepts in safety evaluation of experiments

(1) Experiments must be conducted safely under general procedures in microbiological studies, and planned and performed by applying physical containment according to safety evaluation of the recombinant organisms.

(2) In experiments using animals as host, safety evaluation of recombinant animals must be conducted at each stage of experiments of preparing and using recombinant animals.

Item 2. Standard for containment method according to biological safety evaluation of recombinant animals

(1) Experiments to prepare recombinant animals

1) Standard for physical containment method shall follow the standard given in Table 5 of this guideline. However, experiments to inoculate animals with recombinant organisms must be conducted under physical containment that is considered to be adequately based

on the type of DNA to be introduced and properties of recombinant organisms and animals to which recombinant organisms are to be introduced.

2) When DNA is used which is derived from cells, cloned, or chemically synthesized, and having known function, size and structure, the containment level for experiments can be lowered through review by the safety committee for the following criteria:

- ① pathogenicity
- ② production of toxic substances
- ③ carcinogenicity
- ④ transmittability

(2) Experiments using recombinant animals

1) Standard for physical containment for experiments must be properly chosen according to biological safety evaluation of recombinant animals.

2) In particular, the following precautions must be taken in management of recombinant animals.

① Entrances, ventilation openings, drains, and windows of rearing facilities for animals must be equipped with escape-preventing measures (such as metal wire, rat stopper, or front room. Entrance doors must be closed except for cases of going in and out. Windows must be fixed closed and locked to prevent inadvertent opening.

② Cages or other containers to keep animals must have firmly closed doors or covers which cannot readily be opened by animals or by shaking.

③ Recombinant animals should be recognized individually as much as possible. Those animals unsuitable for individual recognition (such as insects or fishes) should be managed by individual breeding container. The breeding containers must be distinguished from those for non-recombinant animals.

④ Straw beds, excrements, or inhabiting water must be sterilized or disposed by burning, if necessary.

⑤ Control insects and rodents.

⑥ Moving of recombinant animals must be conducted by keeping the animals in a sturdy container that can prevent escape of the animals in case of damage. The container must bear a sign on clearly seen part.

⑦ The laboratory must bear sign of "Recombinant animal experiment area".

Section 3. Transfer and handling of recombinant animals after completion of experiments

Item 1. Transfer of recombinant animals

Recombinant animals can be transferred to other institutions. The institution to receive recombinant animals must take procedures described in Part I, Chapter 1, Item 6 of this guideline for accepting the recombinant animals.

Item 2. Handling of recombinant animals after completion of experiments

Recombinant animals must be inactivated and disposed after completion of experiments. However, when other experiments are to

be conducted by using the same animals, they can be kept by submitting a report of completion of the experiment and notification on location of keeping and name of person in charge to the head of the institution. When recombinant animals prepared by non-standard experiments are to be kept and used in other experiments, governmental guidance must be needed in addition to the procedure described above.

II. Experiments using plants or cultured cells (differentiation purposes only) as host

Experiments using plants or cultured cells (differentiation purpose only) as host (denoted as "experiments using a plant as host" in the following) must be conducted under proper precaution by following this guideline.

Section 1. Non-standard and standard experiments

Item 1. Non-standard experiment

The following experiments using plants as host are classified as non-standard experiments.

(1) Experiment using microbes that are not identified species and not confirmed non-pathogenicity.

(2) Experiments using DNAs having expression-controlling functions only, such as promoters or terminators, not producing infectious virus particles, and being derived from DNA donors listed in Attached Table 2-(4) or Attached Table 3-(4).

(3) Experiments using those listed in Attached Table 1-(1) as vector.

- (4) Experiments producing toxic proteins to vertebrates.
- (5) Experiments to inoculate plants with recombinant organisms prepared by non-standard experiments.
- (6) Experiments in which recombinant plants are grown in unclosed areas or isolated outdoor experiment areas.
- (7) Experiments using recombinant plants prepared in foreign countries.

Item 2. Institution-authorized experiment

All experiments other than non-standard experiments are Institution-authorized experiments.

Section 2. Standard for containment method according to safety evaluation of experiments

Item 1. Basic concepts in safety evaluation of experiments

- (1) Experimental safety must be secured by following general and standard procedures in microbiology laboratories and experiments must be planned and conducted by applying physical containment according to biological safety evaluation of recombinant organisms.
- (2) Experiments using plants as host must be conducted by applying biological safety evaluation at each stage of experiments of preparing and using recombinant plants.

Item 2. Standard for containment method according to biological safety evaluation of recombinant plants

(1) Experiments to prepare recombinant plants

- 1) Physical containment for experiments must follow the standard described in Table 5 of this guideline. However, experiments to

Inoculate plants with recombinant organisms can be conducted by applying proper physical containment standard according to properties of DNA to be introduced, recombinant organisms to be inoculated, and plant to accommodate recombinant organisms.

2) When cell-derived DNA, cloned DNA, or chemically DNA having known function, size and structure is used, the containment level of experiments can be lowered through review by the safety committee for the following criteria:

- ① pathogenicity
- ② production of toxic substance
- ③ carcinogenicity
- ④ transmittability

(2) Experiments using recombinant plants

1) Standard for physical containment for experiments must be properly selected according to biological safety evaluation of recombinant plants.

2) In particular, the following precautions must be taken in management of recombinant plants.

① Closed type plant growth apparatuses, such as growth cabinets, artificial weather apparatuses, ("plant growth apparatus" in the following) must be employed if necessary.

② Ventilation systems of laboratories or plant growth apparatuses must be equipped with filter capable of trapping pollens (including pollens, spores, and seeds. Same in the following). However, this does not apply when plants are covered with bags to prevent release

of pollens.

- ③ Control insects that are potential mediators of pollens.
- ④ Water drain must be equipped with filter to prevent release of recombinant plants to sewage. Waste water must be properly treated, e.g. by thermal sterilization.
- ⑤ Wastes and soil used during cultivation of recombinant plants must be inactivated by proper means that have been proved to be effective.
- ⑥ Transfer of a recombinant plant to outside of laboratory must be conducted by keeping the plant in a sturdy container that can prevent leakage of the plant in case of damage. The container must bear a sign on clearly seen part. Special precaution, such as placing tray at bottom, must be taken to prevent leakage of water, soil or other matters from the bottom part.
- ⑦ The laboratory must bear a sign of "Recombinant plant experiment area".

Section 3. Transfer and handling of recombinant plants after completion of experiments

Item 1. Transfer of recombinant plants

Recombinant plants can be transferred to other institutions. The institution to receive recombinant plants must take procedures described in Part I, Chapter 1, Item 8 of this guideline for accepting the recombinant plants.

Item 2. Handling of recombinant plants after completion of experiments

Recombinant plants must be inactivated and disposed after completion of experiments. However, when other experiments are to be conducted by using the same plants, they can be kept by submitting a report of completion of the experiment and notification on location of keeping and name of persons in charge to the head of the institution. When recombinant plants prepared by non-standard experiments are to be kept and used in other experiments, governmental guidance must be needed in addition to the procedure described above.

<Table 5> Level of containment in experiments using animal or plant

DNA donor Host-vector system		Animal (P2)	Plant (P1)	Attached Table 1-(1) (P3)	Attached Table 1-(2) (P2)	Attached Table 1-(3) (P1)
Animal, Plant,	Attached Table 1-(1) [vector]	Non-standard experiment	Non-standard experiment	Non-standard experiment	Non-standard experiment	Non-standard experiment
Cultured cell (those of defferenti- ation purpose only)	Attached Table 1-(2) [vector]	P2	P2	P3	P2	P2
	Attached Table 1-(3) [vector]	P2	P1	P3	P2	P1
	[host] Direct in- troducti* (not using vector)	P2	P1	P3	P2	P1

- Experiments using microbes that are not identified to species and not confirmed of nonpathogenicity are classified as non-standard experiment.
- Those with containment level only described are institution-authorized experiment.
- When all virus-derived DNAs have expression-controlling functions only, such as promoter or terminator, and not generate infectious virus particles, Attached Table 1 must be replaced by Attached Table 2 or Attached Table 3.
- * Direct introduction means direct gene transfer method.

Chapter 4. Experiment using viruses etc.

Experiments using viruses or related organisms as host-vector system or DNA donor must be conducted with proper measures according to this guideline.

Section 1. Non-standard and standard experiments

Item 1. Non-standard experiment

Experiments which use viruses etc. and fall under one of the following are classified as non-standard experiment:

(1) Experiments using microbes that are not identified species and are not confirmed nonpathogenicity.

(2) Experiments using DNA donor listed in Attached Table 2-(4) or Attached Table 3-(4).

(3) Experiments using host-vector system other than authorized host-vector system.

(4) Experiments to clone genes producing toxic proteins to vertebrates.

(5) Experiments in which animals or plants are inoculated with recombinant organisms.

(6) Large-scale culture experiment except the following:

% Experiments, which correspond to P1 or P2 level containment in less than 20-liter scale and use recombinant organisms made by introducing cell-derived, cloned, or chemically synthesized DNA having known function, size, and structure, with useful function such as production of useful protein, into authorized host-vector system.

(7) Experiments in which recombinant organisms are released to

natural environment.

Item 2. Institution-authorized experiment

Experiments other than non-standard experiments are institution-authorized experiments.

Section 2. Standard for containment method according to safety evaluation of experiments

Item 1. Basic concepts in safety evaluation of experiments

(1) Experiment must be conducted under proper measures to ensure safety, based on common standard procedures in microbiological laboratories, and under planning for proper physical and/or biological containment.

(2) Biological safety evaluation for biological containment shall be conducted according to biological properties of host-vector system and DNA donor used in the experiment.

(3) Safety for large-scale culture experiments must be secured as described above and additionally by using well-equipped experimental facilities using various tightly containing apparatuses such as large-scale fermenters. However, large-scale culture experiments using recombinant organisms that have been confirmed especially high safety levels can be conducted in a facility having well-maintained large scale fermenters or equivalent facilities.

Item 2. Standard for containment method according to biological safety evaluation of DNA donors

(1) Experiments of 20-liter or smaller scale

Safety classification for viruses etc. used as DNA donor is :

given in Attached Table 2 and Attached Table 3. Standard containment methods corresponding to this safety evaluation are given in Table 6.

(2) Large-scale culture experiments

1) DNAs to be used in large-scale culture experiments must be limited to cell-derived DNAs, cloned DNAs, or chemically synthesized DNAs that have known function, size and structure, and are known to have certain utility such as production of useful proteins.

2) When the experiment requiring P1 level physical containment, performed at below-20-liter scale, is to be performed at above-20-liter scale, LS-1 level physical containment shall apply. Also, when the experiment requiring P2 level physical containment when performed at below-20-liter scale is to be performed at above-20-liter scale, LS-2 level physical containment shall apply.

3) However, those experiments which use recombinant organisms with confirmed high level of biological safety can be conducted according to the following rules under the guidance of the government:

① physical containment of LS-C level

② special physical containment method other than physical containment levels described in Part I, Chapter 2, Section 1, Item 3.

(3) Exception to containment level for DNA donor

When DNA donor is chosen from cell-derived DNAs, cloned DNAs; or chemically synthesized DNAs that have known function, size and structure, the containment level for experiment can be lowered through review by the safety committee for the following criteria:

① pathogenicity

- ② production of toxic substances
- ③ carcinogenicity
- ④ transmittability

Section 3. Transfer and handling of recombinant organisms after completion of experiments

Item 1. Transfer of recombinant organisms

Recombinant organisms can be transferred to other institutions. The institution to receive recombinant organisms must take procedures described in Part I, Chapter 1, Item 6 of this guide line for accepting the recombinant organisms.

Item 2. Handling of recombinant organisms after completion of experiments

Recombinant body must be inactivated and disposed after completion of experiment. However, when other experiments are to be conducted by using the same recombinant organisms, they can be kept by submitting a report of completion of the experiment and notification on location of keeping and name of persons in charge to the head of the institution. When recombinant organisms prepared by non-standard experiment are to be kept and used in other experiments, governmental guidance must be needed in addition to the procedure described above.

<Table 6> Level of containment in experiments using viruses

DNA donor	Attached	Attached	Attached	Attached	(Excluding cases in which these are the sole DNA donor.)				
	Table	Table	Table	Table					
	2-(1) or	2-(2) or	2-(3) or	2-(4) or					
Host-vector system	Attached	Attached	Attached	Attached	Animal	Plant	Attached	Attached	Attached
	Table	Table	Table	Table			Table	Table	Table
	3-(1)	3-(2)	3-(3)	3-(4)			1-(1)	1-(2)	1-(3)
	(P3-B1)	(P2-B1)	(P1-B1)	(Non-					
	(P2-B2)	(P1-B2)	(P1-B2)	standard)					
B1 series host-vector system.	P3	P2	P1	Non-standard experiment	P2	P1	P3	P2	P1
B2 series host-vector system.	P2	P1	P1	Non-standard experiment	P1	P1	P2	P1	P1
Experiment using host vector system other than authorized host-vector system	Non-standard experiment	Non-standard experiment	Non-standard experiment	Non-standard experiment	Non-standard experiment	Non-standard experiment	Non-standard experiment	Non-standard experiment	Non-standard experiment

- Experiments using microbes which is not identified to species and not confirmed of nonpathogenicity are non-standard experiment.
- Experiments for which only containment level is described are institution-authorized experiment.

Attached Table 1. Safety classification of microbes used in
experiments

(Including rickettsia and chlamydia;
excluding protozoa)

(1) Those requiring P3-level containment

<u>Bartonella</u>	<u>B. bacilliformis</u>
<u>Brucella</u>	<u>B. abortus</u>
	<u>B. canis</u>
	<u>B. melitensis</u>
	<u>B. ovis</u>
	<u>B. suis</u>
<u>Coccidioides</u>	<u>C. immitis</u>
<u>Coxiella</u>	<u>C. burnetii</u>
<u>Francisella</u>	<u>F. tularensis</u>
<u>Histoplasma</u>	<u>H. capsulatum</u>
	<u>H. duboisii</u>
	<u>H. farciminosum</u>
<u>Mycobacterium</u>	<u>M. avium/intracellulare</u>
	<u>M. bovis</u>
	<u>M. fortuitum</u>
	<u>M. kansasii</u>
	<u>M. szulgai</u>
	<u>M. tuberculosis</u>
<u>Mycoplasma</u>	<u>M. mycoides</u>
<u>Paracoccidioides</u>	<u>P. braziliensis</u>

Pseudomonas

P. mallei (Actinobacillus mallei)

P. pseudomallei

Rickettsia

R. akari

R. australis

R. canada

R. conorii

R. montana

R. parkeri

R. prowazekii

R. rhipicephali

R. rickettsii

R. sibirica

R. tsutsugamushi

R. typhi

Rochalimaea

R. quintana

R. vinsonii

Yersinia

Y. pestis

(2) Those requiring P2-level containment

Acinetobacter

A. calcoaceticus

Actinobacillus

All species except for A. mallei

(Pseudomonas mallei)

Actinomyces

A. bovis

A. israelii

A. naeslundii

<u>Aeromonas</u>	<u>A. pyogenes</u>
	<u>A. hydrophila</u> (Toxinogenic strain)
	<u>A. punctata</u> (Toxinogenic strain)
<u>Arcanobacterium</u>	<u>A. hemolyticum</u>
<u>Bacillus</u>	<u>B. anthracis</u>
	<u>B. cereus</u> (Toxinogenic strain)
<u>Blastomyces</u>	<u>B. dermatitidis</u>
<u>Bordetella</u>	<u>B. pertussis</u>
<u>Borrelia</u>	All species
<u>Calymatobacterium</u>	<u>C. granulomatis</u>
<u>Campylobacter</u>	<u>C. coli</u>
	<u>C. fetus</u>
	<u>C. subspecies fetus</u>
	<u>C. subspecies venerealis</u>
	<u>C. jejuni</u>
<u>Chlamydia</u>	<u>C. pneumoniae</u>
	<u>C. psittaci</u>
	<u>C. trachomatis</u>
<u>Cladosporium</u>	<u>C. carrionii</u>
	<u>C. trichoides</u>
<u>Clostridium</u>	<u>C. botulinum</u>
	<u>C. chauvoei</u>
	<u>C. difficile</u>
	<u>C. haemolyticum</u>
	<u>C. histolyticum</u>

	<u>C. novyi</u>
	<u>C. perfringens</u>
	<u>C. septicum</u>
	<u>C. tetani</u>
<u>Corynebacterium</u>	<u>C. bovis</u>
	<u>C. diphtheriae</u>
	<u>C. ovis/pseudotuberculosis</u>
	<u>C. ulcerans</u>
	<u>C. renale</u>
<u>Cryptococcus</u>	<u>C. neoformans</u>
<u>Erysipelothrix</u>	<u>E. rhusiopathiae</u>
<u>Exophiala</u>	<u>E. dermatitidis</u>
<u>Escherichia</u>	<u>E. coli</u> (All antigen types of intestinal pathogenicity)
<u>Fusobacterium</u>	<u>F. necrophorum</u>
<u>Fonsecaea</u>	<u>F. pedrosoi</u>
<u>Haemophilus</u>	<u>H. ducreyi</u>
	<u>H. influenzae</u>
<u>Klebsiella</u>	<u>K. pneumoniae</u>
<u>Legionella</u>	All species
<u>Leptospira</u>	<u>L. interrogans</u> (All serum type)
<u>Listeria</u>	<u>L. monocytogenes</u>
<u>Mycobacterium</u>	<u>M. africanum</u>
	<u>M. bovis</u> (BCG strain)
	<u>M. chelonae</u>

	<u>M. leprae</u>
	<u>M. marinum</u>
	<u>M. paratuberculosis</u>
	<u>M. scrofulaceum</u>
	<u>M. simiae</u>
	<u>M. ulcerans</u>
	<u>M. xenopi</u>
<u>Mycoplasma</u>	<u>M. pneumoniae</u>
<u>Neisseria</u>	<u>N. gonorrhoeae</u>
	<u>N. meningitidis</u>
<u>Nocardia</u>	<u>N. asteroides</u>
	<u>N. brasiliensis</u>
	<u>N. otitidisovariarum</u>
	<u>N. farcinica</u>
<u>Pasteurella</u>	<u>P. haemolytica</u>
	<u>P. multocida</u>
	<u>P. pneumotropica</u>
<u>Plesiomonas</u>	<u>P. shigelloides</u>
<u>Rhodococcus</u>	<u>R. equi</u>
<u>Salmonella</u>	All serum type
<u>Shigella</u>	<u>S. boydii</u>
	<u>S. dysenteriae</u>
	<u>S. flexneri</u>
	<u>S. sonnei</u>
<u>Sporothrix</u>	<u>S. schenckii</u>

<u>Staphylococcus</u>	<u>S. aureus</u>
<u>Streptobacillus</u>	<u>S. moniliformis</u>
<u>Streptococcus</u>	<u>S. agalactiae</u>
	<u>S. pneumoniae</u>
	<u>S. pyogenes</u>
<u>Toxocara</u>	<u>T. canis</u>
<u>Treponema</u>	<u>T. carateum</u>
	<u>T. pallidum</u>
	<u>T. pertenu</u>
<u>Trichinella</u>	<u>T. spiralis</u>
<u>Vibrio</u>	<u>V. cholerae</u>
	<u>V. parahaemolyticus</u>
	<u>V. vulnificus</u>
<u>Yersinia</u>	<u>Y. enterocolitica</u>
	<u>Y. pseudotuberculosis</u>

(3) Those requiring P1-level containment

Species other than those described in (1) or (2), but
excepting those which are not identified species and
nonpathogenicity has not been confirmed.

Attached Table 2 Safety classification of viruses and viroids of
eukaryotes (except for fungi) used as DNA donor
in experiments

(1) DNA donor requiring P3-B1 or P2-B2 containment

California encephalitis virus

Chikungunya virus

Hemorrhagic fever with renal syndrome virus

Herpes ateles virus

Herpes saimiri virus

Hog cholera virus

HIV (Human immunodeficiency virus)*1

SIV (Simian immunodeficiency virus)*2

Japanese encephalitis virus

La Crosse virus

LCM virus

Monkeypox virus

Murray Valley encephalitis virus

O'nyong-nyong virus

Powassan virus

Rabies (street) virus

St. Louis encephalitis virus

Tacaribe virus

Vesicular stomatitis virus

West Nile virus

*1: HTLV-III=HIV-1, HTLV-IV=HIV-2, LAV-1=HIV-1, LAV-2=HIV-2

*2: STLV-III is included in SIV.

(2) DNA donor requiring P2-B1 or P1-B2 containment

Adenovirus (human)

Avian reticuloendotheliosis virus

BIV (Bovine immunodeficiency virus)

Batai virus

Cowpox virus

Coxsackie virus (A, B)

Cytomegalovirus (human, animal)

Dengue virus (1-4)

Eastern equine encephalitis virus

EB virus

Echovirus (1-34)

Ectromelia virus

EMC (Encephalomyocarditis virus)

Enterovirus (68-71)

Equine infectious anemia virus

Equine rhinopneumonitis virus

FIV (Feline immunodeficiency virus)

Hepatitis A virus

Hepatitis B virus

Hepatitis C virus

Hepatitis D virus

Hepatitis E virus

Herpes simplex virus (1, 2)

HVJ (Sendai virus)

Infectious bovine rhinotracheitis virus (bovine herpes
virus) 7

Influenza virus (human)

Mammalian retrovirus*3

HTLV (Human T-cell leukemia virus)*4

STLV (Simian T-cell leukemia virus)*5

other mammalian lentivirus

Measles virus

Molluscum contagiosum virus

Mouse hepatitis virus

Mumps virus

NDV (Newcastle disease virus)

Papovavirus

human: BKvirus, JCvirus, human papillomavirus

non-human: Bovine papilloma, lymphotropic papovavirus,

polyoma virus, SV40, other non-human

papillomavirus, other non-human polyomavirus

Parainfluenza virus (1-4)

Pichinde virus

Poliovirus (1-3)

Suid herpes virus 1 (Aujeszky's disease virus)

Rabies (fixed, attenuated) virus

Rhinovirus

Rinderpest virus (vaccine strain)

Rotavirus

Rubella virus

Semliki Forest virus

Simian herpes virus (Excepting Herpes B virus, Herpes Ateles virus and Herpes samiri virus)

SSPE agent

Tanapox virus

Vaccinia virus

Varicella virus

Western equine encephalitis virus

Yaba virus

*3 Excepting HIV, SIV, HTLV, and STLV.

*4 Excepting HTLV-III and HTLV-IV.

*5 Excepting STLV-III.

(3) DNA donor requiring P1-B1 or P1-B2 containment

Adenovirus (avian, canine, bovine, porcine, murine)

Aino virus

Akabane virus

Avian encephalomyelitis virus (Picornaviridae)

Avian enterovirus

Avian poxvirus

Avian retrovirus (Excepting Avian reticuloendotheliosis virus)

Bluetongue virus
 Bovine viral diarrhea virus (Togaviridae)
 Bunyamwera virus
 Calicivirus (human, animal)
 Canine distemper virus
 Canine herpesvirus
 Coronavirus (mammalian, avian)
 Duck hepatitis virus
 Enterovirus (Swine, Bovine)
 Equine arteritis virus (Togaviridae)
 Feline rhinotracheitis virus (Feline herpesvirus)
 Fish viruses (IPN, IHN, EVA, EVE, and LV only.)
 Getah virus
 Infectious bursal disease virus (Birnaviridae)
 Infectious laryngotracheitis virus (Herpesviridae)
 Influenza virus (avian, equine, swine)
 Insect viruses (In the narrow sense; i.e., excepting those
 infectious to vertebrates such as Arbovirus)
 Kilham rat virus
 Lactic dehydrogenase virus
 Langat virus
 Live virus vaccine strains (Excepting Rinderpest vaccine
 strain)
 Lucke virus
 Marek's disease virus (Including herpes virus of turkey)

Mouse encephalomyelitis virus (Picornaviridae)

Parvovirus (human, animal)

Plant viruses

Pneumonia virus of mice (PVM) (Paramyxoviridae)

Poikilothermal vertebrate retrovirus

Ross River virus

Reovirus (1-3)

Shope fibroma virus

Simbu virus

Sindbis virus

Swinepox virus

Viroids

(4) DNA donor with no classification for containment

Species other than those described in (1), (2), or (3).

Attached Table 3 Safety Classification of protozoa of
vertebrates used as DNA donor in
experiments .

(1) DNA donor requiring P3-B1 or P1-B2 containment

None

(2) DNA donor requiring P2-B1 or P2-B2 containment

<u>Balantidium</u>	<u>B. hominis</u>
<u>Entamoeba</u>	<u>E. histolytica</u>
<u>Giardia</u>	<u>G. lamblia</u>
<u>Hartmannella</u>	All species
<u>Leishmania</u>	<u>L. braziliensis</u>
	<u>L. donovani</u>
	<u>L. mexicana</u>
	<u>L. peruviana</u>
	<u>L. tropica</u>
<u>Naegleria</u>	All species
<u>Piroplasma</u>	All species
<u>Plasmodium</u>	<u>P. falciparum</u>
	<u>P. malariae</u>
	<u>P. ovale</u>
	<u>P. vivax</u>
<u>Simian malarial parasites</u>	
<u>Sarcocystis</u>	<u>S. suis</u>
<u>Toxoplasma</u>	<u>T. gondii</u>

Trypanosoma

T. cruzi

T. gambiense

T. rhodesiense

(3) DNA donor requiring P1-B1 or P1-B2 containment

Babesia

B. bovis

Chilomastix

C. mesnili

Cryptosporidium

All species

Dientamoeba

D. fragilis

Enbdomonas

E. intestinalis

Endolimax

E. nana

Entamoeba

E. coli

E. gingivalis

E. hartmanni

Enteromonas

E. hominis

Iodamoeba

I. buetschli

Isospora

I. belli

I. hominis

Histomonas

All species

Eimeria

All species

Leucocytozoon

All species

Pneumocystis

P. carinii

Plasmodium

P. berghei

Retortamonas

R. intestinalis

Sarcocystis

S. hominis

S. lindemanni

Torichomonas

T. tenax

T. hominis

T. vaginalis

Trypanosoma

T. brucei

T. rangeli

(4) DNA donor with no classification for containment

Species other than those described in (1), (2), or (3).

Carnegie Group file:

THE WHITE HOUSE
WASHINGTON

Mari Oct 5, 9:20 am - telephone discussion

1. SSC - Mari made report to Prime Minister.
- 2 bodies - ^{a)} US-Japan Corp Group
- ^{b)} Council for S & T.

In ^{b)} still taking testimony from broad spectrum gentlemen
Maybe recommend to PM end of year

2. HFSP - Send fax re Bogorad.
Sept 15 was deadline - Send this cv to our
US trustee to head of meeting of trustee
Mr. Myazgacki is the chairman of trustee committee

3. WHO - Sec. Gen.
Mari met with Ministers of Health & Welfare
Not nearly as powerful now and Minister of
Foreign Affairs in saddle. Very anxious to
have a chair of major UN organization
Suggest we stick to our position

4. Cold Fusion.

Talked to Dir. General of Atomic Power and
Nuclear Fusion

Some researchers still looking at cold fusion
One newspaper reported that govt would spend
lots of money on it - but not true
Gov. is pessimistic about university work.
Main policy focused on tokamak.



Dr Bromley

CABINET OFFICE
Office of Public Service and Science

Office of Science and Technology

With compliments

Professor Stewart.

70 Whitehall, London SW1A 2AS
Telephone: 071-270

CARNEGIE COMMISSION

ON SCIENCE, TECHNOLOGY, AND GOVERNMENT

10 WAVERLY PLACE, NEW YORK, NY 10003, PHONE: (212) 998-2150, FAX: (212) 995-3181
EMAIL: CARNEGIE@ACF1.NYU.EDU

Mr. Golden's private office:

40 Wall Street, New York, NY 10005

July 29, 1992

Dear Allan:

Re Carnegie Group

The letter about Professor Mori is surprising. Maybe the Japanese felt it wouldn't hurt to try. Or maybe they don't find it easy to get government funds for travel expenses. I hope you will find David Beckler's response appropriate.

I would not trouble you with this were it not for its broader implications. You will remember on two occasions it was suggested to the Carnegie Group that private funding could probably be obtained for the relatively small sums that might be needed (e.g. for Boris Saltykov) to permit continuation of the Carnegie Group meetings. In both instances the group response was that the members of the group could make it on their own. Naturally I hope this is so, but if there are problems I repeat my confidence that private funds would be available through an appropriate 501 (c) (3) channel (to provide tax deductibility).

On reflection, I think it would be better if the funds came from more than one source, perhaps half from the U.S. and half from a U.K. source; or some other combination. But this is not an absolute necessity.

With best regards,

Sincerely,

William T. Golden

Dr. D. Allan Bromley
Assistant to the President
for Science and Technology
Old Executive Office Building
Suite 358
Washington, DC 20506

cc: Prof. William D.P. Stewart

CABINET OFFICE

W777

3 AUG 1992

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Adm. James D. Watkins (Ret.)

Herbert F. York

Charles A. Zuckert

*Through April 1990

**Through January 1989

Allan

This is a try-on
I support Dave Beckler
I like Bertwies
Bertwies
4/1/92
Thanks for the
card!!
Bertwies

Bertwies
Bertwies

COPY

Withdrawal/Redaction Sheet

(George Bush Library)

Document No. and Type	Subject/Title of Document	Date	Restriction	Class.
01. Letter	To: William Golden From: Allan Bromley Re: Carnegie Group (2 pp.)	8/12/92	(b)(1)	

Collection:

Record Group: Bush Presidential Records
Office: Science and Technology Policy, Office of (OSTP)
Series: Bromley, D. Allan, Files
Subseries: Organization Files - Non-Government Organizations
WHORM Cat.:
File Location: Association - Carnegie Group [3 of 3] [1992]

Date Closed: 5/18/2010 **OA/ID Number:** 62085-010

FOIA/SYS Case #: 2005-0336-F

Appeal Case #:

Re-review Case #:

Appeal Disposition:

P-2/P-5 Review Case #:

Disposition Date:

AR Case #:

MR Case #:

AR Disposition:

MR Disposition:

AR Disposition Date:

MR Disposition Date:

RESTRICTION CODES

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Freedom of Information Act - [5 U.S.C. 552(b)]

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(b)(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
(b)(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
(b)(9) Release would disclose geological or geophysical information

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Removed as a personal record misfile.

200

CARNEGIE COMMISSION

ON SCIENCE, TECHNOLOGY, AND GOVERNMENT

10 WAVERLY PLACE, NEW YORK, NY 10003, PHONE: (212) 998-2150, FAX: (212) 995-3181
EMAIL: CARNEGIE@ACF.LNYU.EDU

Mr. Golden's private office:
40 Wall Street, New York, NY 10005

July 29, 1992 MAIL 11 01

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Charles A. Zacker

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With best regards,

Sincerely,



William T. Golden

Dr. D. Allan Bromley
Assistant to the President
for Science and Technology
Old Executive Office Building
Suite 358
Washington, DC 20506

cc: Prof. William D.P. Stewart

*Through April 1990
**Through January 1989

FROM

(HON) 7.27.'92 9:28 NO.2060209650 PAGE 2

PRIME MINISTER'S
COUNCIL FOR SCIENCE AND TECHNOLOGY

Kasumigaseki 2/2/1, Chiyoda-ku, Tokyo, 100 JAPAN

Phone:(81)(3) 3581 1357, Fax(81)(3) 3581 3079

July 27, 1992

Dr. David Z. Beckler
Associate Director
Carnegie Commission on
Science, Technology and Government
10 Waverly Place, New York
N.Y. 10003

Dear Dr. Beckler;

I am writing to you about the arrangements for Prof. Mori's attendance at the fourth Carnegie Group meeting to be held in France in December.

I understand from your letters to Prof. Mori that the Carnegie Commission on Science, Technology and Government will reimburse participants for costs of travel. As you know, at the third meeting in Leeds Castle, U.K, it was agreed that the meeting would be held at the member countries of the Carnegie Group meeting in turn. So, we would like to know whether the Carnegie Commission will reimburse Prof. Mori for travel costs to attend the meeting to be held in Europe, as well as in U.S.A.

With best regards,

Sincerely yours,



Shushi Ueda

Director,

Office of Planning,

Council for Science and Technology

COPY

Draft July 27, 1992

Dr. Shushi Ueda
Director
Office of Planning
Council for Science and Technology
Prime Minister's
Council for science and Technology
Kasumigaseki 2/2/1, Chiyoda-ku
Tokyo, 100 Japan

Dear Dr. Ueda,

This is in response to your FAX of July 27, 1992 concerning the travel costs for Dr. Mori's attendance at the next meeting of the Carnegie Group in France next December.

The Carnegie Commission was pleased to sponsor the first two meetings of the Carnegie Group held in the U.S. Having launched these productive meetings, it was the Commission's hope that the Group would continue to meet in the countries of the members and that resources would be available from other sources to cover their costs of participation. The Commission has not budgeted for the support of further meetings of the Group, and we regret that it will not be possible to cover the travel cost of Dr. Mori.

Since the members have found the meetings to be highly valuable and wish to continue them indefinitely, it would seem desirable for the members to arrange, individually or as a group, for sustained funding in a way that will preserve its informal and independent character.

Sincerely,

David Z. Beckler
Associate Director

COPY

"Document Control"

TYPE: ACTION DOCUMENT NUMBER: 9202236
ORIGINATOR: 02 STATUS I DIRECTORATE STATUS

FROM: GOLDEN, William: CARNEGIE COMMISSION

TO: DR. D.A. BROMLEY

DATE OF
CORRESPONDENCE: 07/29/92

SUBJECT: HE IS WRITING REGARDING THE CARNEGIE GROUP

DIRECTORATE STAFF
ASSIGNED: D. Allan Bromley ASSIGNED:

ACTION STAFF
REQUIRED: AS/IF NECESSARY ACTION:

SENDER'S DUE DATE:
OSTP DUE DATE: 08/20/92 STAFF DUE DATE
DATE COMPLETED: DATE COMPLETED/DEPT:

COPIES TO:

WHITE HOUSE TRACKING #: CONTACT PERSON:
PHONE: EXT:
REMARKS:

OSTP RECEIVED: 08/06/92 DEPT RECEIVED:
FILE: P-DAB-MEMBERSHIP
CENTRAL FILES:

THE WHITE HOUSE
WASHINGTON

September 30, 1992

Dear Bill and Josh:

Thank you for your letter of September 15 inviting me to the Carnegie Commission dinner scheduled for November 30, 1992 at the New York Academy of Sciences.

I am happy to accept your invitation but must caution that occasionally I have to cancel engagements at the last moment due to Presidential requests. I sincerely hope that this does not happen.

I am pleased that you thought of me and look forward to the occasion.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "D. Allan Bromley". The signature is fluid and cursive, with the first name "D. Allan" written in a more compact, stylized manner and "Bromley" written in a more extended, flowing script.

D. Allan Bromley
The Assistant to the President
for
Science and Technology

Messrs William T. Golden and Joshua Lederberg
Carnegie Commission
on Science, Technology, and Government
10 Waverly Place
New York, New York 10003

"INVITATION FOR DR. BROMLEY"

TYPE: INVITATION

DOCUMENT NUMBER: 9202763

ORIGINATOR: 02

SPEECH: YES NO

FROM: GOLDEN, William T. and LEDERBERG, Joshua: CARNEGIE
COMMISSION

DATE OF EVENT: 11/30/92 THRU:
TENTATIVE DATES:

LOCATION OF EVENT: NEW YORK ACADEMY OF SCIENCES

TIME OF EVENT:

SUBJECT: AN INVITATION TO ATTEND DINNER ON THE OCCASION OF
THE COMMISSIONS NEXT-TO-LAST MEETING.

RSVP: 10/02/92

CONTACT PERSON:

CONTACT NUMBER:

INVITATION ACCEPTED?

YES NO

COPIES TO:

REMARKS:

DATE OF LETTER: 09/15/92

DATE RECEIVED: 09/18/92

FILE: P-INVITATION

CARNEGIE COMMISSION

ON SCIENCE, TECHNOLOGY, AND GOVERNMENT

10 WAVERLY PLACE, NEW YORK, NY 10003, PHONE: (212) 998-2150
FAX: (212) 995-3181, EMAIL: CARNEGIE@ACF1.NYU.EDU

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Jonas Salk

Maxine F. Singer

Hon. Dick Thornburgh

Adm. James D. Watkins

(Ret.)

Herbert F. York

Charles A. Zraket

September 15, 1992

Dr. D. Allan Bromley
Assistant to the President for Science and Technology
Old Executive Office Building
17th Street & Pennsylvania Avenue, NW
Washington, DC 20506

Dear Allan:

The Carnegie Commission on Science, Technology, and Government will have its next-to-last meeting on November 30, December 1. At this meeting we will be reflecting on our major recommendations in preparation for our final report. The report will cover the full range of the Commission's activities—including our work on the Congress, the states, nongovernmental organizations, the Judiciary, international organizations, scientists and engineers in the federal government, and the Executive Branch agencies as well as the White House. We will also be assessing our plans for implementation of our recommendations in light of the election results.

The purpose of this letter is to invite you to join us for dinner, to be held at the New York Academy of Sciences on November 30, 1992, to give us the benefit of your reflections on the historic period preceding the date and your projections for the period to come—on whatever topic(s) you choose.

We truly hope that you will be able to accept our invitation, and we look forward to hearing from you.

Sincerely,

Bill

William T. Golden
Co-chair

Josh

Joshua Lederberg
Co-chair

*Through April 1990

**Through January 1989

Withdrawal/Redaction Sheet

(George Bush Library)

Document No. and Type	Subject/Title of Document	Date	Restriction	Class.
02. Letter	To: William Golden From: Allan Bromley Re: Carnegie Group (2 pp.)	8/12/92	(b)(1)	

Collection:

Record Group: Bush Presidential Records
Office: Science and Technology Policy, Office of (OSTP)
Series: Bromley, D. Allan, Files
Subseries: Organization Files - Non-Government Organizations
WHORM Cat.:
File Location: Association - Carnegie Group [3 of 3] [1992]

Date Closed: 5/18/2010 **OA/ID Number:** 62085-010

FOIA/SYS Case #: 2005-0336-F

Re-review Case #:

P-2/P-5 Review Case #:

AR Case #:

AR Disposition:

AR Disposition Date:

Appeal Case #:

Appeal Disposition:

Disposition Date:

MR Case #:

MR Disposition:

MR Disposition Date:

RESTRICTION CODES

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PRM. Removed as a personal record misfile.

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Mr. Golden's private office:
40 Wall Street, New York, NY 10005

July 29, 1992 MAIL

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Re Carnegie Group

The letter about Professor Mori is surprising. Maybe the Japanese felt it wouldn't hurt to try. Or maybe they don't find it easy to get government funds for travel expenses. I hope you will find David Beckler's response appropriate.

I would not trouble you with this were it not for its broader implications. You will remember on two occasions it was suggested to the Carnegie Group that private funding could probably be obtained for the relatively small sums that might be needed (e.g. for Boris Saltykov) to permit continuation of the Carnegie Group meetings. In both instances the group response was that the members of the group could make it on their own. Naturally I hope this is so, but if there are problems I repeat my confidence that private funds would be available through an appropriate 501 (c) (3) channel (to provide tax deductibility).

On reflection, I think it would be better if the funds came from more than one source, perhaps half from the U.S. and half from a U.K. source; or some other combination. But this is not an absolute necessity.

With best regards,

Sincerely,

WJG

William T. Golden

Dr. D. Allan Bromley
Assistant to the President
for Science and Technology
Old Executive Office Building
Suite 358
Washington, DC 20506

cc: Prof. William D.P. Stewart

*Through April 1990
**Through January 1989

PRIME MINISTER'S
COUNCIL FOR SCIENCE AND TECHNOLOGY

Kasumigaseki 2/2/1, Chiyoda-ku, Tokyo, 100 JAPAN

Phone:(81)(3) 3581 1357, Fax:(81)(3) 3581 3079

July 27, 1992

Dr. David Z. Beckler
Associate Director
Carnegie Commission on
Science, Technology and Government
10 Waverly Place, New York
N.Y. 10003

Dear Dr. Beckler,

I am writing to you about the arrangements for Prof. Mori's attendance at the fourth Carnegie Group meeting to be held in France in December.

I understand from your letters to Prof. Mori that the Carnegie Commission on Science, Technology and Government will reimburse participants for costs of travel. As you know, at the third meeting in Leeds Castle, U.K, it was agreed that the meeting would be held at the member countries of the Carnegie Group meeting in turn. So, we would like to know whether the Carnegie Commission will reimburse Prof. Mori for travel costs to attend the meeting to be held in Europe, as well as in U.S.A.

With best regards,

Sincerely yours,



Shushi Ueda

Director,

Office of Planning,

Council for Science and Technology

COPY

Draft July 27, 1992

Dr. Shushi Ueda
Director
Office of Planning
Council for Science and Technology
Prime Minister's
Council for science and Technology
Kasumigaseki 2/2/1, Chiyoda-ku
Tokyo, 100 Japan

Dear Dr. Ueda,

This is in response to your FAX of July 27, 1992 concerning the travel costs for Dr. Mori's attendance at the next meeting of the Carnegie Group in France next December.

The Carnegie Commission was pleased to sponsor the first meetings of the Carnegie Group held in the U.S. Having launched these productive meetings, it was the Commission's hope that the Group would continue to meet in the countries of the members and that resources would be available from other sources to cover their costs of participation. The Commission has not budgeted for the support of further meetings of the Group, and we regret that it will not be possible to cover the travel cost of Dr. Mori.

Since the members have found the meetings to be highly valuable and wish to continue them indefinitely, it would seem desirable for the members to arrange, individually or as a group, for sustained funding in a way that will preserve its informal and independent character.

Sincerely,

David Z. Beckler
Associate Director

COPY

"Document Control"

TYPE: ACTION

DOCUMENT NUMBER: 9202236

ORIGINATOR: 02

STATUS I

DIRECTORATE STATUS

FROM: GOLDEN, William: CARNEGIE COMMISSION

TO: DR. D.A. BROMLEY

DATE OF
CORRESPONDENCE: 07/29/92

SUBJECT: HE IS WRITING REGARDING THE CARNEGIE GROUP

DIRECTORATE

STAFF

ASSIGNED: D. Allan Bromley

ASSIGNED:

ACTION

STAFF

REQUIRED: AS/IF NECESSARY

ACTION:

SENDER'S DUE DATE:

OSTP DUE DATE: 08/20/92

STAFF DUE DATE

DATE COMPLETED:

DATE COMPLETED/DEPT:

COPIES TO:

WHITE HOUSE TRACKING #:

CONTACT PERSON:

PHONE:

EXT:

REMARKS:

OSTP RECEIVED: 08/06/92

DEPT RECEIVED:

FILE: P-DAB-MEMBERSHIP

CENTRAL FILES:

THE WHITE HOUSE
WASHINGTON

May 18, 1992

Dear Bill:

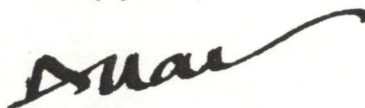
Lynn and I also very much enjoyed seeing you at the AAAS dinner and I remain amazed at the many things you do and all of them well!

I think that your idea of having the President stop by your museum is one that he would find attractive and I will make the suggestion through the appropriate channels so that it is considered for inclusion on his schedule when next he is in New York.

I shall keep you informed.

In the meantime, warmest best wishes and I look forward to seeing you in London shortly at the Carnegie Group meeting at Leed's Castle.

Sincerely yours,

A handwritten signature in dark ink, appearing to read 'D. Bromley', with a long, sweeping flourish extending to the right.

D. Allan Bromley
The Assistant to the President
for
Science and Technology

Mr. William T. Golden
Chairman
American Museum of Natural History
Central Park West at 79th Street
New York, New York 10024

"Document Control"

TYPE: INFORMATION

ORIGINATOR: 02

STATUS C

DOCUMENT NUMBER: 9201565

DIRECTORATE STATUS

FROM: GOLDEN, WILLIAM: AMERICAN MUSEUM OF NATURAL HISTORY

TO: DR. D.A. BROMLEY

DATE OF
CORRESPONDENCE: 04/29/92

SUBJECT: PLEASURE SEEING DR. BROMLEY AT THE AAAS DINNER.

DIRECTORATE
ASSIGNED: STAFF
ASSIGNED:

ACTION
REQUIRED: STAFF
ACTION:

OSTP DUE DATE: SENDER'S DUE DATE:
DATE COMPLETED: STAFF DUE DATE
DATE COMPLETED/DEPT:

COPIES TO: D. Allan Bromley

WHITE HOUSE TRACKING #: CONTACT PERSON:
REMARKS: PHONE: EXT:

OSTP RECEIVED: 05/04/92
FILE: DAB-PERSONAL

DEPT RECEIVED:

CENTRAL FILES:

THE WHITE HOUSE
WASHINGTON

May 18, 1992

MEMORANDUM FOR KATHY SUPER

FROM: D. ALLAN BROMLEY *Alan*
SUBJECT: A POSSIBLE PRESIDENTIAL ACTIVITY

Enclosed herewith is a letter from William T. Golden, the Chairman of the Board of the American Museum of Natural History.

Depending upon how things go in Rio it might well be that the President might wish to stop by to see their global warming exhibit later in the summer.

I promised Bill that I would pass on his request but I would certainly not advise that the President respond positively until we see how the Rio conference goes and can then make a much better judgment as to whether this would be a profitable expenditure of Presidential time. For the moment this is just a heads up and I will get back to you after Rio.

Enclosure

1565 I

AMERICAN MUSEUM OF NATURAL HISTORY

CENTRAL PARK WEST AT 79TH STREET

NEW YORK, N.Y. 10024-5192

769-5752

OFFICE OF THE CHAIRMAN

April 29, 1992

40 Wall St., 4201
New York, NY 10005

MAIL ROOM

02 MAY 4 14:00

Dear Allan:

It was a joy to see Lynn (and you!) again at the AAAS dinner on Friday night and to learn of Lynn's romantic and happy marriage (how pleased Pat would be) and to learn of the "dinosaur" book that Lynn's writing.

Now I revert to our brief conversation about the global warming exhibit that will open at the American Museum of Natural History in mid-May. It will be a pioneering presentation, done jointly with the Environmental Defense Fund. It will be highly informative, stimulating, and noncontroversial. It has been two years in preparation under fine scientific oversight.

As you know, the Museum is one of the three great institutions of its kind in the world. It is visited by some three million people a year, including some half million school children, has a distinguished scientific staff, and important educational programs. And we have an outstanding board of trustees, greatly strengthened in the past two years under the leadership of the new management. It would be splendid and attract much attention if President Bush, on some occasion when he is in New York, would seize the opportunity to visit the Museum and specifically to see this exhibit. President Langdon, the trustees, and I would be honored to welcome him. If you think well enough of this idea to broach it to President Bush and the appropriate staff members, I would be grateful.

With warm regards,

Sincerely,

W T

William T. Golden

Dr. D. Allan Bromley
Assistant to the President
for Science and Technology
Old Executive Office Building
Suite 358
17th St. & Pennsylvania Ave., NW
Washington, DC 20506

THE WHITE HOUSE
WASHINGTON

April 27, 1992

Dear Bill:

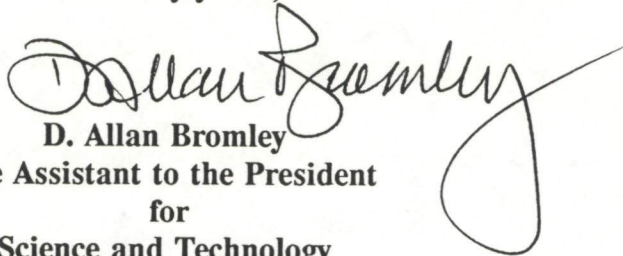
Your idea of establishing a 501(c)(3) foundation to be called Friends of the National Science Foundation is, of course, an excellent one and I congratulate you upon it.

However, I must say that given the negative cash flow that I am currently running, in large measure because I have been unable to sell my home in New Haven and must maintain, insure, and pay taxes on it as well as my home in Bethesda, my finances are not such at this moment that I feel that I can join you in contributing to this worthy cause.

I do, however, like to think that I can be classed among the friends of the National Science Foundation in terms of the budgets that we have been able to develop for NSF over these past three years!

With warmest best wishes,

Sincerely yours,



D. Allan Bromley
The Assistant to the President
for
Science and Technology

Mr. William T. Golden
40 Wall Street
New York, New York 10005

"Document Control"

TYPE: ACTION DOCUMENT NUMBER: 9201366
ORIGINATOR: 02 STATUS I DIRECTORATE STATUS

FROM: GOLDEN, William T.

TO: DR. D.A. BROMLEY

DATE OF
CORRESPONDENCE: 04/10/92

SUBJECT: HE IS WRITING TO ASK DR. BROMLEY FOR FINANCIAL
SUPPORT FOR A PROGRAM HE HAS STARTED TO SUBSIDIZE
TRAVEL FOR FORIEGN SCIENTISTS TO NSF FUNCTIONS.

DIRECTORATE STAFF
ASSIGNED: D. Allan Bromley ASSIGNED:

ACTION STAFF
REQUIRED: AS APPROPRIATE ACTION:

SENDER'S DUE DATE:
OSTP DUE DATE: 05/01/92 STAFF DUE DATE
DATE COMPLETED: DATE COMPLETED/DEPT:

COPIES TO: INTERNATIONAL/POLICY

WHITE HOUSE TRACKING #: CONTACT PERSON:
REMARKS: PHONE: EXT:

OSTP RECEIVED: 04/17/92
FILE: INTERNATIONAL

DEPT RECEIVED:

CENTRAL FILES:

THE WHITE HOUSE

January 22 '72

Dear Fall:-

Many thanks for the copy of your
Toronto Talk. I shall crib from it
shamelessly!

With warmest best wishes..

Sincerely
Alan

"Document Control"

TYPE: INFORMATION

DOCUMENT NUMBER: 9200180

ORIGINATOR: 02

STATUS C

DIRECTORATE STATUS

FROM: GOLDEN, William T.: CARNEGIE COMMISSION

TO: DR. D.A. BROMLEY

DATE OF
CORRESPONDENCE: 01/13/92

SUBJECT: HE IS FORWARDING A COPY OF HIS REMARKS AT THE ROYAL
ONTARIO MUSEUM ON ISSUES CONFRONTING MUSEUMS TODAY.

DIRECTORATE
ASSIGNED: STAFF
ASSIGNED:

ACTION
REQUIRED: STAFF
ACTION:

SENDER'S DUE DATE:

OSTP DUE DATE: STAFF DUE DATE
DATE COMPLETED: DATE COMPLETED/DEPT:

COPIES TO: DR. BROMLEY
INTERNATIONAL

WHITE HOUSE TRACKING #:

CONTACT PERSON:
PHONE:

EXT:

REMARKS:

OSTP RECEIVED: 01/17/92
FILE: SOCIAL SCIENCES

DEPT RECEIVED:

CENTRAL FILES:

WILLIAM T. GOLDEN

40 WALL STREET
NEW YORK 10005

January 9, 1992

Dear Sir: *

Please accept my apologies for using an incorrect title in Mr. Golden's letter of December 26 to Dr. Winegard. Our address list has been amended, and I have also alerted the office of the Carnegie Commission on Science, Technology, and Government.

A corrected letter is attached.

Christie Van Kehrberg
Christie Van Kehrberg
Assistant

*A Winegard's chief of staff was
misled*

CARNEGIE COMMISSION

ON SCIENCE, TECHNOLOGY, AND GOVERNMENT

10 WAVERLY PLACE, NEW YORK, NY 10003, PHONE: (212) 998-2150, FAX: (212) 995-3181
EMAIL: CARNEGIE@ACF1.NYU.EDU

Mr. Golden's private office:
40 Wall Street, New York, NY 10005

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H. Guyford Stever
Sheila E. Widnall
Jerome B. Wiesner

December 26, 1991
[Dictated December 22
Olive Bridge, NY]

Dear Bill:

As the eventful year comes to an end, I am sequestering myself in the country, am catching up on my correspondence, and trying to make a dent in my reading pile.

It was a great pleasure to see you at the Mount Kisco meeting of the Carnegie Group in October, and it was gratifying to sense the esprit de corps that has developed among the members. The informality and openness bode well for increasing comity among the countries represented. This should benefit science and the citizenry generally, with open communication among scientists leading the way to greater understanding and trust at all levels.

With warm regards,

Sincerely,

William T. Golden

Dr. William Winegard
Minister for Science
235 Queen Street, 11 East
Ottawa, Ontario K1A 0H6
Canada

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*Through April 1990
**Through January 1989

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COPY

Mr. Golden's office address is
40 Wall St., 4201, New York, NY 10005

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January 8, 1992

Dear Graciela:

It was good to hear from from you, and I was most favorably impressed by the speed and comprehensiveness with which the Transcripciones de la Reunion De Responsables De Cuerpos Asesores En Ciencia Y Tecnologia Al Mas Nivel De Los Gobiernos, held in Ixtapa-Zihuatanejo, were prepared. Congratulations.

I will keep the document for reference. It will be valuable. I confess that I have not read every word of the Spanish (or even of the English), but I have read a good deal of it to refresh my memory. The only error worth mentioning that I have found is on page nine of the Inaugural Session, second paragraph, first line: "en perfecto" should read "imperfecto." A big difference in a small matter! While I'm at it, a still smaller matter: the last line of page 191, "preacher" should be "creature."

I presume that when you publish the proceedings you will include a list of the participants with their titles, etcetera.

I truly believe that the Ixtapa-Zihuatanejo meeting may prove to be an historic event. It could, should, and, I hope will, lead to the formation of a lasting organization of science advisers of the Pan American countries: from the North Pole to Tierra del Fuego--or maybe including Antarctica. Informality and relative freedom from governmental restraints will make for congenial personal relationships and greater ease of communication and openness of expression. All of this would be helpful to relationships between the many and varied countries in our western hemisphere--not limited to communications on strictly scientific matters. So I hope there will be another session, perhaps in a year, under Mexican leadership. After that, the organization might be self-sustaining.

It was unfortunate that Dr. Bromley had to cancel his participation in the Ixtapa-Zihuatanejo event, because of the concurrent meeting of the President's Council of Advice on Science and Technology in Washington. Such a conflict should not arise in the future, and I'm confident that Dr. Bromley (and Dr. Winegard of Canada) will participate.

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Hon. Dick Thornburgh
Adm. James D. Watkins (Ret.)
Herbert F. York
Charles A. Zrak

*Through April 1990

**Through January 1989

With renewed expressions of admiration and with
thanks to you and Dr. Soberon and your colleagues for your
many personal kindnesses, I am

Sincerely yours,

A handwritten signature in dark ink, appearing to read 'W. Golden'.

William T. Golden

Dra. Graciela Rodriguez
Secretaria Ejecutiva
Consejo Consultivo De Ciencias
Av. Felix Cuevas No. 301-4° Piso
Col. Del Valle
10200 Mexico, D.F.

via FAX

bc: Dave Beckler
Tom Ratchford