Corporation obtaining approval, the name of its representative, and the address of its main office

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Approved Type 1 Use Regulation

Name of the type of Living Modified Organism	Cotton resistant to Lepidoptera (*cry1Ac*, *Gossypium hirsutum* L.) (757, OECD UI : MON-ØØ757-7)
Content of the Type 1 Use of Living Modified Organism	Provision as food, provision as feed, processing, storage, transportation, disposal and acts incidental to them.
Method of the Type 1 Use of Living Modified Organism	—

Outline of the Biological Diversity Risk Assessment

I. Information concerning preparation of living modified organisms

1. Information concerning donor nucleic acid

(1) Composition and origins of component elements

Composition of donor nucleic acid used for the production of cotton resistant to Lepidoptera (*cry1Ac*, *Gossypium hirsutum* L.) (757, OECD UI: MON-ØØ757-7) (hereafter referred to as "this recombinant cotton") and the origins of component elements are shown in Table 1. This recombinant cotton expresses Cry1Ac protein which has been created by modifying the amino acid sequence of the wild-type Cry1Ac protein in order to enhance its expression levels in plants. The two proteins exhibit 99.4% of amino acid sequence homology. The Cry1Ac protein expressed in this rcombinant cotton is hereinafter referrred to as "modified Cry1Ac protein".

(2) Functions of component elements

a) Functions of individual component elements of donor nucleic acid that was used for the development of this recombinant cotton are shown Table 1.

The modified *cry1Ac* gene is the target gene contributing to the resistance to Lepidoptera; it has been created by modifying the amino acid sequence of the wild-type Cry1Ac protein which is produced in *Bacillus thuringiensis* subsp. *kurstaki* HD-73 strain. The Cry1Ac protein, as well as the modified protein, exhibits insecticidal activity against insects of the order Lepidoptera, including Tobacco budworm (*Heliothis virescens*), Pink bollworm (*Pectinophora gossypiella*) and Cotton bollworm [also called Corn earworm] (*Heliocoverpa zea*), which are the major pest insects of order Lepidoptera that damage cotton cultivation in the US and Australia. The modified Cry1Ac protein was produced by modifying amino acid sequence only for the N-terminal sequence of the wild-type Cry1Ac protein in order to enhance its expression level in plants. Therefore, the modified Cry1Ac protein has insecticidal activity against Lepidoptera as high as the wild-type Cry1Ac protein. Cry1Ac protein, including the modified Cry1Ac protein, exhibits insecticidal activity also against insects other than order Lepidoptera: for example, European corn borer (*Ostrinia nubilialis*) of the family *Pyralidae*. However, it is known that the protein exhibits no insecticidal activity against larvae

of any insect other than order Lepidoptera.

B.t. proteins which are produced by the bacterium *B.t.*, including the modified Cry1Ac protein, bind to the specific receptors on the midgut epithelium of the target insects, and form cation selective pores, which lead to the inhibition of the digestive process and result in the insecticidal activity. Also, the core protein, i.e. the active site of the modified Cry1Ac protein produced in this recombinant cotton is identical to the core of the Cry1Ac protein in Bt preparation, which is a commercialized microbial agricultural insecticide. In the US, European countries and Japan, Bt preparation, which contains Cry1Ac protein, has been safely used for crops and trees as an insecticide to control order Lepidoptera.

The expression of the modified Cry1Ac protein confers resistance to Lepidoptera to this recombinant cotton, including Tobacco budworm, Pink bollworm and Cotton bollworm that damage cotton cultivation. In the traditional cotton cultivation methods, it was required to use a great deal of insecticide to control such insects of order Lepidoptera. Because of that, the amount of insecticides used for cotton cultivation accounted for no less than 25% of all the insecticide used in the world. But it is reported in cotton-cultivating countries, such as the US, Australia and China, that the introduction of this recombinant cotton has dramatically reduced the amount of used chemical insecticide.

In addition, this recombinant cotton exhibits insecticidal activity against the only limited insect species of order Lepidoptera that damage cotton. Unlike chemical insecticides with wide insecticidal spectrum, this recombinant cotton does not affect on the existence of beneficial insects that prey on secondary pest insects such as aphids. As a result, it has been reported that, in China, there has been a 24% increase in the number of beneficial insects in the fields where this recombinant cotton is cultivated, compared to the fields where cotton is cultivated in a traditional method.

An *nptII* gene encodes an enzyme protein, neomycin phosphotransferase type II (NPTII), which transfers the terminal phosphate group of adenosine 5'-triphosphate (ATP), to a hydroxyl group at the aminoglycoside region of antibiotics. As a result, aminoglycoside antibiotics such as paromomycin and kanamycin become inactivated. In general, these aminoglycoside antibiotics bind specifically with a protein on ribosome in a cell; then protein synthesis is inhibited, and the cell is killed. However, when these antibiotics are phosphorylated by NPTII protein, they cannot bind with the target protein on ribosome any longer. Consequently, they

cannot kill cells due to the absence of the ability to inhibit protein synthesis.

b) In order to investigate whether the modified Cry1Ac protein and NPTII protein share functionally important amino acid seuqnece with known contact allergens, the modified Cry1Ac protein and NPTII protein were compared with contact allergens in the database (SwissProt, GenPept, PIR, GenBank/EMBL). As a result, the modified Cry1Ac protein and NPTII protein did not share structurally related homologous sequences with any of the known allergens examined.

Table 1 Component elements of plasmid vector PV-GHBK04

Component elements	Origin and Function
Modified *cry1Ac* gene expression cassette	
E35S	Promoter with duplicated enhancer, from cauliflower mosaic virus (CaMV). It has a function to make target genes expressed constantly.
Modified *cry1Ac*	A gene that encodes the modified Cry1Ac protein that exhibits insecticidal activity against order Lepidoptera that damage cotton cultivation, such as Tobacco budworm (*Heliothis virescens*), Pink bollworm (*Pectinophora gossypiella*) and Cotton bollworm [also called Corn earworm] (*Heliocoverpa zea*). It encodes the protein which shows 99.4% of amino acid sequence homology with the wild-type Cry1Ac protein produced by *Bacillus thuringiensis* subsp. *kurstaki.*
7S 3'	3' untranslated region of soybean *β-conglycinin* gene. Contains a signal for the polyadenylation of mRNA, and functions to terminate transcription of the target gene.
nptII gene expression cassette	
35S	35S promoter region of cauliflower mosaic virus (CaMV). It has a function to make target genes expressed constantly.
nptII	A gene derived from a transposon of *E. coli*, Tn5 (Beck *et al*, 1982). Encodes neomycin phosphotransferase type II. It confers resistance to kanamycin. In introducing genes, it is used as a marker to select recombinant plants.
NOS3'	3' untranslated region of nopaline synthase (NOS) gene. It terminates transcription of the target gene.
Other component elements	
Right border sequence (Right Border)	A DNA sequence containing right border sequence (24bp) of nopaline type T-DNA derived from Ti plasmid pTiT37. Used as the initiation point of T-DNA transfer from *Agrobacterium tumefaciens* to plant genome.
Aad	A gene encoding 3''(9)-0-aminoglycoside adenyltransferase (AAD) derived from *Staphylococcus aureus.* Confers resistance to spectinomycin and streptomycin.
oriV	The replication origin region derived from the broad-recipient range plasmid RK2. Permits autonomous replication of vectors in *Agrobacterium tumefaciens* ABI strain.
ori322/rop	The replication origin region derived from *E. coli* plasmid pBR322. Permits autonomous replication of vectors in *E. coli.* This region contains not only replication origin, but also *rop* region that is involved in the regulation of the replication initiation, and *oriT* sequence that is necessary for conjugal transfer from *E. coli* to *Agrobacterium tumefaciens*.

2. Information concerning vector

(1) Name and origin

The plasmid vector used to generate this recombinant cotton is assembled from plasmids including pBR322, which is a synthetic plasmid from *Escherichia coli*.

(2) Properties

This vector is composed of *ori-322*, the region for replication origin to allow replication by *E. coli*, and *oriV*, the region for replication origin to allow replication by *Agrobacterium*.

The total number of base pairs of the plasmid vector PV-GHBK04 used to generate this recombinant cotton is 11,407bp.

The infectivity of this vector is not known.

3. Method of preparing living modified organisms

(1) Structure of the entire nucleic acid transferred in the recipient organism

Figure 1 shows the location, orientation and the section broken by restriction enzyme of the component elements of the nucleic acid in vector.

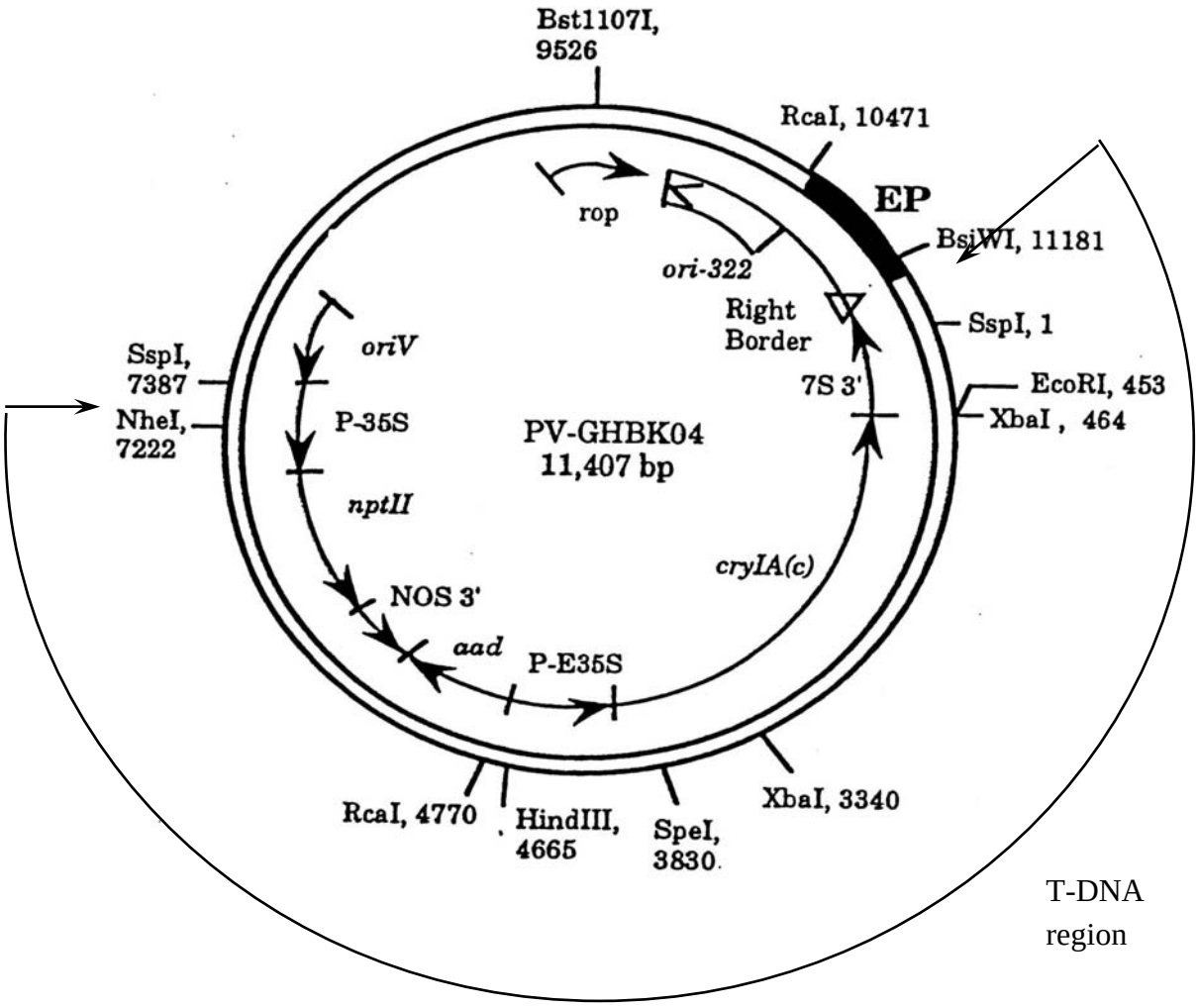

Figure 1 Map of the PV-GHBK04 plasmid

(2) Method of transferring nucleic acid transferred in the recipient organism

T-DNA region of the plasmid vector PV-GHBK04 was introduced into a current cotton cultivar, Coker 312, by the *Agrobacterium* method.

(3) Processes of rearing of living modified organisms

a) T-DNA region of the plasmid vector PV-GHBK04 was introduced into the hypocotyls of Coker 312 by the *Agrobacterium* method, and then regenerated individuals were obtained by culturing them in media containing kanamycin.

b) In order to eliminate *Agrobacterium* from the regenerated plant, the regenerated plant was cultivated in media containing carbenicillin and paromomycin, and then it was cultivated in regenerating media containing no antibiotics.

c) Regarding the obtained regenerated individuals, further selection was carried out based on the analysis of inserted genes and the expression level of the modified Cry1Ac protein. Tests in climate chamber and greenhouse were then carried out, and actual pest insect resistance and agronomic characters were examined in outdoor field tests. This recombinant cotton was selected upon the comprehensive evaluation of these results.

The following shows the approvals received from organizations abroad.

June, 1995: The US Food and Drug Administration (FDA) approved the safety of the cultivar as food and feed.

July, 1995: The United States Department of Agriculture (USDA) approved unlimited cultivation of the cultivar.

August, 1995: The US Environmental Protection Agency (EPA) exempted the Cry1Ac protein from the specification of a residual standard value.

August, 1996: The Australian Interim Office of Gene Technology Regulator (IOGTR) approved the cultivar being safe as feed and for the environment.

July, 2000: Food Standards Australia New Zealand (FSANZ) approved the safety of the cultivar as food.

The following shows the approvals received from organizations in Japan.

December, 1999: The Ministry of Agriculture, Forestry and Fisheries ensured the compatibility to the guideline regarding recombinant being imported to Japan (used for processing and feed), based on the “Guideline for the use of recombinant in agriculture, forestry and fisheries”.

May, 1997: The Ministry of Health, Labor and Welfare ensured the safety of use for food, based on the “Guideline for the conduct of Food Safety Assessment of Food and Additives derived from Recombinant-DNA Plants, Chapter 4”.

June, 1997 The Ministry of Agriculture, Forestry and Fisheries ensured the safety of use of the cultivar for feed in accordance with “Guideline for the safety evaluation of feed derived from recombinant-DNA plants, 6-(2)”.

March, 2001: The Ministry of Health, Labor and Welfare ensured the safety of use of the cultivar for food, in accordance with “Safety Evaluation Criteria for Food and Additives derived from Recombinant-DNA Techniques”.

March, 2003: The Ministry of Agriculture, Forestry and Fisheries ensured the safety of the use of the cultivar as feed, following “Procedure to Check the Safety of Feed and Additives Produced by Recombinant-DNA Techniques”.

4. State of existence of nucleic acid transferred in cells and stability of expression of traits caused by the nucleic acid

The inserted genes were analyzed in genome walking method, Southern blotting analysis, PCR method and sequencing method. As a result, gene insertion in this recombinant cotton was found in one site on the genome in the following two (2) regions: the 1st inserted gene consisting of the modified *cry1Ac* gene expression cassette, *aad* gene expression cassette, *nptII* gene expression cassette, *oriV,* and *ori322*; the 2nd inserted gene that consists of a 3'-terminal fragment of *cry1Ac* gene bound with the 7S 3' transcription terminator, and a 5'-terminal fragment of *cry1Ac* gene bound with the e35S promoter which has lost the upstream region. Transcription of mRNA from the 5'-terminal fragment of the modified *cry1Ac* gene was confirmed. Then Western blotting analysis was conducted using the polyclonal antibody prepared with use of the modified Cry1Ac protein for the entire length and as a result, there was no protein detected which was translated from the mRNA.

As a result of Southern blotting analysis on the R2 and R4 generations, it was confirmed that the inserted genes were stably inherited in progeny.

In addition, it was confirmed that the resistance to Lepidoptera was also stably expressed in multiple generations, according to simple ELISA analysis which only detects the expression of the modified Cry1Ac protein.

5. Methods of detection and identification of living modified organisms and their sensitivity and reliability

For the detection and identification of this recombinant cotton, a qualitative PCR method has been developed where the DNA sequences of the inserted genes and neighboring areas of plant genome are used as primers. This method makes it possible to specifically detect this recombinant cotton.

6. Difference from the recipient organism or the taxonomic species to which the recipient organism belongs

(1) It was confirmed based on the ELISA analysis conducted in the US on the samples of leaf, seed, young leaf and whole plant body of this recombinant cotton that the modified Cry1Ac protein, which is encoded by the modified *cry1Ac* gene, is expressed in this recombinant cotton.

(2) To compare R4 generation of this recombinant cotton and the recombinant mother plant, Coker312 as the control cotton, isolated field tests were carried out at Kyusyu National Agricultural Experiment Station from May 1998 to September 1998.

However, during the tests, lateral branch type plant was discovered that stopped the growth of trunk and developed lateral brachnes at the earlier stages of growth of the recombinant cotton from second leaf stage to fourth leaf stage. Then in the additional tests conducted in the US from October 1998 to February 1999, incidence rate of lateral branch type plants was investigated. As a result, incident rate of lateral branch type plants in the R3 generation of this recombinant cotton (plant body derived from the seeds used for the production of seeds sown in isolated field tests in 1998) and R4 generation (plant body derived from the seeds used for the production of seeds sown in isolated field tests in 1998) was found 33% and 41% respectively. However, incident rate of lateral branch type plants in R5 generation derived from the normal strain of the recombinant cotton and R5 generation derived from the lateral branch type plants of the recombinant cotton was 3% and 0% respectively, and no lateral branch type plant was observed in the commercialized variety of this recombinant cotton and the non-recombinant plants. In addition, it was confirmed based on the Southern blotting analysis that the generations examined in the additional tests all possess the *cry1Ac* gene. Consequently, it was considered that there is no correlation between the incidence of lateral branch type plants and the inserted genes.

a) Morphological and growth characteristics

As mentioned in the preceding section, Ⅰ-6-(2), in R4 of this recombinant cotton, lateral branch type strain which stopped the growth of trunk and developed lateral branches at the early stage of growth was observed. However, for evaluation of the morphological and growth characteristics of R4 of this recombinant cotton, comparison was made for the results of observation between the normally growing strain and the non-recombinant cotton.

Differences in the following 19 items of morphological and growth characteristics were examined between R4 of this recombinant cotton and the non-recombinant control cotton: the uniformity of germination, germination rate, plant type, culm length, flowering time, flower color, leaf shape, the number of effective flower buds, the number of bearing shoots, boll opening time, the color of fiber (lint), the shape of bolls (fruits of cotton), the number of bolls per plant, the number of segments of a boll, the number of seeds per boll, the color of seeds, harvest time, the dry weight of a boll, and the weights of above- and under-ground parts at the harvest time.

For the following characteristics among those listed above, five (5) individual plants were selected from individual rows of each plot and analyzed: plant type, culm length, the number of effective flower buds, the number of bearing shoots, the color of fiber (lint), the shape of bolls (fruits of cotton), the number of bolls per plant, the number of segments of a boll, the number of seeds per boll, the color of seeds, the dry weight of a boll, and the weights of above- and under-ground parts at the harvest time. As for the analysis of bolls among these items, two (2) bolls were selected from each individual plant. With regard to the analysis of the following items, including uniformity of germination, germination rate, flowering time, boll opening time, and harvest time, all individuals were analyzed.

As a result, a statistically significant difference was found between R4 of this recombinant cotton and the non-recombinant control cotton in the number of effective flower buds and the number of bolls per plant: the number of effective flower buds was 24.5 on average in R4 of the recombinant cotton and 14.1 on average in the non-recombinant control cotton. Likewise, a statistically significant difference was found in the number of bolls per plant: the number of bolls per plant was 12.5 on average in R4 of the recombinant cotton and 9.1 on average in the non-recombinant control cotton. In the other items, no statistically significant difference was observed.

A possible reason for the significant differences can be as follows: The R4 of the recombinant cotton remained undamaged from cotton leafroller (*Notarcha derogata*) and cotton bollworm (*Helicoverpa armigera*) due to the inserted genes, whereas the non-recombinant cotton was damaged by cotton leafroller (*Notarcha derogata*) and cotton bollworm (*Helicoverpa armigera*) and as a result, the number of effective flower buds and the number of bolls per plant decreased.

The number of effective flower buds and the number of bolls were also examined in the field experiments conducted in 1993 in 7 fields in the US, and as a result, in all of the fields examined, no difference was observed between the recombinant cotton and the non-recombinant control cotton.

b) Chilling-tolerance and heat-tolerance at the early stage of growth

Chilling-tolerance (temperature of 10°C) of the seedlings of this recombinant cotton and the non-recombinant control cotton was evaluated. On the 18th day after start of exposure to low temperature, all died almost completely, and no difference was observed between this recombinant cotton and the non-recombinant control cotton in chilling-tolerance.

At the same time, regarding the lateral branch type strain of this recombinant cotton, chilling-tolerance (temperature of 10°C) of the seedlings derived from the lateral branch type strain of this recombinant cotton was also evaluated. As a result, on the 18th day after exposure to low temperature, all of the seedlings from the lateral branch type strain of this recombinant cotton, normal strain of this recombinant cotton and the non-recombinant cotton died almost completely, and no differecne was observed between this recombinant cotton and the non-recombinant cotton in chilling-tolerance.

c) Wintering ability and summer survival of the matured plant

Basically cotton is a perennial plant, but only in tropical regions. In other cotton cultivation regions in the world, including Japan, cotton naturally dies in winter seasons after fruit-bearing. In practice, it was observed that the plants were partly dead when the isolated field tests of this recombinant cotton were completed. Based on the above, the wintering ability test was not conducted for adult plants.

d) Fertility and size of the pollen

In Japan, there are no plans for selling the seeds of this recombinant cotton, and cotton is not cultivated for commercial use. Therefore, if this recombinant cotton caused Adverse Effect on Biological Diversity in Japan, it would be in the following way: cotton seeds imported for oil extraction and feed are spilled during transportation in Japanese natural environment; then, the spilled seeds grow or become self-seeding, and expel other plants from the area. However, the fertility and the size of pollens were not examined, because there have been no reports that seeds spilled during transportation grow or become self-seeding under natural conditions in Japan.

e) Production, shedding habit, dormancy and germination rate of the seed

Regarding seed production, as desribed above in "a) Morphological and growth characteristics," the differences between this recombinant cotton and the non-recombinant control cotton were examined in the number of bolls per plant, the number of segments of a boll, and the number of seeds per boll. As a result, statistically significant difference was found between this recombinant cotton and the non-recombinant control cotton in the number of bolls per plant ($P < 0.05$). However, in other items, no difference was found. The number of bolls per plant, in which a statistically significant difference was found, was 12.5 in this recombinant cotton and 9.1

in the non-recombinant control cotton.

As described above in "a) Morphological and growth characteristics," the following is a possible reason for the significant difference found in the number of bolls per plant: Though insecticide was sprayed, the non-recombinant control cotton was damaged by order Lepidoptera: cotton leafroller (*Notarcha derogata*) and cotton bollworm (*Helicoverpa armigera*). As a result, the number of bolls per plant decreased in the non-recombinant control cotton, becoming less than in this recombinant cotton.

For the number of bolls, as a result of examination in the field experiments conducted in 1993 in seven (7) fields in the US, no difference was observed between this recombinant cotton and the non-recombinant control cotton.

In both this recombinant cotton and the non-recombinant control cotton, seeds are covered with lint at harvest time. Therefore, shedding habit of the seeds under natural conditions was not observed.

It is known that the level of seed dormancy of cotton is extremely low. In fact, as a result of examination on the germination rate at 25°C which is the optimum temperature for germination, this recombinant cotton exhibited a high germination rate similarly as the non-recombinant cotton and thus it was considered that the dormancy is extremely low. In addition, it is also known that the longevity of cotton seeds is short under natural condition, and most of them decay in soil if sown before a period when soil temperature reaches 15 - 16°C. Based on the above understanding, the test concerning dormancy was not conducted.

Germination rate was examined in "a) Morphological and growth characteristics." As a result, no statistically significant difference was observed between this recombinant cotton and the non-recombinant control cotton.

Regarding the lateral branch type strain of the recombinant cotton, germination rate was also exmained on the seeds derived from the normal strain of this recombinant cotton, the seed derived from the lateral branch type strain of this recombinant cotton, and the seeds of the non-recombinant control cotton. As a result, no statistically significant difference was observed among them.

f) Crossability

In Japan, no wild relatives exist that belong to *Gossypium* which crosses with tetraploid cotton cultivar (*Gossypium hirsutum*) to which this recombinant cotton belongs. Thus, crossability was not assessed.

g) Productivity of harmful substances

As described in d), if this recombinant cotton could produce harmful substances and cause any Adverse Effect on Biological Diversity in Japan, it would be in the following way: cotton seeds imported for oil extraction and feed are spilled during transportation; after that, such spilled seeds grow or become self-seeding at places which are not under human control, and expel other plants from the area. The productivity of harmful substances of this recombinant cotton was not examined, because it is considered that, until spilled cotton seeds germinate and become matured to a certain extent, harmful substances would not be produced in the root or aerial parts of the plant, up to a level where the environment may be affected; and because there are no reports that seeds spilled during transportation grow or become self-seeding under natural conditions in Japan.

Regarding the lateral branch type strain of this recombinant cotton, evaluation was made in the succeeding crop test and soil microflora tests on seeds derived from the normal strain of this recombinant cotton, seeds from the lateral branch type strain of this recombinant cotton, and seeds of the non-recombinant control cotton. As a result, no statistically significant difference was observed among them.

II. Review by persons with specialized knowledge and experience concerning Adverse Effect on Biological Diversity

A review was made by persons with specialized knowledge and experience concerning Adverse Effect on Biological Diversity (called Experts) for possible Adverse Effect on Biological Diversity caused by the use in accordance with the Type 1 Use Regulation for Living Modified Organism applied based on the "Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms." Results of the review are listed below.

1. Item-by-item assessment of Adverse Effect on Biological Diversity

(1) Competitiveness

The plant body of cotton (*Gossypium hirsutum* L.), to which the recipient organism belongs, dies during winter seasons in Japan, and the level of seed dormancy is extremely low. Therefore it is considered unlikely that cotton becomes self-seeding in Japan. Cotton has long been distributing as seed cotton in Japan, though there has been no report that cotton becomes self-seeding in Japan.

The introduction of the modified *cry1Ac* gene confers resistance to Lepidoptera to this recombinant cotton. However, from the result of the examination of characteristics in competitiveness (examination such as morphological and growth characteristics, and

productivity of the seeds in isolated fields), it is considered unlikely that a significant difference will arise in such characteristics between this recombinant cotton and the non-recombinant cotton under natural conditions in Japan. Therefore, it is considered unlikely that this recombinant cotton will grow or become self-seeding in Japan. Consequently, it is judged that, even though this recombinant cotton is resistant to Lepidoptera, it will unlikely become more competitive than the non-recombinant cotton.

Based on the above understanding, it was judged that there are no specific wild plants and wild animals that are possibly affected by this recombinant cotton, and that the conclusion made by the applicant that the use of such cotton poses no risk of Adverse Effect on Biological Diversity attributable to competitiveness is valid.

(2) Productivity of harmful substances

Into this recombinant cotton, the modified *cry1Ac* gene has been introduced, conferring the ability to produce Cry1Ac protein that has insecticidal activity against larvae of order Lepidoptera. However, the content of Type I Use of this recombinant cotton does not include "cultivation." Therefore, it is only when this recombinant cotton grew after spilled during transportation that order Lepidoptera could be exposed to Cry1Ac protein. Also, it is considered that, even if this recombinant cotton seeds grew after spilled during transportation, such seeds would not grow and become self-seeding, as was discussed in the section of "Competitiveness." Therefore, it was judged that the conclusion made by the applicant that the use of this recombinant cotton poses no risk of Adverse Effect on Biological Diversity that is attributable to the productivity of harmful substances is valid.

(3) Crossability

In the Japanese natural environment, there are no wild species which cross with cotton. Therefore, it was judged that there are no specific wild plants or wild animals that are possibly affected by this recombinant cotton, and that the use of such cotton poses no risk of Adverse Effect on Biological Diversity that is attributable to crossability. It was judged that the conclusion above made by applicant is valid.

2. Conclusion

Based on the above understanding, the Biological Diversity Risk Assessment Report concluded that there is no risk that the use of this recombinant cotton in accordance with Type 1 Use Regulation causes Adverse Effect on Biological Diversity. It was judged that the conclusion above is valid.