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 tolerant to glyphosate herbicide (*cp4 epsps, Gossypium hirsutum* L.) (MON 88913, OECD UI : MON-88913-8)
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 Report

I. Information concerning preparation of living modified organisms

1 Information concerning donor nucleic acid

(1) Composition and origins of component elements

Composition of the donor nucleic acid that was used for the development of cotton tolerant to glyphosate herbicide (*cp4 epsps, Gossypium hirsutum*) (MON 88913) (hereinafter referred to as "this recombinant cotton") and the origin of components are shown in Table 1.

In the amino acid sequence of CP4 EPSPS protein encoded by the *cp4 epsps* gene introduced into this recombinant cotton, the second amino acid from the N-terminal is modified to leucine, instead of serine found in the original amino sequence of the protein derived from *Agrobacterium* sp. strain CP4. This alterlation was occured because the cp4 epsps gene sequence was modified in order to confer an *Nde*I restriction enzyme site around the 5' end.. Therefore, the *cp4 epsps* gene introduced into this recombinant cotton is referred to as "modified *cp4 epsps* gene", and the CP4 EPSPS protein encoded by the gene as "modified CP4 EPSPS protein".

(2) Functions of component elements

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

The modified *cp4 epsps* gene produces the modified CP4 EPSPS protein which has high tolerance to the herbicide glyphosate. Glyphosate is the active ingredient in Roundup® herbicides. Glyphosate is a nonselective herbicide that inhibits the activity of 5-enol-pyruvylshikimate-3-phosphate synthase (EPSPS) (E.C.2.5.1.19), one of the enzymes in the shikimate pathway for aromatic amino acid biosynthesis, by specifically binding to the enzyme. As a result, plants treated with glyphosate cannot synthesize enough amounts of aromatic amino acids essential for protein syhthesis due to the inhibition of EPSPS, resulting in the death of the plant. The activity of the modified CP4 EPSPS protein that is produced by the modified *cp4 epsps* gene is not inhibited under the presence of glyphosate. Thus, recombinant plants that express

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this protein have normal functions of shikimate synthesis and can grow in the presence of glyphosate.

EPSPS is one of the enzymes that catalyze the shikimate pathway for aromatic amino acid biosynthesis that is specific to plants and microorganisms, and is located in chloroplasts and plastids in plants. The shikimate pathway is an important metabolic pathway that is considered to be involved in one fifth of carbon fixation in plants. This pathway is regulated by 3-deoxy-D-arabino-heptulonate-7-phosphate (DAHP) synthase, which is involved in the first step of the pathway, but it has been clarified to be extremely unlikely that the steps from DAHP to the systhesis of chorismic acid are inhibited or suppressed by metabolic intermediates or end products of this pathway. This suggests that EPSPS is not a rate-determining enzyme, and as such it is not considered that enhanced EPSPS activity will increase the concentration of aromatic amino acid, the end products of this pathway. In fact, it is reported that plant cells that produce 40 times as much EPSPS as compared to average do not synthesize excessive aromatic amino acids. In addition, Monsanto Co. examined amino acid contents in the seeds of the recombinant crops in the process of food/feed safety assessment of crop plants (soybean, coleseed, cotton, and maize) that are tolerant to the Roundup herbicides, and confirmed that there is no difference in the aromatic amino acid content between the original non-recombinant plants and the recombinant plants. These facts support that EPSPS is not the rate-determinig enzyme in this pathway. Besides, EPSPS is the enzyme that catalyzes a reversible reaction to produce EPSP and inorganic phosphate (Pi) from phosphoenolpyruvate (PEP) and shikimate-3-phosphate (S3P), and is known to specifically react with these substrates. The only substance that is known to react with EPSPS other than these is shikimate, an analogue of S3P. However, the reactivity with shikimate is only one two millionth of the reactivity with S3P, and it is unlikely that shikimate acts as the substrate of EPSPS in the living body.

Consequently, it is considered to be extremely unlikely that the production of the modified CP4 EPSPS protein, which is functionally parallel to plant EPSPS protein, has an effect in someway on the metabolic pathways of plants.

In the United States and Australia, a cotton tolerant to glyphosate herbicide (*cp4 epsps*, *Gossypium hirsutum* L.) (1445, OECD UI: MON- Ø1445-2) (hereinafter referred to as “1445”) has been already commercialized and widely introduced into cotton farmers. However, with regard to 1445, the period when glyphosate could be sprayed over the top of the plants was limited up to the stage of the fourth leaf (node), and over-the –top weed control sprays could not be carried out throughout the cultivation period. As a result, Monsanto Co. developed a second generation glyphosate-tolerant cotton. In

1445, one copy of the modified *cp4 epsps* gene expression cassette is regulated by the *Figwort Mosaic Virus* (FMV) promoter. In contrast, in MON 88913, two modified *cp4 epsps* gene expression cassettes are regulated by respectively different promoters. These two modified *cp4 epsps* gene expression cassettes enhance tolerance to glyphosate in general, but especially in the productive organs, which allows spraying of glyphosate over-the-top of the crop in the period closer to the harvest season, aiming at preventing weeds that regrow throughout the cultivation period of cotton and cause problems at the time of harvest. By reducing weeds at harvest, color staining onto lint due to weeds mixed in machine harvested cotton is prevented, and cotton of a high quality can be produced. Actually, an experiment was conducted in which herbicide glyphosate was sprayed on this recombinant cotton and 1445, and then, morphological features associated with reproductive organs (number of pollen grains on stigma; the rate of anther dehiscence; pollen viability; stamen length; staminal column height; anther height; and pollen deposition rating) were compared. The results demonstrated that, in all the items above except the length of a pistil including an ovary, tolerance to glyphosate in reproductive organs was higher in this recombinant cotton than in 1445. Besides, this recombinant cotton showed a higher yield than did 1445 line, as demonstrated by experiments conducted at nine fields in the US in which glyphosate was sprayed on this recombinant cotton and the 1445 line at their third, sixth, tenth and fourteenth leaf stages in succession. These phenomena can be explained by a higher tolerance to glyphosate in reproductive organs in this recombinant cotton than in the 1445 line, which results in the former’s increased tolerance to glyphosate during post-growth period (during and after the fourth leaf stage).

Table 1 Component elements of the expression vector PV-GHGT35

Component elements	Origin and Function
Modified *cp4 epsps* gene expression cassette which is regulated by P-FMV/TSF1	
P-FMV/TSF1	A chimeric promoter which was prepared by attaching *Arabidopsis thaliana* TSF1 promoter and enhancer sequence of *Figwort Mosaic Virus* (FMV) 35S promoter. Involved in the constant expression of introduced gene in reproductive organs as well as in vegetative organs. It has not been reported that viruses of genus *Caulimovirus*, which FMV belongs to, infect plants of genus *Gossypium*. Therefore, it is considered extremely unlikely that new types of virus will be created as a result of this recombination.
L-TSF1	Leader sequence (exon 1) of *Arabidopsis thaliana* TSF1 gene that encodes translation elongation factor EF-1 alpha. Enhances the expression of introduced gene.
I-TSF1	Intron sequence of *Arabidopsis thaliana* TSF1 gene that encodes translation elongation factor EF-1 alpha. Enhances the expression of introduced gene.
TS-*ctp2*	A sequence that encodes chloroplast transit peptide derived from *Arabidopsis thaliana* EPSPS, which transfers the CP4 EPSPS protein to the chloroplast, where aromatic amino acids are synthesized.
CR-*cp4 epsps* (modified *cp4 epsps*)	5-enol-pyruvyl-shikimate-3-phosphate synthase gene derived from *Agrobacterium* strain CP4. A modification is given to the nucleotide sequence to enhance its expression in plants without changing the function of the CP4 EPSPS protein. Only a single modification is introduced to the amino sequence: the second amino acid from the N-terminal is modified to leucine, instead of serine.
T-E9	3' untranslated region of pea ribulose-1, 5-bisphosphate carboxylase E9 gene. Terminates transcription of mRNA and induces polyadenylation.
Modified *cp4 epsps* gene expression cassette which is regulated by P-35S/ACT8	
P-35S/ACT8	A chimeric promoter which was prepared by attaching *Arabidopsis thaliana* ACT8 promoter and enhancer sequence of cauliflower mosaic virus (CaMV) 35S promoter. Involved in the constant expression of the introduced gene in vegetative organs. It has not been reported that viruses of genus *Caulimovirus*, which CaMV belongs to, infect plants of genus *Gossypium*. Therefore, it is considered extremely unlikely that new types of virus will be created as a result of this recombination.
L-ACT8	Leader sequence of *Arabidopsis thaliana* ACT8 gene. Enhances the expression of the introduced gene.
I-ACT8	Intron sequence and nearby exon sequence of *Arabidopsis thaliana* ACT8 gene. Enhances the expression of the introduced gene.
TS-*ctp2*	A sequence that encodes a chloroplast transit peptide derived from *Arabidopsis thaliana* EPSPS, which directs the CP4 EPSPS protein to the chloroplast, where aromatic amino acids are synthesized.
CR-*cp4 epsps* (modified *cp4 epsps*)	5-enol-pyruvyl-shikimate-3-phosphate synthase gene derived from *Agrobacterium* strain CP4. A modification is given to the nucleotide sequence to enhance its expression in plants without changing the function of the CP4 EPSPS protein. Only a single modification is introduced to the amino sequence: the second amino acid from the N-terminal is modified to leucine, instead of serine.
T-E9	3' untranslated region of pea ribulose-1, 5-bisphosphate carboxylase E9 gene. Terminates transcription of mRNA and induces polyadenylation.

Component elements	Origin and Function
Components of plasmid backbone	
B-Left Border (Left Border Sequence)	A DNA sequence containing the left border sequence (25 bp) derived from Ti plasmid pTiA6. Defines the T-DNA transferred from *Agrobacterium tumefaciens* to the plant genome.
OR-ORI V	The replication origin isolated from the broad-recipient range plasmid RK2. Permits autonomous replication of vectors in *Agrobacterium tumefaciens.*
CR-rop	A coding sequence to repress primer protein to maintain the number of copies of plasmids in *E. coli*.
OR-ORI-PBR 322	Replication origin region isolated from pBR322, a plasmid derived from *E. coli*. Permits autonomous replication of vectors in *E. coli.*
CR-*aad*	The gene that encodes aminoglycoside adenyltransferase (AAD) derived from *E. coli* transposon Tn7. Confers resistance to spectinomycin or streptomycin.
B-Right Border (Right Border Sequence)	A DNA sequence containing right border sequence (25bp) of nopaline type T-DNA derived from Ti plasmid pTiT37. Defines the T-DNA transferred from *Agrobacterium tumefaciens* to plant genome.

2 Information concerning vector

(1) Name and origin

The synthetic plasmid vector PV-GHGT35 used to generate this recombinant cotton is derived from pBR322, which is a synthetic plasmid from *E.coli.*

(2) Properties

The total number of base pairs of this plasmid vector PV-GHGT35 is 13,741 bp.
The plasmid vector pBR322 is a double strand circular DNA which has tetracyclin/ampicillin resistance as a selectable marker for construction vector in *E.coli*, and ori sequence, the origin of DNA replication.

3 Method of preparing living modified organisms

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

The plasmid vector PV-GHGT35 used to generate this recombinant cotton was a synthetic plasmid vector designed based on plasmid pBR322 derived from *E. coli.* Its T-DNA region contains both the modified *cp4 epsps* gene expression cassette ([P-FMV/TSF1]-[L-TSF1]-[I-TSF1]-[TS-*ctp2*]-[CR-*cp4 epsps*]-[T-E9]) regulated by the P-FMV/TSF1 chimeric promoter, and the modified *cp4 epsps* gene expression

cassette ([P-35S/ACT8]-[L-ACT8]-[I-ACT8]-[TS-*ctp2*]-[CR-*cp4 epsps*]-[T-E9]) regulated by the P35S/ACT8 chimeric promoter.

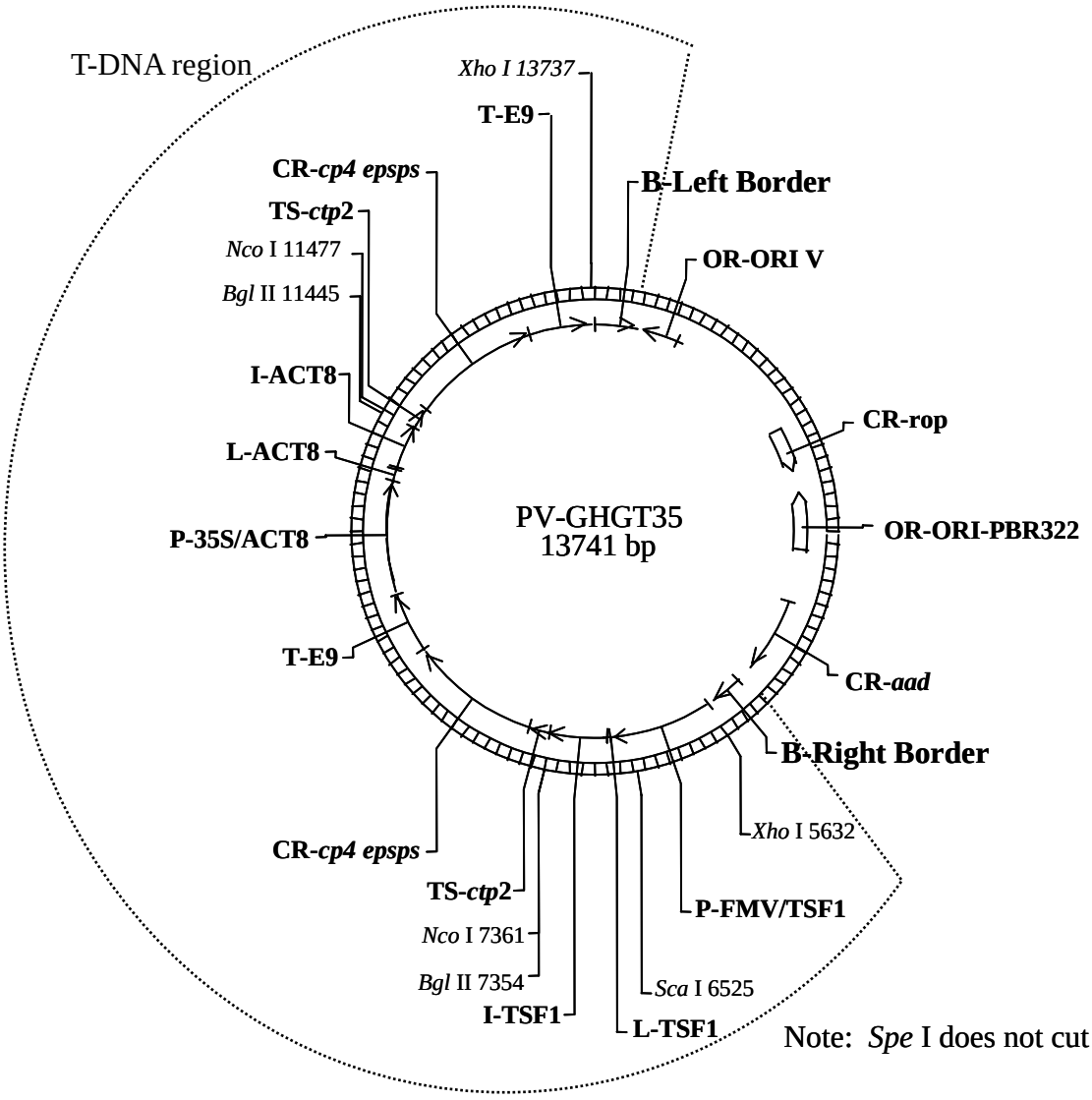

Figure 1 Map of the PV-GHGT35 plasmid

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

The T-DNA region of the plasmid vector PV-GHGT35 was introduced to a tetraploid cotton cultivar, Coker 312, by the *Agrobacterium* method.

(3) Processes of rearing of living modified organisms

The development of the recombinant cotton began in 1998. After the introduction of T-DNA regions of the plasmid vector PV-GHGT35 into the tissue section of Coker 312 by the *Agrobacterium* method, regenerated individuals were obtained by selecting transformed callus on the medium containing glyphosate. At this time, it was also confirmed that there was no remaining *Agrobacterium*. For the individual regenerated plants, further selection was carried out based on the analysis of the inserted genes and the level of the modified CP4 EPSPS protein. Tests in a climate chamber and greenhouse were then conducted. Glyphosate tolerance and agronomic characteristics were examined in outdoor field tests. The recombinant cotton to be commercialized (MON 88913) was selected based on the comprehensive evaluation of these results.

The following shows the approvals received from organizations in Japan.

November 5, 2004:
We filed for safety approval for this recombinant cotton to be used as animal feed, with the Ministry of Agriculture, Forestry and Fisheries. Examination is in progress at present.

April 7, 2005:
The Ministry of Health, Labor and Welfare ensured the safety of this recombinant cotton to be used as food.

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

(1) Location of copies of the introduced nucleic acids

On the chromosome

(2) Number of copies of the introduced nucleic acids and inter-generational inheritance stability of copies of the introduced nucleic acids

Based on Southern blot analyses, it was confirmed that one copy of the T-DNA region was inserted at a site in the genome of the recombinant cotton (Figure 2). The plasmid backbone region outside of the T-DNA region was not inserted, and the two intact modified *cp4 epsps* gene expression cassettes inside the T-DNA region were inserted as expected. Furthermore, Southern blot analyses on multiple generations indicated that inserted genes were stably inherited in offspring.

(3) Inter-individual or inter-generational expression stability under natural conditions

We examined the levels of the modified CP4 EPSPS protein using samples obtained at four different fields in the U.S. (Alabama, California, Georgia and Texas) by ELISA analysis. As a result, it was confirmed that the modified CP4 EPSPS protein was produced in every organ examined. Furthermore, the inter-generational expression stability of the modified CP4 EPSPS protein was evaluated based on tolerance to herbicide glyphosate across several generations.

(4) Existence of transmission routes and its scale, if it is possible that nucleic acids introduced via viral infection or other routes might be transmitted to wild animals and plants

It is only in Gram-negative bacteria, such as *E.coli* and *A. tumefaciens*, that the plasmid PV-GHGT35 can sustain autonomous replication. Therefore, there is no possibility that the introduced nucleic acids might be transmitted to wild animals and plants under natural conditions.

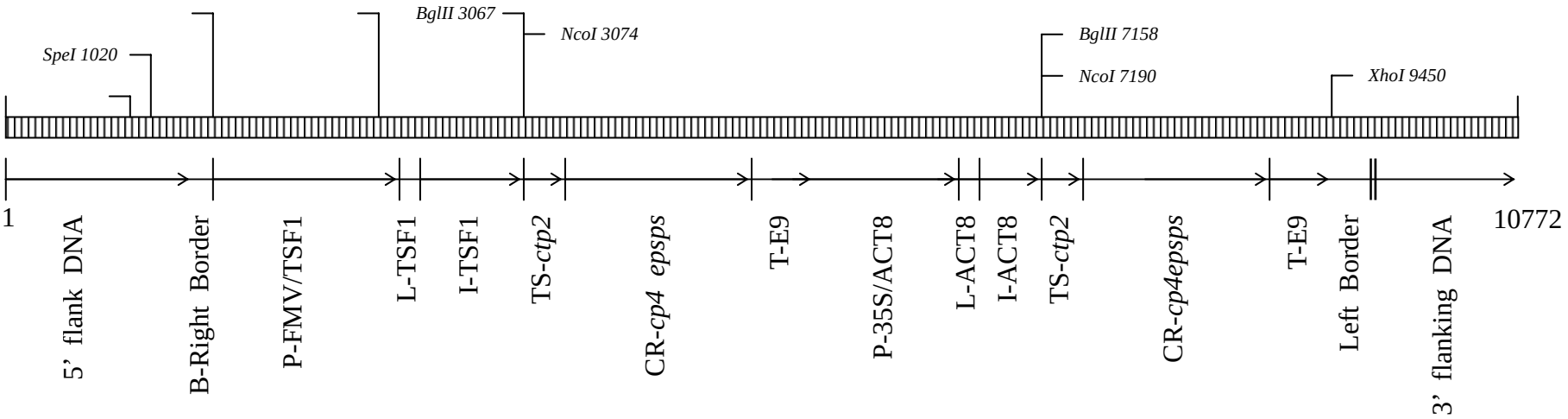

Figure 2 Genetic map of inserted genes in cotton tolerant to glyphosate herbicide, MON 88913

It shows a genetic map of the inserted genes in MON 88913 and boundary regions between the inserted DNA and the cotton genome. This genetic map contains each of the inserted components and restriction sites used in Southern blot analysis.

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 DNA and the nearby regions of the 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 species to which the recipient organism belongs

(1) Details of physiological or ecological properties conferred as a result of the expression of copies of the introduced nucleic acids

This recombinant cotton shows tolerance to herbicide glyphosate, by expressing the modified *cp4 epsps* gene to produce the modified CP4 EPSPS protein. In a tolerance test against herbicide conducted as part of this isolated field test, the control null-type cotton showed 100% sensitivity to herbicide glyphosate, while this recombinant cotton showed 100% tolerance, demonstrating the properties of the modified CP4 EPSPS protein.

(2) Differences between genetically modified crops and the taxonomic species to which the recipient organism belongs

The isolated field test for this recombinant cotton was conducted at an isolated field in Kawachi Research Field of Monsanto Co. Japan from May 2004 to February 2005. Cottons used in this test were as follows: for the recombinant cotton, seeds (= R3 generation) harvested from the R2 generation of this recombinant cotton was used; and for a control non-recombinant cotton, null-type cotton was used which was obtained through the screening of the inserted DNA in R2 generation carried out during the cultivation of this recombinant cotton. The null-type cotton was considered appropriate to be used as a control because its genetic background is the most similar to the recombinant cotton due to the following reasons: it is basically difficult to equalize the genetic background of cotton even if self-fertilization is repeatedly performed; and therefore, cottons having morphological characteristics—such as yield and plant height—in common are regarded, and actually registered, as a cultivar. It was confirmed by Southern blot analyses and PCR analyses that the introduced gene had not been

introduced into the genome of the null-type cotton.

For reference, we attached—and where necessary quoted—the results of field tests conducted in the US in 2002, at 14 typical cotton cultivation fields under different environmental conditions.

(a) Morphological and growth characteristics

Differences in morphological and growing characteristics were examined between this recombinant cotton and the control null-type cotton with respect to the following 18 items: the uniformity of germination; germination rate; plant type; plant height; the number of flowers; flower color; leaf shape; the number of effective flower buds; the number of bearing shoots; boll opening time; the shape of bolls; the color of fiber (lint); the number of bolls per plant; the number of segments of a boll; the number of seeds per boll; the color of seeds; the weight of a boll; and the weights of above and under-ground parts at the harvest time.

Measurement and statistical analysis were performed especially with respect to the following items: germination rate; plant height; the number of flowers; the number of effective flower buds; the number of bearing shoots; the number of bolls per plant; the weight of a boll; the number of segments of a boll; the number of seeds per boll; and the weights of an above and under-ground parts at the harvest time. As a result, statistically significant differences ($p < 0.05$) between this recombinant cotton and the control null-type cotton were found in germination rate and plant height, but not in other items.

The germination rate, in which a statistical difference was observed, averaged 41.1% in this recombinant cotton, and 55.8% in the control null-type cotton. For reference, in germination tests carried out in 2002 at three fields in the US (California [CA], Georgia [GA], and Alabama [AL]), seeds from the recombinant cotton and the controlnull-type cotton collected in Georgia and Alabama showed low germination rates, as well, at less than 50% on average.

The plant height, in which a statistical difference was also observed, averaged 167.2 cm in this recombinant cotton, and 175.2 cm in the control null-type cotton. For reference, in study carried out at 14 fields in the U.S. in 2002 to examine plant height 4 weeks (first plant height), 8 weeks (second plant

height) and 12 weeks (third plant height) after seeding, no statistical differences were observed between this recombinant cotton and the control null-type cotton.

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

The seedlings of this recombinant cotton and of the control null-type cotton were set under cold conditions. As a result, they had both died almost completely by the 24th day. No differences were observed between them.

(c) Overwintering ability and summer survival of the matured plant

Both this recombinant cotton and the control null-type cotton had shed all their leaves and the color of the plant body had turned brown by January 7, on which this study was carried out. No differences were observed between them.

(d) Fertility and size of the pollen

The fertility and the size of pollen grains were not eximamined in this isolated field test. In the US, however, a fertility test was carried out based on the two staining methods. Neither of the two methods showed statistically significant differences between this recombinant cotton and the control null-type cotton.

(e) Productivity, dormancy, and germination rate of the seeds

We compared the number of bolls per plant and of seeds per boll between this recombinant cotton and the control null-type cotton. As a result, no differences were observed between them.

Low shattering habit was expected in both this recombinant cotton and the control null-type cotton because fiber twining around seeds does not allow them to shed.

As for dormancy and germination rate, it was found that the germination rates of the seeds from this recombinant cotton and the control null-type cotton were low, at 58.9% and 54.4%, respectively. No statistically significant differences were observed between them.

For reference, here is presented the results of germination tests conducted in the U.S. in 2002, using seeds from this recombinant cotton and the null-type cotton collected at three fields in California (CA), Georgia (GA) and Alabama (AL), as well as from additional six conventional cultivars. Seeds from the recombinant cotton and the control null-type cotton collected in Georgia and Alabama showed low germination rates, as well, at less than 50% on average. In addition, all the seeds were found to be in the condition of germination, death or imbibition (viable firm swollen), and none of them was in the condition of dormancy (viable hard).

(f) Crossability

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

(g) Production of harmful substances

A soil microflora test, a plowing test and a succeeding crop test were carried out for comparison between this recombinant cotton and the control null-type cotton.

[Soil microflora test]
According to the test carried out before seeding, no statistically significant differences were observed in the number of microorganisms (the numbers of bacteria, actinomyces and filamentous fungi) in the soil taken from cultivation fields, between this recombinant cotton and the control null-type cotton. According to the test carried out at the time of harvesting, too, no statistically significant differences were observed in the number of microorganisms (the numbers of bacteria, actinomyces and filamentous fungi) in the soil taken from cultivation fields, between this recombinant cotton and the control null-type cotton.

[Plowing test]
No statistically significant differences were observed between this recombinant cotton and the control null-type cotton, in the plant height and the fresh weight of radish seedlings (test plant).

[Succeeding crop test]

No statistically significant differences were observed between this recombinant cotton and the control null-type cotton, in the plant height and the fresh weight of radish seedlings (test plant).

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 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) dies during winter seasons in Japan, due to coldness; and the level of seed dormancy is extremely low. Therefore, it is considered unlikely that cotton becomes self-seeding in Japan. Though cotton seeds have long been available on the market in Japan, it has not been reported that cotton becomes self-seeding in Japan.

The introduction of the modified *cp4 epsps* gene expression cassette confers tolerance to herbicide glyphosate to this recombinant cotton. In addition, studies conducted at isolated fields in Japan showed that, between this recombinant cotton and a non-recombinant cotton, there were statistically significant differences noted in germination rate and plant height among various traits relevant to its competitiveness. However, it is highly unlikely that glyphosate will function as a selective pressure under the natural environment, and that the differences noted in germination rate and plant height will lead this recombinant cotton to become more fertile and survivable in the natural environment, and then to grow or become self-seeding in Japan.

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

There have been no reports that cotton produces harmful substances that have an effect on wild animals and plants.

This recombinant cotton produces the modified CP4 EPSPS protein that is tolerant to herbicide glyphosate; however, it has not been reported that this protein is harmful. In addition, EPSPS protein is a member of enzymes that catalyze the shikimate pathway to synthesize aromatic amino acids, but not a rate-determining enzyme in this pathway. It is therefore believed that the increase of EPSPS activity do not result in the excessive production of aromatic amino acids. In fact, the aromatic amino acid content did not change in other recombinant crops (four types of crop, including cotton) into which *cp4 epsps* gene had been introduced. Besides, EPSPS protein is an enzyme that specifically reacts with phosphoenolpyruvic acid and shikimate-3-phosphate. Therefore, it is unlikely that the CP4 EPSPS protein, by catalyzing a reaction between other substances, contributes to the production of an unexpected substance.

At isolated fields in Japan, studies have been conducted to examine the productivity of harmful substances (such as substances that are secreted from roots and have adverse effects on other plants; substances that are secreted from roots and have adverse effects on soil microorganisms; and substances that are kept inside a plant body and, after the death of the plant body, have adverse effects on other plants). The results showed no differences between this recombinant cotton and a non-recombinant cotton.

Therefore, it is very unlikely that this recombinant cotton has an effect on wild plants and animals beyond the recipient cotton itself.

These mentioned above support the conclusion of the applicant who judged that there would be no specific wild plants and wild animals that would possibly be affected by this recombinant cotton, and that the use of such cotton would pose no risk of Adverse Effect on Biological Diversity that might be attributable to the productivity of harmful substances.

(3) Crossability

In the Japanese natural environment, there are no wild species which can 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.

Based on the above understanding, the conclusion made by the applicant that the use

of such cotton poses no risk of Adverse Effect on Biological Diversity attributable to crossability is valid.

2. Conclusion

Based on the above understanding, the Biological Diversity Risk Assessment Report concluded 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 made by the applicant is valid.