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	Maize tolerant to glyphosate herbicide (*cp4 epsps, Zea mays* subsp. *mays* (L.) Iltis) (NK603, OECD UI: MON-ØØ6Ø3-6)
Content of the Type 1 Use of Living Modified Organism	Provision as food, provision as feed, cultivation, 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 collected prior to assessing Adverse Effect on Biological Diversity

1. Information concerning a recipient organism or the species to which the recipient organism belongs

(1) Taxonomical position and state of distribution in natural environment

i) The general academic name for maize is *Zea mays* L. However, in recent years, since the annual teosinte, a related species of maize, has been classified into *Z. mays*, maize has been classified into *Z. mays* subsp. *mays* (L.) Iltis as a subspecies of *Z. mays*.

ii) The recipient organism is *Zea mays*, which belongs to the genus *Zea* of the family *Gramineae*. The recipient organism belongs to the dent type.

iii) The origin is considered to be the area from the southwest region of the United States to Mexico, Central America, and South America, but there is no conclusive theory. There are two theories; one is that the independent origins are considered to be each of the aforementioned regions, and the other is that the exclusive origin is considered to be the south region of Mexico. There is no report of natural distribution in Japan.

(2) History and present state of Use

i) It is generally understood that the earliest cultivation could date back 9,000 years. It is considered that cultivation and breeding were later carried out by indigenous inhabitants, and in about 3000 BC to 1500 BC maize near to the modern cultivation type was cultivated in earnest, and was introduced to the various regions of the north-south Americas. It is understood that in the process of the introduction, various types such as dent, pop, and sweet were differentiated. The first introduction to Japan is said to have been in 1579 to Nagasaki or Shikoku, and maize has long been cultivated in Japan since then.

ii) At present, maize is used mainly for feed, but also for food and various food products including cooking oil and starch. Currently, it is the most widely cultivated grain in the world and can be grown in the area from a latitude of 58 degrees north to 40 degrees south mainly in the US, China, Brazil, Argentina, and European countries and others. Based on the statistical information of the Food and Agriculture Organization (FAO) of the United Nations, in 2002 the world's cultivated area of maize was about 140 million hectares. The seven top countries were the US (28 million hectares), China (25 million hectares), Brazil (12 million hectares), Mexico (7 million hectares), India (6 million hectares), Nigeria (4 million hectares), and South Africa (3 million hectares). Also,

according to the same statistical information of the FAO, the cultivated area of maize in Japan in 2002 was about 30 thousand hectares.

Japan currently imports about 16 million tons of maize for feed and food. Maize imported for feed totals about 11 million tons and about 5 million tons is imported for food, and is mainly used for starch and isomerized sugar.

The practical cultivation method of maize for feed in Japan is as follows. The optimum sowing season in cold to mild-temperature regions is May, and April to June in some warmer regions. The optimum density is 6,000 to 8,000 plants per 10 ares. For weed control, herbicides are sprayed and intertillage and molding are applied two to three times at the early stages of growing maize. Aerial parts of maize are harvested in the yellow ripe stage, 35 to 45 days after ear emergence.

In addition, based on the lists of maize varieties of major seed and plant companies in Japan, currently almost all maize for cultivation available on the market is F1 hybrid, and it is not general to sow the harvested seeds for cultivation in the following year.

(3) Physiological and ecological properties

i) Environmental conditions allowing inhabiting or growth

The optimum germination temperature of maize is 32-36℃ and the minimum germinating and minimum growing temperature is 6-10℃. In practice, the optimum sowing season is considered to be the period when the temperature is 13-14℃ or over. It varies somewhat by variety and place, but usually maize is sown in spring and harvested in autumn as an annual plant. In addition, maize is usually a short-day plant, and its photosensitivity is higher in the late variety and lower in the early variety. Other than temperature, the following environmental conditions affect the growth of maize. Regarding the absorption of water, 70% of seed weight for dent type and 90% of seed weight for sweet type allows the maize to germinate. Moreover, humid soil with a pH of 5.5-8.0 is suitable for maize cultivation.

Modern maize is a plant highly acclimatized for human cultivation, and it has lost the ability to reproduce and grow in natural conditions.

ii) Mode of propagation or reproduction

a) A fully-ripened seed is covered with the bract of the ear, and the seed does not have natural shedding habits. Maize has long been cultivated and it has lost the ability to survive as a wild plant. Maize requires the assistance of human beings to disperse its seeds. The dormancy of the seed is extremely low, and even when seeds fall to

the ground, they do not germinate until the soil temperature reaches 10°C. In most cases the seeds would decay and die before germinating.

Moreover, even if seeds germinate, they cannot subsist under conditions of exposure to temperatures below 0°C for more than 6-8 hours or over at the early stage of growth (5th-7th leaf stage), that is when the growing point reaches the above-ground level. The longevity of seeds is short if stored at room temperature, and the germination rate decreases from the second year.

b) Maize does not reproduce by vegetative propagation. It reproduces only by seed. There is no report so far of maize having the budding property in the tissues or organs that can regenerate the plant body.

c) Maize is a monoecious annual plant which propagates by seed mostly through cross-pollination, although it can be self-pollinated due to the absence of self-incompatibility. Species related to maize are teosinte, of the same genus *Zea*, as well as some other species classified into the genus *Tripsacum*. Maize can be hybridized only with teosinte in nature, and natural crossing with any species of the *Tripsacum* is not known. Natural distribution of teosinte is only seen in Mexico and Guatemala. On the other hand, the distribution area of the genus *Tripsacum* is divided broadly into three areas including the south-eastern part of North America, the lowland area of the eastern Andes from Colombia to Bolivia, and the area of Mexico and Guatemala that is considered the center of this genus. In Japan, the growth of teosinte and wild species of the *Tripsacum* has not been reported.

d) Maize has a typical wind pollinated flower. A tassel of maize has 1,200-2,000 spikelets, and produces 16 million to 30 million pollen grains. The longevity of pollen is within 24 hours in the conditions of a field in high summer, but there is a range of longevity of from two hours to eight days according to the environmental conditions. Maize pollen is spherical and the diameter of the pollen is 90-100 μm. Maize mainly propagates through cross-pollination by wind, but there is a 1-5% possibility of self-pollination in normal field conditions. The pollens dispersing from bloomed tassels attach to the silks extracted from ears and then they germinate. The fertilization of maize is completed within 24 hours. The dispersion distance of maize pollen differs by the presence of barriers such as woods or mountains, or the direction of the wind, but is considered to be approximately 300-500 m.

iii) Productivity of harmful substances

Regarding maize, productivity of harmful substances that can affect the growth or habitat of other wild fauna and flora has not been reported.

iv) Other information

It has not been reported so far that maize seeds which were spilled during transportation, etc., on locations other than cultivation fields have grown.

2. Information concerning preparation of living modified organisms

(1) Information concerning donor nucleic acid

i) Composition and origins of component elements

The composition of donor nucleic acid and the origins of component elements used for the development of the maize tolerant to glyphosate herbicide (*cp4 epsps*, *Zea mays* subsp. *mays* (L.) Iltis) (NK603, OECD UI: MON-ØØ6Ø3-6) (hereinafter referred to as "this recombinant maize") are shown in Table 1.

ii) Functions of component elements

Functions of component elements which were used for the development of this recombinant maize are shown in Table 1.

a) Glyphosate is the active ingredient in Roundup, a nonselective herbicide, and 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 aromatic amino acids essential for protein synthesis due to the inhibition of EPSPS, and die. The target gene, *cp4 epsps* gene, expresses the CP4 EPSPS protein which has high tolerance to the herbicide glyphosate. The activity of the CP4 EPSPS protein that is produced by the *cp4 epsps* gene is not inhibited even under the presence of glyphosate, thus, the recombinant plants that express this protein have normal functions of shikimate synthesis and can grow.

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 or plastids in plants. The shikimate pathway is an important metabolic pathway that is considered to be involved in one fifth of carbon fixation by plants. This pathway is regulated by 3-deoxy-D-arabino-heptulosonate-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 stages from DAHP to the synthesis 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 acids, the end products of this pathway. In practice, it is reported that plant cells that produce 40 times as much EPSPS as compared to normal do not synthesize excessive aromatic amino acids. In addition, Monsanto Co. examined amino acid content 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 recombinant plants. These facts support the theory that EPSPS is not the rate-determining enzyme in this pathway. Besides, EPSPS is the enzyme that catalyzes a reversible reaction to produce EPSP and inorganic phosphates (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, but the reactivity with shikimate is only one two millionth of the reactivity with S3P, and it is unlikely that shikimate reacts as the substrate of EPSPS in the living body.

b) In order to investigate whether the CP4 EPSPS protein shares functionally important amino acid sequences with known allergens, the CP4 EPSPS protein was compared with contact allergens in the database. As a result, the CP4 EPSPS protein did not share structurally related homologous sequences with any of the known allergens examined.

(2) Information concerning vector

i) Name and origin

The vector used for the production of this recombinant maze is plasmid pUC119 from *Escherichia coli.*

ii) Properties

The total numbers of base pairs of the vectors are 9,307 bp. These vectors contain a kanamycin/neomycin-resistant gene (*nptII* gene) derived from *E.coli* transposon Tn5 as the selectable marker gene for the construction vector. The infection of this vector is not known.

(3) Method of preparing living modified organisms

i) Structure of the entire nucleic acid transferred in the recipient organism

For the production of this recombinant maize, the plasmid PV-ZMGT32 was constructed by connecting the two *cp4 epsps* gene cassettes ([P-ract1]- [ract1 intron]-[CTP2]-[*CP4 EPSPS*]-[NOS 3'] and [e35S]-[*Zmhsp70*]-[CTP2]-[*CP4 EPSPS*]-[NOS 3']) to a basic vector derived from pUC119 containing the above-mentioned *nptII* gene. When the genes were introduced into plant cells, a linear plasmid (PV-ZMGT32L) was used, after treating this PV-ZMGT32 with restriction enzyme *MluI* to remove the plasmid-backbone containing the *nptII* gene region.

Table 1 Component elements of plasmids PV-ZMGT32L which were used for insertion, and their origins and functions

Component elements	Size (Kpb)	Origin and function
cp4 epsps gene cassette (1)		
P-ract1	0.9	Promoter region of actin 1 gene derived from rice. It makes target genes expressed.
ract1 intron	0.5	Intron of rice actin gene. It makes target genes expressed by enhancing splicing.
CTP 2	0.2	N-terminal chloroplast transit peptide sequence derived from the *Arabidopsis epsps* gene. Transfers target proteins from cytoplasm to chloroplast.
Cp4 epsps	1.4	5-enol-pyruvylshikimate-3-phosphate synthase (EPSPS) gene from *Agrobacterium* CP4. Details of functions are shown on p4-5.
NOS 3'	0.3	3' untranslated region of nopaline synthase (NOS) gene from T-DNA of *Agrobacterium tumefaciens.* It terminates transcription of mRNA and induces polyadenylation.
cp4 epsps gene cassette (2)		
E35S	0.6	Contains 35S promoter and duplicated enhancer from cauliflower mosaic virus (CaMV). Makes target genes expressed in all the tissues constantly.
ZmHsp70 Intron	0.8	Intron of heat shock protein gene from maize. ZmHsp70 intron is used to enhance the expression of foreign genes in plants.
CTP2	0.22	N-terminal chloroplast transit peptide sequence derived from the *Arabidopsis epsps* gene. Transfers target proteins from cytoplasm to chloroplast.
Cp4 epsps	1.36	5-enol-pyruvylshikimate-3-phosphate synthase (EPSPS) gene from *Agrobacterium* CP4. Details of functions are shown on p4-5.
NOS 3'	0.26	3' untranslated region of nopaline synthase (NOS) gene from T-DNA of *Agrobacterium tumefaciens*. It terminates transcription of mRNA and induces polyadenylation.

ii) Method of transferring nucleic acid transferred in the recipient organism

PV-ZMGT32L, a linear nucleic acid, was introduced by particle gun bombardment to the variety AW×CW that is classified into dent type.

iii) Processes of rearing of living modified organisms

a) The callus to which PV-ZMGT32L was introduced was grown on a tissue culture media containing 2,4-D for a certain period of time, and then the recombinant plant was selected on a glyphosate-containing medium. From the selected callus, the regenerated plant was obtained and the expression of the CP4 EPSPS protein was analyzed.

b) A plasmid was introduced to the recombinant plant by particle gun bombardment, so, confirmation of remaining Agrobacterium was not carried out.

c) Pedigree selection was started in 1997, and field experiments were carried out at 103 field sites from 1997 to 1999. Finally, an excellent line was selected. In these field experiments, the morphological and growing characteristics of this line were investigated and also analysis of the expression of the CP4 EPSPS protein and inserted genes were implemented. Based on these results, necessary approval was obtained in the US and general commercial cultivation began in 2001.

The situation of approval in Japan is the following.

March, 2001: Based on the "Guideline for the conduct of Food Safety Assessment of Food and Additives derived from Recombinant-DNA Plants", safety of use for food was approved by the Ministry of Health, Labour and Welfare.

March, 2001: Based on the "Guideline for the safety evaluation of feed derived from recombinant-DNA plants, 6-(2)", safety of use for feed was approved by the Ministry of Agriculture, Forestry and Fisheries.

May, 2001: Based on the "Guideline for the use of recombinant in agriculture, forestry and fisheries", the compatibility to the guideline regarding recombinant being imported to Japan (used for processing and feed) and being cultivated was certified by the Ministry of Agriculture, Forestry and Fisheries.

March, 2002: Additional information regarding the insertion gene that was submitted was confirmed not to change the conclusion of the safety for food, feed and environment as stated above. March, 2003: Based on the "Procedure to confirm the safety of feed and additives derived from recombinant-DNA plants", safety of use for feed was approved by the Ministry of Agriculture,

Forestry and Fisheries.

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

State of existence of nucleic acid transferred in cells and stability of expression of traits caused by the nucleic acid, including additional information regarding inserted genes which were already approved for safety in March 2002, is the following.

As a result of Southern blotting analysis, it was confirmed that 1 copy of the DNA fragment is inserted into the genome of this recombinant maize at 1 site. Also it was proved that 217bp fragment which is P-ract1 promoter exists in the contrary direction near the 3'-terminal of the inserted gene by Southern blotting analysis and the analyses of base sequence of 3'-terminal. As a result of Southern blotting analysis, it was also proved that the inserted gene is descended stably to the progeny in multiple generations. In addition, as a result of the glyphosate-spraying test, it was confirmed that CP4 EPSPS protein is stably expressed in multiple generations.

Also, as a result of strand-specific RT-PCR to confirm whether transcription product is produced in this region regarding 217bp fragment which is P-ract1 promoter near the 3'-terminal of this inserted gene, transcription product was found that was considered to start from either P-ract1 promoter of the inserted gene or E35S promoter and to read through NOS 3' terminator. However, as a result of Western blotting analysis that used a polyclonal antibody of CP4 EPSPS protein in this recombinant maize, only CP4 EPSPS protein which was approximately 46kDa was detected, and no larger protein was detected. It was reported that the reading through of terminator commonly takes place in plants, and single protein is transferred from transcription product because of the function of static codon. Consequently, it was confirmed that the reason only CP4 EPSPS protein was found in this recombinant maize is owing to the function of static codon preserved in the upstream of the transcription termination signal in the transcription product to read through the terminator of the insertion gene of this recombinant maize. It was concluded that this reading through does not affect the safety evaluation.

In addition, in the inserted gene of this recombinant maize each of the 456th base and the 641st base from 5'-terminal of coding region in *cp4 epsps* gene was changed from thymine (T) to cytosine (C) compared to the base in plasmid for expression of plant. It was proved that the change of the 456th base is not connected with the change of amino acid, but in CP4 EPSPS protein which is expressed by the E35S promoter by the change of the 641st base, leucine changes to praline in the 214th amino acid from N-terminal in the original CP4 EPSPS protein (hereinafter this protein is referred to as "L214P").

Regarding L214P, the following are considered: 1) Seven amino acids essential for activating

the EPSPS protein family are also preserved in L214P, and proline which is the 214th amino acid from N-terminal is not included in these seven amino acid residues; 2) This change of the amino acid does not affect the active site of the EPSPS protein and three-dimensional structure; and 3) As the traits of enzyme activity and immune response of L214P protein and CP4 EPSPS protein are substantially comparable, the structure and function of L214P protein and CP4 EPSPS protein are substantially comparable.

In order to investigate whether the L214P shares functionally important amino acid sequences with known contact allergens, it was compared with contact allergens in the database. As a result, the L214P did not share structurally related homologous sequences with any of the known allergens examined.

The change of the base was confirmed in multiple generations, and stably descended to the progeny.

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

Specific detection method for this recombinant maize is available by using the DNA sequence of the plant genome of the inserted gene and its surroundings as primers.

(6) Difference from the recipient organism or the species to which the recipient organism belongs

a) With the expression of the CP4 EPSPS protein, which is encoded by this *cp4 epsps* gene, in various regions of the plant, tolerance to glyphosate herbicide is conferred to this recombinant maize. In practice, the non-recombinant control maize died due to the influence of glyphosate herbicide, while the recombinant maize grew normally.

b) The tests were carried out in the isolated field using NK603-A and NK603-B lines which belong to this recombinant maize, as well as Cont-A and Cont-B as the control lines. NK603-A and NK603-B are the F1 hybrids derived from the different rearing process from the first generation (R0) of this recombinant maize. While, Cont-A and Cont-B are F1 hybrids of non-recombinant control maize hybridized to have the same hereditary background with NK603-A and NK603-B.

(a) Morphological and growth characteristics

For this recombinant maize and the non-recombinant control maize, evaluation was conducted regarding uniformity of germination, germination rate, time of tassel exertion, time of silking, culm length, plant shape or plant type, tiller number, height of ear, maturation time, number of ears, and plant weight at harvesting time. Statistically significant difference was not observed between recombinant and non-recombinant control maize lines in any of the characteristics.

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

Sensitivity to low temperature (temperature of 4°C) of the seedlings of this recombinant maize and non-recombinant control maize was evaluated. Almost all died on the 14th day after exposure to low temperature, and no difference was observed between this recombinant maize and non-recombinant control maize.

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

Maize is a summer type annual plant, and after ripening it usually dies out in winter, and it does not regrow and propagate vegetatively, or produce seeds. It was observed that dying started after ripening at the end of the tests carried out in the isolated field for both this recombinant maize and non-recombinant control maize in practice. Based on the above, an overwintering test for the matured plant of this recombinant maize was not carried out.

(d) Fertility and size of the pollen

To examine the fertility (maturity) and size of the pollens, pollens were stained with potassium iodine solution and observed under a microscope. As a result, no difference was observed between this recombinant maize and non-recombinant control maize.

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

Regarding the production of the seed, ear length, ear diameter, row number per ear, grain number per row, grain color, 100-kernel weight, and grain shape after sib-mating were examined. As a result, no statistically significant difference was observed between this recombinant maize and non-recombinant control maize in any of the characteristics examined except in 100-kernel weight. Regarding 100-kernel weight, statistically significant difference was found between the recombinant maize, NK603-B, and the non-recombinant control maize, Cont-B, and the average value of 100-kernel weight was 33.6g for NK603-B and 35.1g for Cont-B. Meanwhile, no

statistically significant difference was observed between the recombinant maize, NK603-A, and the non-recombinant control maize, Cont-A. Regarding shedding habit of the seed, shedding habit was not observed in natural conditions, since the ears of both recombinant maize and non-recombinant control maize were covered with bracts at the time of harvesting. Regarding germination rate on the 10^{th} day of sowing of harvested seeds, no difference was observed between the recombinant maize and non-recombinant control maize, and no dormancy of the seed was examined.

(f) Crossability

Crossability test was not performed since no wild relatives that can be hybridized grow in Japan.

(g) Productivity of harmful substances

Soil microflora tests, succeeding crop tests, and plow-in tests were performed for this recombinant maize and non-recombinant control maize. Statistically significant difference was not observed in any of the items.

3. Information concerning the Use of living modified organisms

(1) Content of the Use

Provision as food, provision as feed, cultivation, processing, storage, transportation, disposal and acts incidental to them.

(2) Information obtained from Use abroad

Field tests were implemented at 17 field sites in the US in 1999 to observe the characteristics including morphological and growth characteristics, sensitivity to pests, characteristics of propagation, and characteristics to become weed, between this recombinant maize and non-recombinant control maize. As a result, no statistically significant difference was observed in morphological and growth characteristics between the recombinant maize and non-recombinant control maize in any of the characteristics examined except height of ear and time of 50% silking in an accumulated number of days.

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

1. Competitiveness

Regarding the maize (*Zea mays* subsp. *mays* (L.) Iltis.), to which the recipient organism belongs, the Type 1 Use has been conducted in Japan, but there is no report that it has become self-seeding so far.

The recombinant maize is given a trait to be strongly tolerant to glyphosate herbicide by transferred *cp4 epsps*, but it is not generally considered that the glyphosate exerts pressure for selection under a natural environment. In addition, it was judged that the use of the recombinant maize in the isolated field posed no statistically significant differences with non-recombinant control maize in any traits relevant to competitiveness, except the small difference in 100-kernel weight. Based on the above understanding, it is unlikely that the recombinant maize will be more competitive than the non-recombinant maize in competition with wild plants.

Based on the above, no wild plants and wild animals are specified to be possibly affected by the competitiveness of this recombinant maize. Consequently, it was judged that the conclusion by the applicant that the use of this recombinant maize posed no significant risk of Adverse Effect on Biological Diversity attributable to c**ompetitiveness** is reasonable.

2. Productivity of harmful substances

Regarding the maize (*Zea mays* subsp. *mays* (L.) Iltis.), to which the recipient organism belongs, there is no report that it produces harmful substances to affect wild animals and wild plants.

The recombinant maize possesses a trait to produce CP4 EPSPS protein that has a strong tolerance to glyphosate herbicide, but this protein is not reported as a harmful substance. EPSPS protein is one of the enzymes in the shikimate pathway for aromatic amino acid biosynthesis, but it is proved that EPSPS is not the rate-determining enzyme. It was also confirmed that the content of aromatic amino acid in the other recombinant maize in which *cp4 epsps* is transferred has not changed. It is thus concluded that the recombinant maize does not produce an excess of aromatic amino acid. In addition, since EPSPS protein is an enzyme that reacts specifically with phosphoenolpyruvate (PEP) and shikimate-3-phosphate (S3P), CP4 EPSPS protein is thought not to produce different substances to catalyze the other substances.

In Japan, the productivity of harmful substances (including secretion from roots to affect the other plants, secretion from roots to affect microorganisms in soil, and substances in the plant body to affect the other plants) has been investigated in the isolated fields, but there is no significant difference between recombinant maize and non-recombinant maize.

Based on the above understanding, no wild animals and wild plants are specified to be possibly affected, and it was judged that the conclusion by the applicant that there is no significant risk of

Adverse Effect on Biological Diversity attributable to the productivity of harmful substances is reasonable.

3. Crossability

In Japan, the growth of wild species that can hybridize with maize in natural environment has not been reported.

Based on the above understanding, it was concluded that no wild species can be specified as to be possibly affected. Therefore, it was judged that the conclusion by the applicant that there is no significant risk of Adverse Effect on Biological Diversity attributable to crossability is reasonable.

III. Comprehensive assessment of Adverse Effect on Biological Diversity

Consequently, it was judged that there is no risk of Adverse Effect on Biological Diversity in Japan attributable to the use of this recombinant maize for provision as food, for provision as feed, cultivation, processing, storage, transportation, disposal and acts incidental to them.