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

Name: Syngenta Seeds K.K.
Robert Mullins, President
Address: 401-2, Mukounodai, Takatsuhara,
Tako-machi, Katori-gun, Chiba

Approved Type 1 Use Regulation

Name of the Type of Living Modified Organism	Maize resistant to Lepidoptera and tolerant to glufosinate herbicide (Modified *cry1Ab, pat, Zea mays* subsp. *mays* (L.) Iltis) (Bt11, OECD UI：SYN-BTØ11-1)
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 preparation of living modified organisms

(1) Information concerning donor nucleic acid

1) Composition and origins of component elements

The composition of donor nucleic acid and the origins of component elements that were used for the production of maize resistant to Lepidoptera and tolerant to glufosinate herbicide (Modified *cry1Ab*, *pat*, *Zea mays* subsp. *mays* (L.) Iltis) (Bt11, OECD UI：SYN-BTØ11-1) (hereinafter referred to as "this recombinant maize") are shown in Table 1.

2) Functions of component elements

(a) Functions of individual component elements of donor nucleic acid, including target gene, expression regulatory region, localization signal, and selective marker

Functions of component elements of donor nucleic acid are shown in Table 1.

Table 1 Component elements of pZO1502 and their sizes, origins and functions

Component elements	Size (kb)	Origin and Function
Gene cassette resistant to Lepidoptera		
35S promoter	0.51	A promoter obtained as *Dde* Ⅰ-*Dde* Ⅰ fragment derived from cauliflower mosaic virus (CaMV) CM1841 strain. This promoter makes the target gene (modified *cry1Ab*) expressed in all the tissues constantly (Reference 22).
IVS6-ADH1	0.47	Intron derived from alcohol dehydrogenase 1S (Adh1-S) gene of maize (Reference 23). Adh1-S intron was used to enhance the expression of target gene (modified *cry1Ab*) in plants (Reference 24).
Modified *cry1Ab*	1.85	A modified version of the full-length *cry1Ab* gene that encodes Cry1Ab protein of *Bacillus thuringiensis* subsp. *kurstaki* HD-1 strain, by partially deleting the C-terminal code region which is independent from the insecticidal activity of Cry1Ab protein and modifying some base sequences to enhance its expression level in plants. This modification does not change any amino acid sequences of the core protein.
NOS term	0.25	3' untranslated region of nopaline synthase (NOS) gene of *Agrobacterium tumefaciens*, which contains a transcription terminator and a signal for polyadenylation of mRNA (Reference 3, Reference 14). This sequence terminates transcription of target gene (modified *cry1Ab*).
Gene cassette tolerant to glufosinate herbicide		
35S promoter	0.42	A promoter obtained as *Alu*I-*Dde*I fragment derived from cauliflower mosaic virus (CaMV) Cabb-s strain. This promoter makes the target gene (*pat*) expressed in all the tissues constantly (Reference 18).
IVS2-ADH1	0.18	An intron derived from alcohol dehydrogenase 1S (Adh1-S) gene of maize (Reference 23). Adh1-S intron was used to enhance the expression of target gene (*pat*) in plants (Reference 24).
pat	0.55	A gene that encodes the PAT protein of *Streptomyces viridochromogenes*. PAT protein, that confers glufosinate herbicide tolerance, was used as a selective marker for recombinant plants at the time of introduction of genes. The *pat* gene has some base sequences modified to enhance its expression level in plants. The amino acid sequence of PAT protein expressed by the modification remains unchanged (Reference 20).
NOS term	0.25	3' untranslated region of nopaline synthase (NOS) gene of *Agrobacterium tumefaciens*, which contains a transcription terminator and a signal for polyadenylation of mRNA (Reference 3, Reference 14). This sequence terminates transcription of target gene (*pat*).
Other regions		
ColE1 ori	0.67	The replication origin derived from *Escherichia coli* plasmid pUC18 (Reference 12, Reference 15). Permits replication of plasmid in bacteria.
amp^R	0.86	Derived from *Escherichia coli*, it has the function to code β-lactamase and confer the tolerance to antibiotic ampicillin (Reference 15).

(b) Functions of proteins produced by the expression of target genes and selectable markers, and the fact, if applicable, that the produced protein is homologous with any protein which is known to possess any allergen

Modified Cry1Ab protein

The insecticidal protein (=Bt protein), isolated from the soil microorganism *Bacillus thuringiensis*, exhibits its insecticidal activity against limited species of insects. It is known that the Bt protein, when fed and digested by sensitive species of insects, becomes an active polypeptide (= core protein) through specific digestion of protein, which specifically binds to the specific receptors on the surface of midgut of insects, causing cytoclasis or cell-destruction and leading to destructed digestive tracts and death of the insects. This mechanism of action also holds for the Cry1Ab protein derived from *Bacillus thuringiensis* subsp. *kurstaki*. Regarding the insecticidal activity of Cry1Ab protein, detail investigational results are listed in the database operated by the Canadian Government (Reference 7), showing that it exhibits its insecticidal activity against European corn borer (*Ostrinia nubilalis*), Corn earworm (*Helicoverpa zea*), Fall armyworm (*Spodeptera frugiperda*) and other order Lepidopteran insects which are the major pest insects for cultivation of maize. On the other hand, Cry1Ab protein exhibits no or little insecticidal activity against any insects other than the order Lepidoptera. The Cry1Ab protein is known to be very sensitive to the digestion by protease that exists in the digestive systems of mammals. Thus, the protein, even if ingested by humans and other mammals, will be digested together with the core protein, and it is unlikely to affect humans and other mammals that do not have any receptors for the core protein.

The modified *cry1Ab* gene, used for the production of this recombinant maize, has some amino acid sequences deleted and some base sequences modified, though the amino acid sequence in the core protein showing the insecticidal activity of Cry1Ab protein remains unchanged.

Biological pesticides to which the protein produced by *Bacillus thuringiensis* has been applied as an active ingredient have been used since 1961 in US and European countries for maize, cotton, apple, cabbage, tomato, avocado and other crops, stored grains and forests to control pest insects. Also in Japan, since the early 1980s, biological pesticides, which contain the Cry1Ab protein produced by the *Bacillus thuringiensis* subsp. *kurstaki* HD-1 strain as an active ingredient, have been used for vegetables and fruit trees as an insecticide to control the order Lepidoptera.

The modified Cry1Ab protein is found to have a half life of 8 to 12 days based on the investigations by Syngenta using three (3) different types of agricultural soils (2 types of clay soils and one type of sandy clay loam). In addition, there is a report that the survival rate of Cry1Ab protein in soils after 40 days is approx. 1/3 in farm fields and approx. 1/10 or less in laboratories (Reference 13).

In order to investigate whether the modified Cry1Ab protein shares functionally important amino acid sequences with known allergens, the

modified Cry1Ab protein was compared with allergens in the database (SWISS-PROT, FFARP, BLASTP, etc.). The results showed the modified Cry1Ab protein did not share structurally related homologous sequences with any of the known allergens examined.

PAT protein

The *pat* gene has some base sequences modified to enhance its expression in plants, though the amino acid sequence in the PAT protein expressed by this gene remains unchanged. The glufosinate herbicide inhibits glutamine synthase in plants and then it causes plants to die due to the accumulated ammonia in the cells. However, the expression of PAT protein acetylates and inactivates the glufosinate, which relieves the glutamine synthase from inhibition. Consequently, the plants, which express the PAT protein, exhibit the tolerance to glufosinate herbicide and thus they have been used as a selection marker for recombinant plants.

In order to investigate whether the PAT protein shares functionally important amino acid sequences with known allergens, the PAT protein was compared with allergens in the database (SWISS-PROT, FFARP, BLASTP, etc.). The results showed the PAT protein did not share structurally related homologous sequences with any of the known allergens examined.

(c) Contents of any change caused to the metabolic system of recipient organism

Based on the fact that modified Cry1Ab protein does not possess any enzyme activity and it works independently from the metabolic system of recipient organism, modified Cry1Ab protein is unlikely to affect the metabolic pathway of recipient organism. In addition, PAT protein possesses very high substrate specificity, so it is unlikely to transfer the acetyl group to any compounds other than glufosinate; therefore, it is not considered that PAT protein can affect the metabolic system of recipient organism (Reference 11).

(2) Information concerning vectors

1) Name and origin

The vector used for the production of this recombinant maize is pZO1502. This vector was produced from pUC18 derived from *Escherichia coli* (Reference 15).

2) Properties

The total number of base pairs of the vectors is 7,240bp.

The pZO1502 contains amp^R gene used as a selective marker for bacteria, which confers the resistance to ampicillin. However, before the transfer of nucleic acid into recipient organism, the plasmid is cleaved by the restriction enzyme *Not* I and the amp^R gene is deleted and thus it is not introduced to this recombinant maize.

In addition, the pZO1502 also contains the segment ColE1 ori that contains the replication origin region of *E. coli* plasmid pUC18, though the range of recipient

organisms for the autonomous replication is limited to *E. coli* and some gram-negative bacteria.

(3) Method of preparing living modified organisms

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

In the recipient organism, Lepidoptera resistant gene cassettes, glufosinate tolerant gene cassettes and ColE1 ori are transferred.

2) Method of transferring nucleic acid transferred to the recipient organism

The electroporation method was used to transfer the nucleic acid to the protoplast of recipient organism.

3) Processes of rearing of living modified organisms

(a) Mode of selecting the cells containing the transferred nucleic acid

Using the fact that the *pat* gene confers the glufosinate tolerant characteristics, regenerated individuals were obtained by selecting callus in media containing glufosinate.

(b) Presence or absence of remaining Agrobacterium in case of using Agrobacterium method for transferring nucleic acid

This does not apply since *Agrobacterium* method has not been used for transferring nucleic acid.

(c) Processes of rearing and pedigree trees of the following lines; cells to which the nucleic acid was transferred, the line with which the state of existence of replication products of transferred nucleic acid was confirmed, the line subjected to isolated field tests; and the line used for collection of other necessary information for assessment of Adverse Effect on Biological Diversity

The regenerated individuals that exhibit glufosinate tolerance were subjected to immunoassay specific to the modified Cry1Ab protein and bioassay regarding the resistance to European corn borer, and the individuals that expressed consistently were selected as the parent strain of Bt11. A backcross of the parent strain with excellent species of maize was repeated, and the stack line was raised through selection based on glufosinate tolerance tests and field tests on European corn borer resistance and subsequent self-reproduction.

For this recombinant maize, in addition to the commercial species produced by crossing with dent type for use as feed or food processing, another commercial species produced by crossing with sweet type for raw eating have been raised. Then, in the isolated field tests, the variety obtained by backcrossing of dent type of the recipient organism and also the variety obtained by backcrossing with sweet type were used for a wider range of varieties.

The permits and approvals regarding this recombinant maize obtained from the related regulatory agencies in Japan are listed below.

Environmental safety

The environmental safety in accordance with the "Guideline for the use of recombinant in agriculture, forestry and fisheries" was approved.

October, 1996: The environmental safety for use as food processing and feed (8th Agriculture, Forestry and Fisheries Research Council Notice No. 1897) was approved.

June, 2002: The environmental safety for use in an open system for cultivation (14th Agriculture, Forestry and Fisheries Research Council Notice No. 377) was approved.

Safety as feed

The safety for use as feed in accordance with the “6-(2) of the Guideline for the safety evaluation of feed derived from recombinant-DNA plants (8th Livestock Industry Department B Notice No. 585 dated April 19, 1996)” was approved.

September, 1996: Safety for use as feed (8th Livestock Industry Department B Notice No. 1365) was approved.

The safety for use as feed in accordance with the "Safety Evaluation Criteria for Feed and Additives Produced by Recombinant-DNA Techniques" was approved.

March, 2003: The safety for use as feed of Bt11 maize (dent type) (disclosed March 27, 2003) was approved.

Safety as food

The safety for use as food in accordance with the "Guideline for the safety evaluation of food and additives derived from recombinant-DNA techniques" was approved.

September, 1996: The conformity with the "Guideline for the safety evaluation of food and additives derived from recombinant-DNA techniques (Enforcement of Ordinance for Food Sanitation Law No. 229)" was approved.

The safety for use as food in accordance with the "Standards and regulations on food and additives derived from recombinant-DNA techniques" was approved.

March, 2001: The conformity with the "Guideline for the safety evaluation of food and additives derived from recombinant-DNA techniques (Ministry of Health, Labour and Welfare Notice No. 108)" was approvred.

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

1) Place where the replication product of transferred nucleic acid exists

The nucleic acid transferred to the cells exists on the chromosome. It is confirmed based on the chromosome mapping that the nucleic acid exists on the 8th chromosome.

2) The number of copies of replication products of transferred nucleic acid and stability of its inheritance through multiple generations

As a result of Southern blotting analysis for existence of the transferred genes, it was confirmed that one copy of nucleic acid is transferred for each of modified *cry1Ab* gene and *pat* gene, and also that modified *cry1Ab* gene and *pat* gene are both inherited stably in multiple generations.

3) Inter-individual or inter-generational expression stability under a natural environment with respect to the characteristics referred to specifically in (6)-1)

As a result of ELISA method for determination of the amount of expression of modified Cry1Ab protein in this recombinant maize, the largest amount of expression was observed in the leaves, and larger amount of expression was found especially at relatively earlier stages of growth. In addition, as the plant body became matured and aged, the modified Cry1Ab protein was observed to decompose.

Regarding the inter-generational expression stability, a total of 120 or more field tests were carried out from 1992 to 1995 mainly in US for this recombinant maize and the non-recombinant control maize. As a result, a significant difference was observed in breakdown and lodging resistance and susceptibility to insect damage between this recombinant maize and the non-recombinant control maize. The significant difference was considered to result from the fact that this recombinant maize is free from any insect damage by Lepidopteran insects due to the resistance to European corn borer (*Ostrinia nubilalis*) and thus, it was judged that the target characteristics are given to the recipient organism by the transferred nucleic acid.

In addition, also in the isolated field tests conducted in Japan, as a result of bioassay on the Pseudozizeeria maha using the pollen of this recombinant maize, the insecticidal activity was clearly observed.

Also regarding the glufosinate herbicide tolerance, in the process of rearing in the US fields, glufosinate was sprayed and glufosinate tolerant varieties were selected. As a result, the stable expression has been observed.

(5) Methods of detection and identification of living modified organisms

For the method of detection and identification of this recombinant maize, a TaqManPCR method using plant genome and Bt11 specific primers can be used as an effective method to determine this recombinant maize in the grains mixed with various

genetically modified maize varieties. This method was developed jointly by National Veterinary Institute (Norway) and Institute National de la Recherche Agronomique (France), and validated by DG JRC Community Reference Laboratory of European Commission.

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

1) Specific contents of physiological or ecological characteristics that were accompanied by the expression of replication products of transferred nucleic acid

With the modified Cry1Ab protein encoded by the modified *cry1Ab* gene and the PAT protein encoded by the *pat* gene, this recombinant maize shows resistance to European corn borer (*Ostrinia nubilalis*) and other order Lepidoptera and tolerance to glufosinate herbicide.

2) With respect to the physiological or ecological characteristics listed below, presence or absence of difference between genetically modified agricultural products and the taxonomic species to which the recipient organism belongs, and the degree of difference, if present

For this recombinant maize, in addition to commercial species produced by crossing with dent type maize for use as feed or food processing, another commercial species produced by crossing with sweet type for raw eating have been raised. Then, in the isolated field test conducted in 2001 at the National Institute for Agro-Environmental Sciences, this recombinant maize and the F1 hybrid variety obtained by a backcross with dent type, the recipient organism, as the non-recombinant control maize, F1 hybrid variety obtained by a backcross with sweet type and its control variety were used. In addition, in 2006, in the isolated field at Kanza Experiment Center, Central Research Laboratory, Central Research Station of Syngenta Japan K.K., test on the productivity of harmful substances (plow-in test) was carried out.

(a) Morphological and growth characteristics

For the morphological and growth characteristics, comparison was examined between this recombinant maize and the non-recombinant control maize regarding the uniformity of germination, time of tasseling, time of silking, time of flower initiation, time of flower completion, flowering period, maturation time, plant type, tiller number, total number of ears, number of productive ears, ear grain color, ear grain shape, culm length and height of ear, ear length, ear diameter, row number per ear, grain number per row, 100-kernel weight, and fresh weight after harvesting. As a result, in all characteristics evaluated, no significant difference was observed between this recombinant maize and the non-recombinant control maize.

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

In order to investigate any possibility of whether the seeds spilled by accident during transportation could germinate and grow and the seedlings could survive over the winter, cold-tolerance of seedlings derived from the seeds

harvested from this recombinant maize was examined.

Sensitivity to low temperatures was evaluated for the seedlings on the 13th day after sowing (at about three-leaf stage), which were put in a growth cabinet assuming the winter season (between 12 and 14℃ with a 12-hour lighting under sunshine lamp and 2℃ with a 12-hour darkness). As a result, with the start of cold treatment, some seedlings began to exhibit white spots followed by expanding white streaks, opened leaves lost chlorophyll and then the seedlings began to wilt. Regarding the progress of wilting, no difference was observed between this recombinant maize and the non-recombinant control maize.

Based on the above results, it was judged that, regarding the cold-tolerance at the early stage of growth, there is no difference between this recombinant maize and the non-recombinant control maize.

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

Maize is a summer type annual plant, and after maturing, it usually dies out, and does not re-grow and propagate vegetatively, or produce seeds. It was observed in the isolated field that the maize plants died after maturation. Based on the above, an over-wintering test for the matured plant of this recombinant maize was not carried out. In addition, there is no report in the use of this recombinant maize in foreign countries that the matured plant of this recombinant maize could successfully overwinter.

(d) Fertility and size of the pollen

To examine differences in the shape, fertility and size of the pollen and other characteristics relating to reproduction and propagation between this recombinant maize and the non-recombinant control maize, pollen were observed under a microscope.

As a result of the observation with pollen stained with 0.1% neutral red solution, no difference was observed in the shape and size of the pollen between this recombinant maize and the non-recombinant control maize. In addition, the pollen were all found with the plasma stained, so they were considered fully matured. Based on the above results, also regarding the fertility, it was considered that there is no difference between this recombinant maize and the non-recombinant control maize.

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

Regarding the measured results of ear length, ear diameter, row number per ear, grain number per row, and 100-kernel weight of the self-fertilized and harvested ears and the germination rate of harvested seeds, no significant difference was observed between this recombinant maize and the non-recombinant control maize. Consequently, regarding the production and germination rate of seeds, it was considered that there is no difference between this recombinant maize and the non-recombinant control maize.

Regarding shedding habit of the seed, shedding habit was not observed in the natural condition, since the ears of this recombinant maize and the non-recombinant control maize were covered with skins at the time of harvesting.

Regarding the dormancy, the seeds of both this recombinant maize and the non-recombinant control maize harvested in the field tests all germinated and thus, it was judged that dormancy of the seeds of this recombinant maize and the non-recombinant control maize is extremely low.

(f) Crossability

Crossability test was not performed for this recombinant maize, since no wild relatives that can be crossed with this recombinant maize exist in Japan.

(g) Productivity of harmful substances

As the succeeding crop test, the soils (surplus soils) from individual experimental plots where this recombinant maize and the non-recombinant control maize were cultivated were packed in pots, to which the seeds of lettuce were sown per pot to examine the number of seeds germinated and the growth. In addition, as the plow-in test, the surplus soils from the plots where this recombinant maize and the non-recombinant control maize were cultivated were mixed with the seedlings thinned out in the individual plots and dried and crushed, then packed in pots, to which the seeds of lettuce were sown to examine the number of seeds germinated and growth.

In the results of the both tests, regarding the number of seeds of lettuce germinated and the fresh weight, no significant difference was observed between this recombinant maize and the non-recombinant control maize.

As the plow-in test in 2006, the leaves and stems of both this recombinant maize and the non-recombinant control maize cultivated were dried and crushed then mixed with soil and packed in pots, to which the seeds of radish were sown per pot to examine the germination rate and as a result, no significant difference was observed between this recombinant maize and the non-recombinant control maize. Also, as a result of examination on the fresh weight and dry weight of grown radish, no significant difference was observed between this recombinant maize and the non-recombinant control maize.

To identify a possibility of whether cultivation of this recombinant maize could affect the soil microflora, soil samples were collected from individual experimental plots at two different periods of time (approx. 3 weeks after sowing and after harvesting of ears) to examine the number of filamentous fungi, bacteria and actinomyces. As a result, at the both periods of time, no significant difference was observed between the plots of both this recombinant maize and the non-recombinant control maize. Consequently, it was judged that there is no difference in the possibility of affecting the soil microflora between this recombinant maize and the non-recombinant control maize.

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

Maize (*Zea mays* subsp. *mays* (L.) Iltis), to which the recipient organism belongs, has been used, including for cultivation, etc., in Japan, though there is no report that it has become self-seeding in Japan.

In addition, as a result of examination of the morphological and growth characteristics of this recombinant maize in the isolated field tests in Japan, no difference was observed from the non-recombinant control maize regarding the risk of Adverse Effect on Biological Diversity attributable to competitiveness.

This recombinant maize is given traits to be resistant to Lepidoptera and tolerant to glufosinate herbicide due to the introduced modified *cry1Ab* gene and the *pat* gene respectively. However, it is not generally considered that the insect damage by Lepidopteran insects is the major cause making the maize difficult to grow and glufosinate exerts pressure for selection in the natural environment; therefore it is unlikely that these characteristics cause this recombinant maize to be dominant in competitiveness.

Based on the above understanding, it was judged that the conclusion by the applicant that the wild animals and wild plants likely to be affected cannot be specified and that the use of this recombinant maize poses no significant risk of Adverse Effect on Biological Diversity attributable to competitiveness is reasonable.

(2) Productivity of harmful substances

Regarding the maize, to which the recipient organism belongs, there is no report that it produces harmful substances to affect wild animals and wild plants.

Productivity of harmful substances of this recombinant maize (including secretion from roots to affect the other plants, secretion from roots to affect microorganisms in soil, and the possession in the plant body to affect the other plants after dying) has been investigated in the isolated field tests in Japan, but there is no significant difference between this recombinant maize and the non-recombinant maize.

This recombinant maize produces the modified Cry1Ab protein, which possesses an insecticidal activity against Lepidopteran insects, and the PAT protein, which confers the tolerance to glufosinate.

There is no report that PAT protein is harmful to wild animals and wild plants. In addition, PAT protein possesses high substrate specificity and thus it is considered not to affect the metabolic system of the recipient organisms.

On the other hand, the modified Cry1Ab protein possesses an insecticidal activity against Lepidopteran insects. As a result, there is a possibility that the modified Cry1Ab protein expressed by the pollens could affect the order Lepidoptera inhabiting around the fields where this recombinant maize is cultivated, though the level of expression due to the pollens of the protein is low. Also based on the results including bioassay in which pollens were actually ingested together with feed plants, the effects, if any, will be limited to a very confined range. Consequently, it is very unlikely that the insects of the order Lepidoptera could be affected at the level of individual population by the pollens dispersed from this recombinant maize.

As a result of the investigation on whether PAT protein and modified Cry1Ab protein shares functionally important amino acid sequence with known allergens, it was confirmed that the PAT protein and the modified Cry1Ab protein do not share structurally related homologous sequences with any of the known allergens examined.

Based on the above understanding, it was judged that the conclusion by the applicant that the wild animals and wild plants likely to be affected cannot be specified and that the use of this recombinant maize poses no significant risk of Adverse Effect on Biological Diversity attributable to productivity of harmful substances is reasonable.

(3) Crossability

In Japan, the growth of wild relatives (teosinte) that can be crossed with maize in natural environment has not been reported. Based on the above understanding, no wild species that can be affected by this recombinant maize is specified, it is judged that the conclusion made by the applicant that there is no risk of Adverse Effect on Biological Diversity attributable to crossability is valid.

2. Conclusion based on the Biological Diversity Risk Assessment Reports

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

Bibliography

Not made available or disclosed to unauthorized person

Biological Diversity Risk Assessment Report
Annex List