

FACT SHEET

APPLICATION FOR APPROVAL FOR RELEASE ACTIVITY OF GENETICALLY MODIFIED (GM) RICE, *Oryza sativa* L. variety MR219 FOR THE PURPOSE OF CONDUCTING A CONFINED FIELD TRIAL

NBB REFERENCE NO: JBK (S) 600-2 /1/44

The objective of the Biosafety Act 2007 is to protect human, plant and animal health, the environment and biological diversity. Under the Biosafety Act 2007, the National Biosafety Board (NBB) is currently evaluating an approval application submitted by Zen Cropsience Sdn Bhd.

1. What is the application for?

The application is for release of genetically modified (GM) rice, *Oryza sativa* L. variety MR219 in a confined field trial site at Kawasan Perindustrian Tungzen, Kg Kepayang, Perak.

2. What is the purpose of the release?

The purpose of the release is to conduct a field trial to evaluate the GM rice in terms of its agronomic traits, glyphosate resistance, transgene flow and transgene stability under contained field conditions. The GM MR219 rice planted in this field trial will not be used for human consumption.

3. How has the MR219 rice been genetically modified?

MR219 rice was genetically modified to express resistance against glyphosate herbicide, the bacterium *Xanthomonas oryzae* pv. *oryzae* (Xoo) which causes Bacterial Leaf Blight disease, and the fungus *Pyricularia* spp. (which causes Rice Blast disease). This was achieved by introducing the *cp4-epsps* gene and the *WRKY45* gene using the Agrobacterium-mediated transformation method.

Additionally, the *hptII* gene that confers resistance to hygromycin was introduced into the GM MR219 rice as a molecular marker gene to facilitate the screening and identification of positive transformants during the development of the GM rice plants. This GM rice was produced from a research by Malaysian Agricultural Research and

Development Institute (MARDI) that was previously approved by the National Biosafety Board (NBB).

4. Characteristics of the GM MR219 Rice (LMO)

a) Details of the Parent Organism

The parent organism is *Oryza sativa L. indica* variety MR219, also known as MR219 rice, which is a Malaysian variety. The native habitat of rice is tropical wetlands, but rice is now cultivated across various tropical and subtropical climates. MR219 is widely grown as a commercial cultivar in Malaysia. MR219 rice reproduces sexually, predominantly through self-pollination. However, cross-pollination with other rice varieties can occur. Currently, the major rice plant disease in Malaysia is caused by *Xanthomonas oryzae pv. oryzae* (Xoo) bacteria and *Pyricularia spp.* fungus.

b) Details of the Inserted Gene

Name of Gene	Donor (where the gene was obtained from)
<i>cp4-epsps</i>	<i>Agrobacterium tumefaciens</i> strain CP4 . It is a gram-negative soil bacterium that causes crown gall disease in more than 140 species of flowering plants.
<i>WRKY45</i>	<i>Oryza sativa spp. indica</i> (rice). This gene in rice naturally provides disease resistance in rice and protects the plant from destructive bacteria and fungus.
<i>hptII</i>	<i>Escherichia coli</i> It is a gram-negative bacterium commonly found in the environment and the intestines of humans and animals.

c) Description of the trait(s) and characteristic(s) which have been introduced or modified

Name of Gene	Trait
<i>cp4-epsps</i>	Provides resistance to the herbicide glyphosate
<i>WRKY45</i>	Provides resistance/tolerance to diseases caused by the bacterium <i>Xanthomonas oryzae pv. oryzae</i> (Xoo) and the fungus <i>Pyricularia spp.</i> Overexpression of this gene is expected to provide stronger disease resistance.
<i>hptII</i>	Confers resistance to hygromycin, hence serves as a selection marker during <i>in vitro</i> culture stage, facilitating screening of positive transformants

d) Safety of the Expressed Proteins

The *WRKY45* gene was synthesized based on the sequence of the japonica rice cultivar, which is widely grown as a commercial cultivar in Japan and China for human consumption. This gene is involved in the salicylic acid signalling pathway and can be found in all rice plants. Therefore, the GM MR219 rice expresses the exact same protein as conventional rice.

The *cp4-epsps* gene was synthesized based on the original gene sequence found in *Agrobacterium tumefaciens* strain CP4, with a predicted potential hazard that is very low. The *cp4-epsps* gene is involved in the shikimate pathway, which occurs in bacteria, plants, and fungi, but is absent in animals. Therefore, the *cp4-epsps* gene is predicted to have a very low potential hazard [1].

5. Assessment of the risks to human health

At this stage of the evaluation process for the confined field trial of the GM rice, acute toxicological data is not yet available. However, no toxic or allergenic effects have been reported for the *cp4-epsps* [2][3][4].

WRKY45 is a transcription factor gene in rice (*Oryza sativa*) responsible for regulating plant immunity and stress responses. It is not considered toxic or allergenic to humans, as it is a natural plant protein that functions purely to regulate gene expression within rice cells [5][6].

6. Assessment of risks to the environment

a) Environmental Considerations

Pollen movement is very limited because rice is a self-pollination plant and there is no known report on pollination of plant species other than rice by the rice plant pollen. To date no evidence on horizontal gene transfer from rice to other plant species other than rice and weedy rice has been reported. The controlled field trial is located at Kawasan Perindustrian Tungzen, Kg Kepayang, Perak which is an industrial area and far from any agricultural land.

The contained field trial will be conducted inside an insect-proof net house measuring 45 m x 18 m x 3 m, fully equipped with containment features and restricted access. The entire contained field trial area including the roof will be enclosed by two layers of wire mesh separated by a distance of 1 meter (mesh size no. 38), and each wire mesh will be lined with 1 layer of nylon netting (mesh size no. 32) at a height of 3 meters. Alongside two metal mesh doors will be installed and secured with 24-hour security. The doors also will be lined with nylon netting (mesh size no. 32). The 3-meter height is designated to prevent any animals or humans from entering the controlled trial facility. The use of nylon netting with mesh size No. 32 will trap pollen and prevent its release into the external environment.

b) Biological Containment

Cultivated rice (*Oryza sativa* L.) originates from Asia. There are several *Oryza sativa* cultivars that can hybridize with *Oryza sativa* cv. MR219. However, the risk of cross-pollination is low because the study plot is isolated at a distance of approximately 80

meters from any nearest rice plants. The trial area will be sprayed with herbicides other than glyphosate before and after the field trial is carried out. This is intended to eliminate any plants and seeds (not limited to rice plants and seeds). All seeds will be stored in accordance with the approved Standard Operating Procedures. The contained field trial site will be monitored after the end of the trial to ensure no growth of rice plants. Any plants found growing (e.g. volunteers – plants that are not intentionally planted or regrowth of the GM rice plant), will be removed from the trial site before flowering.

c) Staff Training

All personnel will be trained on the regulations and procedures for handling research materials, as well as the methods and objectives of the genetic transformation study before they undertake any work on this project.

d) Maintenance

Technicians at the field trial plot will carry out routine maintenance duties after receiving instructions from the trained personnel involved in this project.

7. What is the Emergency Response Plan?

a) First Aid Measures

In the event of an accidental release or any adverse effects, the Biosafety Officer of Zen Cropscience will be notified immediately. All corrective actions will be taken and documented, and the Institutional Biosafety Committee (IBC) and NBB will be informed.

b) Accidental Release Measures

In any event of an accidental release, any other plants or prohibited plants can be controlled with herbicides and destroyed by incineration. The area of accidental release will be treated using appropriate methods to prevent it from occurring again. All plants will be collected and handled according the approved Standard Operating Procedures and finally incinerated. Access to waste storage area is restricted to authorized personnel only. The contaminated area will be decontaminated using chemicals such as hypochlorite (10%). In cases where the net structure is damaged

due to strong winds or other environmental factors, immediate action will be taken to repair or replace the netting. If the damage cannot be repaired immediately, all flowers from the GM rice will be removed and destroyed.

c) Handling and Storage

The GM MR219 rice seeds are currently stored at the Molecular Analysis Laboratory, Transgenic Greenhouse Complex, Biotechnology Research Centre, MARDI, until they are ready to be germinated for field studies to verify their traits. After planting the GM MR219 rice seeds at the contained field trial site, seeds from lines that do not show potential will not be collected; instead, they will be destroyed by incineration. Harvested seeds will be packed using heavy-duty bags as primary containers, which will then be placed into a sealed, leak-proof, and waterproof secondary container. The seeds will be kept in a laboratory in the same location as the contained field trial site (Kawasan Perindustrian Tungzen, Kg Kepayang, Perak.)

d) Disposal Considerations

All GM rice and non-GM rice materials shall be rendered non-viable before disposal as to prevent the unintended release of GM rice into the environment. All plants will be collected, dried and handled according the approved Standard Operating Procedures and finally incinerated. Access to waste storage area is restricted to authorized personnel only.

8. How can I submit comments on this application?

Any member of the public may submit their comments or queries on publicly notified information about the application. Before submission of comments or queries, the person should review the information provided. Your comments and queries on any possible impacts/risks to the health and safety of human, animals and the environment that may be posed by the proposed release are appreciated.

The submission of comments/queries should be prepared carefully as it will be given the same scrutiny as the application received by the NBB. The submission of comments and clarifications of queries should contribute to the NBB's assessment. Even if the submission is not science-based and focuses on cultural or other values, it should still be developed-in the form of a well-founded argument.

Please note that the consultation period closes on **August 8, 2026** and written submissions are required before or on that date. Submissions must be addressed to:

Director General

Department of Biosafety

Ministry of Natural Resources and Environmental Sustainability

Level 4, Block F11, Complex F,

Lebuh Perdana Timur, Precinct 1

62000 PUTRAJAYA, MALAYSIA

Email: dob@biosafety.gov.my

Please include your full name, address, and contact details together with the submitted comments/queries.

References:

1. Gurvan Michel, Aleksander W. Roszak, Ve´ronique Sauve´, John Maclean, Allan Matte, John R. Coggins, Mirosław Cygler, and Adrian J. Lapthorn. Structures of Shikimate Dehydrogenase AroE and Its Paralog YdiB. March 12, 2003, DOI 10.1074/jbc.M300794200
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5. Shimono M, Koga H, Akagi A, Hayashi N, Goto S, Sawada M, Kurihara T, Matsushita A, Sugano S, Jiang CJ, Kaku H, Inoue H, Takatsuji H. Rice WRKY45 plays important roles in fungal and bacterial disease resistance. *Mol Plant*

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6. Kun-Lu Wu, Ze-Jian Guo, Hai-Hua Wang and Jing Li. The WRKY Family of Transcription Factors in Rice and December 2004.