

Republic of the Philippines  
 Department of Agriculture  
 BUREAU OF PLANT INDUSTRY

PLANT QUARANTINE SERVICE  
 Manila

**Application for Biosafety  
 Permit for Direct Use as  
 Food and Feed, or for  
 Processing**

\_\_\_\_\_  
 (Date)

The Director  
 Bureau of Plant Industry

Sir:  
 We –

| Information   | Applicant                                                                                                                                                                                                                | Responsible Officer (RO)                                                                                       | Representative of RO (if applicable)                                                                                                                          |
|---------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name          | Philippines Rice Research Institute<br>(PhilRice)<br>—and—<br>International Rice Research<br>Institute (IRRI)                                                                                                            | Dr. Sailila E. Abdula<br>Executive Director, PhilRice<br>—and—<br>Dr. Matthew Morell<br>Director General, IRRI | Dr. Roel Suralta<br>Golden Rice Project Leader, PhilRice<br>—and—<br>Dr. Donald J. MacKenzie<br>Regulatory Affairs & Stewardship Leader,<br>Golden Rice, IRRI |
| Address       | PhilRice Central Experimental Station<br>Maligaya, Science City of Munoz, 3119 Nueva Ecija<br>Philippines<br>—and—<br>International Rice Research Institute,<br>Pili Drive, UPLB, Los Baños, 4031, Laguna<br>Philippines |                                                                                                                |                                                                                                                                                               |
| Tel. No.      |                                                                                                                                                                                                                          |                                                                                                                | +63 444560112<br>—and—<br>+1 (202) 695-0436                                                                                                                   |
| Fax No.       |                                                                                                                                                                                                                          |                                                                                                                | +63 444560112<br>—and—<br>+1 (202) 478-0755                                                                                                                   |
| Email Address |                                                                                                                                                                                                                          |                                                                                                                | rrsmfs@yahoo.com<br>—and—<br>d.mackenzie@irri.org                                                                                                             |

hereby request for issuance of Biosafety Permit for Direct Use for the genetically modified (GM) plant/plant product described below.

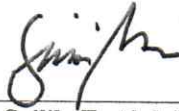
| Designation        | Regulated Article                                                                                                                          | Donor Organism(s)                                                                        | Host Organism          | Vector or Vector Agent                                                                     | Constituents of the Regulated Article                                                                                                                                                                                                                                                                                                                                                                                     |
|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|------------------------|--------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Common Name        | GR2E and all progenies derived from crosses of the product with any conventionally bred rice, and rice containing approved biotech events. | Corn (maize) and commonly occurring bacterial species.                                   | Rice                   | GR2E was produced by <i>Agrobacterium</i> -mediated transformation using vector pSYN12424. | Molecular characterization demonstrated that rice line GR2E contains a single copy of the introduced DNA at a single locus within the rice genome. The insert contains one intact copy each of the <i>Zmpsy1</i> , <i>crti</i> , and <i>pmi</i> expression cassettes. There are no detectable plasmid backbone sequences and no additional elements, either linked or unlinked, from the pSYN12424 transformation vector. |
| Scientific Name    | <i>Oryza sativa</i> L.                                                                                                                     | ZmPSY1: <i>Zea mays</i><br>CRTI: <i>Pantoea ananatis</i><br>PMI: <i>Escherichia coli</i> | <i>Oryza sativa</i> L. |                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Trade Name         |                                                                                                                                            |                                                                                          |                        |                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Other Designations | Golden Rice                                                                                                                                |                                                                                          |                        |                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                           |

|                   |                                                                                                  |
|-------------------|--------------------------------------------------------------------------------------------------|
| Country of Origin | The Philippines is an intended country of cultivation of GR2E rice and is the country of origin. |
| Quantity          | Not applicable.                                                                                  |
| Flight/Voyage No  | Not applicable.                                                                                  |
| Port of Entry     | Not applicable.                                                                                  |
| Proposed Schedule | Not applicable.                                                                                  |

**\*The following supporting documents are attached**

1. In the case of imported regulated article, notification from the exporter or country of origin in accordance with existing international agreements on the transboundary movement of genetically modified organisms;
2. Information on socio-economic, cultural and ethical considerations;
3. Copy of the proposed PIS for Direct Use, (Annex "F") including information required for evaluation of environmental and health impacts;
4. In cases of renewal, certified true copy of expired Biosafety Permit for Direct Use issued by BPI; and
5. Proof of payment of fees.
6. To facilitate review of the application, the applicant may submit documents to show that the regulated article is allowed for commercial distribution as food and feed by the regulatory authorities in the country of origin; and poses no greater risks to biodiversity, and human and animal health than its conventional counterpart. If the regulated article is intended for use as feed or for processing into feeds, the applicant may submit documents to show that the regulatory authorities in the country of origin have likewise determined that the regulated article poses no greater risks to biodiversity, and human and animal health than its conventional counterpart.


The undersigned certifies that based on his/her personal knowledge and/or authentic documents: (i) all the information in this application is true and correct; and (ii) this application contains all information and views on which to base a decision and includes any relevant data and information known to the applicant which are unfavorable to the application. The undersigned likewise warrants that, in the case of importation, the Regulated Article is to be imported solely and exclusively for direct use as food and feed or for processing.



**Dr. Sailila E. Abdula**

Executive Director, PhilRice

(Printed name and Signature of Responsible Officer/Authorized Representative - PhilRice)



**Dr. Matthew Morell**  
Director General, IRRRI

(Printed name and Signature of Responsible Officer/Authorized Representative - IRRRI)

Republic of the Philippines)

PROVINCE OF LAGUNA

SUBSCRIBED AND SWORN TO before me this 10<sup>TH</sup> day of January, 2017, affiant exhibiting to me his/her Passport No. PE 0396315 issued on 2 Dec 2015 at Australia.

Doc. No. 275;  
Page No. 55;  
Book No. 4;  
Series of 2017.

**EUGENIANO E. PEREZ, III**  
Notary ~~Public~~ PUBLIC  
Until 31 December 2017  
PTR No. 362178  
Issued at Sta. Cruz, Laguna  
On 8 Jun. 2016