

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 (PhilRice) —and— International Rice Research Institute (IRRI)	Dr. Sailila E. Abdula Executive Director, PhilRice —and— Dr. Matthew Morell Director General, IRRI	Dr. Roel Suralta Golden Rice Project Leader, PhilRice —and— Dr. Donald J. MacKenzie Regulatory Affairs & Stewardship Leader, Golden Rice, IRRI
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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> CRTI: <i>Pantoea ananatis</i> 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.

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

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

Republic of the Philippines)

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SUBSCRIBED AND SWORN TO before me this ____ day of _____, 20____, affiant exhibiting to me his/her _____ No. _____ issued on _____ at _____.

Doc. No. _____;
Page No. _____;
Book No. _____;
Series of 20____.

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