

**Form: Health Impact Assessment Report**  
**APPLICATION FOR A BIOSAFETY PERMIT FOR THE DIRECT USE IN FOOD, FEED, OR FOR PROCESSING OF**  
**PROVITAMIN A BIOFORTIFIED GR2E RICE**

**General Framework for Health Impact Assessment**

<b>Establishment of Baseline Health Status</b>	
<ul style="list-style-type: none"> <li>○ What are the primary and secondary health data to establish the baseline health status of the affected community/workers and for assigning a reference or control community?</li> </ul>	<p><b>Vitamin A is an essential nutrient required for normal functioning of the visual system and protection from disease and infection. In south and southeast Asian countries, where two-thirds or more of daily calories are obtained from rice, many people are battling against vitamin A deficiency due to an imbalanced diet with limited access to fresh fruit, vegetables, and animal products. Persistent vitamin A deficiency (VAD) is the leading cause of childhood blindness and increases the risk of death from common childhood infections.</b></p> <p><b>Despite significant progress since 2003, VAD remains a serious public health nutrition problem in the Philippines, particularly among preschool age children where the prevalence ranges from 19.6 percent for 1–5-year olds up to 27.9 percent for children under one year of age.</b></p> <p><b>FNRI (2016). Vitamin A deficiency (VAD) among Filipino preschool children, pregnant, and lactating women: 1993-2013. In 42nd FNRI Seminar Series, First 100 Days, pages 1–12, Los Banos, Laguna, Philippines.</b></p>
<ul style="list-style-type: none"> <li>○ What is the possible correlation between the biotechnology project and the changes in the health status of the people within the community concomitant with the environmental changes brought about by the project?</li> </ul>	<p><b>GR2E rice differs from standard rice in that it contains extra genes added through genetic modification to ensure the production of provitamin A in the rice grains. Once absorbed into the body, provitamin A is converted into vitamin A as needed. Provitamin A is found in many fruits and vegetables and is what makes carrots orange, for example.</b></p> <p><b>GR2E rice is intended to complement existing VAD control efforts, such as food fortification, vitamin A supplements, and dietary diversification, by supplying up to 30–50 percent of the estimated average requirement for vitamin A for preschool age children and pregnant or lactating mothers.</b></p> <p><b>Thus, the utilization of GR2E rice in Philippines communities is intended to improve nutritional and health status, and there are no indicators of potential adverse health impacts.</b></p>
<ul style="list-style-type: none"> <li>○ What are the data and information as to health resources available in the area?</li> </ul>	<p><b>Not applicable in the context of this FFP application for national approval.</b></p>
<ul style="list-style-type: none"> <li>○ What are the capability of national and local government agencies, NGOs and the community in monitoring control hazards?</li> </ul>	<p><b>There are no relevant risk hypotheses related to the FFP approval of GR2E rice that would necessitate post-market monitoring for adverse consequences by either national or local agencies.</b></p>
<b>Identification of Hazards and Evaluation of Potential Health Impact</b>	
<ul style="list-style-type: none"> <li>○ What are the potential environmental health impacts, whether adverse or beneficial to affected communities/ workers? Identify and evaluate these.</li> </ul>	<p><b>Not applicable in the context of this FFP application for national approval.</b></p>
<ul style="list-style-type: none"> <li>○ What are the potential health hazards posed by the introduction of a project into a particular area?</li> </ul>	<p><b>Not applicable in the context of this FFP application for national approval.</b></p>
<ul style="list-style-type: none"> <li>○ What necessary changes or measures made to mitigate, if not to totally eliminate, possible adverse effects to the community done by the project proponents?</li> </ul>	<p><b>Not applicable in the context of this FFP application for national approval.</b></p>
<ul style="list-style-type: none"> <li>○ What are the existing conditions or hazards (prior to project implementation) that may interact with the project and further increase the risk?</li> </ul>	<p><b>Not applicable in the context of this FFP application for national approval.</b></p>
<b>Identification and Assessment of Community Exposure</b>	
<ul style="list-style-type: none"> <li>○ What are the possible routes of exposure of the impact community and workers?</li> </ul>	<p><b>Not applicable in the context of this FFP application for national approval.</b></p>
<ul style="list-style-type: none"> <li>○ What are the potential routes of exposure if projects prove to be damaging to the environment and, particularly, to human health?</li> </ul>	<p><b>Not applicable in the context of this FFP application for national approval.</b></p>
<ul style="list-style-type: none"> <li>○ What are the sources of potential hazards?</li> </ul>	<p><b>Not applicable in the context of this FFP application for national approval.</b></p>
<ul style="list-style-type: none"> <li>○ What are the potential routes of exposure for the community and the workers?</li> </ul>	<p><b>Not applicable in the context of this FFP application for national approval.</b></p>
<ul style="list-style-type: none"> <li>○ How do the following affect the community and workers: <ul style="list-style-type: none"> <li>- Project processes and activities?</li> <li>- Raw materials/GM seeds?</li> <li>- The products and by-products?</li> <li>- And more importantly, the amount and nature of waste emissions/generations expected from the project?</li> </ul> </li> </ul>	<p><b>Not applicable in the context of this FFP application for national approval.</b></p>

<b>Identification of Risk Groups</b>
<ul style="list-style-type: none"> <li>○ What are the risk groups who have a higher probability either of exposure or developing the adverse health effect? <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>
<ul style="list-style-type: none"> <li>○ What is the demographic profile of the affected communities, and the geographical location of the project in relation to where these communities are situated? <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>
<ul style="list-style-type: none"> <li>○ What are the means of protection and cure for those who will be affected? <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>
<b>Prediction of Health Consequences and Outcomes</b>
<ul style="list-style-type: none"> <li>○ What are the predicted health consequences and outcomes, whether these are direct or indirect effects of the development project or whether they result with or without the project? <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>
<ul style="list-style-type: none"> <li>○ What direct health consequences and outcomes are predicted to occur? such as: <ul style="list-style-type: none"> <li>- acute and chronic poisoning,</li> <li>- respiratory diseases,</li> <li>- skin diseases,</li> <li>- cancer, and</li> <li>- injuries?</li> </ul> <b>Not applicable in the context of this FFP application for national approval.</b> </li> </ul>
<b>Prediction of Health Trends With or Without the Project</b>
<ul style="list-style-type: none"> <li>○ What are the perceived or expected health trends should the project be allowed or disallowed to operate?</li> </ul>
<b>Assessment of Indirect Health Determinants</b>
<ul style="list-style-type: none"> <li>○ What are the indirect health determinants of the community residents like water supply and sanitation, access roads, increased income, electricity and public health services? <i>These factors have significant impact on the health of the people because they determine accessibility to factors that have direct impact on the general health condition of the people? For instance, a household's level of income determines the quality of nutrition available to the family. Discuss and assess.</i> <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>
<b>Control Measures</b>
<ul style="list-style-type: none"> <li>○ What are the control measures that must be undertaken to prevent or minimize environmental health impact to communities and workers where projects are introduced? <i>This will ensure that the proponents in biotechnology projects (field trial, commercial propagation) or/phases of their projects proactively consider the health and welfare of the community and the workers.</i> <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>
<b>Mitigating Measures</b>
<ul style="list-style-type: none"> <li>○ What are the mitigating measures that must be put in place to minimize the adverse health consequence should the control measure fail and the environmental hazard is released? <i>This will help prepare national and local government agencies, NGOs and the community members themselves to formulate a plan of action in cases of emergencies or situations arising from environmental and health-related problems.</i> <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>
<ul style="list-style-type: none"> <li>○ What are the other mitigating measures that are established for (but not limited to): community livelihood projects, environmental management program, occupational health and safety program, and health emergency preparedness plan? <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>
<b>Monitoring and Auditing Plan</b>
<ul style="list-style-type: none"> <li>○ What are the monitoring strategy and auditing design to keep track of the changes in the health situation of the impact community throughout the development and implementation of the biotechnology project, to ensure that these are continuously abiding by the conditions specified in the ECC and that they do not pose harm to the environment and to the health of the community in all stages of their operations? <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>

**Health Impact Assessment of Proposed Biotechnology Projects  
(Technical Scoping/Screening to be used by BPI)**

<b>Screening for Health Sensitive Project Location</b>
<ul style="list-style-type: none"> <li>○ What are the identified health hazards either to workers or impact communities (currently in residence or developed due to in-migration) may be increased based on the geographic location and environmental attributes of the project site. Screening for health sensitive project location must consider the following:</li> </ul>
<ul style="list-style-type: none"> <li>○ presence of endemic diseases like malaria, schistosomiasis, filariasis and other diseases to which workers and developing communities may be exposed during the development of biotechnology project? Will these existing endemic diseases be reduced or exacerbated in magnitude brought about by the project? <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>

<ul style="list-style-type: none"> <li>○ presence of vulnerable environmental pathways near the project site which may carry hazards from the site to the receptors, like lands, bodies of water, and other locations used by nearby communities for livelihood, sustenance and other necessities vital to the maintenance of health? <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>
<ul style="list-style-type: none"> <li>○ pre-existing communities near the project site where high-risk groups vulnerable to the adverse effects of the project may be located? Does this include indigenous cultural communities, communities with significantly high proportion of children and elderly, communities with significantly high incidence or prevalence of communicable and non-communicable diseases and with limited access to medical and health services? <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>
<ul style="list-style-type: none"> <li>○ pre-existing natural hazards in the area like volcanic activities, earthquakes, floods, etc. which may affect project construction, operation and decommissioning and thereby pose additional hazards or risks to the resident communities? <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>
<b>Scoping and Profiling</b>
<b>Environmental Health Hazard Listing</b>
<ul style="list-style-type: none"> <li>○ What are the physical, chemical, biological, ergonomics and indirect health hazards identified based on the initial assessment or examination of the location and process flows of biotechnology projects by proponent? <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>
<ul style="list-style-type: none"> <li>○ From the list above, what are the significant health hazards? <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>
<ul style="list-style-type: none"> <li>○ Who are the receptor groups (as either workers or community residents)? <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>
<b>Identification of Vulnerable Population and other Significant Stakeholders</b>
<ul style="list-style-type: none"> <li>○ Who are the vulnerable sectors in the impact community (i.e. children, elderly, sick, unemployed, etc.) and other stakeholders such as NGOs, media, government agencies (local and national), who may be affected either directly or indirectly by the project? <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>
<b>Identification of Important Environmental Factors</b>
<ul style="list-style-type: none"> <li>○ What are the special environmental characteristics of the proposed project location, which can increase or decrease the adverse health impact of the project to its workers and the community? <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>
<ul style="list-style-type: none"> <li>○ Is the location prone to typhoons, earthquakes and other natural calamities? <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>
<ul style="list-style-type: none"> <li>○ Are there inadequate transportation and communication facilities in the area? <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>
<ul style="list-style-type: none"> <li>○ Is there low literacy rate of the general population? <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>
<ul style="list-style-type: none"> <li>○ Is there inadequacy of health and other social services? <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>
<ul style="list-style-type: none"> <li>○ Is there limited LGU capability and resources? <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>
<ul style="list-style-type: none"> <li>○ Are provisions made available on-site by the project proponent to ensure that the mentioned above services and activities? –by the regulatory agencies? <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>
<b>Health Risk Assessment Process</b>
Based on the data and information noted in the sections above:
<ul style="list-style-type: none"> <li>○ What are the health hazards to workers and the community? Comprehensively identify each. <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>
<ul style="list-style-type: none"> <li>○ Which activity/ies has/have the greatest potential risk to health? Prioritize on the detailed health risk assessment to be conducted. <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>
<ul style="list-style-type: none"> <li>○ What priority control and mitigating measures shall be implemented and incorporated even during the early design phase of the project? <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>
<ul style="list-style-type: none"> <li>○ What IEC measures shall be conducted to educate the – <ul style="list-style-type: none"> <li>- The regulatory agency?</li> <li>- The community?</li> </ul> </li> </ul>

<ul style="list-style-type: none"> <li>- Other stakeholders On health hazards and risks of the project, their appropriate control and mitigating measures? <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>
<ul style="list-style-type: none"> <li>o What are the appropriate recording, monitoring and auditing strategies to ensure that identified health risks remain under control during the entire life cycle of the projects? <b>Not applicable in the context of this FFP application for national approval.</b></li> </ul>
<p><b>Qualitative health risk assessment</b></p>
<ul style="list-style-type: none"> <li>• What are the identified adverse health consequences on the human receptors? <b>There are no identified adverse health consequences arising from the approval of GR2E rice for direct use in food, feed, or for processing. The Health Impact Classification of this activity is C (no significant adverse health impact) and a Health Impact Assessment (HIA) is not required.</b></li> </ul>
<ul style="list-style-type: none"> <li>• What is the health consequence rating (see Table 2) of the identified adverse health consequences on the human receptors based on the severity of ill-health? <b>Not applicable as HIA is not required.</b></li> </ul>
<ul style="list-style-type: none"> <li>• What is the estimated probability of occurrence of the exposure incident? This can be estimated using the exposure rating technique (projects already in place) or the incidental potential rating technique (see Table 3) (for proposed projects currently only in the development state), which is based on information of past occurrences of the exposure situation being assessed. <b>Not applicable as HIA is not required.</b></li> </ul>
<ul style="list-style-type: none"> <li>• What is the health risk prioritization matrix that shall come up based on the integration of the adverse health consequence rating with either the exposure rating or the incident potential rating? <b>Not applicable as HIA is not required.</b></li> </ul>
<ul style="list-style-type: none"> <li>• What are the planning and prioritization of control and preventive measures based on the health risk prioritization matrix? <b>Not applicable as HIA is not required.</b></li> </ul>