

DIR. GEORGE CULASTE

Bureau of Plant Industry
Department of Agriculture
692 San Andres St., Malate, Manila

October 16, 2019

COMMENTS REGARDING CONSOLIDATED REPORT OF PHILRICE AND IRRI'S GR2E RICE APPLICATION FOR DIRECT USE AS FOOD AND FEED, OR FOR PROCESSING

Dear Dir. CULASTE,

This letter is in response to the submission to the Department of Agriculture – Biosafety Committee of the Consolidated Report of Philrice and IRRI's GR2E Rice Application for Direct Use as Food and Feed, or for Processing. I STRONGLY OPPOSE the results of the report based on the following:

- (a) Golden Rice is a staple food and it is the first GMO to be used for staple food. As such, Golden Rice should be subjected to very rigorous safety testing and its safety should be proven beyond reasonable doubt. The claims of the proponents that GR is safe have no scientific basis, or at best their data are incomplete—the claim of safety by the proponents is wishful thinking.
- (b) ***The use of substantial equivalence is not the best way to ensure safety of GM products, especially staple food such as rice.*** The toxicological assessment report submitted by the proponents only based their findings on the proteins produced independently of regulated article. No studies were done to assess Golden Rice as a whole/finished product. Traits of genetically engineered crops, such as Golden Rice, are susceptible to rearrangement, silencing or repetitions thus it is highly possible that new proteins may be expressed.
 - The toxicological assessments of proteins expressed by Golden Rice such as CRTI and PMI needs further or follow-up studies.
 - Reading from the report, it was stated that the CRTI protein share homology with three (3) known toxins from snake venom. While the research design used a high amount of CRTI to test acute toxicity to rats, the research design however should have used longer time series, including

intergenerational studies to prove whether CRTI might induce chronic toxicity to test subjects.

- The same with the research design used to prove toxicity of CRTI, the study on PMI only covered 14 days observation period to check for acute toxicity. As what has been pointed out earlier, rice is a staple food consumed by the population three times a day possibly during their lifetime. Chronic test should have been done to eradicate possibilities of the effect of PMI. Homologies were also used to ascertain safety of the protein, however this is not a valid replacement for feeding tests to ascertain toxicity.
 - The report also stated 'significantly' lower testicular weight and epididymal weights and slightly higher adrenal weights in females. The report suggested that organ weight alterations 'probably' represented physiological responses of a non-adverse nature. These studies are not conclusive and suggests a follow-up experiment to ensure safety of Golden Rice.
- That the Golden Rice variety was tested only for three (F3) generations for its stability, when in fact in normal rice breeding, genetic re-arrangements occur up to 6th generation. The proponents should have studied at least up to 6th generation (F6). Scientific studies made by Bollinedi et al. (2017) on the effects of the new gene constructs disrupting the native *OsAux1* gene thereby affecting the fine balance of plant growth regulators resulting to a substantial reduction in the content of chlorophyll essential for the vital functions of the plant. The study also stated that the derived lines of Golden Rice from Swarna showed phenotypic abnormality and poor agronomic performance making it unfit for commercial cultivation.
 - That the GR2E expressed not only beta carotene but other carotenoids as well, such as B-cyptoxanthin, all trans a-carotene and 9'-cis-B-carotene. No studies were done to check whether these newly expressed carotenoids would produce anti-nutritive properties or possible toxicity.
 - The report also noted that no unintended horizontal gene transfer to unrelated species occurred, however no data were presented to support such claim. Also the data used from contained use and multi-location confined testing were done during 2015 and 2016. We have to note that during these period, the Supreme Court ruled the temporarily halt all activities regarding GM research, field tests, importation among others. The data should have not been used as data for submission as

no existing policies were in place to safeguard the people's right to health and healthy environment were in place.

- Up until today, the departments tasked to regulate GM crops under JDC 1 of 2016 has yet to present risk assessment procedures, guidelines or administrative orders while the application for direct use of Golden Rice/GR2E is ongoing.
 - **Safety feeding tests of the product Vitamin A rice to test animals should be done before approval of direct use** for food, feed, and processing. And feeding tests should not only be for acute toxicity (45-90 days), but it should include i) feeding for the life duration of the test animal, and ii) transgenerational (effect on the offsprings). Safety assessment using bioinformatics, comparing the genes to known allergens in a database is not enough as basis for safety, especially for a staple food.
 - Safety studies on the Vitamin A rice should include Genomics and metagenomics, Epigenomics and metaepigenomics, Transcriptomics, Proteomics, Metabolomics, and Phenomics.
- (c) Based on the submitted documents, the proponents admitted that Golden Rice contains less than 10% of an equivalent amount of carrots. Many green and leafy vegetables contain much more beta carotene than the golden rice (3.57ug/g), like jute (60 ug/g), malunggay (67 ug/g), alugbati (38 ug/g), and many more, as well as squash (46 ug/g), and orange sweet potato tuber (200 ug/g) and these are readily available and safe. Therefore, there is **no compelling reason to allow a GMO rice into the food of people.**
- The proponents of the Vitamin A rice selectively believe in the unproven benefits of golden rice, while benefits from other natural foods high in beta carotene is debunked by them. For example, they claim that golden rice with 3.5 ug/g can prevent blindness, but I am sure if somebody says that saluyot with 60 ug/g beta carotene or carrots with 82.9 ug/g can prevent blindness, the same Golden rice proponents would be viciously on the attack.
 - The proponents are biased and unscientific when they were computing the amount of beta carotene using 7 ug/g from golden rice when in fact that is the maximum. It is worthwhile to note that their supporting dossier reported 1.96 ug/g – 7.31 ug/g beta carotene, with an average of 3.57 ug/g. Scientific writing uses the average, NOT the maximum level. In this case they are already promoting their product, and therefore biased. The government assessors used the same maximum level of beta carotene.

- The claim of the proponents that Golden Rice could provide the necessary vitamin A to deficient children has no scientific proof provided. It is common knowledge that provitamin A or Vitamin A is fat soluble, and if fats are not present in the diet of the poor, how can this be absorbed by their body? This is bioavailability issue.
 - It is stated that there is a statistically significant difference in the mean concentration of crude fiber between samples of GR2E and PSB Rc82 rice grain. However, this finding was dismissed as the difference was relatively small and unlikely biologically meaningful. The report is contradicting the findings of the research. This is also cited on the stearic acid concentrations in samples of GR2E and control PSB Rc82, wherein the statistically significant difference was dismissed, and concluded haphazardly that this is unlikely to be biologically relevant.
 - It is also interesting to note the degradation of beta carotene during storage and cooking. It was studied that Golden Rice will have no impact on curbing Vitamin A Deficiency due to the fast degradation of beta carotene. The report even stated that there was a decrease of beta carotene upon storage within two weeks at room temperature (Bollinedi et al. 2019)
 - While no adverse effects upon prolonged consumption of B-carotene in food have been reported, these results were studies using beta carotene existing in naturally occurring food, not on Golden Rice. There is a need to generate data on Golden rice before processing the application for direct use for food, feed and processing.
- (d) The assessors are claiming to have '*found scientific evidences*' that the regulated article (Golden Rice) applied for human food and/or animal feed use is as safe as its conventional counterpart. However, the assessors, we believe, relied most or entirely on the data submitted by the proponents and available data are incomplete to come to such conclusion.
- (e) The DENR Biosafety Committee also stated that the chances of unintended release or planting of regulated article is very minimal and will not cause any damaging and lasting effects to the environment. However, there is no study to back up this claim. No environmental impact assessment or study was also done to conclude that Golden Rice is not expected to pose any significant risk to the environment and to non-target organisms.
- (f) The Health Impact Assessment Report (HIA) by the Department of Health also heavily relied on the documents provided by the proponents. The Health Impact Assessment, like ERA, should be done by an independent group, and

the process cannot be confined in a questions and answers, because the product has to be assessed and probed deeper in terms of its safety.

(g) **Why should the applicant be the one declaring that HIA is not required?** (see the answers in the Qualitative Health Risk Assessment question). It should be the Department of Health that has authority to do so. **Golden Rice is a GMO, and rice is a staple food, therefore, HIA is a must.**

(h) Socio, economic and cultural impacts

(i) The proponents clearly shied away from answering significantly the socio, economic and cultural impacts of Golden Rice, stating that it does not anticipate having any measurable impact on current patterns of rice production, consumption and trade.

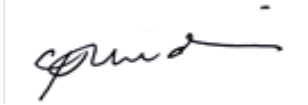
(ii) On such impact is the possible contamination of indigenous and local varieties wherein indigenous communities and farming groups rely for food and livelihood as what have been raised during the consultation with the National Ant-Poverty Commission last April 2018.

(iii) It also did not study possible impacts of patenting and privatization of seeds thru genetic modification. For example, farmers who are planting GM corn in the Philippines are spending thousands of pesos for the purchase of the privately owned seeds and its accompanying toxic chemicals. While it was said that no additional costs will be spent in the use of Golden Rice, we do not have any control if the owners of patents such as Syngenta (now owned by Chemchina) decide to get royalties from Golden Rice. We see that Golden Rice is a Trojan Horse that will open up the rice industry for further corporate control thru genetic engineering and patents.

(i) **In the absence of law on liability and redress on GMO environmental contamination and health negative effects, the application for field testing and direct use for food should be denied.**

Since existing safety data on golden rice is very limited and therefore inconclusive, while alternative sources of beta carotene from naturally occurring foods are abundant, then **there is no compelling reason to approve the application for direct use for food, feed, and processing of Vitamin A rice.** I earnestly hope that the government regulators decide on the side of safety.

Truly yours,



Charito P. Medina, Ph.D.
Concerned Consumer

Copy furnished:

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