

Jonathan Latham, PhD  
Executive Director  
The Bioscience Resource Project,  
Ithaca, NY 14850 USA

By e mail: [jrlatham@bioscienceresource.org](mailto:jrlatham@bioscienceresource.org)

4<sup>th</sup> June 2018

Dear Dr Latham,

I have been sent a copy of the e mail, to which this letter is attached. I have provided a few references in this reply, and so have used a pdf format so that they are retained.

You mention the US FDA, and perhaps have missed Health Canada's equivalent document registering Golden Rice GR2E as safe in Food, Feed and in processed form. I attach both documents here, for the convenience of your readers in highlighted form. The links to the originals are below.

Although differently explained, both the statements concerning nutritional impact in the US FDA document, and the passage marked 'A' in the Health Canada document, are in relation to the North American diet. And not in relation to the amount of  $\beta$ -carotene required to combat the nutritionally acquired immune deficiency syndrome<sup>1</sup> which is vitamin A deficiency (VAD) in developing countries where whole populations are vitamin A deficient

Indeed, Health Canada in the passage marked B, clarifies: "*The efficacy of the GR2E rice in helping vitamin A deficiency in affected populations was not evaluated*". It would perhaps be clearer, given the widely known purpose of Golden Rice, for the US FDA also to have made a similar statement, or to have explained what the implications are of a "nutrition content claim".

In the USA to make a "nutrition content claim" the food has to deliver more than 10% of the Recommended Daily Intake<sup>2</sup> of a nutrient (such as pro-vitamin A) in a 45g serving<sup>3</sup> (weighed as dry, uncooked grain). Recommended Daily Intake (RDI), of a nutrient is the average to meet the nutrient requirements of 97-98% of healthy individuals. For the North American population and sources of vitamin A "healthy individuals" is essentially everyone. Vitamin A deficiency is not a public health problem – and is very unusual - in North America. The recommendations about consumption of the RDI, in the case of provitamin A, is designed to maintain 3 months-worth of liver stores of vitamin A.

RDI (also called RDA – Recommended Daily Allowance) is actually mathematically derived (+/- two Standard Deviations) from the scientifically derived Estimated Average Requirement (EAR) for the same nutrient.

There are no RDI/RDA's derived for non-industrialised countries. And 3 months liver stores are not required to prevent vitamin A deficiency. Additionally, in such RDI calculations the standard conversion rate assumed for beta-carotene to circulating retinol (vitamin A) is 12:1. Actually a huge range of conversion rates is known, depending on the source of beta-carotene<sup>4</sup>, from 28:1 to 3.6:1 with the most efficient, 3.6:1, being the beta-carotene from Golden Rice.

---

<sup>1</sup> Semba R. The vitamin A story: lifting the shadow of death. World Rev Nutr Diet. 2012;104:207.

<sup>2</sup> [http://www.ecfr.gov/cgi-bin/text-idx?SID=3ee286332416f26a91d9e6d786a604ab&mc=true&tpl=/ecfrbrowse/Title21/21tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?SID=3ee286332416f26a91d9e6d786a604ab&mc=true&tpl=/ecfrbrowse/Title21/21tab_02.tpl)

<sup>3</sup> <http://www.fda.gov/FoodGuidances>

<sup>4</sup> Tang G, 2010 Bioconversion of dietary provitamin A carotenoids to vitamin A in humans<sup>1-5</sup>, Am J Clin Nutr 2010;91(suppl):1468S-73S summary Table 1

Nutritionists calculate that 30 – 40% of the EAR for a source of vitamin A, in this case such as the beta-carotene in Golden Rice, consumed daily is sufficient to prevent the two separate morbidities of VAD, blindness and the loss of a functional immune system, often leading to death from common infections especially in young children and their mothers. One to two million children die annually (about 5000 deaths every day) and hundreds of thousands go blind annually from VAD, despite existing interventions.

Of course, in countries where rice is the staple food, especially for people whom for one reason or another can't access a properly varied diet, including relatively expensive animal products and coloured fruits and vegetable, a lot more rice is eaten daily than 45 grams: maybe 300g of dry rice daily, even 100g for a young child.

With adults (in the USA) and most importantly children (in China), careful and sophisticated research has shown that the beta-carotene in Golden Rice, following only a single meal, is very efficiently converted to vitamin A by the human body. Only a few tens of grams of dry Golden Rice, when cooked and consumed daily, is expected to combat vitamin A deficiency and save life and sight. The results show that Golden Rice "may be as useful as a source of preformed vitamin A from vitamin A capsules, eggs, or milk to overcome vitamin A in rice-consuming populations".

It has already been well established<sup>5</sup>, although ignored by critics, for the GR2E Golden Rice, already registered safe in Australia, Canada, New Zealand and the USA, that the yield is the same as the wild type of the same Indica rice cultivar without the beta-carotene trait. It is also well established that all calculations of requirements of Golden Rice, as an additional intervention for vitamin A deficiency, are based on worst case estimates, compared to actual measurements, of beta-carotene losses in storage and cooking.

Continuing research will clearly be necessary, after registration, to fully understand the benefits of Golden Rice to public health. Will regular Golden Rice consumption reduce the population's morbidity and mortality associated with vitamin A deficiency as expected, and as it was created to do? Of particular interest are neonates (babies under a month old). Vitamin A capsules are only recommended for children of six months and older, and very young children do not consume solid food. These children are the most vulnerable to vitamin A deficiency: neonate deaths in 2011 accounted for 43 per cent (increased from 36 per cent in 1990) of all deaths among under five-year-olds. Can a good source of vitamin A, such as Golden Rice, when part of the staple diet, improve the mother's vitamin A status, benefiting her health, and simultaneously via the placenta and breast milk increase the baby's resistance to disease, and reduce neonate and child mortality?<sup>6</sup>

I trust that this letter corrects the misapprehensions which you have formed previously.

Best wishes



Adrian Dubock(PhD)  
Member, and Executive Secretary,  
Golden Rice Humanitarian Board

---

<sup>5</sup> Dubock A, 2017 ..Overview... <http://rdcu.be/wwui>

<sup>6</sup> Dubock A. Golden Rice: a long-running story at the watershed of the GM debate. 2013. p. 1–12.  
[http://www.goldenrice.org/PDFs/GR\\_A\\_long-running\\_story.pdf](http://www.goldenrice.org/PDFs/GR_A_long-running_story.pdf)

