Introduction of Fortified Rice Using the Ultra Rice® Technology

Frequently Asked Technical Questions

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What is Ultra Rice?

The Ultra Rice[1] micronutrient delivery system employs a unique mechanism for incorporating vitamins and minerals within an extruded "rice grain" made from rice flour to minimize nutrient losses. These fortified extruded grains (called "Ultra Rice grains") resemble natural milled rice in size, shape, and density. After drying, Ultra Rice grains are blended with local rice, typically in a ratio of 1:100. When cooked, the fortified rice has the same taste, color, and texture as unfortified rice.

All ingredients in the Ultra Rice grains are compliant with international regulatory standards, are vegetarian, and include no genetically modified substances. Ultra Rice has been intensively studied to ensure it is efficacious, shelf-stable, and acceptable to consumers.

Health issues

What harm does micronutrient malnutrition do in society?

Billions of people in the world today suffer from micronutrient malnutrition—a factor that substantially contributes to the global burden of disease. The debilitating effects of vitamin and mineral deficiencies are a major impediment to a population's socioeconomic progress.

Annually, vitamin A deficiency contributes to the deaths of 2 to 3 million children; iron deficiency saps the energy and active learning capacity of a billion people; lack of folic acid during the first days of pregnancy causes over 200,000 severe birth defects; zinc deficiency affects the growth and immune system functioning of hundreds of millions, in particular leading to longer and more severe bouts of diarrhea in children; and thiamin deficiency quietly continues to affect populations primarily consuming diets of polished rice.

How can Ultra Rice help overcome those problems?

The Ultra Rice technology provides a relatively simple method for adding nutrients to rice at levels that will prevent micronutrient deficiency diseases from developing. Consumers may not even know that their rice has been fortified, but they obtain the benefits anyway. These nutrients are added to the rice in such a way that the essential vitamins and minerals are protected from loss caused by storage, rinsing before preparation, and cooking.

[1] Ultra Rice is a registered trademark in the United States of Bon Dente International, Inc.

Research on Ultra Rice

What research has been done on Ultra Rice?

Research on the Ultra Rice technology began in 1989, when the technology was first developed by Bon Dente International. Years of subsequent evaluation led to significant improvements in the range of micronutrients Ultra Rice can deliver; the appearance of the grains; and the retention of micronutrients and stability of the grains during storage, rinsing, and cooking.

The initial research on Ultra Rice was performed on a formulation containing only vitamin A. Studies conducted in Brazil and Nepal produced findings that confirmed its bioavailability, efficacy, safety, and consumer acceptance. In 2000, research began on a separate formulation that could carry iron. The current iron formula was tested in a study in 2005 that showed iron and additional micronutrients (thiamin, folic acid, niacin, and zinc) were stable when placed in the same grain.[i]

In total, 28 studies to date across eight countries form the evidence base around Ultra Rice. The studies evaluate the safety of Ultra Rice (3 studies), its stability (11), bioavailability (2), sensory acceptability (6), and efficacy/effectiveness (6). The Ultra Rice Research Summary Table that accompanies this document contains a summary of each study, and below is a general description of the results by category.

Safety: In the area of safety, three studies were conducted between 1994 and 2001 to establish the safety of Ultra Rice. A 1994 study conducted in Brazil assessed the potential for vitamin A toxicity and detected no adverse effects by either clinical, physical, or laboratory evaluation.[ii] A study in 1999 helped to establish that the maximum level of vitamin A required to meet normative requirements in children is 17 IU/g cooked rice, well under the upper limit (30 IU/g) considered safe for consumption by pregnant women.[iii] Finally, in 2001, a study conducted in Brazil and Canada assessed circulating retinol levels after ingestion of rice fortified with Ultra Rice grains, comparing vitamin A at 6 and 12 times the RDA per single meal. Serum retinol increased on average 25%–50% above baseline levels, and no individual increased more than 2.5 times baseline levels.[iv] Based on this assessment, consumption of very high levels of rice fortified with vitamin A enriched Ultra Rice could be expected to provide vitamin A levels well below the safety threshold.

Stability: Eleven studies conducted between 1989 and 2005 examined the stability of various vitamin A and iron fortified formulas under various storage and preparation conditions. Collectively, these studies demonstrate that the type of antioxidants and lipids used in the formulation are significant factors in the stability of vitamin A; that the stability of retinyl palmitate is affected much more by temperature than variation of relative humidity; that rice fortified with elemental iron alone or with multiple fortificants has better storage characteristics than that fortified with ferrous sulfate alone or with multiple fortificants; and that it is possible to produce Ultra Rice with good stability, combining several B vitamins, iron, and zinc. The studies also showed favorable findings on the retention of nutrients (99%) after repeated rinsing and cooking. The current Ultra Rice formulation has good micronutrient stability and undergoes

minimal changes in color and flavor, even under harsh environmental conditions, for storage periods up to 6 months.

Bioavailability: A 1994 test conducted in Brazil assessed the bioavailability of vitamin A in Ultra Rice grains and indicated that retinol in Ultra Rice was absorbed and transported.[ii] Several studies were also conducted to identify an appropriate iron fortificant that was bioavailable, affordable, and did not discolor the fortified grains or react with other ingredients. In 2004, a study was conducted in the United States to assess the relative bioavailability of iron from four ferric pyrophosphate (FePP) compounds using a rat model.[v] Based on this study, FePP was determined to be the most appropriate iron fortificant and is now used in all iron-containing formulations of Ultra Rice.

Sensory acceptability: The early sensory testing pursued in Brazil and in the United States on small panels of participants (12–14) found no significant difference in taste between fortified and traditional rice. A large sensory study (600 participants) that followed in 2003 in India confirmed these findings, although a small percentage did not like the grayish color or reported an aftertaste.[vi] A study of similar size was pursued in the same year in Ecuador and found the concept of fortified rice to be important among those surveyed, with respondents likely to buy the fortified rice (4.3 on a five-point "intent to purchase" scale).[vii] The study also found that the effect of iron on flavor was dependent upon its source and concentration.

Efficacy/Effectiveness: Four studies were conducted between 1994 and 2008 to measure the efficacy of both vitamin A and iron in Ultra Rice grains. The 1994 study conducted in Brazil indicated that 8.8% of the children presented with serum retinol levels below the proposed cut-off point of 1.05 umol/L, compared to 51% of the children at baseline, showing that consuming Ultra Rice-fortified rice improved serum retinol status.[viii] Although not all the children received satisfactory vitamin A status in the 30-day pilot period, the frequency distribution of serum retinol values showed a significant favorable impact. A second study in Brazil that year indicated that after a full year no children were deficient compared to 44% at baseline, and a considerable favorable shift of the frequency distribution of values was noted. Correspondingly, the prevalence of morbidity fell from 75% to 59% between the control and intervention groups.

Two small-scale effectiveness studies were conducted in India in 2007 and 2008 to assess the impact of iron-fortified Ultra Rice on the iron status of children in a mid-day meal program.[ix] Hemoglobin (Hb) and ferritin levels increased in children who consumed unfortified rice as well as Ultra Rice. Although there was a greater increase in the Ultra Rice group, the average increase was not statistically significant. However, the mean increase in Hb was significantly higher between control and intervention groups when baseline Hb levels were low (7–10 g/dl) and in children who participated in the study for >60 or >75 days. Due to this positive trend in Hb levels, the study was continued during the following academic year to increase the period of exposure. Results from this second study are still pending.

The effect of Ultra Rice has also been studied among women. A 2005 study conducted among women in Mexico showed that mean plasma ferritin concentration and estimated body iron stores were significantly higher and transferrin receptors lower in the group receiving iron fortified rice compared to a control group consuming unfortified grains.[x] Mean Hb concentration

also increased in the treatment group; however, the increase was only significant among those whose baseline Hb was <12.8g/dL. Overall in the treatment group, there was an 80% reduction in the prevalence of anemia and a 29% reduction in the prevalence of iron deficiency, whereas there was no statistically significant difference in these conditions from baseline in the control group. An earlier study was completed in 2003 among pregnant nightblind Nepalese women.[xi] Vitamin A supplements were found to have a greater impact on plasma retinol concentrations than vitamin A fortified rice, but this effect is likely due to the short (6-week) duration of the intervention.

In 2008, a study was conducted to compare the effectiveness of iron-fortified Ultra Rice with iron drops in improving young child iron status in a southeast region of Brazil.[xii] In this study, 175 anemic children, aged 6 to 24 months, were divided into two groups. Group 1 received iron-fortified Ultra Rice and placebo iron drops, and group 2 received unfortified rice with iron drops. After 5 months there was a significant improvement in iron status in both groups; however, the shift from severe to moderate and light hemoglobin levels was significantly greater in the group receiving iron-fortified rice. Although insufficient compliance in giving the iron drops may have contributed to the superior performance of Ultra Rice in reducing anemia, the short duration of the study highlights the value of food fortification as a means of improving iron status. This was the first time that Ultra Rice had been proven efficacious among children of this age group. The study also generated important information on the carbohydrate intake of 6- to 24-month-olds, which provides a better understanding of the appropriate iron dosage needed to treat iron deficiency in young children.

With a strong evidence base behind it, several demonstration trials have been planned to determine the operational feasibility and effectiveness of introducing Ultra Rice into large-scale public-sector feeding programs in India, Brazil, and Colombia. If positive, these trials will help pave the way for full integration of Ultra Rice into these programs.

Advantages of Ultra Rice

What are the technical advantages of the Ultra Rice technology?

The Ultra Rice technology seals nutrients into extruded grains that look and taste nearly identical to natural rice. This keeps nutrient losses minimal during transit, storage, food preparation, and cooking. This helps ensure that label claims regarding nutrient content are met and consumers get maximum benefit from consumption of rice fortified using the Ultra Rice technology.

The price premium of a rice product fortified with Ultra Rice grains (Ultra Rice grains blended with regular local rice) as compared to traditional rice is only marginally higher (2 to 6 percent). This is because existing equipment can generally be modified to accommodate the relatively simple Ultra Rice technology and the ratio of Ultra Rice grains to traditional rice can usually be 1:100 or less. The nutritional benefits consumers receive from fortified rice may outweigh the small increment in price.

Growing interest in fortification is leading many governments to mandate fortification of staple foods with iron and folic acid. Until Ultra Rice was developed, this was not possible in places

where consumers rinse their rice before cooking it. In the coming years, there may be a push by governments to mandate rice fortification in addition to other staple foods. The Philippines has already adopted mandatory rice fortification and many other governments are considering requiring that the food they purchase for social programs be fortified as well.

Ultra Rice grains

What factors determine the concentration of micronutrients in the Ultra Rice grains?

The formulation takes into consideration the following four factors when determining micronutrient concentrations:

- Targeted percentage of local recommended dietary intake.
- Typical rice serving size and expected daily consumption.
- Planned ratio of Ultra Rice grains to regular rice according to the needs of the target population.
- Most practical micronutrient density in the Ultra Rice grains (because there is a limit to the amount of micronutrient that can be put into a manufactured rice grain).

Is there a difference between weight and bulk density of the Ultra Rice grains?

Bulk density is a measure of the weight of Ultra Rice grains needed to fill a specified volume and is a figure used in dosification calculations. *Absolute density* of a dry extruded grain is important in that it must be greater than water or the grain will float. If they were much lighter in density than rice, the manufactured grains would separate out easily. In fact, the closer the density of the Ultra Rice grains can be to that of natural rice, the less settling will occur during transport of the fortified rice blend. The density of the Ultra Rice grains is controlled through proper manufacturing parameters.

How hard are the Ultra Rice grains?

The Ultra Rice grains should have physical properties quite similar to those of milled white rice. The grains should be able to withstand a few minutes of soaking, or multiple washings. The PATH team will work closely with technology recipients to ensure that operating conditions are adjusted appropriately.

What is the caloric value of the Ultra Rice grains?

Analysis of the Ultra Rice grains indicates that 100 g. of vitamin A fortified Ultra Rice grains would provide 366 calories compared to 358 calories for natural rice. The multi-micronutrient grain would be similar. Thus, Ultra Rice provided at a ratio of 1:100 adds only a tiny fraction of a single calorie per 100-g. serving of fortified rice.

Can fortified rice using the Ultra Rice technology act as a substitute for fortified products already included in ongoing feeding programs?

Most vitamins and minerals need to be consumed on a daily basis for the human body to function efficiently. At present, in many countries worldwide, there are a variety of interventions to increase the intake of micronutrients. It is always important to consider all possible sources of micronutrient delivery when implementing a new program. The goal is to ensure that the minimum physiological needs are met in the most cost-effective manner, while avoiding the rare circumstances when excess consumption could be harmful.

In most populations, multiple staple foods are consumed, but the total amount of calories from staple foods tends to remain constant. Thus, fortifying all staple foods at a similar and reasonable level will ensure that a rather constant level of each nutrient included is obtained each day by most of the population. Once this is achieved, it is possible that fortification of condiments, for example, will no longer be needed and could possibly be discontinued to save money.

How is iron fortification achieved?

Micronized ferric pyrophosphate performs best for rice fortification. Different types are available. Micronized and encapsulated varieties have the highest bioavailability but are much more expensive. PATH recommends the use of ferric pyrophosphate compounds having 24 to 26 percent iron, with an average particle size of 3 microns.

Why is ferric pyrophosphate used in making the Ultra Rice grains instead of other iron compounds?

Ferric pyrophosphate is now manufactured with such small particle size (and thus high surface area) that it has better bioavailability than most nonsoluble forms of iron. Soluble iron salts impart grayish or brownish coloring to the Ultra Rice grains, but ferric pyrophosphate imparts little if any color. Certain other iron salts also convey a slight taste that some consumers do not like, whereas ferric pyrophosphate has no taste.

Production and micronutrient losses

What is the overall production loss?

Production losses (yield losses) are on average 2 to 3 percent, which are typical for a pasta extruding operation.

What are the main causes of micronutrient losses?

The reasons for and degree of micronutrient losses vary. Degradation can be caused in varying degrees by contact with ultraviolet light, oxygen, temperature, and humidity, but will vary according to the type of nutrient, the compounds added to the Ultra Rice grains, and the interaction of various nutrients with each other as well with the environment.

How are these micronutrient losses handled?

Micronutrient losses are minimal in the Ultra Rice production process and are compensated for by adding appropriate overages. PATH will work with each commercial partner to decide on the

optimal micronutrient overages needed based on processing, environmental, and food preparation conditions.

Manufacturing process

What steps are involved in the Ultra Rice production process?

The commercial manufacturing process for producing the Ultra Rice grains is separated into two major steps: (1) a "batching" step, where dry ingredients are weighed and blended with the rice flour carrier, and (2) a "dough-making" step, where this dry-blend is accurately combined with an oil blend and with water. The first step is not continuous and can be performed at a location remote from the dough-making step as long as transport and storage times are not longer than a few days. Where large-volume production is needed, both steps can be carried out on a continuous basis.

Just prior to extruding, the three major components (dry-blend, oil-blend, and water) are accurately metered and combined. The oil phase is pre-blended in a steam kettle to melt the fat-soluble antioxidants included in the formulation.

At this step, component metering is critical because the total component flow rate must be varied as the extruder is started and balanced, while the ratio of the three components (dry-blend, oil-blend, and water) remains constant. Metering devices are optimized for each component.

The dough is extruded at about 35 percent moisture through a rice-grain–shaped die, cut with a rotary knife, and passed through a pre-dryer where surface moisture is removed. The still-moist, but separated, extruded grains are passed through a rotating spray-drum, where a solution of calcium chloride is sprayed on the grains' surface. This salt serves as a gelling agent when it reacts with a sodium alginate binder included in the dry-blend. This forms a structure that, after drying, will not dissolve into starch when it is placed in water.

The drying process needs to be gradual, passing through two additional drying units, until the moisture level is equalized at about 12 percent moisture.

What quality control measures are used?

Quality control measures—developed locally for operations specific to each setting—will include:

- Ingredient specifications and ordering procedures.
- Proper and calibrated scales and check weights for ingredient measurement.
- Proper and controlled component and ingredient inventory storage.
- Mixing and batch records.
- In-process metering accuracy and calibration.
- Sampling for moisture determinations.
- Analysis for micronutrient concentrations.
- Sanitation and hygiene.

What specific equipment will be needed?

Major equipment needed for manufacturing the Ultra Rice grains that is not part of a typical extrusion set-up would include:

- Precise weighing and dry-blending equipment.
- Steam-jacketed oil-blending and metering equipment.
- Dry-blend metering equipment.
- Rotating spray-drum and metering pump and holding tank for calcium salt solution application.
- A blending/mixing system to ensure that the required blend ratio of Ultra Rice grains to rice is maintained at or before the final packing operation.

Where can the needed equipment be found?

All necessary equipment components should be available locally in most countries. Off-the-shelf items may be more expensive than similar systems fabricated locally. PATH's technical staff will work with commercial partners on appropriate and economical equipment procurement.

What capital investment is required to use the Ultra Rice technology?

Depending upon the proportion of new, leased, and locally fabricated equipment employed, and the capacity needed, a total capital investment of US$50,000 to $300,000 can be anticipated.

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