Golden Rice is safe to eat, says FDA

Golden Rice, the staple food genetically designed to contain beta carotene, a precursor to vitamin A, has been judged safe to eat by the US Food and Drug Administration (FDA). A letter from the FDA on May 24 stated that the agency had no further questions about the safety of the rice, originally developed to provide a rich source of vitamin A for children whose diets are deficient in this nutrient.

The rice has now been declared safe in four countries, including Australia, New Zealand and Canada. None of these decisions, including the FDA's, is a formal approval, but rather the local regulators reviewed data submitted by the Philippines-based International Rice Research Institute (IRRI) and declared they had no further questions about the rice's safety. Many, however, will see this latest move from the US agency as a stamp of approval, says Jennifer Kuzma, who studies attitudes to genetic engineering at North Carolina State University in Raleigh. And the regulators' positive opinion will be incorporated into the Organisation for Economic Co-operation and Development's consensus documents on biosafety, which other countries consult to help guide their own decisions on food safety.

Although the US has no plans to grow or import the rice, the FDA's decision is still important, says Kuzma. "Other countries often look to the FDA as the first mover," she says. And it will protect against legal issues and help defuse any controversy should imports of regular rice ever become accidentally contaminated with Golden Rice.

Golden Rice was created in response to a major nutritional crisis affecting some of the poorest countries in the world. But because it is genetically modified (GM), the beta-carotene-enriched crop has struggled to overcome public fears over genetically modified organisms (*Nat. Biotechnol.* **30**, 1017–1019, 2012). Opposition has been fierce throughout, even though the Golden Rice Project has a humanitarian board that included the crop's creators, and set out to make the nutritionally enriched rice available to low-income farmers and researchers throughout the developing world. The hope is that now, with the FDA's endorsement and other approvals, regulators in countries like Bangladesh and the Philippines, which are in the process of considering applications, will be emboldened to allow large-scale cultivation of the rice.

Work on Golden Rice began in the late 1990s by plant scientist Ingo Potrykus at the Swiss Federal Institute of Technology in Zurich, and biochemist Peter Beyer, at the University of Freiburg in Germany, as a way to combat vitamin A deficiency in the developing world. The technology, first reported in 2000 (*Science* **287**, 303–305, 2000) and later in 2005 (*Nat. Biotechnol.* **23**, 482–487, 2005), consists of inserting genes that control the biosynthetic pathway for beta carotene, a precursor to vitamin A, into rice. Initially, Potrykus and Beyer added two genes to the plant—a phytoene synthase from daffodils and a phytoene desaturase from a common soil bacteria—to turn on the beta-carotene-synthesis pathway in the grains. The beta-carotene-rich grains turned a deep golden color, giving the rice its name.

Vitamin A deficiency affects 250 million children, causing blindness in an estimated 250,000–500,000 children each year. This nutrient deficiency also compromises the immune system, leading to death from common childhood diseases like measles or diarrhea. By improving access to vitamin A, the enriched crop could prevent around 1–2 million childhood deaths each year, says Adrian Dubock,

David Greedy/Getty Images

It's been a bumpy road for Golden Rice, but now four countries have given it a green light.

First migraine-prevention antibody approved

On May 17, the US Food and Drug Administration approved a first-in-class monoclonal antibody drug to prevent migraine headache. Amgen's Aimovig (erenumab) is the first biologic drug to target the calcitonin-gene-related peptide (CGRP) receptor. CGRP signaling contributes to migraine pain, by inducing blood vessel dilation and pain sensitization on the trigeminal ganglion, outside the central nervous system. The antibodies act to prevent migraine pain by blocking CGRP. Unlike existing small-molecule CGRP antagonists used to treat acute migraine episodes, direct targeting of the peptide or its receptor with a monoclonal antibody is more specific, with few or no apparent adverse effects, and can be used as prevention (*Nat. Biotechnol.* **36**, 207–208, 2018). In phase 2 and 3 studies in chronic and episodic migraine, Aimovig significantly reduced monthly migraine days and use of acute migraine medications compared with placebo. In an ongoing open-label extension study in episodic migraine (4–14 headache days per month), these effects were sustained for up to 15 months. Also, a dedicated phase 3b study (LIBERTY) in individuals with episodic migraine who had failed two to four prior treatments showed that those taking Aimovig had nearly threefold higher probability of cutting their migraine days by half or more compared with placebo. Anticipating a crowded field for CGRP biologics, Amgen set Aimovig's price at $6,900 per year—considerably lower than analysts' expectations. Other monoclonal antibodies targeting the CGRP pathway in late-stage development include Petach Tikva, Israel–based Teva Pharmaceuticals' eptinezumab, Alder Biopharmaceuticals' fremanezumab and Eli Lilly's galcanezumab. Unlike Aimovig, these antibodies target the peptide itself. Amgen is partnering with Novartis to co-commercialize Aimovig in the US. In the deal, the Basel-based pharma also gained exclusive commercialization rights to the drug in Europe, Canada and elsewhere. Following on the heels of the US approval, on June 1, the European Medicines Agency's Committee for Medicinal Products for Human Use recommended granting a marketing authorization for Aimovig.

"[The thrill] is tainted with the knowledge that people are sick and dying. I think that tempers the excitement, because there's a reality that accompanies that that's very, very sad." Nancy Sullivan of the NIH Vaccine Research Center expresses mixed feelings about the start of a long-awaited vaccine trial with the recent Ebola outbreak in the Democratic Republic of the Congo. (*STAT*, 22 May 2018)