Vitamin A deficiency remains a critical nutrition issue in many developing countries where the majority of the population may be overly dependent on single staple crops, such as rice, for most energy and nutrition needs. Globally, approximately 670,000 children die every year and another 350,000 children go blind because of the deficiency. Southeast Asia has the highest number of people suffering from vitamin A deficiency.

From an idea 27 years ago, to the first technical success 12 years ago, the development of Golden Rice, in which a transgenic approach has been used to produce beta carotene (the vitamin A precursor) in the portion of the rice grain most often eaten, has gone through a number of subsequent stages: the multiyear, multi-institution research aimed at raising the level of beta carotene from the breakthrough level to a level that could have a more important contribution to dietary needs; the screening of the leading events, especially after 2006, for stability and performance in a wide range of rice varieties for Asia; the selection of the final event; and the preparation for the advanced regulatory phase of the project. The final event was also chosen so as to minimize complexity in the regulatory phase.

In some respects, in the preparation for the advanced regulatory phase, Golden Rice benefits from some precedents: the regulatory approval of rice with GM or novel traits in the US, Canada, and China; the contemporaneous development of other GM traits in rice and other food crops, and especially in the early countries targeted; the growing experience of regulators and the transparency of the processes for the assessments of the food, feed, and environmental safety of GM crops and foods in these same countries, and an alignment of stated official policy to use modern biotechnology prudently for the improvement of agriculture and of the processes established to enable the development and adoption of GM crops and products. An embodiment of these processes includes the openness to dialog by regulators and to the early determination of the data requirements that the regulators need to conduct the appropriate safety assessment of the crop and food. A familiarity and participation in the OECD Novel Foods proceedings and of the rice consensus documents has also been a benefit. The adoption of procedures following the guidance provided by Annex 2 (nutritionally enhanced crops and food) to the Codex Guidelines has also provided clarity in assessment planning. These latter areas, based on international guidelines, also provide support for the review by second countries of the data produced in others.