

## **GMO-TECHNOLOGY AND MALNUTRITION – PUBLIC SECTOR RESPONSIBILITY AND FAILURE**

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### **Summary**

The message of this paper is based on six years of experience from the Humanitarian Golden Rice project, whose aim it is to transfer the benefits of a scientific break-through to the needy in developing countries. Golden Rice could substantially reduce vitamin A malnutrition in rice-based societies, but can not yet do so, because its deployment is severely delayed by the requirements imposed by ‘extreme precautionary regulation’. Other ‘Golden’ food security GM crops are in the pipeline and multi-trait nutritional optimisation is the next task. But product development and deregulation will again be blocked, leading to millions of avoidable deaths. ‘Extreme precautionary regulation’ is unjustified, irrational, and an opportunistic response to extreme pressure groups. The benefits of GMO technology will become available for food security and poverty alleviation only if regulations are changed from the present ‘extreme precautionary attitude’ to science-based ‘rational regulations’, and if these regulations are applied with ‘common sense’, not ideological attitude. There is no scientific justification for specific GMO regulation. To support future food and environmental safety, regulation should focus on ‘traits’ not ‘technologies’.

### **1. Micronutrient malnutrition**

Micronutrient malnutrition is the source of severe medical problems in developing countries. Of the 24’000 deaths per day attributed to this problem, probably 6’000 are due to vitamin A malnutrition. Traditional interventions do not reach the majority of the

needy and, therefore, alternative interventions are required. Biofortification – improvement of the micronutrient content of crops on a genetic basis - has been recognized as a cost-effective, sustainable, complementary intervention. Golden Rice represents the first case of GM-based biofortification. In Golden Rice genes have been introduced to activate the biochemical pathway leading to the synthesis and accumulation of carotenoids (pro-vitamin A) in the rice endosperm, the edible part of the rice seed. Scientific proof-of-concept was completed in spring 1999 (Ye et al., *Science* 287: 301-305, 2000). The motivation for this ‘scientific tour de force’ was from the onset a humanitarian one: to contribute to a reduction in vitamin A malnutrition in developing countries. The scientists involved did not expect that transferring the benefits of the scientific breakthrough to the needy would constitute such a complex and time-consuming task (see also– *Genetic engineering of plants*). And in view of the problem it is difficult to accept that it is taking at least ten years, to deliver a deregulated product.

Golden Rice was moved into the political limelight as an example of what benefits consumers could expect from the new technology, but also as the favourite target of the GMO-opposition, which was disturbed by the positive response, and which fought the case for its potential as a “Trojan horse”, opening the ground for acceptance of the technology (see also– *Why genetic modification arouses concern*). Their claim that Golden Rice was ‘Fools’ Gold’ because children would have to eat up to 9 kg per day became a politically very effective counter-strategy. Although this claim was never true, it had a pronounced negative effect on the media, the public, and governmental agencies. Meanwhile, lines have been developed and are available to the Humanitarian project, where ca. 70g per day would provide the recommended daily allowance of vitamin A

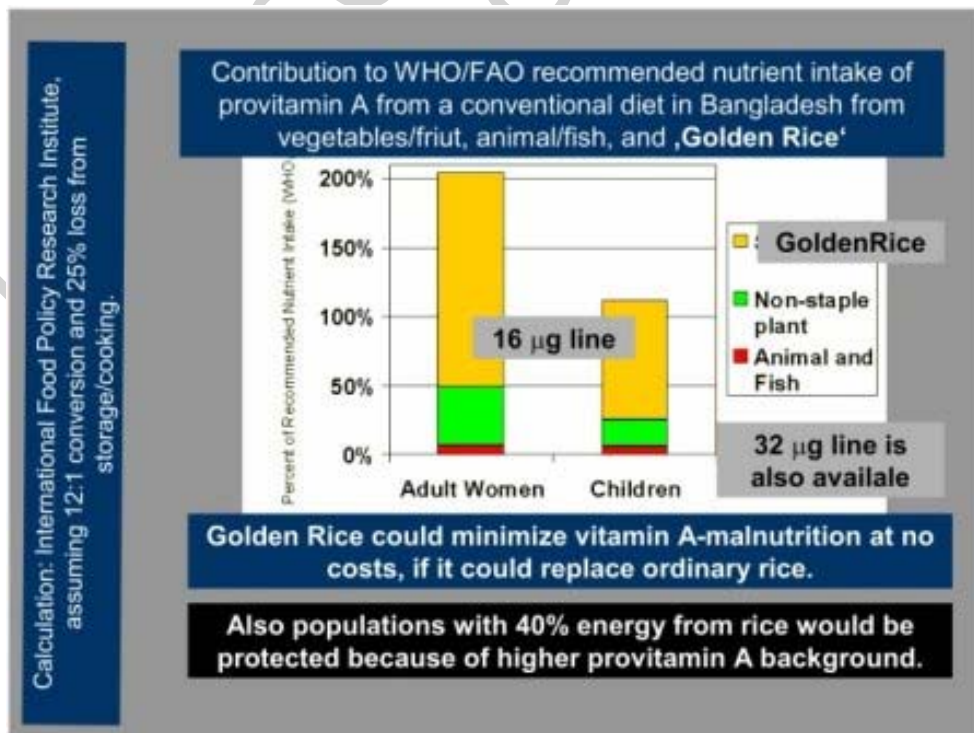


Figure 1: WHO/FAO recommended nutrient intake of pro-vitamin A

The above calculation is based on a 16 µg/g line, but lines with more than 32 µg/g are now available. With these lines the GMO opposition has definitely lost its last argument against Golden Rice and, hopefully, will finally accept that GMO technology can be used to the benefit of the poor. For its potential, Golden Rice should be made available to the poor as fast as possible, but under the present regulatory regime this is a very time-consuming and expensive task. The inventors of Golden Rice realized soon that the public domain was not in the position to carry Golden Rice successfully through the process of product development and deregulation, and it was a fortunate coincidence that the private sector, the companies Zeneca and subsequently Syngenta, were ready to support the humanitarian project in exchange for commercial rights in the invention. This ‘Public-Private-Partnership’ (see also– *The Public-Private Debate in Agricultural Biotechnology and the IPR Regime*) was instrumental for the entire further process, including organization of free licences for involved intellectual property rights. Over the years, it became more and more obvious that under the present regulatory regimes, public humanitarian projects, such as Golden Rice, will fail if not supported by the private sector. The public sector has little expertise and experience in and no financial resources for product development; but the almost insurmountable hurdle is the extremely complex, time-consuming, and expensive process of deregulation, which has ‘evolved’ to such a level, that only large and financially strong companies can cope with it. The effect is that public R&D can at best compete in basic research, but is cut off from product development and release of public GMOs into the marketplace.

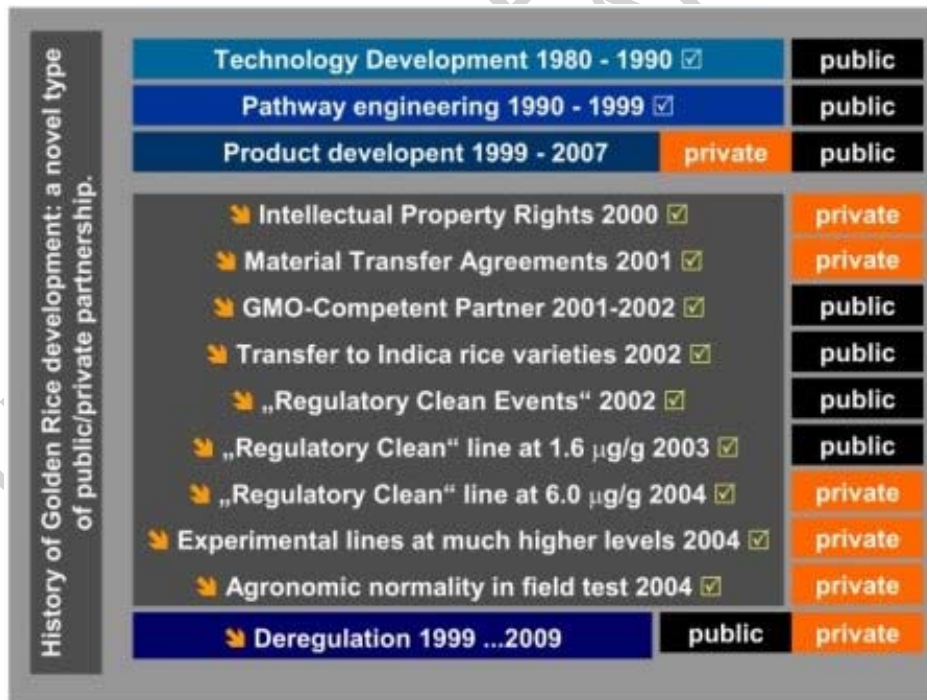


Figure 2: History of Golden Rice Development

This is a very serious consequence, because it affects virtually all possible public contributions to solutions of humanitarian problems (see also– *Health and Genetic Engineering*; – *The regulation of genetically modified food*). And it is the public domain which is responsible for solving humanitarian problems. This responsibility can not be

delegated to the private sector, which is dependent upon commercial success. The progress achieved with the humanitarian Golden Rice project was possible only because a successful Public-Private-Partnership could be established between the inventors of the Golden Rice technology and the Syngenta company.

## **2. Cost-effective and sustained production of nutritious food**

The great advantage of GMO seeds is the fact that the entire technology is embedded in the seed (see also –*Genetic engineering of plants; –Transgenic Plants*). Looking at the potential of one Golden Rice seed, we realize that each seed can produce 20'000 metric tons of Golden Rice within two years (1 seed grows into a plant with 1'000 seeds or 20 g; the next generation will arrive at 20 kg; the next at 20 t and the next at 20'000). 20'000 t of rice are sufficient to feed 100'000 people for one year which, if in the case of Golden Rice will also protect them from vitamin A deficiency. All a farmer needs to benefit from this technology is one seed. He needs no additional agrochemicals or pesticides nor novel farming systems. He may use part of his harvest for the next sowing. No new dependencies are created. Furthermore, the technology is free up to a yearly income of USD 10'000 per farmer or local trader per year. World Bank Policy Research Working Paper no. 3380, from August 2004 carrying the title 'Genetically Modified Rice Adoption: Impact for Welfare and Poverty Alleviation' by K Anderson, LA Jackson, and CP Nielson concludes that impressive benefits might be accrued for countries adopting the technology. The paper uses the 'global economy-wide computable general equilibrium model' to analyse the potential economic effects of adopting first and second generation GMO crops in Asia. Two citations from the abstract: 'The results suggest that farm productivity gains could be dwarfed by the welfare gains resulting from the potential health-enhancing attributes of Golden Rice.' 'Projected gains from Golden Rice adoption by developing Asia would amount to USD 15.2 billion.' But extreme precautionary regulation, so far, prevents use of the technology.

'Extreme precautionary regulation' has been adopted world wide and is, to date, widely accepted, and international organizations are helping to introduce it into numerous developing countries (see also– *Why genetic modification arouses concern*). In the context of the Humanitarian Golden Rice project the experience is that this approach delays product development and deregulation by at least six years, and consequently the question should be asked: "Is GMO over-regulation costing lives?" The following, straightforward calculation arrives at a shocking answer: If Golden Rice would not have been a GMO (which is not possible, because production of provitamin A in rice endosperm is only possible via genetic engineering), breeders would have been able to develop varieties by 2002 (e.g. seven backcrossing generations into IR64) and farmers could have started using Golden Rice from 2003 on. Because of GMO regulation Golden Rice will not reach the farmer before 2009 – with at least 6 years of delay. Every day 6'000 children die from vitamin A deficiency; probably half of those (3'000) from rice-dependent vitamin A deficiency. Assuming only a 1 percent Golden Rice adoption (far higher values are probably more realistic), 65'700 GMO regulation caused deaths could be prevented (30X365X6). How can our society tolerate 65'700 avoidable deaths, by supporting an 'extreme precautionary regulation' approach?

### 3. Why do we have GMO regulations?

We have GMO regulations for historic reasons: At the beginning of GMO technology development the scientists themselves established regulations and it was sensible to be ‘precautious’ during the early phases of technology development. The main argument was, and still is, that the technology could lead to unpredictable and uncontrolled alterations in the genome of the experimental organism (see also– *The regulation of genetically modified food; – Why genetic modification arouses concern*). This was and still is true. However, experience from more than 20 years of deregulation, from thousands of ‘biosafety’ experiments and from experiments performed to satisfy the requirements of hundreds of dossiers for deregulation, from release of GM plants into the environment on over 90 million hectares, and from deliberations of several academies and numerous publications we know nowadays that there is no technology-specific risk which did not exist before as the consequence of traditional plant breeding (see also –*Plant Breeding and Molecular Farming; – Conventional Plant Breeding for Higher Yields and Pest Resistance*), and for which we have ample of experience to control it, if necessary. Why then do we maintain ‘extreme precautionary regulation’? The argument is, that this regulation is mandatory to build trust for acceptance by consumers. Experience has widely demonstrated that this does not work, and that is not surprising: How can an unbiased citizen trust a technology which is so tightly regulated. If something is regulated in the way that GMOs are, the conclusion is that it must be dangerous! And how do we continue to justify ‘extreme precautionary regulation’? It is stated that it can not be excluded with 100 percent certainty that unintended alterations of the genome may have adverse effects which may even show up only in evolutionary time scales (how is it possible to relate this argument of an imaginary, potential adverse effect on an evolutionary time scale with the 65’700 regulation-caused deaths!). Above all, this argument applies to all our crop plants, which have been developed using traditional plant breeding techniques, and which we have been consuming for ages without any regulation – and without ‘adverse effects’. So, where is the argument which justifies maintenance of ‘extreme precautionary regulation’?

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#### **Important websites**

[www.goldenrice.org](http://www.goldenrice.org)

[www.fao.org/waicent/faoinfo/economic/esn/codex/default.html](http://www.fao.org/waicent/faoinfo/economic/esn/codex/default.html)

[www.vm.cfsan.fda.gov/list.html](http://www.vm.cfsan.fda.gov/list.html)

[www.nationalacademies.org/nrc/](http://www.nationalacademies.org/nrc/)

[www.fao.org/ag/cgrfa/default.html](http://www.fao.org/ag/cgrfa/default.html)

[www.fao.org/biotech/forum.html](http://www.fao.org/biotech/forum.html)

[www.aphis.usda.gov/ppq/biotech/](http://www.aphis.usda.gov/ppq/biotech/)

[www.who.int/](http://www.who.int/)

[www.fsis.usda.gov/](http://www.fsis.usda.gov/)

[www.ific.org](http://www.ific.org)

[www.agbioworld.org/](http://www.agbioworld.org/)

[www.croplife.org](http://www.croplife.org)

[www.foodfuture.org.uk/index.html](http://www.foodfuture.org.uk/index.html)

[www.osu.orst.edu/food-resource/index.html](http://www.osu.orst.edu/food-resource/index.html)

[www.centreforfoodsafety.org/](http://www.centreforfoodsafety.org/)

[www.foodsafety.gov/](http://www.foodsafety.gov/)

[www.foodstandards.gov.uk/](http://www.foodstandards.gov.uk/)

[www.africabio.com](http://www.africabio.com) (the source for the above websites).

#### **Biographical Sketch**

Career: PhD in Plant Genetics 1968 at Max-Planck-Institute for Plant Breeding Research, Cologne, Germany; Ass. Professor, Institute of Plant Physiology, Stuttgart-Hohenheim 1970-74. Research Group Leader, Max-Planck-Institute for Genetics, Ladenburg-Heidelberg 1974-76; Research Group Leader, Friedrich Miescher-Institute, Basel, Switzerland 1976-86; Full Professor in Plant Sciences, Swiss Federal Institute of Technology (ETH), Zuerich 1986-99.

Science: Contributions to food security in developing countries. Focusing on development and application of genetic engineering technology for and to "food security" crops such as rice (*Oryza sativa*), wheat (*Triticum aestivum*), sorghum (*Sorghum bicolor*), and cassava (*Manihot esculenta*). Focusing on problems areas of disease- and pest resistance, improved food quality, improved yield, improved exploitation of natural resources, and improved bio-safety. Inventor of "Golden Rice" and chairman of Humanitarian Golden Rice Board and Network. Ca 340 publications in peer-reviewed journals; 30 patents.

Distinctions: KUMHO (ISPMB) Science International Award in Plant Molecular Biology and Biotechnology 2000. American Society of Plant Biologists (ASPB) Leadership in Science Public Service Award 2001. Crop Science of America (CSSA) Klepper Endowment Lectureship 2001, CSSA President's Award 2002, European Culture Award in Science 2002, Honorary Doctor, Swedish University of

Agricultural Sciences 2002, University of Freiburg, Germany 2007.

“Top100 living contributor to biotechnology”, elected by the peers of the journal “Scientist” in 2005.  
“The most influential scientist” in the area of Agricultural, Industrial, and Environmental Biotechnology for the decade 1995-2005, elected by the peers of Nature Biotechnology 2006. Cover TIME Magazine July 31, 2000. Elected to Academia Europaea, Pontifical Academy of Sciences, Hungarian Academy of Sciences, Swiss Academy of Technical Sciences,

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