

bioVISION 2005


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Is GMO over-regulation costing lives?

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GMO over-regulation is unjustified, it is blocking product development in public goods R&D, thus preventing solutions for humanitarian problems, and it is costing millions of lives.




In 'Golden Rice' genes have been activated to provide provitamin A in the polished grain to reduce vitamin A deficiency in rice-based populations which cannot afford a diversified diet and which are out of reach for vitamin A distribution programs.

The genes introduced lead to synthesis and accumulation of provitamin A, which becomes visible as the 'golden colour' of the polished grain.

'Biofortification' – genetic improvement of the micronutrient content of crops – can reduce malnutrition in a cost-effective and sustained manner.

Polished normal rice

Polished Golden Rice



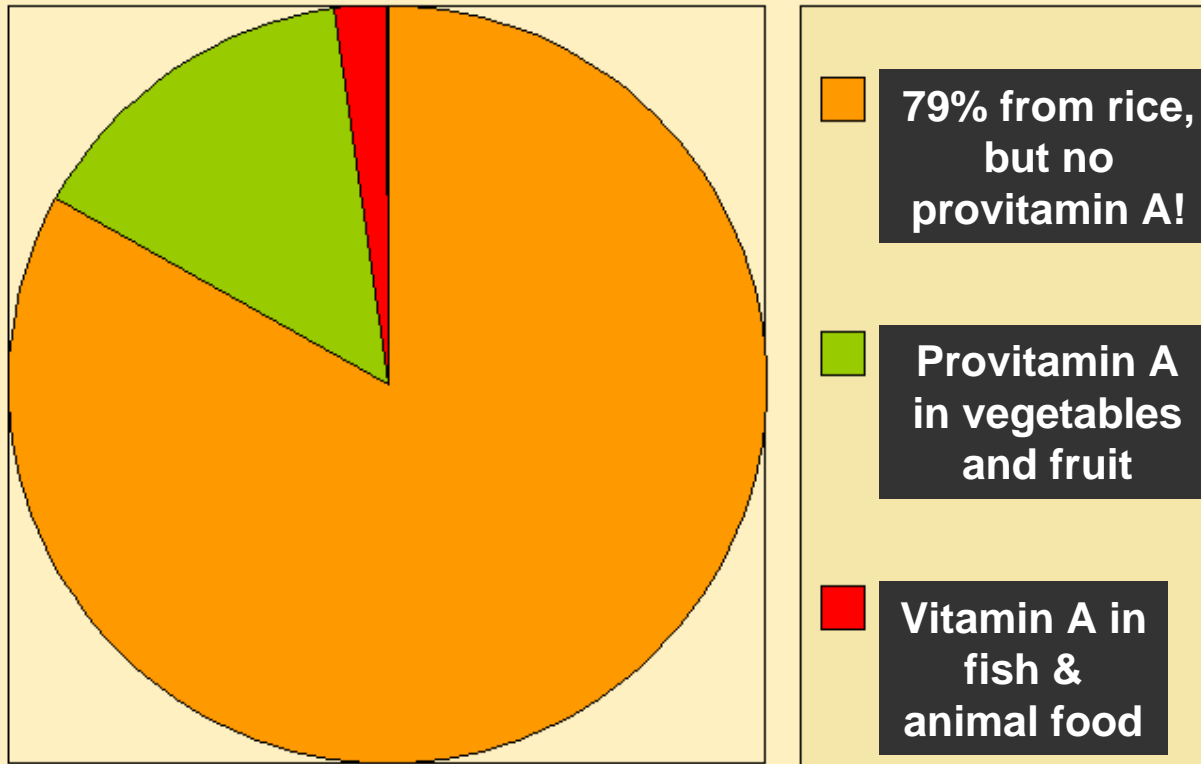
Golden Rice has been called 'Fools' Gold' because children would have to eat 9 kg per day.

How much Golden Rice has a child to eat to prevent vitamin A malnutrition?

Amount depends upon a typical diet. Example Bangladesh.

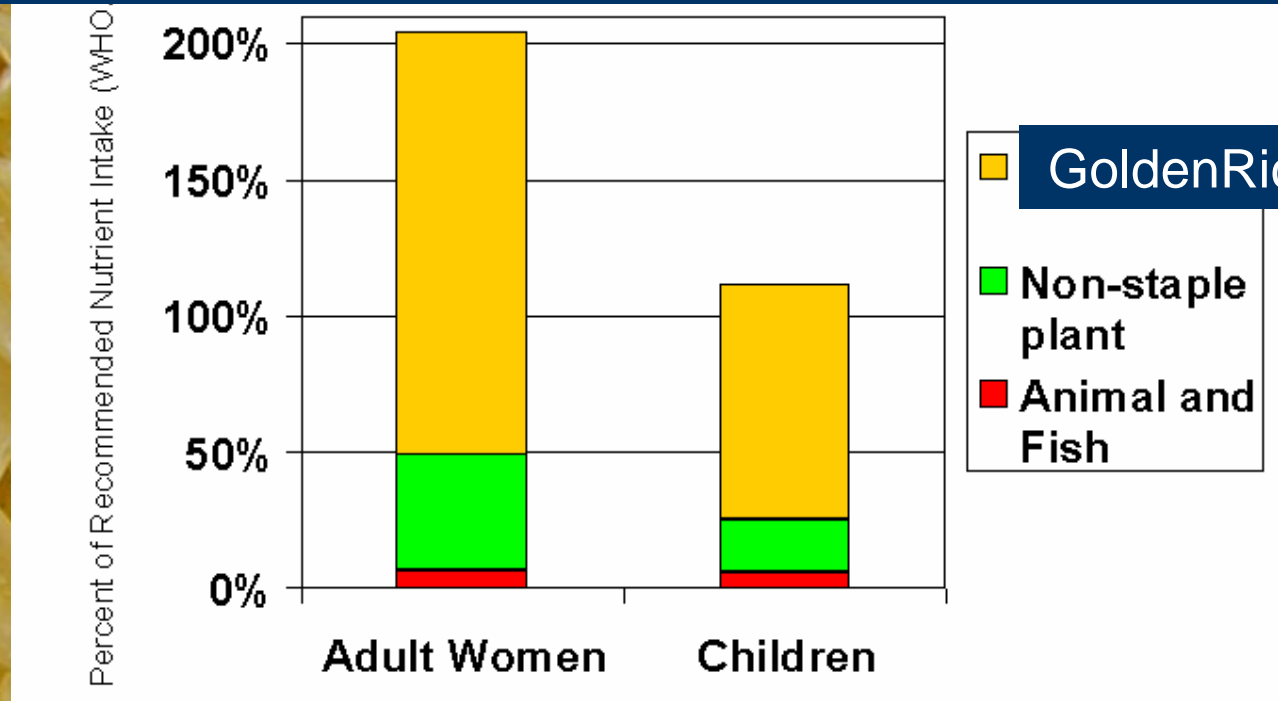
Calculation by the International Food Policy Research Institute

Share of calories intake for rural Bangladesh:



Average energy intake from rice in Southeast Asia: 40%

Contribution to WHO/FAO recommended nutrient intake of provitamin A from a conventional diet in Bangladesh from vegetables/fruit, animal/fish, and Golden Rice



Golden Rice could eradicate vitamin A malnutrition by replacing ordinary rice.

Also populations with 40% energy from rice would be protected because of higher provitamin A background.

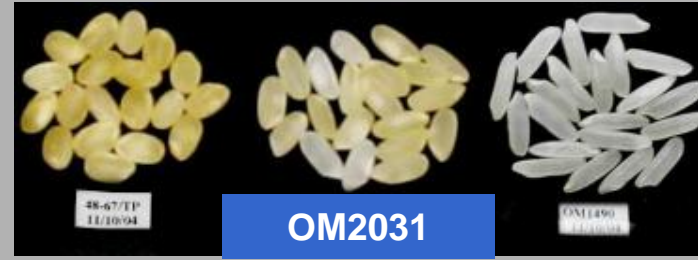
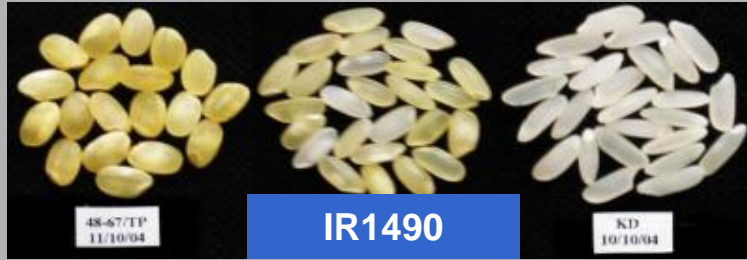


The first Golden Rice field trial (Louisiana) did not indicate any agronomic or ecological problem; provitamin A content was even higher than in the greenhouse, and taste trials were positive.

Similar field tests will follow in India and the Philippines this year.

The 'GoldenRice' trait has been transferred into numerous Southeast Asian rice varieties including 'high iron'- 'aromatic'- 'grain quality' varieties.

Tran Thi Cuc Hoa, Cuu Long Delta Rice Research Institute, Can Tho, Vietnam.



The Golden Rice trait expresses in each of the popular, agronomically valuable varieties!



Golden Rice would be ready to substantially reduce deaths and blindness caused by vitamin A deficiency in rice-dependent poor societies, but it cannot help, so far, because of its GMO nature!



The potential of one Golden Rice seed:

1 seed ➤ 1 plant ➤ 1 000 seeds / 20 g

**In two
years**

➤ 1 000 000 seeds / 20 kg

➤ 1 000 000 000 seeds / 20 t

➤ 1 000 000 000 000 seeds / 20 000 t

All a farmer needs to benefit from this technology is one seed. He doesn't need additional agrochemicals nor pesticides, novel farming system or seed. He may use part of his harvest for the next sowing period. No new dependencies are created. The technology is free up to a yearly income from rice of \$ 10'000 per farmer or local trader.

Each seed has the potential to produce within two years food for 100'000 poor; and it carries the technology to reduce vitamin A malnutrition in a cost-effective, sustained manner.

Cost-effective and sustained production of nutritious food.

GMO Regulation, so far, prevents use of this technology by the farmer.

“Is GMO over-regulation costing lives?”

- e.g. in conjunction with Golden Rice, which exists since 1999.
- If not a GMO, breeders would have developed varieties by 2002, and farmers could have used them from 2003 on.
- It could prevent vit A malnutrition on the basis of a normal diet.
- Because of GMO regulations Golden Rice will not reach the farmer before 2009 - with at least 6 years of delay.
- Every day 6'000 die from vitamin A deficiency, probably more than 50% from rice-dependent vit A deficiency.
- Even with only 1% Golden Rice usage, 65'700 GMO regulation-caused deaths could be preventable in 6 years (30X365X6).
- How can our society justify 65'700 avoidable dead children?

So, what justifies 'extreme precautionary regulation' ?

Why do we have a GMO regulation?

History: precaution was sensible at the beginning of technology development. Key argument: the technology leads to 'unpredictable genome alterations'.

Experience from 20 years of deregulation, biosafety research, and knowledge from basic biology and plant breeding prove no specific risks associated with GMOs.

Why do we maintain 'extreme precautionary' regulation?

'To built trust for acceptance of GMOs.'

Experience: This does not and cannot work.

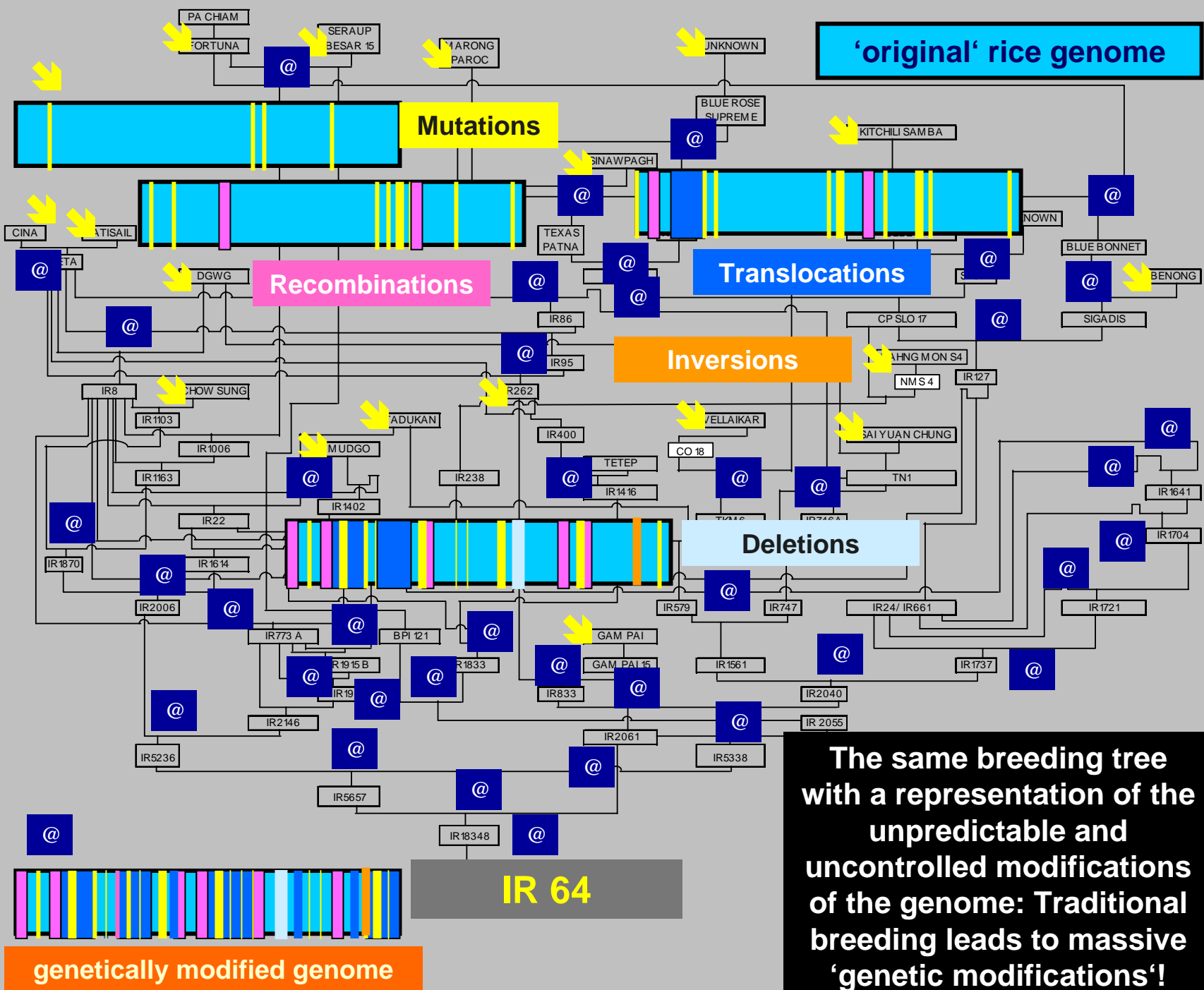
How do we justify 'extreme precautionary' regulation?

'It cannot be excluded with 100% certainty that unintended alterations of the GMO genome may have adverse effects.'

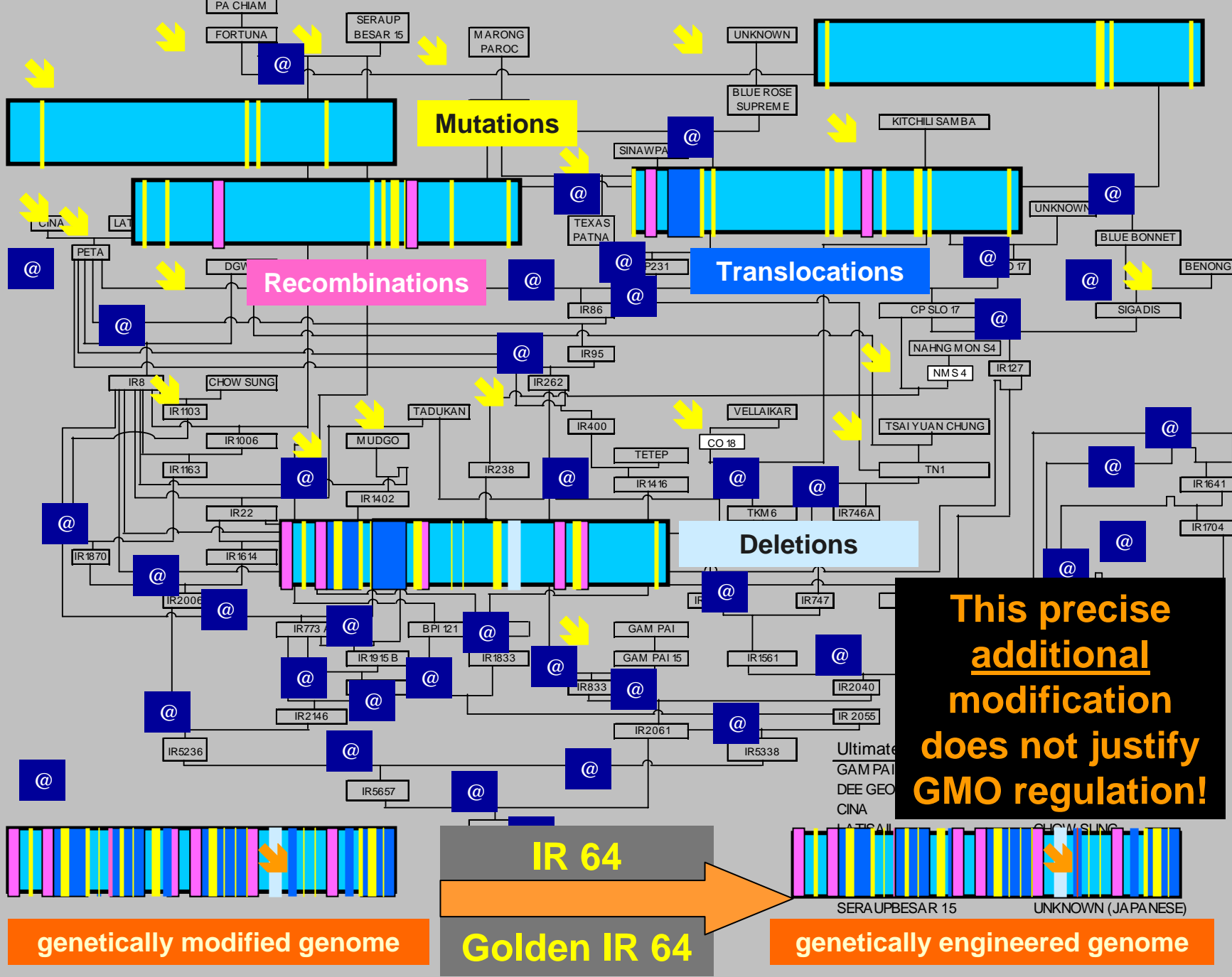
This applies to all our traditionally bred crop plants as well, which we consume without any regulation.

What then justifies the deaths of so many children?

The genome of each variety of every crop plant is highly 'genetically modified' – and unregulated!



Golden IR64 differs from IR64 by a relatively tiny, carefully studied, precisely described recombination.



This precise additional modification does not justify GMO regulation!

genetically modified genome

IR 64
Golden IR 64

genetically engineered genome

Ultimate
GAM PAI
DEE GEO
CINA
LATSAI

SERA UPBESAR 15 UNKNOWN (JAPANESE)

The previous 3 slides have shown that there is no scientific basis for specific GMO regulation.

This is confirmed by (a) all biosafety research, (b) all results of regulatory review, and (c) numerous publications of independent scientific academies/public institutions.

Therefore, it does not make sense to maintain the present 'extreme precautionary' GMO regulation - even if it were not costing lives.

Our society has the duty of establishing rational regulation, including evaluation of benefits and its application using common sense.

Present regulatory regimes ignore benefits, are obsessed with hypothetical risks, and are an opportunistic response to anti-GMO activists!

What could be considered 'rational' regulation?

What is novel? e.g. carotenoids in the endosperm.

Any possible negative effects on the environment?

No, because no basis for any selective advantage.

Therefore, no restriction for growth in the field.

Any possible effects for the consumer?

Positive: reduction of vitamin A deficiency.

Therefore, apply as soon as possible.

Negative? Any unintended products?

No, activation of the natural pathway with not a single novel product (Schaub et al. Plant Physiology 2005).

Therefore, immediate and unrestricted development and registration of locally adapted varieties.

Regulate the trait, not the technology, and use common sense!



Instead of 'rational' regulation, the Convention on Biodiversity has spawned a bureaucratic, legalistic, unscientific regulatory process which is interpreted so as to ignore benefits, and is obsessed with hypothetical risks.

Let common sense prevail, not political pressure!

www.goldenrice.org

Food-Related Illness and Death in the United States 2002.

P.S.Mead et al., Centers for Disease Control and Prevention, Atlanta, Georgia, USA

Known Pathogens Non-Gastroenterit.	Known Pathogens Acute Gastroenter.	Unknown Agents Acute Gastroenter.	GMO-derived Health Problems ?
Illness 120 000	Illness 14 000 000	Illness 62 000 000	Illness 0
Hospitalization 5 000	Hospitalization 55 000	Hospitalization 263 000	Hospitalization 0
Deaths 900	Deaths 900	Deaths 3 400	Deaths 0
Total Illness 76 000 000	Total Hospitalizat. 323 000	Total Deaths 5 200	Total GMO-derived 0

The trend towards organic food, not GMOs, enhances the problem.

Deregulation → → →

Exposure evaluation

- Modelling analysis for intended use.
- Bioavailability studies.

Protein production and equivalence

- Extraction from GMO plant or heterologous source
 - Biochemical characterisation
 - Function/ specificity/ mode of action.

Protein evaluation

- No homology with toxins and allergens.
- Rapid degradation in gastric /intestinal studies.
 - Heat lability
- No indication of acute toxicity in rodents.
- Further allergenicity assessments (Daffodil!)

Event independent studies

Molecular characterization and genetic stability

- ↘ Single-copy effect; marker gene at same locus.
- ↘ Simple integration; Mendelian inheritance over three generations (minimum).
 - ↘ No potential gene disruption.
 - ↘ No unknown open reading frames.
 - ↘ No DNA transfer beyond borders.
- ↘ No antibiotic resistance gene or origin of replication.
 - ↘ Insert limited to the minimum necessary.
 - ↘ Insert plus flanking plant genome sequenced.
- ↘ Phenotypic evidence for stability over 3 generations
 - ↘ Biochemical evidence for stability.
 - ↘ Unique DNA identifier for traceability/detection.

Expression profiling

- ➡ Gene expression levels at key growth stages.
- ➡ Evidence for seed-specific expression.

Phenotype analysis

- ➡ Field performance, typical agronomic traits -yield- compared to isogenic lines.
- ➡ Pest and disease status to be same as isogenic background.

Compositional analysis

- ➡ Data from 2 seasons x 6 locations x 3 reps on proximates, macro and micronutrients, antinutrients, inherent toxins and allergens. Data generated on modified and isogenic background.

Environmental risk assessment

- ➡ Minimize potential for gene flow.
- ➡ Evaluate any change in insect preference – by field survey.

GMO Product Development:

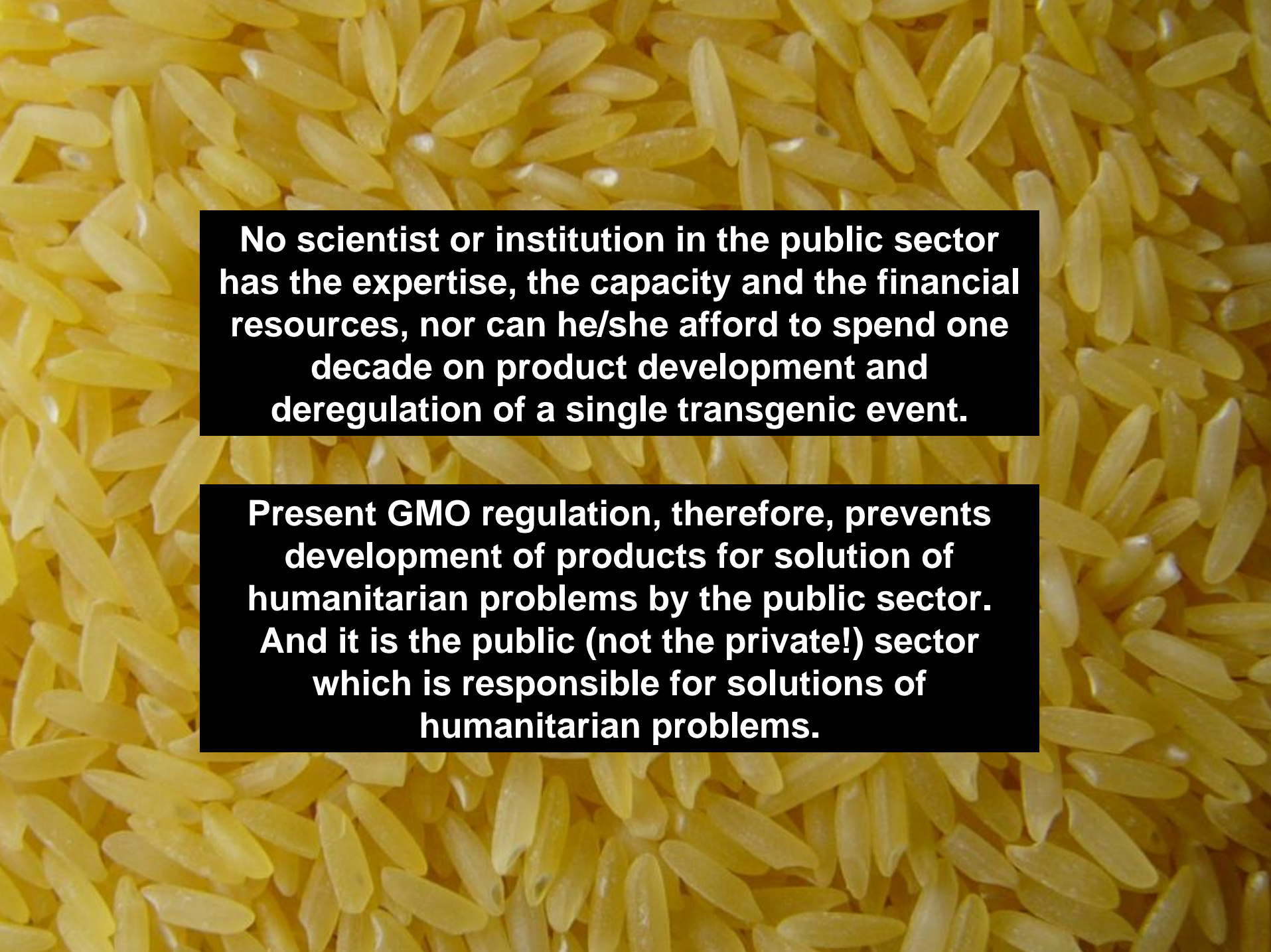
Following proof-of-concept repetition of the same experiment with “regulatory-clean“ technology, until one “regulatory-clean“ transformation event is found, to provide the basis for product development with a chance to pass through the deregulatory procedure:

4-8 years of intensive experimental work with no chance for publication, and difficult to finance!

GMO Deregulation:

Exposure evaluation, Protein production and equivalence, Protein evaluation. Molecular characterization and genetic stability, Expression profiling, Phenotype analysis, Compositional analysis, Environmental risk assessment, etc.

5 years of intensive experimental work with no chance for publication, and difficult to finance!

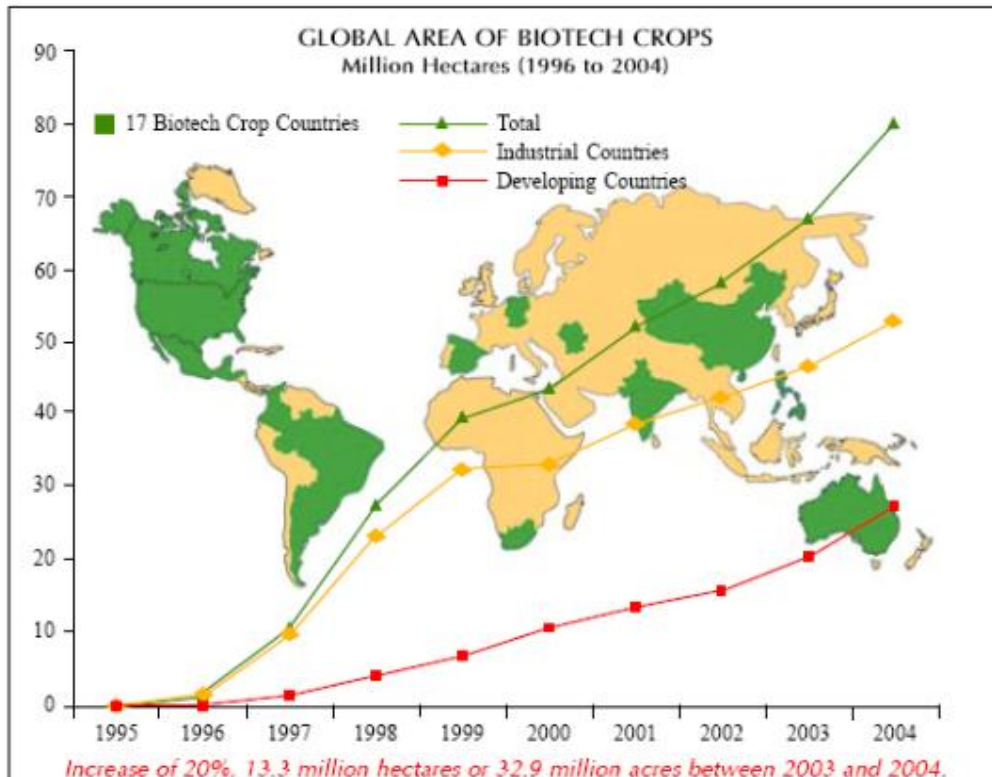
The background of the entire image is a close-up, high-resolution photograph of numerous yellow rice grains. The grains are elongated and have a slightly glossy texture, filling the frame from edge to edge. The lighting is even, highlighting the natural color and shape of the rice.

No scientist or institution in the public sector has the expertise, the capacity and the financial resources, nor can he/she afford to spend one decade on product development and deregulation of a single transgenic event.

Present GMO regulation, therefore, prevents development of products for solution of humanitarian problems by the public sector. And it is the public (not the private!) sector which is responsible for solutions of humanitarian problems.

The progress with biotech crops looks impressive, however ...

... the increase is based on only two traits and four species, all developed and deregulated by the private sector in the U.S. and subsequently adopted by developing countries (cotton, maize, soybean, canola with herbicide-tolerance and insect-resistance).



Clive James
ISAAA 2005

Novel cases from the public sector have little chance to contribute to this optimistic scenario in the near future, if present regulation is maintained.

“Is GMO over-regulation costing lives?”

There are hundreds of ‘food-security’ transformation events produced in the public domain in Egypt, Kenya, South Africa, Zimbabwe, China, India, Indonesia, Malaysia, Pakistan, Philippines, Thailand, Argentina, Brazil, Costa Rica, and Mexico,

... established in rice, maize, pearl millet, sorghum, wheat, potatoes, cassava, sweet potatoes, melons, cucumbers, squash, watermelons, tomatoes, bananas, plantain, beans, papaya, sunflower, soybean, ground nut, chickpea, oil palm, cabbage, cauliflower, cacao, mango,

... with improved agronomic performance, stress tolerance, and nutritional value, *)

... which all are faced with the same prohibitory regulation.

The number of GMO regulation- caused death will extend into the hundreds of thousands!

Golden Rice follow-up projects.

„Biofortification“- genetics-based improvement of the nutritional value of crops for sustained reduction of micronutrient malnutrition.

International, multidisciplinary.

“Grand Challenges in Global Health“

Rice

Sorghum

Cassava

Potato

Banana

“HarvestPlus“. CGIAR

Rice

Maize

Wheat

Cassava

Sweet Potato

Beans

Two international programs, using traditional and molecular techniques, are supporting the concept of “biofortification“ with support from The World Bank and the NIH-Gates Foundation.

⇒ others ?

⇒ Lipids ?

High quality protein:

Arg, His, Ile, Leu, Lys, Met, Phe, Thr, Trp, Val

⇒ Vitamin A

Vitamin E ✓

γ-Oryzanol ✓

Carotenoids: ✓

β-carotene, lutein, zeaxanthin

Iron- & Zinc Bio-availability:

Ferritin, Phytase,

“Is GMO over-regulation costing lives?”

- Iron deficiency affects 3 billion people, zinc 1 billion, essential amino acids 0,5 billion, and most suffer from multiple deficiencies.
- Scientists are developing provitamin A, high-iron, high-zinc, high-quality protein rice, sorghum, cassava, maize, banana, and combinations of these traits to nutritionally optimize ‘biofortified’ crops.
- For each single trait, present regulations will have similar disastrous consequences as for Golden Rice.
- Multiple trait transgenics will have no chance for deregulation at all.

Therefore, the number of GMO regulation-caused deaths will expand into the millions!



In the early 19th century a Thai princess celebrated her 18th birthday. She fell into the palace pond ...

... and drowned in front of hundreds of guests. Nobody helped her out of the water.

It was “taboo“ to touch a member of the “divine“ royal family!

Everybody likes to believe that he/she would have saved the princess, ...

... in the early 21st century 500'000 children per year become blind and 6'000 per day die from vitamin A malnutrition. This could be prevented. However, GMOs are so over-regulated that they cannot be used for solutions of humanitarian problems.



www.goldenrice.org

We, our society, has the responsibility of de-demonising GMOs. If not, history will hold us responsible for avoidable death and suffering of millions – a crime against humanity.