**Contents**

- Vitamin A Deficiency (VAD)
- Current status and perspectives
**Global population annual mortality (millions)**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Mortality (millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A Deficiency (VAD)</td>
<td>1.0 – 2.5</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>1.7</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>1.7</td>
</tr>
<tr>
<td>Malaria</td>
<td>0.75</td>
</tr>
</tbody>
</table>

Source: Adrian C Dubock, Green & Life Technology Forum, National Science & Technology Commission, Seoul, Korea. 28th February 2012
VAD disorders (numbers affected annually)

<table>
<thead>
<tr>
<th></th>
<th>estimated in million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children</td>
<td>150 – 200</td>
</tr>
<tr>
<td>Pregnant women</td>
<td>20</td>
</tr>
<tr>
<td>Xerophtalmia</td>
<td></td>
</tr>
<tr>
<td>Children</td>
<td>3</td>
</tr>
<tr>
<td>Pregnant women</td>
<td>3</td>
</tr>
<tr>
<td>Blindness</td>
<td>0.5</td>
</tr>
</tbody>
</table>

Source: Adrian C Dubock, Green & Life Technology Forum, National Science & Technology Commission, Seoul, Korea. 28th February 2012
Vitamin A deficient regions

Countries categorized by degree of public health importance of vitamin A deficiency

The designations employed and the presentation of material on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city, or area of its authority, or concerning the determination of its frontiers or boundaries. Dotted lines represent approximate border lines for which there may not yet be full agreement.
World rice distribution, ca. 2005 (first approximation)
Source: RJ Hijmans, IRRI
The Golden Rice vision

- To create a ‘public good ‘source of Vitamin A
- Free of charge for the trait
- Available to those who want to grow or consume it
- An additional intervention to combat Vitamin A deficiency

www.goldenrice.org
Contents

- Vitamin A Deficiency (VAD)


- Current status and perspectives
Carrots: Successful breeding
Rice traits cannot be bred because there is no adequate trait variability

- **Provitamin A**: not found in the grains of existing cultivars
- **Water soluble B vitamin**: Practically absent
- **Iron**: low variability, ranging from 1 - 8 ppm

Source: Adrian C Dubock, Green & Life Technology Forum, National Science & Technology Commission, Seoul, Korea. 28th February 2012
Golden Rice 1 (GR1)

- Developed from 1991 to 2000 by Ingo Potrykus (Swiss Federal Institute of Technology in Zuerich, Switzerland) and Peter Beyer (University of Freiburg, Germany)
  - early example for the use of pathway engineering

- Funded by the Rockefeller Foundation, Swiss Federal Institute of Technology, the European Community Biotech Program and Swiss Federal Office for Education and Science

Multiple technologies

- Plant Seed Sources
- Gene Constructs
- Vectors
- DNA Amplification Technologies
- Plant Regeneration Techniques
- Transformation Techniques
Rights from a patent ...

Provisional Rights: Patentee under certain circumstance has a right to an appropriate remuneration
## Infringement and Freedom-to-operate (FTO)

<table>
<thead>
<tr>
<th>Literal infringement</th>
<th>Activity within the literal scope of claims</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equivalent infringement</td>
<td>Small but insignificant variation from the literal wording of the claims</td>
</tr>
<tr>
<td>Contributory infringement</td>
<td>Supplying vital components to third parties to enable them to infringe</td>
</tr>
</tbody>
</table>

FTO landscape analysis ideally conducted before starting a project and double-checked (at least) before launch of the product (clearance)

IGNORANCE IS NO DEFENCE
Exemptions

No infringement are ..... 

● Acts done for private and non-commercial purpose

● Acts done for experimental purposes relating to (but not with !) the subject matter of the patented invention
  - context of the research (academic / commercial) is irrelevant
  - only research directed to obtain further information about the patented subject matter is excepted but not the use as research tools (promoters, selection markers etc.)

● The use of biological material for the purpose of breeding, discovering, and developing a new plant variety (only Germany / France).

Caveat: Exemptions and their interpretation differ from country to country!
Patents: How to read and assess them

Where are the claims?

Where is the description and the examples?

PATENT ATTORNEY

RESEARCH SCIENTIST
Golden Rice 1 (GR1)
A worst case example for multiple dependency

Falls into the scope of at least 46 patent families owned by at least 31 companies / institutes

Text mining on patent publications of GR1 technologies

- 1'979 citations on 46 patent families
- Text mining with ThemeScape on 2'225 documents
- Patents infringing

- Common conceptual terms (thematic content) are displayed in a two-dimensional map
- Peaks representing a concentration of documents and showing the relative relationship of one record to another
Contents

- Vitamin A Deficiency (VAD)
- Current status and perspectives
Development of GR2

- Building on a well established patent portfolio of enabling and trait technologies
- In-depth FTO landscape searches and analysis
- Cooperation with the developers of GR1
Text mining on Syngenta’s WO 2004/085656 of GR2

- Text mining with ThemeScape on citations
  - 13 1st level citations on WO2004/085656
  - 267 2nd level citations on 1st citations

- Syngenta’s “closest” patents
  - Other Syngenta patents
  - “Closest” third party patents
GR2

- GR2 developed by Syngenta scientists in cooperation with the inventors of GR1 were produced in 2005

- Show higher levels of beta-carotene (pro-vitamin A) than the original materials in the Potrykus-Beyer work

- Has been estimated, on the basis of the Tufts University Medical School-led study, to meet much of the dietary requirements for Provitamin A for those that need it


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- Vitamin A Deficiency (VAD)
- Current status and perspectives
Golden Rice is an exclusively humanitarian project

- With licenses from inventors Potrykus and Beyer as well as from Bayer, Monsanto and Oryanova, GR2 was donated to International Rice Research Institute (IRRI) in 2006
- Syngenta making Golden Rice technology freely available to farmers earning less than US$10’000 a year from rice
- Farmers will also be able to save seed from their initial crop for future plantings, rather than buy it every year

Sources: Syngenta web site and www.goldenrice.org
### Disease burden of VAD in India and impact and cost effectiveness of GR2

<table>
<thead>
<tr>
<th></th>
<th>High impact scenario</th>
<th>Low impact scenario</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of DALYs</strong>* saved annually</td>
<td>1’382’000</td>
<td>204’000</td>
</tr>
<tr>
<td><strong>Number of lives saved annually</strong></td>
<td>39’700</td>
<td>5’500</td>
</tr>
<tr>
<td><strong>Cost per DALY saved through GR2</strong></td>
<td>$3.1</td>
<td>$19.4</td>
</tr>
</tbody>
</table>

World Health Organization standard for valuing DALYs $620–1’860

*DALY = Disability Adjusted Life Year

Source: Stein et al., Nature Biotechnology 24, 1200 (2006)
Golden Rice: towards a biofortified stable food

1. One lead event - GR2 selected
2. Introgressed into 5 mega-rice varieties
3. Regulatory data generation underway
4. Intention to submit in Philippines & later, in Bangladesh
5. Golden Rice to all countries for introgression into locally adapted and preferred varieties of rice

www.goldenrice.org

Source: Adrian C Dubock, Green & Life Technology Forum, National Science & Technology Commission, Seoul, Korea. 28th February 2012

Bringing plant potential to life