The Golden Rice Project – Use of Patent Analytics for Non-Commercial Activities

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Contents

Global population annual mortality (millions)

Vitamin A Deficiency (VAD)	**1.0 – 2.5**
HIV/Aids	1.7
Tuberculosis	1.7
Malaria	0.75

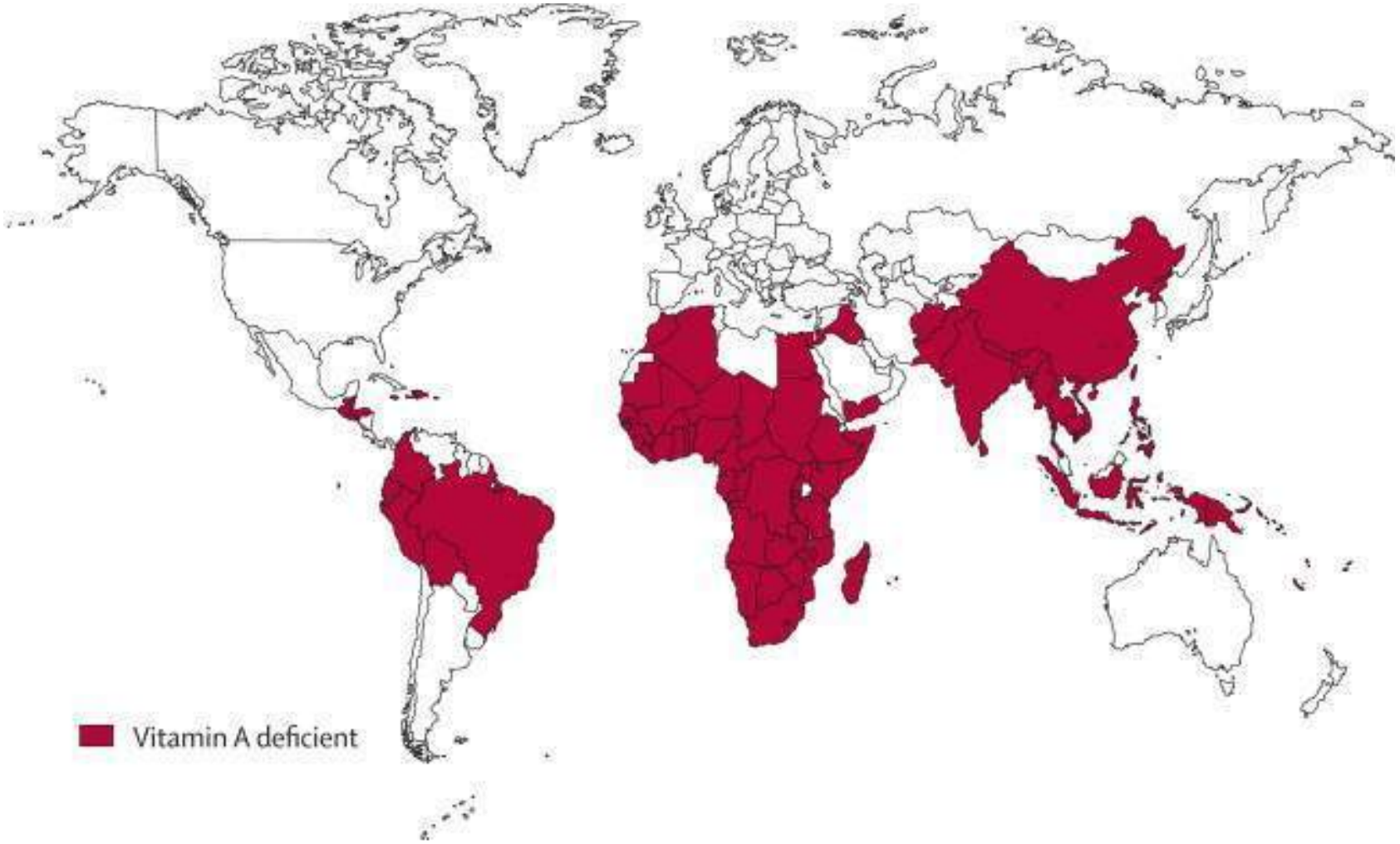
Source: Adrian C Dubock, Green & Life Technology Forum, National Science & Technology Commission, Seoul, Korea. 28th February 2012

VAD disorders (numbers affected annually)

	estimated in million
Children	150 – 200
Pregnant women	20
Xerophtalmia Children Pregnant women	 3 3
Blindness	0.5 (of which ~ 2/3 die within a few months)
Preventable deaths	1 – 2.5

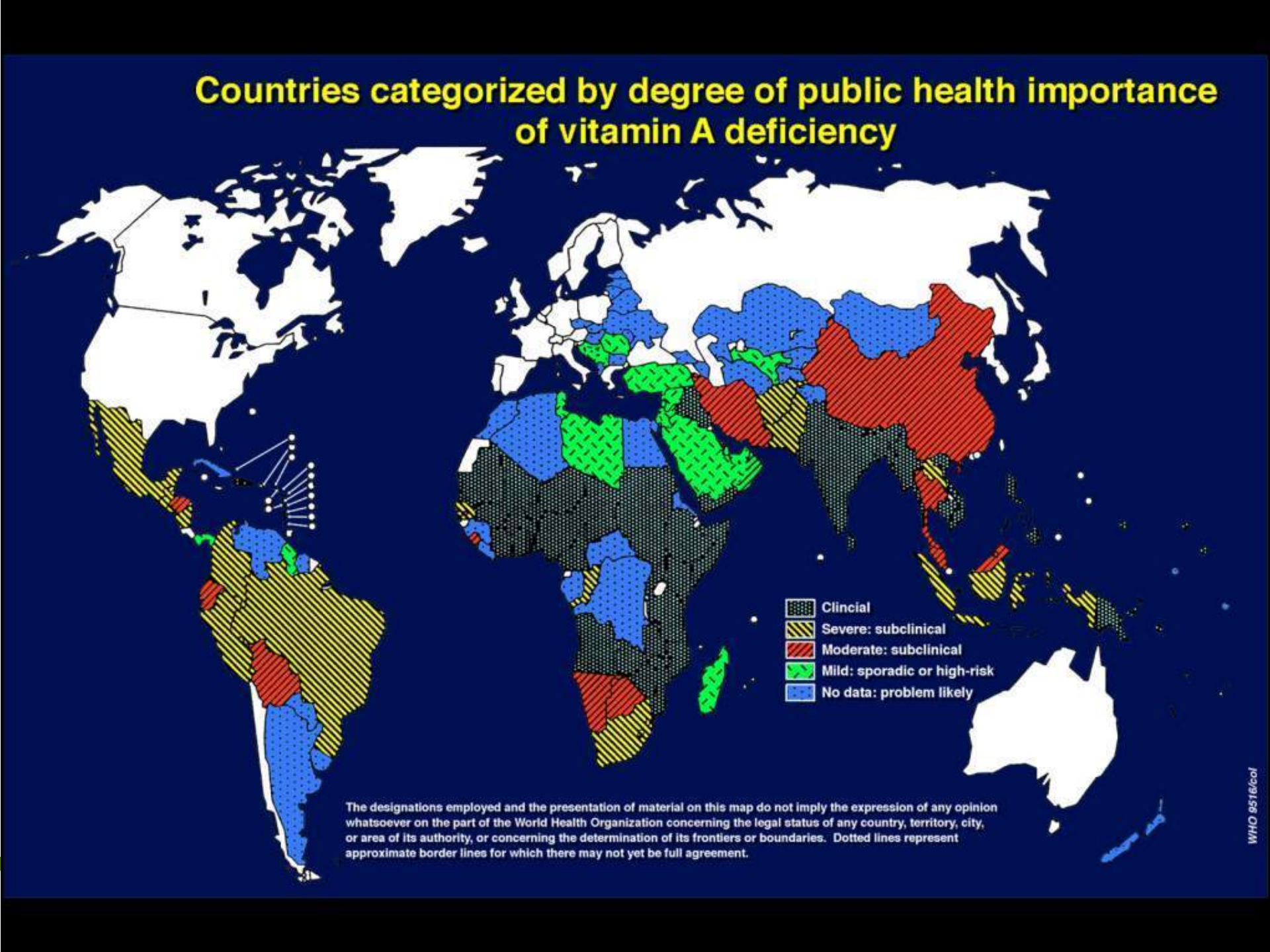
Source: Adrian C Dubock, Green & Life Technology Forum, National Science & Technology Commission, Seoul, Korea. 28th February 2012

Vitamin A deficient regions



The Lancet, Volume 371, Issue 9608, Pages 243 - 260, 19 January 2008

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

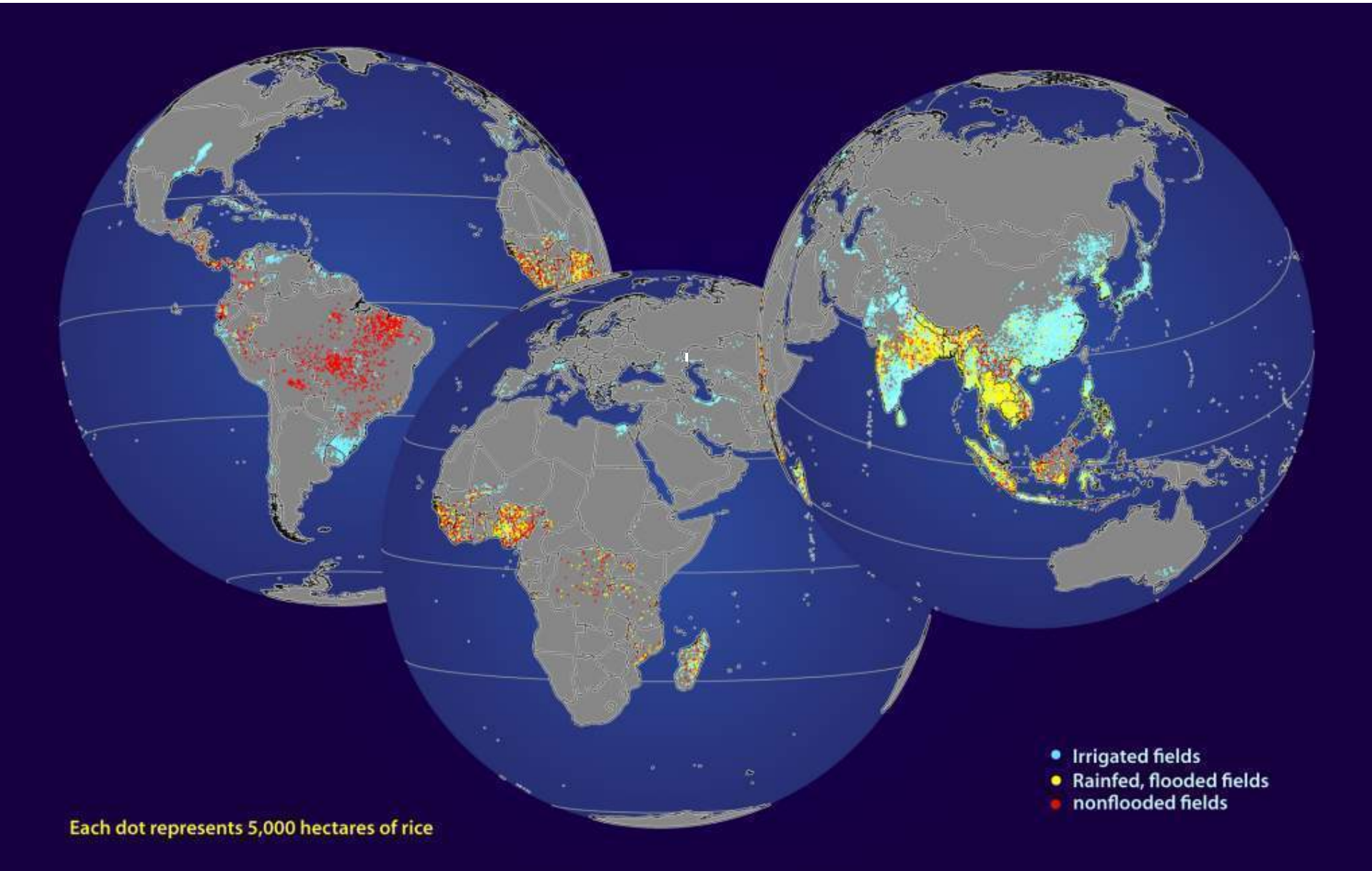


The designations employed and the presentation of material on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city, or area of its authority, or concerning the determination of its frontiers or boundaries. Dotted lines represent approximate border lines for which there may not yet be full agreement.

WHO 9516/col

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)
- Golden Rice 1 (GR1): Development and Patent Analytics
- Golden Rice 2 (GR2): Development and Patent Analytics
- 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

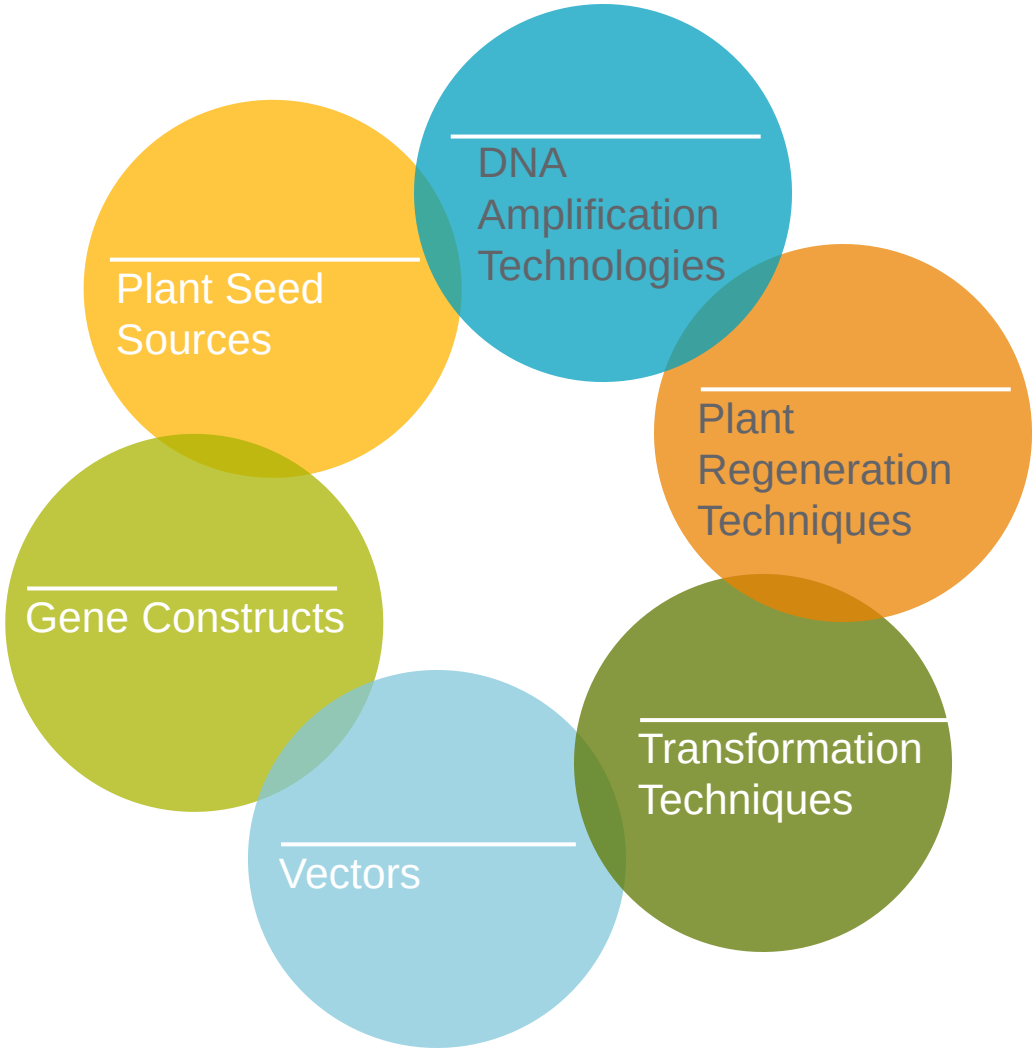
Golden Rice 1 (GR1)

- 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

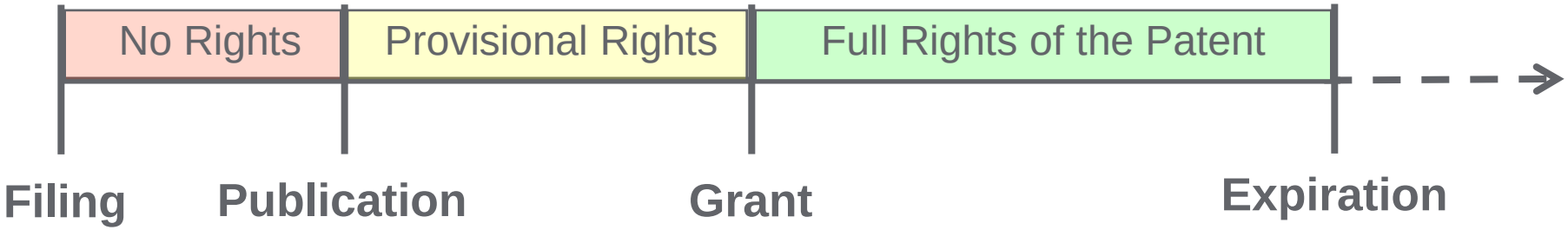
- Funded by the Rockefeller Foundation, Swiss Federal Institute of Technology, the European Community Biotech Program and Swiss Federal Office for Education and Science

* Kryder D, SP Kowalski and AF Krattiger. 2000. The Intellectual and Technical Property Components of pro-Vitamin A Rice (*Golden*Rice™): A Preliminary Freedom-to-Operate Review. *ISAAA Briefs* No 20. ISAAA: Ithaca, NY. www.isaaa.org/kc/bin/isaaa_briefs/index.htm.

Multiple technologies



Rights from a patent ...



Provisional Rights: Patentee under certain circumstance has a right to an appropriate remuneration

Infringement and Freedom-to-operate (FTO)

Literal infringement	Activity within the literal scope of claims
Equivalent infringement	Small but insignificant variation from the literal wording of the claims
Contributory infringement	Supplying vital components to third parties to enable them to infringe

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

IGNORANCE IS NO DEFENCE

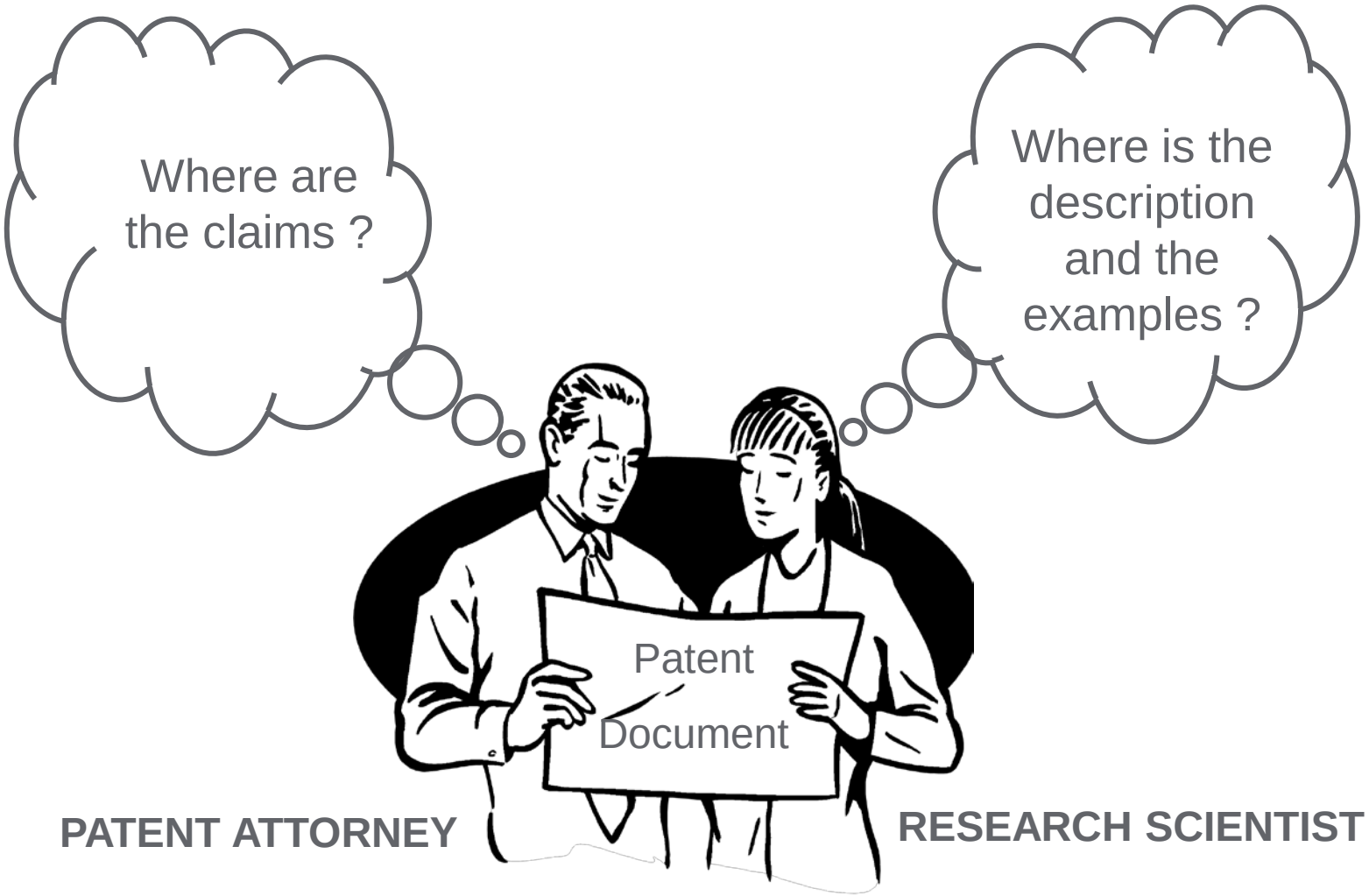
Exemptions

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).

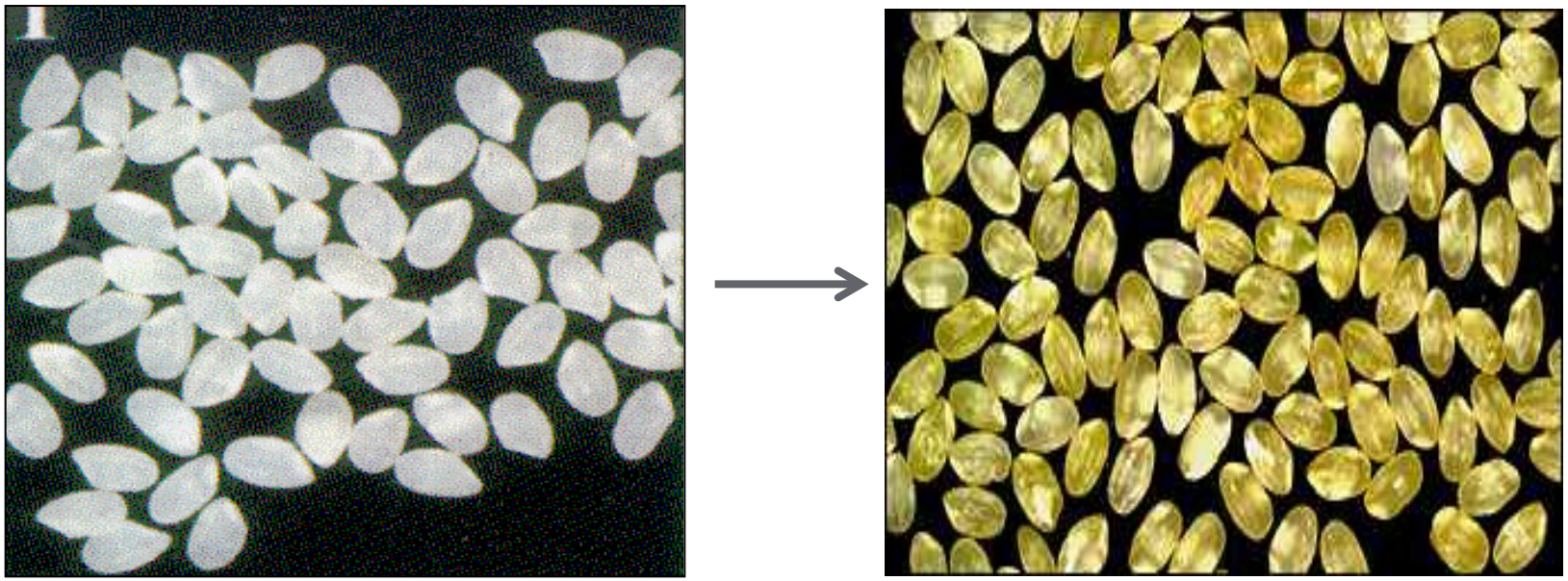
Caveat: Exemptions and their interpretation differ from country to country!

Patents: How to read and assess them



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

Kryder D, SP Kowalski and AF Krattiger. 2000. The Intellectual and Technical Property Components of pro-Vitamin A Rice (*Golden*Rice™): A Preliminary Freedom-to-Operate Review. *ISAAA Briefs* No 20. ISAAA: Ithaca, NY. www.isaaa.org/kc/bin/isaaa_briefs/index.htm.

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

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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

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
7 October 2004 (07.10.2004)

PCT

(10) International Publication Number
WO 2004/085656 A2

(54) Title: ENHANCED ACCUMULATION OF CAROTENOIDS IN PLANTS

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

US ‘04 & ’05 field trials

- 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

Krattiger A and I Potrykus. 2007. Golden Rice: A Product-Development Partnership in Agricultural Biotechnology and Humanitarian Licensing. In Executive Guide to Intellectual Property Management in Health and Agricultural Innovation: Available online at www.ipHandbook.org

Tang G, Hu Y, Yin SA, Wang Y, Dallal GE, Grusak MA, Russell RM (Sept. 2012). *Beta-Carotene in Golden Rice is as good as beta-carotene in oil at providing vitamin A to children*. American Journal of Clinical Nutrition, 96(3), 658-664 (http://www.ncbi.nlm.nih.gov/pubmed/22854406)

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Golden Rice is an exclusively humanitarian project

- With licenses from inventors Potrykus and Beyer as well as from Bayer, Monsanto and Orynova, 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

	High impact scenario	Low impact scenario
Number of DALYs* saved annually	1’382’000	204’000
Number of lives saved annually	39’700	5’500
Cost per DALY saved through GR2	$3.1	$19.4

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

Potrykus, Nature 466, 561 (2010)

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