

The present regulation of GM crops is harming research, development and commercialization

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Contents

1. The issue	1
2. Summary	2
3. The costs and lost benefits of overregulation	2
3.1. Overregulation in Europe cause a stall in innovation and GM crop approvals and cause lost benefits worldwide and Europe.....	2
3.2. Costs and lost benefits in developing countries	4
3.3. The Golden Rice development hampered through over-regulation. Biofortification as an ideal sustainable way of foreign aid in agriculture.	6
4. Cited literature	7

1. The issue

The Cartagena Protocol on Biosafety (CPB) has now been adopted by 157 parties¹. It still builds on the principle that GM crop plants might bare risks in contrast to the conventional crops: Objective ² of CPB. The huge apparatus on risk assessment based on this protocol is building on the principle, that the mechanism of transgenicity is totally artificial and is not found in nature. Modern molecular science

¹ Cartagena Protocol on Biosafety, adoption : <http://www.cbd.int/biosafety/signinglist.shtml>

² Cartagena Protocol on Biosafety, objective: <http://www.cbd.int/biosafety/articles.shtml?a=cpb-01>

insights have proven the contrary, as shown in ASK-FORCE AF-9 on the molecular basis of transgenesis. This results in maintaining to an asymmetric risk assessment of innovation of GM crops. The possible exemption of widespread GM crops in Art. 7.4³ is not even considered officially up to now. In a separate ASK-FORCE contribution the similarities between GM crops and conventionally bred crops on the level of molecular processes⁴

2. Summary

An excellent summary graph is given in (Graff et al., 2009) in fig. 1b: innovations active in the R&D pipeline were growing at an increasing rate during the period before 1998, but declined after 1998. Apart from competition of reasonably close non-transgenic substitutes the authors consider one regulatory reason to be the main culprit: The halting of regulatory approvals in 1998 in Europe. Although the authors consider the full extent of reasons still to be conjectural, their data suggest that changes in regulatory environment may have been a cause. In a combination of high costs for lost implementation and high costs for regulatory approvals the present state and operational experience has grown into a major obstacle of modern crop breeding.

Commentary from Table 1: The primary survey combined records from scientific publications, field trial records and regulatory filings to identify 558 transgenic plants with quality improvements and determine how far they had progressed through stages of R&D by 2004, including those that had only been published in the scientific literature; those that had reached initial field trials (defined as having completed 1–3 field trials), mid-stage field trials (4–9 field trials) or advanced field trials (>10); those that had entered regulatory filings; and those that were commercialized. The secondary survey canvassed expectations of firms and analysts about the likelihood and time frame for future commercialization of transgenic product quality innovations. Complete one-to-one correspondence between individual observations of the two surveys was not possible.

3. The costs and lost benefits of overregulation

3.1. Overregulation in Europe cause a stall in innovation and GM crop approvals and cause lost benefits worldwide and Europe

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The full extent of the GM crop development pipeline can be evaluated in websites like the Information Systems for Biotechnology⁵ alone from the U.S.A., there are (23. Oct. 2009) 14204 notifications with 1586 full field release permits registered in this Database.

³ Cartagena Protocol on Biosafety, Article 7: <http://www.cbd.int/biosafety/articles.shtml?a=cpb-07>

⁴ ASK-FORCE: Difference GM- and non-GM-crops on the molecular level <http://www.efb-central.org/index.php/forums/viewthread/58/>

⁵ ISB, Information Systems of Biotechnology: Field Test Releases in the US: <http://www.isb.vt.edu/cfdocs/fieldtests1.cfm>

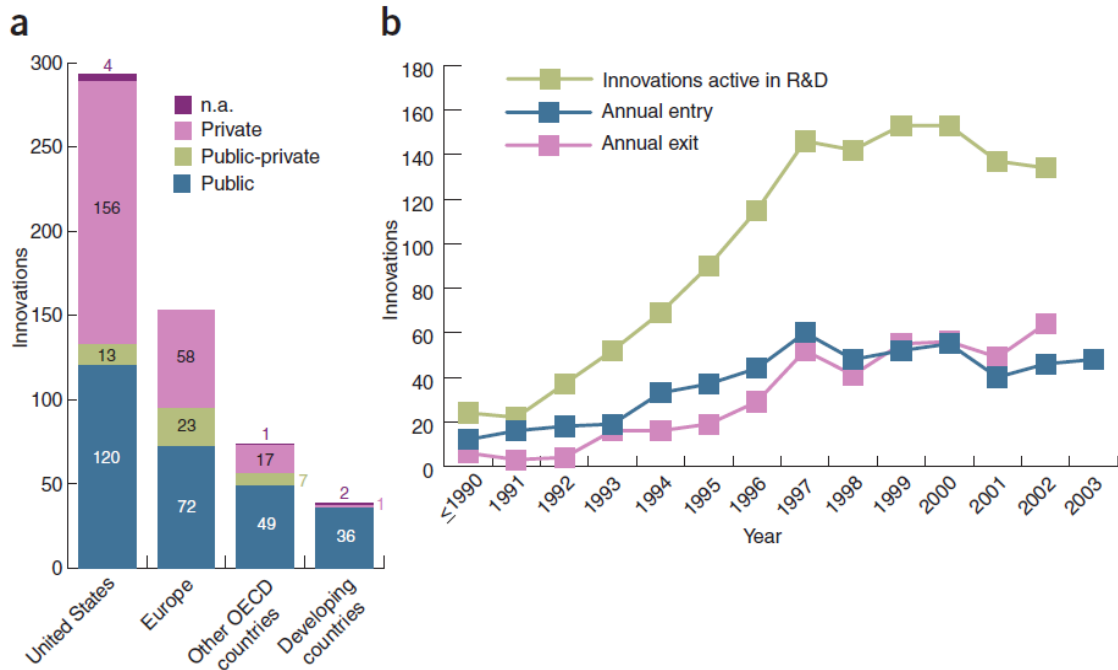


Fig. 1 Innovation in agbiotech. (a) Location and sector of organizations conducting R&D for the 558 transgenic product quality innovations identified. Private sector consists of corporate and privately held firms. Public sector consists of government research laboratories, universities and nonprofit research institutes. (b) Annual entry, exit and the numbers of innovations active in the R&D pipeline were calculated from observations of the 558 innovations tracked in the primary survey. The number of active innovations stopped growing in 1998, after which those new innovations that entered were more likely to be published and less likely to move toward commercialization. From (Graff et al., 2009)

In another comparative account on regulatory procedures and approval rates between Europe and the United States the facts are clearly negative for Europe: (Tencalla, 2006) in Figure 1:

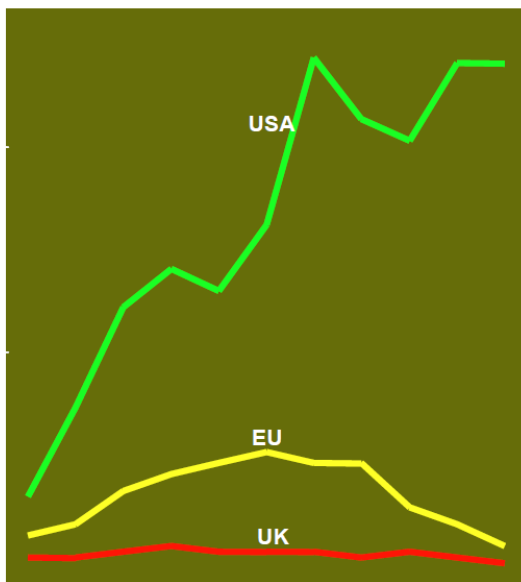


Fig. 2 Approvals for biotech research and development field trials (1992–2002). From (Tencalla, 2006)

Overall, the present day regulatory regime detains public research in molecular breeding considerably due to enormously high regulation costs, more information about this effect for the development of GM trees in Strauss and McLean (McLean & Charest, 2000; Strauss et al., 2009), the abstract:

“Against the Cartagena Protocol and widespread scientific support for a case-by-case approach to regulation, the Convention on Biological Diversity has become a platform for imposing broad restrictions on research and development of all types of transgenic trees.”

Some comprehensive tables on the massive costs of regulation of the major commodity crops are given by Kalaitzandonakes (Kalaitzandonakes et al., 2007): The compliance costs for herbicide tolerant maize alone has been calculated based on the events available in 2006 for the United States: They amount to 6,180,000–14,510,000 US\$, a sum most likely to be prohibitive for any trait developed by a public institution.

Another case is reported by Piero Morandini from Italy: A scientific assessment on a field trial on Bt maize is delayed in publication by the Italian Government, although (or because?) it yields very positive results:^{6 7}

“The grain yield data (tons/ha, GM crop vs. their conventional counterparts) were rather spectacular: 15.9 vs. 11.1 and 14.1 vs. 11.0, translating into a 43 and 28% yield increases for the P67 and Elgina, respectively. These data have already been released by the INRAN (National Institute for Research on Food and Nutrition, a research institution funded and run by the government) in 2006, albeit without the emphasis they deserved.

*The delay in properly communicating these data can be considered as a very costly omission. In fact, taking into account the total area of maize cultivation in Italy together with yield differences, maize prices and pest pressure, **these data translate into a forfeited value of between roughly € 300 million and € 1 billion a year because Italian farmers are not allowed to plant Bt maize.**”*

The present day regulatory “apartheid” of high tech farming versus organic farming, large scale farming against smallholders seriously hampers the development of GM crops which could foster a more ecological production (Ammann, 2008, 2009).

3.2. Costs and lost benefits in developing countries

Even more drastically in the developing world, there is regulatory legislation in place hindering the development of transgenic crop breeding for the benefit of the poor, Driessen, Herring, Paarlberg (Driessen, 2005; Herring, 2007; Paarlberg, 2009; Paarlberg, 2002).

Doubling agricultural research investment per se (no regulatory costs included in the calculation), would reduce poverty in Sub-Saharan Africa by 9% according to Alene & Coulibaly (Alene & Coulibaly, 2009). But these prospects are seriously hindered and as a result practically nullified by the exorbitantly high regulatory costs during the implementation phase.

Moreover, GM-free private standards set up by food companies and distributors in developed countries have influenced biosafety policymaking in developing countries: Gruère & Sengupta (Gruère & Sengupta, 2009) found 29 cases where private importers have affected policy decisions in numerous countries due to irrational fear of export-losses. This is based on two generally misleading premises: (1) Europe or Japan represents the only market for exports, and (2) non-GM segregation is too costly. It is amazing to realize, that many of the cases rely on unpublicized lobbying activities, and because of the

⁶ Morandini Press Release 20071211: <http://www.botanischergarten.ch/ASK-FORCE-NEWS-Maize-Lombardia/Morandini-press-release-20071211.pdf>

⁷ Morandini, Polenta: http://www.botanischergarten.ch/ASK-FORCE-NEWS-Maize-Lombardia/Morandini-polenta_25-04-08.pdf

lack of comprehensive evidence, many cases do not provide straightforward evidence of causality links between importers or traders and policy decisions. There is evidence that development of GM crops in Africa is mainly based on public research, and that the private sector only reluctantly invests in projects for developing countries, although the situation is getting better in the last few years (Cohen, 2005; Spielman et al., 2007).

A blatant case of eco-imperialism is reported from Zambia⁸, where the Norwegian Government has partly sponsored a 400'000\$ laboratory, for which GENOK, a well known anti-biotech NGO^{9, 10} has contributed equipment and training, thus guaranteeing a research policy hostile to GM crops, in accordance with the official policy of the Zambian government, who denominates GM crops as poisonous. Typically enough, the laboratory's priority will be to detect and search for genetically modified seeds and crops. Former Zambian researcher Ed. Rybicki, now working in Cape Town, said, "that the lab would better serve Zambia and the whole region by looking at genuine threats, studying local biodiversity and even making transgenic crops themselves"¹¹.

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Gruère and Smale (Gruere et al., 2007; Smale et al., 2008) report in a carefully calculated assessment, that if rice cultures in India, Bangladesh, Indonesia and the Philippines would be based on present day GM traits, the benefits amount to 4'331 million US-dollars. For the United States, an earlier assessment calculates similar sums of benefits related to the introduction of biotechnology in agriculture (Falck-Zepeda et al., 2000).

There has been much more written about regulatory costs and its negative follow-ups, here only a small selection of important papers (Antle, 1999; Graff & Zilberman, 2004; Kochetkova, 2006; Laget & Cantley, 2001; Pray et al., 2006; Raybould, 2010; Shelton, 2003).

⁸ Andrew Apel in GMobelus: <http://www.gmobelus.com/news.php?viewStory=234>

⁹ Controversy between GENOK and Roush on an alleged case of maize pollen allergy: <http://www.botanischergarten.ch/Allergy/Traavik-Roush-Philippines-controversy-2004.pdf>

¹⁰ Vidal, Guardian: <http://www.guardian.co.uk/science/2004/feb/27/gm.science>

¹¹ Scidev news: http://www.scidev.net/en/news/zambia-s-molecular-biology-lab-fully-functioning-a.html?utm_source=link&utm_medium=rss&utm_campaign=en_news

¹² ISB, Information Systems of Biotechnology: Field Test Releases in the US: <http://www.isb.vt.edu/cfdocs/fieldtests1.cfm>

3.3. The Golden Rice development hampered through over-regulation. Biofortification as an ideal sustainable way of foreign aid in agriculture.

In the case of the Golden Rice this tedious and costly regulation forced upon the regulatory authorities by the CBD solely based on the process of transgenesis has serious ethical consequences¹³ (Bradford et al., 2005; Kalaitzandonakes et al., 2007). A delay of the introduction of the biofortified rice is directly causing each year hundreds of thousands of children to die or to go blind due to severe vitamin A deficiency. Unreasonable and unscientific regulatory obstacles cause massive delay in approvals, especially in developing countries of S.E. Asia (Atanassov, 2004; Bouis, 2007; Depee et al., 1995; Humphrey et al., 1998; Humphrey et al., 1992; Mayer et al., 2008; Miller, 2009; Potrykus, 2003; Qaim et al., 2008; Qaim & Stein, 2008; Qaim et al., 2007; Stein et al., 2008; Stein et al., 2007a; Stein & Qaim, 2007; Stein et al., 2006, 2007b).

Last but not least it should be emphasized that specifically related to the developing world we should refrain from the old myths that international corporate companies are dominating the field – on the contrary: Public Research is responsible for 85% of crop developments, 7% private local companies, and only 1% multinational companies according to figures from Cohen (Cohen, 2005), supported by FAO statistics (Dhlamini et al., 2005). The myth that patenting rules are seriously hampering the spread of helpful biotech crops in poor countries has been seriously contested (Atkinson et al., 2003; Beachy et al., 2002; Krattiger & Mahoney, 2006).

As an example: the Golden Rice project will result into biofortified rice traits which will be distributed to the farmers free of royalties. More about the subject can be found in the important and comprehensive Handbook of Intellectual Property Rights of Krattiger et al. 2007 (Krattiger, 2007), and more: (Delmer et al., 2003; Lawson, 2004; Singh et al., 2009; Wright, 2008).

Biofortification programs are prone to get the highest index numbers in the evaluation system for foreign aid programs of Lempert (Lempert, 2009): Biofortification of indigenous landraces by systematically crossing-in the valuable and royalty free traits to enhance the nutritional value is certainly one of the best ways to sustainably help indigenous people suffering from any kind of malnutrition. In all cases known the technology transfer is royalty free, secured by contracts.

Use of an indicator to assess the quality and success of developing aid projects defined by (Lempert, 2009) reveals that most of the major NGO and UN actors in the field of development are actually providing *relief* rather than *development* and are creating *dependency by treating symptoms* rather than *long-term solutions*. The indicator points to the specific areas where they need to improve in order to fulfill sustainability criteria including tests of whether aid distorts financial markets and business competition, erodes appropriate government functions, and reverses colonial institutions and ideologies that interfere with sustainable consumption within a resource base.

Estimates in costs for vitamin A capsules are clearly incompatible with the living standard in developing countries, a major distribution campaign would result in millions of dollars: Neidecker-Gonzales (Neidecker-Gonzales et al., 2007) produced in their study the following figures: "Total costs are lowest (roughly US\$0.50 per capsule) in Africa, where wages and incomes are lowest, US\$1 in developing countries in Asia, and US\$1.50 in Latin America. Overall, this study derives a much higher global estimate of costs of around US\$1 per capsule."

¹³ See documentation in AgBioWorld : <http://www.agbioworld.org/biotech-info/topics/goldenrice/index.html>

A bibliography of publications of the Golden Rice and Biofortification demonstrates the importance of this field of research, out of a general bibliography of 1640 references a list of over 200 important papers is assembled.¹⁴

It should be mentioned, that biofortification strategies are also proposed for feed (Gressel & Zilberstein, 2003): Straw from harvested crops can be adapted to higher quality feeding straw for cattle.

Conclusions drawn by Ingo Potrykus (Potrykus, 2009)

“The huge potential of plant biotechnology to produce more, and more nutritive, food for the poor will be lost, if GMO-regulation is not changed from being driven by “extreme precaution” principles to being driven by “science-based” principles. Changing societal attitudes, including the regulatory processes involved, is extremely important if we are to save biotechnology, in its broadest applications, for the poor, so that public institutions in developing as well as industrialized countries, can harness its power for good.”

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¹⁴ Bibliography on Golden Rice papers assembled by Klaus Ammann : <http://www.botanischergarten.ch/Golden-Rice/Bibliography-Golden-Rice-WOS-KA-20091008-links-abstracts.pdf>

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