

# The GM crop risk-benefit debate: science and socio-economics

a plea for a new regulatory system for a modern agriculture

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"WHAT'LL IT BE — ONE LARGE RISK OR SEVERAL SMALL ONES?"

Large or small risk?

<http://www.sciencecartoonsplus.com/index.php> a cartoon of S. Harris

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## What this paper is all about

The experience of the author in the debate on GM crops goes back to about 1990, when he was still leading a research group on cryptogamic botany, including activities in lichen chemistry and biomonitoring air pollution. Starting with a doctoral thesis on glacial and vegetation history, my basic interest was always organismal botany and in particular also plant taxonomy and biodiversity, which included also conservation activities on national and international level. This included a “natural” phobia for genetic engineering – and it was Ingo Potrykus and Inge Broer who opened my eyes to see the real science behind modern agriculture. Over the years I have participated intensely in the debate on biosafety science, including extensive experience in communicating with lay people - and with opponents of GM crops. For some years I built up ASK-FORCE blogs (Ammann, 20110921), which I will continue to do so, although a certain reassurance of the GM crop debate to the positive side is emerging. It is time to write up a kind of “balance sheet” on the debate including an outlook, drawn from my personal experience, but by including also the knowledge of international networks, conference contacts and intensive internet discussions – and last but not least, as a summary of extensive readings of scientific literature.

The conclusions of the extensive treaty on the GM debate: It is difficult to continue with a reform of the regulatory system within the Cartagena Protocol, although theoretically possible and certain articles would allow for substantial change towards a more science based system. But the obstacles should not be underestimated: there is a growing community of regulators, NGOs and also a militant fraction of biosafety researchers with a vested interest to keep the pot cooking.

Alternatively, it is maybe easier to create new international institutions with the task to develop a science based regulatory system for all new crop breeds.

Thanks go to a few internet communication friends from a blog of the moderators Prakash and Bruce Chassy, including Mark Cantley and at least two dozens of contributors of corrections and suggestions. It is obvious that without the help of internet facilities such a 170-page undertaking would be impossible.

## Glossary of terms used

### Cases

#### cisgenetics

transgenesis and cisgenesis both use the same genetic modification techniques— namely the introduction of one or more genes and their promoters into a plant—cisgenesis involves only genes from the plant itself or from a close relative. .... 11

#### de minimis regulatory strategy

The principle of de minimis risk offers a reasonable counterweight to the overly zealous application of the PP. It conveys a simple philosophy: that the regulation of risk should exhibit a standard of congruency and proportionality. In other words, regulatory entities must demonstrate that their approaches are congruent with and proportionate to the problem they seek to address. .... 92

#### DNE-Meganuclease Technology

Engineered DNE meganucleases can be used for cloning and molecular analysis purposes in much of the

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Metabolomics	
multiparametric measurement of metabolites in (simple) cell systems .....	11
miRNA	
MicroRNAs (miRNAs), a class of 19-24 nucleotide long non-coding RNAs derived from hairpin precursors, mediate the post-transcriptional silencing of an estimated 30% of protein-coding genes in mammals by pairing with complementary sites in the 3' untranslated regions (UTRs) of target genes, miRNAs have been widely shown to modulate various critical biological processes, including differentiation, apoptosis, proliferation, the immune response, and the maintenance of cell and tissue identity .....	35
proteomics	
study of the full set of proteins encoded by a genome that is expressed at a given time in a cell, tissue, organ or organism.....	11
TALEs Technology	
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## 1. Introduction

### 1.1. The general strategic situation of the debate about green biotechnology today

The aim of this text is to set the framework for a better communication about science and regulation and production of GM crops. GM stands for Genetic Modification, basically an unfortunate denomination, because actually *all* crops are genetically modified, but it is a worldwide accepted term for genetically engineered crops, including transgenes, auto- and allotransgenes, cis- and infra-genes and synthetic genes, for details see Beardmore (Beardmore, 1997). By including gene stacking of various kinds the situation is getting even more complex (Taverniers et al., 2008). With the introduction of in Vivo Mutation (with Zink-Finger Technology and the latest transformation method transcription activator-like family of type III effectors (TALEs)) the situation will change even more, the age of a high precision and targeted change of genomes has only begun and will develop rapidly, see details in section 1.2.. The term LMOs (Living Modified Organisms) which is generally used in the



United Nations Biosafety Protocol (Cartagena Protocol) is nothing but a “Living Proof” that the scientific basis of the Protocol remains questionable, since firstly the term is creating misunderstandings and secondly it is based on an erroneous assumption that GM crops are basically different from conventional crops, as is discussed with detail in the sections 2.4.2. and 2.4.3. More detailed clarification about the terminology of GMOs is given in a text block of the published Statement of the Pontifical Academy of Sciences: (Potrykus & Ammann, 2010a).

*“There are many different terms used to describe the processes involved in plant breeding. All living organisms are made up of cells in which are contained their genes, which give them their distinctive characteristics. The complete set of genes (the genotype) is encoded in DNA and is referred to as the genome; it is the hereditary information that is passed from parent to offspring. All plant breeding, and indeed all evolution, involves genetic change or modification followed by selection for beneficial characteristics from among the offspring. Most alterations to a plant’s phenotype or observable traits (such as its physical structure, development, biochemical and nutritional properties) result from changes to its genotype. Plant breeding traditionally used the random reshuffling of genes among closely-related and sexually compatible species, often with unpredictable consequences and always with the details of the genetic changes unexplored. In the mid-twentieth century this was supplemented by mutagenesis breeding, the equally random treatment of seeds or whole plants with mutagenic chemicals or high-energy radiation in the hope of generating phenotypic improvements; this, too, gave rise to unpredictable and unexplored genetic consequences from which the plant breeder selected the beneficial traits. Most recently, techniques have been developed allowing the transfer of specific, identified and well characterized genes, or small blocks of genes that confer particular traits, accompanied by a precise analysis of the genetic and phenotypic outcomes: this last category is called ‘transgenesis’ (because genes are transferred from a donor to a recipient) or ‘genetic engineering’ (abbreviated to GE in this report) but, in truth, this term applies to all breeding procedures.” (Potrykus & Ammann, 2010a).*

The strategic situation in the debate on GM crops is difficult, but not desperate, particularly in Europe – this is an evaluation shared by lots of experts of the debate about agricultural biotechnology, in Europe it is negatively affecting research and researchers (Rauschen, 2009). We have reached in Europe the peak of anxiety related to GM-crops since the introduction of the new technologies, and some opponents to transgenic crops have taken advantage of this situation. They have organized themselves in a veritable protest industry, see section 6. Nevertheless, the next years should lead to reassurance and scientific consolidation on biotechnology views.

### **1.1.1. Temporal variation and dynamics of the debate**

We encounter the same repeating dynamics as described for previous technology introductions (Showalter, 1997). The Gartner Hype Cycle (Linden & Fenn, 2003) adds another dimension to technology life cycle models: it characterizes the typical progression of an emerging technology from user and media over-enthusiasm through a period of disillusionment to an eventual understanding of the technology's relevance and role in a market or domain.

The details of the cycle (Linden & Fenn, 2003), amended by the author – specified for the technology push in transgenic crop development, it should be noted that there are differences between the development of the technologies in the mind of Linden and Fenn and agricultural technologies, where life sciences, combined with regional and cultural diversity, results into a much more diversified picture, also often not following the below described phases.

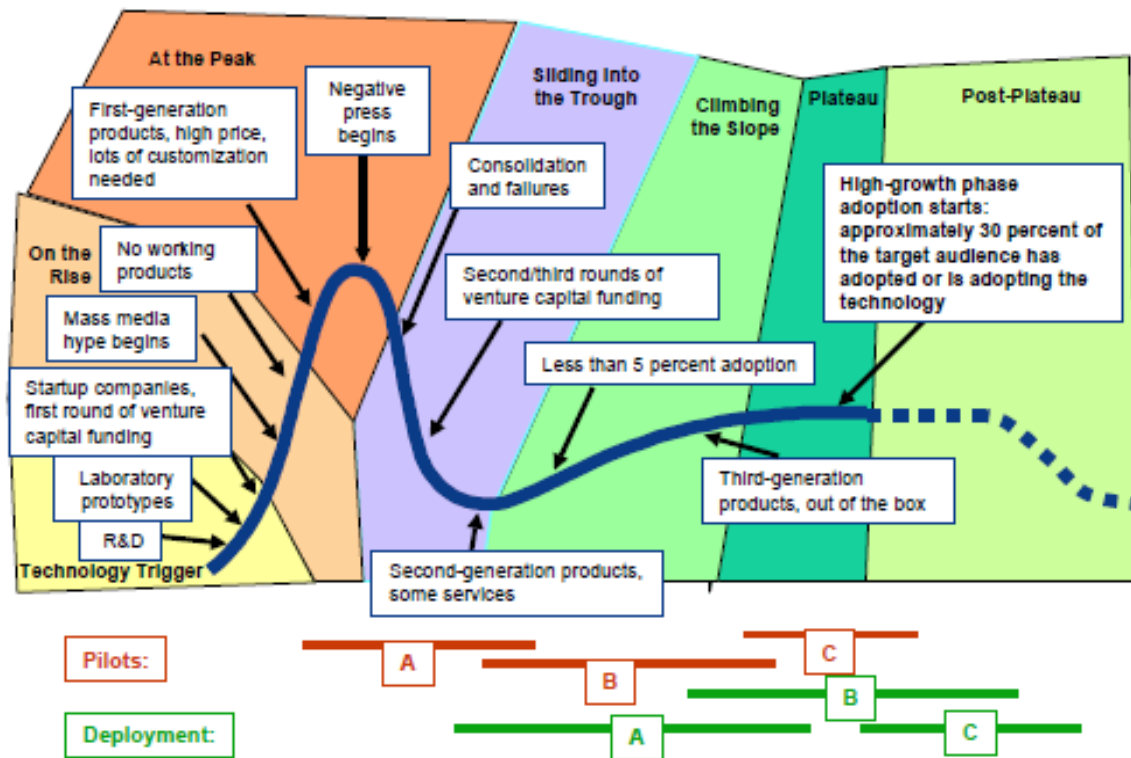


Fig. 1 Gartner Hype Cycle, extended view from (Linden & Fenn, 2003) after Fig. 3. Technologically aggressive ("Type A") enterprises are relatively comfortable adopting the technology, and moderately aggressive ("Type B") enterprises start to investigate and pilot the technology. Conservative ("Type C") enterprises remain wary. From (Linden & Fenn, 2003)

### 2.1 Technology Trigger

The *Technology Trigger* is a technological breakthrough, public demonstration, press release or other event that generates significant publicity and industry interest in an emerging technology. Typically no usable products exist, only research and laboratory prototypes (from the first transgenic plants in the 80ties (Chassy, 2007). Venture capitalists may provide some early funding just after the Trigger, if they expect the technology to be a fast runner.

### 2.2 On the Rise

On the rise to the Peak of Inflated Expectations, media articles explain the technology and discuss its potential impact on business and society. First-generation products emerge like the Flavr-Savr-Tomato (Martineau, 2002), but they usually are highly specialized products or extremely difficult to use or with other hitches in the introductory phase. Products are high margin because vendors are still trying to recover R&D costs, and the technology is expensive compared to its cost of production. For example, in 2002, Bluetooth products such as headsets cost \$200, while the final silicon cost of Bluetooth chips likely will be approximately \$5. This is a good stage for venture capitalists to enter the market, before evaluations are at their apex. During this phase, some particularly aggressive enterprises may start to pilot the technology, particularly if it contributes to critical business issues. These enterprises work closely with the vendors to create customized solutions for their requirements.

### 2.3 At the Peak of Inflated Expectations

As the Peak crests, the number of vendors offering the technology increases. These vendors are primarily startup companies and small vendors that try to use the increasing amount of hype for their marketing benefit. A growing number of enterprises start to examine how the technology may fit within their business strategies, although most do not take action at this stage. Venture capitalists may be interested in selling some of the startups that they equipped with early funding. As problems with first-generation products become visible (e.g. emerging pest resistance in the Bt cotton regions (Carrière et al., 2010; Ellstrand et al., 2010) and the latest success message of Huang et al. (Huang et al., 2011), often because the technology is pushed to its limits, negative publicity starts to push the technology into the Trough of Disillusionment, often the pertinent publications are pushed for negative statements beyond the limit of scientific rules (for example, Web services in 2002 and biometrics in 2003 and two example from the debate on non-target insects related to Bt crops: a) the case of the monarch butterfly (Gatehouse et al., 2002) and b) Lovei et al. (Lovei et al., 2009) giving false alarm for ladybirds and its prompt rebuttal by Antony Shelton et al. (Shelton et al., 2009a)).

### 2.4 Sliding into the Trough of Disillusionment

Because the technology does not live up to enterprises' and the media's overinflated expectations, it is rapidly discredited. Some of the early trials end in highly publicized failures. Media interest wanes, except for a few cautionary tales. A significant amount of vendor consolidation and failure occurs. Later-stage investors may be interested in funding vendors during this phase because equity is fairly inexpensive after the "microbubble" at the Peak of Inflated Expectations has burst.

However, amid the disillusionment, trials are ongoing and vendors are improving products based on early feedback regarding problems and issues. Some early adopters find some benefit in adopting the technology. For some slow-moving technologies (for example, biometrics), workable and cost-effective solutions emerge and provide value in niche domains, even while the technology remains in the Trough. The Trough of Disillusionment coincides with the "chasm" in Geoffrey Moore's classic book, "Crossing the Chasm." (Moore, 2002a). During this stage, vendors need to launch their products from a few early adopters to adoption by a majority of enterprises to begin the climb up the Slope of Enlightenment. There is no real parallel in the GM crop history, except that the differences in GM crop regulation and perception between the Americas and Europe caused a deep transatlantic divide (Thro, 2004).

### **2.5 Climbing the Slope of Enlightenment**

Focused experimentation and real-world experience by an increasingly diverse range of enterprises lead to a better understanding of the technology's applicability, risks and benefits. Vendors seek mezzanine or later-round funding for marketing and sales support to pull them-selves up the Slope. Second- and third-generation products are launched by the leading seed companies, and methodologies and tools are added to ease the development process, see the sections under 1.2. The service component declines as a percentage of the sale. Technologically aggressive ("Type A") enterprises are relatively comfortable adopting the technology, and moderately aggressive ("Type B") enterprises start to investigate and pilot the technology. Conservative ("Type C") enterprises remain wary. At the beginning of the slope, the penetration often is significantly less than 5 percent of the potential market segment. This will grow to approximately 30 percent and more as the technology enters the Plateau of Enlightenment. Examples of more or less unexpected enhancements in science and risk assessment of transgenic crops come from a higher precision of gene transfer methods (see sections under 1.2.), also compare to the latest developments in resistance management with a clear success story this year (Huang et al., 2011).

### **2.6 Entering the Plateau of Productivity**

The Plateau represents the beginning of mainstream adoption, which began in the Americas much earlier from 2000 onwards, when the real-world benefits of the technology are demonstrated and accepted, see the consecutive reports on the world development of transgenic crops on [www.isaaa.org](http://www.isaaa.org). Technologies become increasingly embedded into solutions that increasingly are "out of the box," with decreasing service elements as the technology matures (example conservation tilling). The majority of Type B, then Type C, enterprises adopt the technology. As a high-profile technology matures, an "ecosystem" often evolves around it. The ecosystem supports multiple providers of products and services, and also a market for related products and services that extend or are based on the technology (for example, virtual private networks in 2003 or the growing market for suppliers of molecular laboratories or the growing market for electronic equipment for precision agriculture).

The final height of the Plateau varies according to whether the technology is broadly applicable or benefits only a niche market, depending heavily on crop and region.

### **2.7 Post-Plateau**

As a technology achieves full maturity and supports thousands of enterprises and millions of users, producers and consumers, its hype typically disappears, as seen in the Americas. Only a few specialist magazines continue coverage of new aspects of implementing and maintaining the technology. Often there may be innovations around this technology that will follow their own Hype Cycles (new crop varieties on stress resistance, on bio-fortification, pharmaceutical crop lines etc.)

### **3.0 The Time-to-Maturity Assessment**

Technologies do not move at a uniform speed through the Hype Cycle. It often takes years for a technology to traverse the Hype Cycle — some technologies like GM crops may take decades, with considerable regional differences. There are three adoption speeds:

"Fast-track" technologies go through the Hype Cycle within two to four years. This occurs when the performance curve inflects early in the life cycle of a technology. These technologies find themselves adopted without much fanfare, bypassing the Peak of Inflated Expectations and Trough of Disillusionment. Many enterprises are unaware of their sudden maturity and applicability, such as what has happened with instant messaging and Short Message Service."

It is interesting to note, that the Showalter 'hystories' (a word play with hysteria and history) on the introduction of most new technologies (Showalter, 1997) report no real damage in their subsequent introductory phase – or – the benefits were so overwhelming that the debate was soon fading away. This alone demonstrates clearly that it is the socio-cultural environment strongly influencing the risk debate (Adams, 1995). The most recent events seem to hint that Europe finally finds to a more de-contracted way of looking at GM crops: The new report of the Royal Society (Royal-Society, 2009) tries to unite conventional and biotechnology approaches for the sake of making progress on agricultural management in developing countries:

"Past debates about agricultural technology have tended to involve different parties arguing for either advanced biotechnology including GM, improved conventional agricultural practice or low-input methods. We do not consider that these approaches are mutually exclusive: improvements to all systems require high-quality science. Global food insecurity is the product of a set of interrelated local problems of food production and consumption. The diversity of these problems needs to be reflected in the diversity of scientific approaches used to tackle them. Rather than focusing on particular scientific tools and techniques, the approaches should be evaluated in terms of their outcomes."

It might well be that we arrive sooner than expected from a period of disillusionment to an eventual understanding of the technology's relevance and role in a market or domain.

### 1.1.2. Spatial variation in agriculture and the debate on future trends

Besides this kind of temporal succession and processes we also have to consider the astonishing spatial diversity of existing agricultural strategies. It is a persistent error that farming with biotech crops is exclusively related to industrial farming with gigantic production fields, actually the sturdy statistics of (James, 2011) show that some 80% of farmers cultivating GM crops are smallholders.

The following example, taken from (Ruttan, 2005), demonstrates that there is no such thing as “one size fits all” in agricultural production:

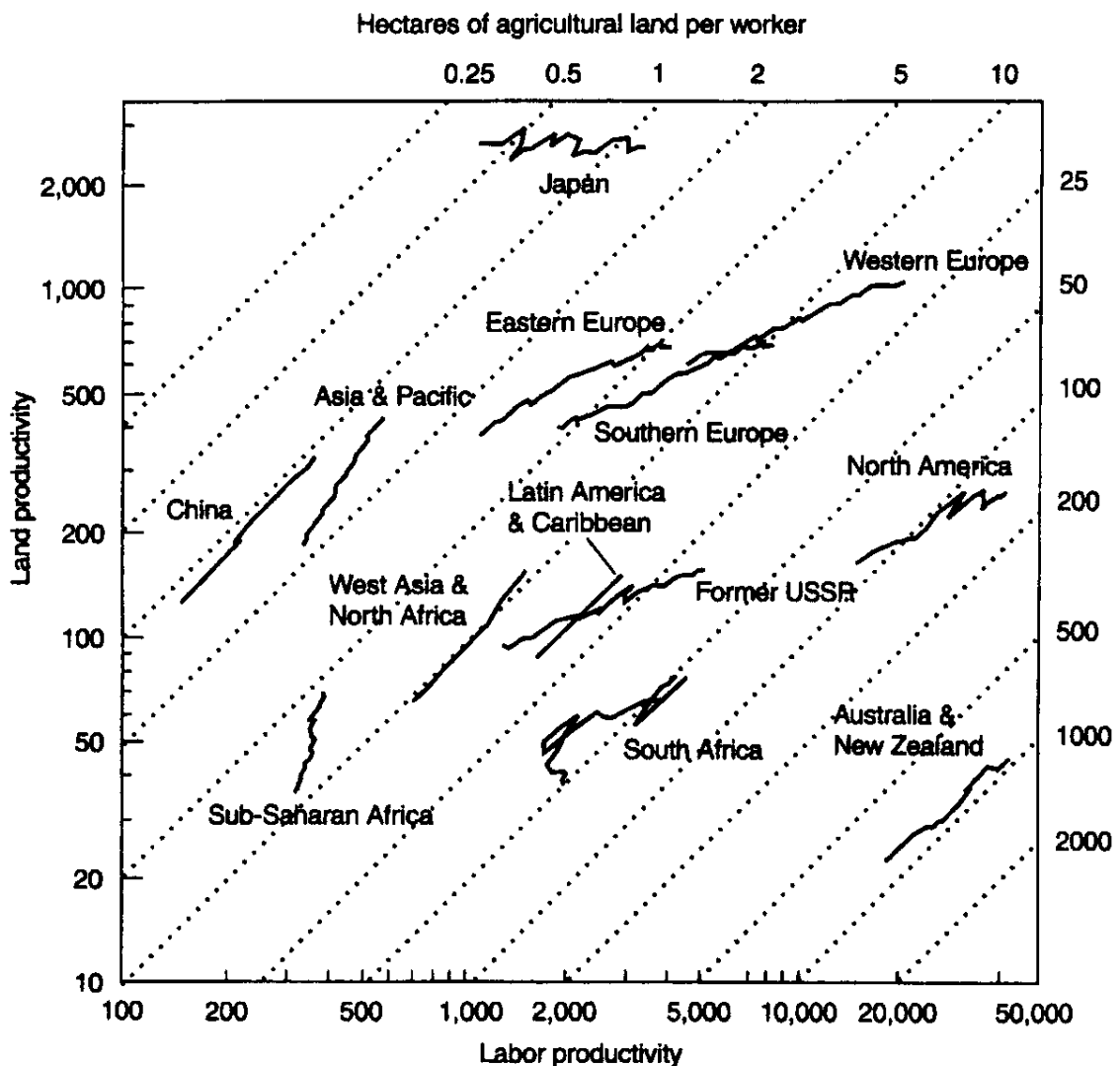


Fig. 2 International comparison of land and labor productivities by region from 1961 to 1990. More information about the literature sources and explanation in the notes of Figure 1 in (Ruttan, 2005)

## **1.2. Innovation in agriculture on all levels will speed up and makes it a necessity to rethink regulation basically and radically, most often in the direction of lowering the regulatory hurdles**

Unfortunately, international and most national regulatory legislation is in its nature static, except countries which have decided for product-oriented like Canada, instead of process-oriented assessment. Process-oriented assessment needs a long time to be settled in international negotiations whenever change happens and then, it needs finally to be settled and approved with an important number of signatory states as the Cartagena Protocol. Thus it is nearly impossible to make the necessary changes based on good science in time. At the time of the establishment of the Cartagena Biosafety Protocol, the similarities between non-transgenic and transgenic organisms on the molecular level were not widely known, although properly published (see latest review with early publications (Arber, 2010), and a correction about these grave errors (recently labeled by the author as 'Genomic Misconception', publication in preparation) in concept is now nearly impossible – details in section 2.4. But the situation is not getting better: with the accelerating speed of scientific progress and discoveries used for new (agricultural) technologies is breathtaking.

A short overview in a few sections below:

### **1.2.1. New biotechnology approaches in plant breeding, introduction**

In an early paper, Britt et al. give an overview on many molecular possibilities which will develop for new breeding successes (Britt & May, 2003), they address the current status of plant gene targeting and what is known about the associated plant DNA repair mechanisms. One of the greatest hurdle that plant biologists face in assigning gene function and in crop improvement is the lack of efficient and robust technologies to generate gene replacements or targeted gene knockouts. They also face an old problem in plant breeding summarized under the complex term of epigenetics (Henderson & Jacobsen, 2007; Johnson, 2007), a problem corrected in conventional plant breeding by careful and often tedious selection processes. Unfortunately, opponents abuse epigenetics as a seemingly new problem for genetic engineering (Moch et al., 2005), avoiding the mention of modern molecular insight and its ease to correct such problems in a more targeted way. It is clear that 'conventional' transgenesis will remain a solid technology for breeding (Potrykus, 1991), but new approaches will appear – as science is always open for progress and new breakthroughs. Here we only mention shortly progress from another more holistic perspective of systems biology: the dynamics of Metabolomics (Smilde et al., 2010) and also the growing speed of discovery in proteomics (Domon & Aebersold, 2010), techniques which will increasingly augment more common types of experimentation, especially as they provide the capacity of generating data sets that can be compared across studies and laboratories (Addona et al., 2009), and because quantitative proteomics data are generated with unprecedented sensitivity, accuracy and reproducibility. There are many new biotechnologies enhancing the speed of achieving targeted breeding successes such as the high throughput marker finding technology (Colbert et al., 2001; Wittenberg et al., 2005), only a few can be mentioned here:

### **1.2.2. Hybrid vigor**

A historical overview (Crow, 1997, 1998) shows the stupendous success of hybrid breeding in order to trigger heterosis which enhances yield considerably, the graph from (Troyer, 2006)

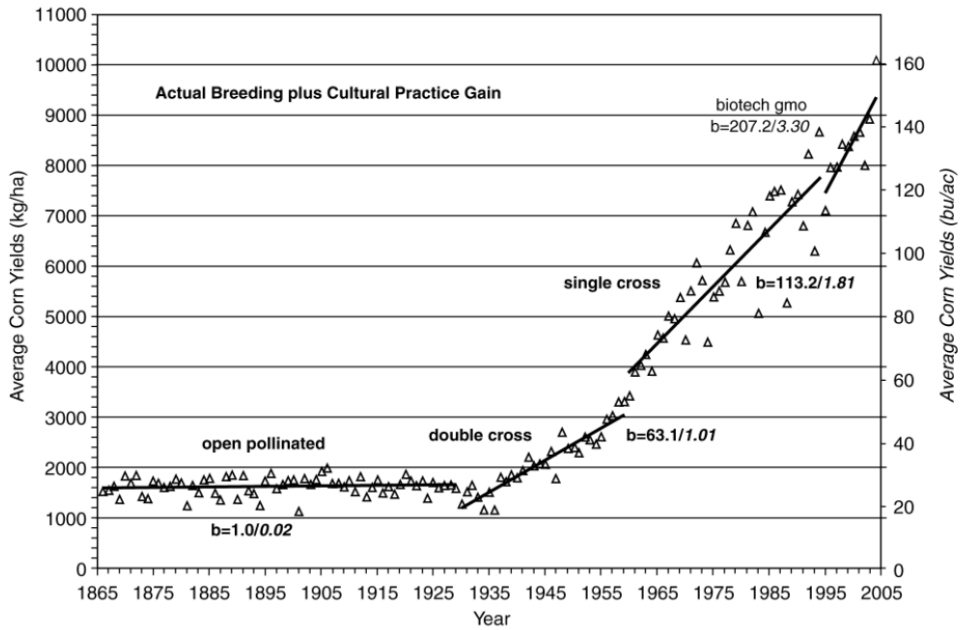


Fig. 3 Average U.S. corn yields and kinds of corn, CivilWar to 2004. “b” values (regressions kg bu<sup>21</sup>) indicate production gain per unit area per year (USDA-NASS, 2005). Figure 1 from (Troyer, 2006)

However, the above graph is smoothed and reality looks a bit different, the influence of the climate and other factors causes short term oscillations which cause amplitudes to be much more important, influencing with strong yield variation markets and crop prices considerably.

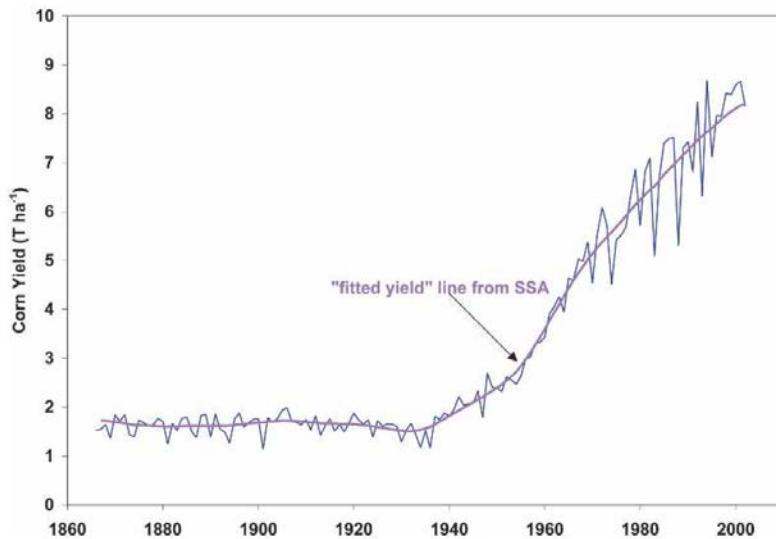
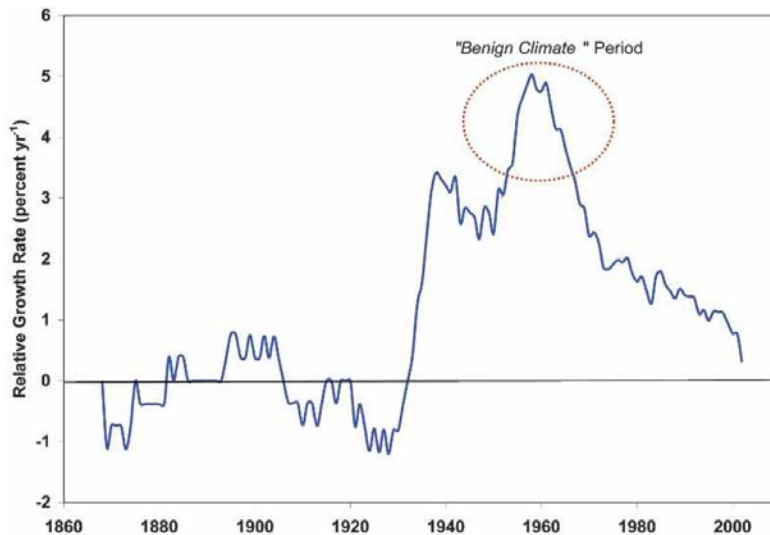


Fig. 4 The U.S. national corn yield average data from the USDA (blue line) and “fitted yield” line (pink line) using SSA. Figure 1 from (Kucharik & Ramankutty, 2005)





**Fig. 5 Heterosis in Maize.** Representative individuals from two inbred maize lines (B73 [far left] and Mo17 [far right]) and the progeny of reciprocal hybrid crosses (B73/Mo17 [left center] and Mo17/B73 [right center]; the female parent is listed first in maize genetics nomenclature) are shown. B73 and Mo17 are two high-quality inbred lines. Nonetheless, the progeny of a hybrid cross between these two lines are taller and more productive than either parent, illustrating the concept of heterosis. Figure 1 in (Birchler et al., 2003)

For many decades, hybrid vigor, based on the Mendelian revolution, is an extremely successful strategy to enhance yield. This yield enhancing vigour is usually achieved by hybridizing two crop traits with an optimal set of differing gene functions. Reviews on hybrid vigor in plant breeding are numerous (with a strong focus on maize, but also many other crops have been subject to such targeted hybridization). Stuber et al. recommend a combination of breeding methods (Stuber et al., 1999) from empirical breeding, marker-assisted selection and genomics to secure yield improvement.

According to James A. Birchler our knowledge on hybrid vigor and its genomic basis is (Birchler et al., 2012) still so limited, that even a clear nomenclature which divides up in various categories of heterosis is still premature:

*“Heterosis refers to the phenomenon that progeny of diverse varieties of a species or crosses between species exhibit greater biomass, speed of development, and fertility than both parents. Various models have been posited to explain heterosis, including dominance, overdominance, and pseudo-overdominance. In this Perspective, we consider that it might be useful to the field to abandon these terms that by their nature constrain data interpretation and instead attempt a progression to a quantitative genetic framework involving interactions in hierarchical networks. While we do not provide a comprehensive model to explain the phenomenology of heterosis, we provide the details of what needs to be explained and a direction of pursuit that we feel should be fruitful.”*

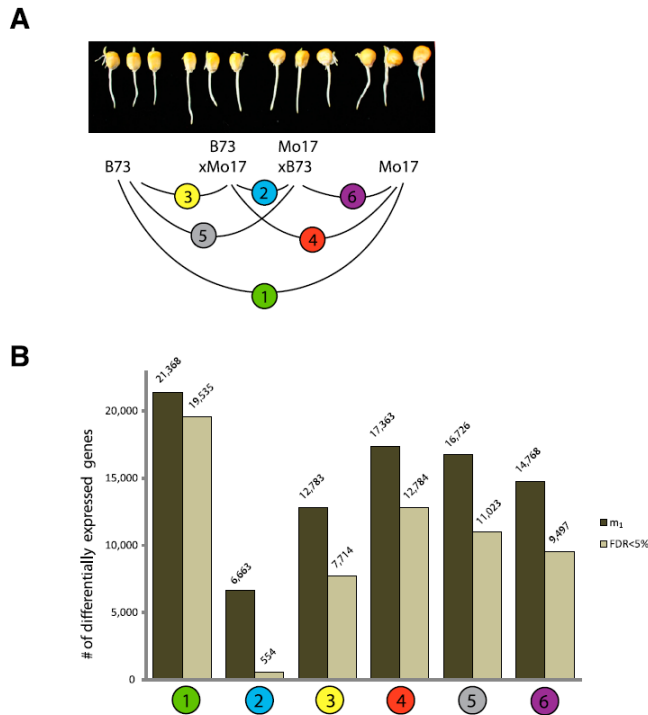
Ti-Fu Zhan admits that heterosis has contributed greatly to yield in maize, but the nature of its contribution is not completely clear. In this study (Zhang et al., 2012), propose that Genome-Wide Transcriptional Analysis of Yield and Heterosis-Associated Genes in Maize can bring more insight: Two strategies using whole-genome oligonucleotide microarrays were employed to identify differentially expressed genes (DEGs) associated with heterosis and yield. The analysis revealed 1 838 heterosis-associated genes (HAGs), 265 yield-associated genes (YAGs), and 85 yield heterosis-associated genes (YHAGs). 37.1% of HAGs and 22.4% of YHAGs expressed additively.

(Groszmann et al., 2011) discussed the complex multigenic system which is responsible for the patterns of gene activity which bring about hybrid vigour in crosses between genetically similar but epigenetically distinct parents. The epigenetic systems discussed are identified as contributing to the heterotic phenotype are the 24nt siRNAs and their effects on RNA dependent DNA methylation (RdDM) at the target loci leading to changed expression levels. Selected review papers, out of a bibliography of over 8000 heterosis references are (Crow, 1998; Dahal et al., 2012; Mladenovic et al., 2012; Oliboni et al., 2012; Riedelsheimer et al., 2012; Shepherd et al., 2006; Waara & Glimelius, 1995).

A unifying theory for general multigenic heterosis related to energy efficiency, protein metabolism, and its implications for molecular breeding is offered by (Goff, 2011).

Many recent papers focus on a multitude of genomic processes involved in hybrid vigour, but recent research suggests that (at least in maize) focus on the favourable root system alterations as the reason for hybrid vigor, better growth and yield (Paschold et al., 2012; Paschold et al., 2010). Another approach improving root growth with targeted heterosis is proposed simultaneously by (Hund et al., 2012).





**Fig. 6** Tests for differential gene expression were conducted on the six pairwise comparisons between the four analyzed genotypes. (A) The transcriptomes of primary roots (2–4 cm long) of 3.5-d-old seedlings of two inbred lines (B73 and Mo17) and their reciprocal hybrids were compared. (B) The estimated total number of differentially expressed genes (i.e.,  $m_1$ ; dark gray) and the number declared to be differentially expressed while controlling the false discovery rate (FDR) at 5% (light gray) are shown. (Paschold et al., 2012)

The conclusions: hybrid vigor is still by far the most successful breeding step to enhance yield, the focus on the main reasons for higher production due to heterosis seems to focus justifiably on the root system. The combination of the multiple causes of heterosis with modern breeding methods below promise for the next decades progress in agricultural production.

### 1.2.3. Cis- and Intragenic approaches

A new technology has now proven to be a successful strategy: As Rommens et al. (Rommens, 2007; Rommens et al., 2006; Weeks et al., 2010) describe it, cisgenetics is a welcome way of combining the benefits of traditional breeding with modern biotechnology. It is an understandable enthusiasm of the first researchers using this technology to emphasize the positive sides by also comparing to transgenesis as an ‘old-fashioned’ method with its problems. But things are certainly not so easy: In section 2.4.2. and 2.4.3. it is made clear that on the genomic level, particularly on the level of molecular processes, there is no difference between transgenic and non-transgenic crops (supported by an important body of scientific literature), and this is certainly also true to cisgenic and intragenic varieties. This is why it is questionable and based on false grounds to make claims that those new methods in transformation would be safer, as Giddings has made it clear in his letter (Giddings, 2006), and his arguments against the the views of (Schouten & Jacobsen, 2007a; Schouten et al., 2006a; Schouten et al., 2006b) and later publications (Conner et al., 2007; Jacobsen & Nataraja, 2008; Jacobsen & Schouten, 2007) could have been targeted as well: they try to demonstrate that the new cisgenics and intragenics are safer than transgenics, which is not based on any facts, rather it is based on accepting without scientific scrutiny the negative public perception on transgenic crops.

It is also wrong to use without clarification the term “alien genes” in view of confirmed and widely accepted *universality* of DNA and genomic structures.

The situation becomes even more complex with the intragenics method, which uses exclusively native promoters and genes from the near relatives, still inserted in the new breed by transgenesis (Rommens, 2007). In the strict sense of the internationally accepted Cartagena Protocol there cannot be any deviation from the clear demand of regulation for all transgenic plants. This is another reason why the focusing on transgenesis in the Cartagena Protocol is wrong and should be changed in direction of a process-agnostic approach - product orientation instead of the process orientation of regulation. But unfortunately for the moment one has to make a point for the exemption of cis- and intragenetics, a point which has little chance to be accepted by the international community of risk assessment specialists. A view clearly to be rejected is the one of Bjoern Myskja (Myskja, 2006), since it is a blow into the face of everyone who seeks a fair dialogue between lay public and science:

*“First, we should respect the opinions of lay people even when their view is contrary to scientific consensus; they express an alternative world-view, not scientific ignorance.”*

However, there is nothing to say against the application of such new methods per se, as (Jacobsen & Nataraja, 2008; Jacobsen & Schouten, 2007) can demonstrate:

*“The classical methods of alien gene transfer by traditional breeding yielded fruitful results. However, modern varieties demand a growing number of combined traits, for which pre-breeding methods with wild species are often needed. Introgression and translocation breeding require time consuming backcrosses and simultaneous selection steps to overcome linkage drag. Breeding of crops using the traditional sources of genetic variation by cisgenesis can speed up the whole process dramatically, along with usage of existing promising varieties. This is specifically the case with complex (allo)polyploids and with heterozygous, vegetative propagated crops. Therefore, we believe that cisgenesis is the basis of the second/ever green revolution needed in traditional plant breeding. For this goal to be achieved, exemption of the GM-regulation of cisgenes is needed.” (Jacobsen & Nataraja, 2008).*

#### **1.2.4. Reverse screening methods: tilling and eco-tilling, genomic prediction**

Two rather independent publications (Parry et al., 2009; Rigola et al., 2009) with largely incongruent literature lists promote a new technology of finding useful genes within the genome of the crops involved: They both promote powerful reverse genetic strategies that allow the detection of induced point mutations in individuals of the mutagenized populations can address the major challenge of linking sequence information to the biological function of genes and can also identify novel variation for plant breeding (Parry et al., 2009). (Rigola et al., 2009) develop reverse genetics approaches which rely on the detection of sequence alterations in target genes to identify allelic variants among mutant or natural populations. Current (pre-) screening methods such as *tilling* and *eco-tilling* are based on the detection of single base mismatches in hetero-duplexes using endonucleases such as CEL 1. However, there are drawbacks in the use of endonucleases due to their relatively poor cleavage efficiency and exonuclease activity. Moreover, prescreening methods do not reveal information about the nature of sequence changes and their possible impact on gene function. (Rigola et al., 2009) present a *KeyPoint<sup>TM</sup>* technology, a high-throughput mutation/polymorphism discovery technique based on massive parallel sequencing of target genes amplified from mutant or natural populations. Thus *KeyPoint<sup>TM</sup>* combines multidimensional pooling of large numbers of individual DNA samples and the use of sample identification tags (“sample barcoding”) with next-generation sequencing technology. (Rigola et al., 2009) can demonstrate first successes in tomato breeding by identifying two mutants in the tomato eIF4E gene based on screening more than 3000 M2 families in a single GS FLX sequencing run, and discovery of six haplotypes of tomato eIF4E gene by re-sequencing three amplicons in a subset of 92 tomato lines from the EU-SOL core collection. This technology will prove to be useful and does not need for its own breakthrough to refer to a scientifically unjustified critique of transgenesis. Whether the new technology will replace the transgenic ‘Amflora potato’ has still to be proven by further scrutinizing of the results of the equivalent trait (Davies et al., 2008).

Another approach which can be seen under 1.2.3 is a new method for the genomic prediction of complex heterotic traits in maize from Riedelsheimer et al. (Riedelsheimer et al., 2012). This is a novel, highly efficient method to achieve new traits of complex genomic composition: Whole-genome and metabolic prediction models were built by fitting effects for all SNPs or metabolites. Prediction accuracies ranged from 0.72 to 0.81 for SNPs and from 0.60 to 0.80 for metabolites, allowing a reliable screening of large collections of diverse inbred lines for their potential to create superior hybrids.

### 1.2.5. Zinc finger targeted insertion of transgenes

Plant breeding has gone through dynamic developments, from marker assisted breeding to transgenesis with steadily improved methods to the latest development of the Zinc finger enzyme assisted targeted insertion of transgenes in complex organisms (Cai et al., 2009; Osakabe et al., 2010; Shukla et al., 2009; Townsend et al., 2009). Zinc-finger nucleases (ZFNs) allow gene editing in live cells by inducing a targeted DNA double-strand break (DSB) at a specific genomic locus. However, strategies for characterizing the genome-wide specificity of ZFNs remain limited. According to (Gabriel et al., 2011) comprehensive mapping of ZFN activity *in vivo* will facilitate the broad application of these reagents in translational research.

The development towards more insertion precision and less genomic disturbance is so rapid, that promoters of organic farming will see dwindling one of their pet arguments even more rapidly: Genomic disturbance of modern breeding is certainly less important and will even be negligible compared to the old breeding methods, still promoted stubbornly by the organic plant breeding community (Ammann, 2008): It is very likely that the transcriptomic disturbances will be even smaller in future – compared to the clumsy and tedious methods of conventional breeding, see also the latest developments in sections 1.2.5 and 1.2.6 below.

### 1.2.6. TALEs: transformation method transcription activator-like family of type III effectors

The generation of double-strand DNA breaks (DSBs) promotes homologous recombination in eukaryotes and can facilitate gene targeting, additions, deletions, and inactivation. Zinc finger nucleases have been used to generate DSBs and subsequently, for genome editing but with low efficiency and reproducibility. In contrast, the transcription activator-like family of type III effectors (TALEs) contains a central domain of tandem repeats that could be engineered to bind specific DNA targets. The new method is capable of generating site-specific DSBs and has great potential for site-specific genome modification in plants and eukaryotes in general (Mahfouz et al., 2011). See also comments on the newswire CNBS (CNBS, 2011) on the discovery:

*“Dr. Mahfouz has developed a “repair tool” (molecular scissors) made out of protein that does two things: it finds the exact place on the genome where it is to be cut using a genetic “postcode” and then deletes, adds or edits the gene with great accuracy and precision.*

*Dr. Mahfouz’s work has the potential for much broader applications including human health. This new technology could enhance the technique that may be used to substitute “good” genes for bad, or to cut out or silence the defective genes that cause disease.*

*Commenting on the research, KAUST Provost Stefan Catsicas saw the technology as a scientific breakthrough and, if the patent is eventually successful, having potentially promising revenues. Dr. Nina Fedoroff, Professor of the Life Sciences at Penn State University, said the Mahfouz paper “shows the practicability of creating DNA-cutting enzymes tailored to cut a desired target sequence with very high specificity. This is an excellent step forward toward creating very specific genetic improvements in crop plants, while avoiding the potential risks many are concerned about with more conventional genetic modification strategies. Moreover, the paper gives the first evidence that this particular strategy will work in plants.” Professor Federoff is “delighted to see such cutting-edge contributions emerging from a university as young as KAUST!”*

### 1.2.7. Precision engineering through DNE meganucleases

Engineered DNE meganucleases can be used for cloning and molecular analysis purposes in much of the same ways as conventional restriction enzymes. The important difference, of course, is that

meganucleases recognize much rarer DNA sequences than restriction enzymes. This makes them particularly well suited to the manipulation of extremely large DNA sequences such as intact genomes. Importantly, DNE meganucleases cleave to leave 4 basepair 3' overhangs suitable for "sticky-end" cloning. The first application with a new tool called Directed Nuclease Editor™ in plant breeding by Bayer Crop Science <http://www.precisionbiosciences.com/> seems promising: The meganucleases have been first used to do precision work in human gene therapy, but an outlook into various other applications was announced as soon as 2003 (Epinat et al., 2003; Paques & Duchateau, 2007; Silva et al., 2011)

### 1.2.8. Synthetic biology

In some 150 laboratories, synthetic biology is intensively researched, and it seems clear that the future will bring here some unexpected revolutions: A new field, synthetic biology, is emerging on the basis of these experiments (Benner, 2004), where chemistry mimics biological processes as complicated as Darwinian evolution. According to (Tian et al., 2009) the emerging field of synthetic biology is generating insatiable demands for synthetic genes, which far exceed existing gene synthesis capabilities. Tian et al. claim that technologies and trends potentially will lead to breakthroughs in the development of accurate, low-cost and high-throughput gene synthesis technology - the capability of generating unlimited supplies of DNA molecules of any sequence or size will transform biomedical and any biotechnology research in the near future. And, according to (Benner et al., 1998), already in 1998 the redesigning of nucleic acids has been judged in an optimistic way, this was confirmed in an important Nature review in 2005 (Benner & Sismour, 2005). The real breakthrough came with the synthesis of an organism including its reproduction, achieved after years of research and a firm belief in success, typical for the senior author of the mega-project still continuing: (Gibson et al., 2008a; Gibson et al., 2008b; Gibson et al., 2010; Rusch et al., 2007).

In a way, the artificial altering of genes producing Bt toxins can strictly spoken also be summarized under synthetic biology, since the specifically altered Bt toxins in order to facilitate resistance management of Bt crops: Bruce Tabashnik, who works on problem solving programs for Bt crops with field research and new concepts of resistance management (Tabashnik et al., 2011): Relative to native toxins, the potency of modified toxins was >350-fold higher against resistant strains of *Plutella xylostella* and *Ostrinia nubilalis*. Previous results suggested that the modified toxins would be effective only if resistance was linked with mutations in genes encoding toxin-binding cadherin proteins (Soberon et al., 2007). Tabashnik et al. report evidence from five major crop pests refuting the Soberon hypothesis. Recently, David Andow co-authored a paper with a positive balance of 15 years of resistance regime for Bt maize (Huang et al., 2011).

Final remarks for sections 1.2.1. to 1.2.7 (most of the above technologies can be summarized under the term 'Targeted Gene Modification' (TagMo).

Not only molecular processes became more precise, it is also the new view on transgenesis, because the 'Genomic Misconception' will soon be widely recognized with its important followup that transgenic crops are not basically different from conventional crops related to the molecular processes (2.4.). But still the worldwide consensus about regulation, frozen in the Cartagena Protocol on Biosafety, still fully reflects the erroneous 'Genomic Misconception'. It is fact that scientific and political organizations dealing with the regulation on worldwide and national levels have grown into powerful units generating large sums of money for their own organization, employing tens of thousands of people. And more, the control of markets with GMOs and watching over the biosafety

of the new breeds has grown into an important economic factor including blatant, but still hidden protectionist motivations. There is a clear tendency that the powerful regulation community will, in their own self-interest, demonstrate a growing reluctance to adapt regulation to the progress of science and to free it from unnecessary risk-mindedness.

### 1.3. Some preliminary regulatory conclusions related to new transformation methods

(Kuzma & Kokotovich, 2011) come with conclusions on how to re-negotiate the GM crop regulation and give a brief overview on the history of the main steps in the refinement of transgenesis until the breakthrough of more targeted insertions beginning with the zinc finger technology, a 'Targeted Gene Modification' (TagMo).

a)	1974–1975 Leading genetic scientists convene at the Asilomar meeting and encourage the US government to develop guidelines for regulating experiments using ribosomal DNA.
b)	1986 The Office of Science and Technology Policy (OSTP) determines that ribosomal DNA is not inherently risky, and that regulations should focus on products and not the processes used to develop them. The OSTP develops a three-agency jurisdictional model known as the Coordinated Framework for the Regulation of Biotechnology (CFRB; Office of Science and Technology Policy, 1986).
c)	1987–1994 The USDA, FDA and EPA interpret existing laws (e.g. FIFRA, TOSCA, and FPPA) and promulgate regulations and policies concerning GMOs.
d)	1992 The FDA issues a new foods policy, which states that foods derived from genetically engineered plant varieties do not differ substantially from conventional counterparts.
e)	1994 First commercial GMO product, the Flavr Savr tomato, emerges on the market.
f)	2000 Starlink, a form of Bt corn that can cause allergic reactions in some people, is found in the food supply, causing food product recalls and controversy over biotechnology regulation.
g)	2002 The National Research Council publishes a report stating that the USDA should more rigorously review the potential environmental effects of transgenic plants before approving them for commercial use (National Research Council, 2002).
h)	2006–2011 In separate cases filed against the USDA, federal judges revoke the USDA's environmental assessment and deregulation of herbicide-tolerant (HT) alfalfa and HT sugar beets. The judges rule that the environmental assessments inadequately addressed the risks posed by genetically engineered crops, specifically regarding gene flow and the possible contamination of conventional and organic crop varieties. The USDA was ordered to complete the more intensive environmental impact statement (EIS) in each instance. After completing the HT alfalfa EIS, the USDA decides to fully deregulate HT alfalfa, allowing its unrestricted use. In the process of completing the EIS for HT sugar beets, the USDA partly deregulates them, allowing their restricted commercial use (Pollack, 2011; Voosen, 2011).
i)	2009 USDA proposes revisions to its rule for GMOs under the FPPA, sparking public comment.
j)	2009 First demonstration showing that zinc-finger nucleases can be used to create plants that have precise changes in endogenous genes (Townsend <i>et al.</i> , 2009; Shukla <i>et al.</i> , 2009).

**Fig. 7 Brief history of the regulation of genetic engineering (Kuzma *et al.*, 2009).** EPA, Environmental Protection Agency; FIFRA, Federal Insecticide, Fungicide and Rodenticide Act; FDA, Food and Drug Administration; FPPA, Farmland Protection Policy Act; GMO, genetically modified organism; TOSCA, Toxic Substances Control Act; USDA, United States Department of Agriculture. A side remark: reference f) is erroneous, the star link Bt gene Cry9c and its protein did not cause a single case of proven allergy, see a selection of scientific papers: (CDC Report to FDA, 2001; Siruguri *et al.*, 2004; Sutton *et al.*, 2003, 2004; Yonemochi *et al.*, 2003). (Kuzma & Kokotovich, 2011)

It is interesting to follow the thoughts of (Kuzma & Kokotovich, 2011): roughly the authors make a plea to change the US regulatory system from product orientation to process orientation with the following arguments:

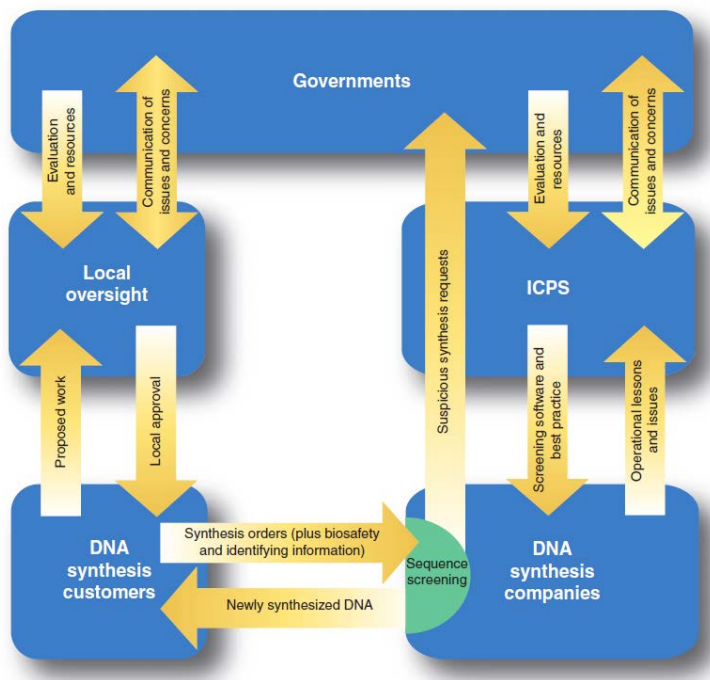
*“TagMo-derived crops that introduce alien transgenes or knock out native genes are similar to traditional GM crops or conventionally mutagenized plants, respectively, but TagMo crops that alter the DNA sequence of the target gene (Fig 1D) are more difficult to classify. For example, a GM plant could have a single nucleotide change that distinguishes it from its parent and that confers a new trait such as herbicide resistance. If such a subtle genetic alteration were attained by traditional mutagenesis or by screening for natural variation, the resulting plants would not be regulated. As discussed above, if rDNA techniques are used to create the single nucleotide TagMo, one could argue that it should be regulated. Regulation would then focus on the process rather than the product. If single nucleotide changes were exempt, would there be a threshold in the number of bases that can be modified before concerns are raised or regulatory scrutiny is triggered? Or would there be a difference in regulation if the gene replacement involves a sexually compatible or an incompatible*



species?(Kuzma & Kokotovich, 2011).

- But there is not much logic in this argumentation for the following two reasons: According to (Arber, 2002; Arber, 2010, 2011) the molecular processes of transgenesis are the same as those for natural mutations. See all the details in the section 2.4. 'Genomic Misconception'.
- Many exaggerations of regulatory rules are based on the process of rather un-precise methods such as biolistics or by transforming *Agrobacterium* with the plasmids, but in contrast to them the TagMo's are getting more and more precise and basically are thus reducing the risks of unwelcome side effects even more.

A pragmatic view of a new regulatory scheme related to a new organization of the difficult discourse, answering to the new biosafety tasks of synthetic biology is proposed by (Bugl et al., 2007):



**Fig. 8** Our framework calls for the immediate and systematic implementation of a tiered DNA synthesis order screening process. To promote and establish accountability, individuals who place orders for DNA synthesis would be required to identify themselves, their home organization and all relevant biosafety information. Next, individual companies would use validated software tools to check synthesis orders against a set of select agents or sequences to help ensure regulatory compliance and flag synthesis orders for further review. Finally, DNA synthesis and synthetic biology companies would work together through the ICPS, and interface with appropriate government agencies (worldwide), to rapidly and continually improve the underlying technologies used to screen orders and identify potentially dangerous sequences, as well as develop a clearly defined process to report behavior that falls outside of agreed-upon guidelines. ICPS, International Consortium for Polynucleotide Synthesis. From (Bugl et al., 2007)

This kind of new regulatory approach, fully including the production side of the industry, will be needed in order to avoid unnecessary regulatory hindering of research progress in synthetic biology, a demand supported with other innovative suggestions for interactive procedures (Maurer et al., 2006). Another balanced view (Serrano, 2007) demonstrates also the new risks arising from synthetic organisms and the accidental (or purposeful) release in the environment. As always, the ethical awareness and behavior has to be developed further, agreeing with (Edmond & Mercer, 2009) not in a way which gives forfeit power to social sciences. What we really need is a new inter-faculty, interdisciplinary or even better trans-disciplinary discursive scheme as proposed in sections 5.2 and

5.3. There is also no reason, to indulge into cheap propaganda features as “revolving doors” between the government regulatory agencies and the industry, or between science and industry, because the advantages of such discursive communication will over-rule the dissatisfaction

It should be a warning, what happened some 35 years ago in the US National Institute of Health with the words of Henry I. Miller (Miller, 2010).

*“Thirty-five years ago, the US National Institutes of Health adopted overly riskaverse guidelines for research using recombinant DNA, or “genetic engineering,” techniques. Those guidelines, based on what has proved to be an idiosyncratic and largely invalid set of assumptions, sent a powerful message that scientists and the federal government were taking seriously speculative, exaggerated risk scenarios – a message that has afflicted the technology’s development worldwide ever since.”*

Final remarks for Section 1.2:

All this enumerated cases of new transgenesis methods, which can be summarized under the term ‘Targeted Gene Modification’ (TagMo), demonstrate that research will continue, new methods will inevitably be found and successfully be applied to plant breeding. The difficulties and basic questions on how to apply the present day biosafety regulation will continue and even grow, *as long as there is no change possible towards product oriented assessment*. It will be simply inevitable in the face of the ever accelerating speed of progress in science to change to a process-agnostic mode of biosafety regulation combined with a de minimis approach (Durham Tim et al., 2011), for the details see section 7.

## **2. Illusions and realities on educational effects in the debate, the dialogue between science and the public**

There is no doubt that there is hope and need to simply start and/or maintain an open dialogue between major stakeholders among young scientists, politicians, industry and society (Keller, 2009), although there are many obstacles such as asymmetric relationships among the partners, which can render the discourse complex and unpredictable. And it is uncontested here that education on all school levels has its justified place, this has again been shown with empirical results from Spain (Harms, 2002; Ramon et al., 2008). Gensuisse should also be mentioned here with educational activities in schools and a popular open day of Genetics in major Swiss cities organized by researchers and institutes every year (Gensuisse, 2011). And education on biotechnology in the developing world is especially important, if done in a participative way, and with proper ramifications in all institutions of communication, science and regulation: In April 2007, biosafety and biotechnology scientists, regulators, educators, and communicators from Kenya, Tanzania, and Uganda, met to examine the status and needs of biosafety training and educational programs in East Africa (Sengooba et al., 2009). See also the section 2.2.3 on Brazil with its regulatory successes, certainly based on excellent communication efforts from NGOs, Government and Industry.

Thus, educational efforts on all levels are not in vain, and deplorably there are too few academic institutions active in biotechnology education (McHughen, 2007). The structure of the debate has shifted: Today the GM crop debate is steered by scientific *and* pseudo-scientific arguments. And this also includes an element of hope for the pro-scene: Slowly but surely the pseudo-scientific arguments are fading away for the opponents, since there is no serious incident known despite the fact that millions of hectares are grown with GM crops worldwide (James, 2009b).

There is a widespread mistrust against new technologies where everybody feels it will change their

own life, and this often happens in a phase where the benefits are not yet clearly visible, especially for the consumers/users. But it is not correct to reduce those difficulties to an exclusive criticism of the so called '*deficit model*' (Sturgis & Allum, 2004; Sturgis et al., 2005a; Sturgis et al., 2005b) where the people just have to be educated and then they would refrain from negative emotions. A question mark on the exclusive use of the '*deficit model*' is justified, but surprising conclusions emerge from the above mentioned critics themselves: They do not discard altogether the traditional deficit model, rather they propose to combine it with the *contextual approach*, thus emphasizing the complex and interacting nature of the knowledge-attitude interface. This highlights the sophistication and value of lay understandings of science that can exist in the absence of formal scientific knowledge (Gaskell et al., 2000; Schuman & Presser, 1980). Surprisingly positive are results of polls which are conducted by Philip Aerni with more closeness to the real life and careful avoiding of polling mistakes (Aerni et al., 2011), the study concludes:

*"The results of our discrete choice analysis show that Swiss consumers treat GM foods just like any other type of novel food. We conclude from our findings that consumers tend to appreciate transparency and freedom of choice even if one of the offered product types is labeled as containing a genetically modified ingredient. Retailers should allow consumers to make their own choice and accept the fact that not all people appear to be afraid of GM food."* (Aerni et al., 2011)

There is growing consensus that scientific knowledge extends beyond the simple learning of 'facts' that can be straightforwardly defined and measured (Irwin, 2006). From this perspective, privileging formal scientific knowledge as the sole basis of rational preference formation leads us to overlook other knowledge domains that may be equally, or even more important determinants of attitudes towards science.

These insights have been condensed into a feasible discursive method of the *Systems Approach* initiated by Churchman (Churchman, 1979; Ulrich, 2002) and refined by Rittel et al. (Protzen & Harris, 2010; Rittel, 1992; Rittel & Webber, 2005). Details on the methodology are given under sections 5.2. and 5.3, where the *solutions* are discussed.

It is an illusion to solve ill-fated GM-disputes by just adding social and cultural aspects, or, that the dispute should so to say start from the other end of the controversy ignoring the biosafety science (Magnan, 2003) or even worse to primarily appeal to feelings and emotions of the public and indulge into entertaining but ultimately meaningless discussions in order to catch the interest of the public – we should not mimic the strategy of the protest corporations. That said, this does not mean, that socio-cultural aspects including emotions should be neglected – even the boulevard press sends out strong signals for learning processes. Vaughan's (Vaughan, 1995) plea is that regulatory officials should engage in an interactive process of information and opinion exchange that is reasonable and effective within vastly different socioeconomic and cultural contexts, This is often a challenge to government employees concentrating on office work routine. Patricia Osseweijer (Osseweijer, 2006a, b) is offering an interesting compromise: a mix of science, ethics and emotions with her '*Three E-Model*' Entertainment (getting attention), Emotion (identification) and Education (information and skills for (future) decision-making)). It has been developed on the basis of long-term experience and observation of public communication by individuals in the Department of Biotechnology of the Delft University of Technology (Osseweijer, 2006c; Osseweijer et al., 2010).

Despite of all possible refinements and enhancements of the dialogue with the public: we should not under-estimate the negative role of the opponents of genetic engineering in plant breeding organized as professional protest corporations, see section 3.



## 2.1. How the internet is influencing the debate

We still under-estimate the internet as a worldwide literacy practice environment, although it has created a new situation in communication, providing a new dynamic field for research and knowledge accumulation. (Koutsogiannis & Mitsikopoulou, 2004).

It has created an internet based debate culture with all its ramifications from classic email over blogs of all sorts and better organized social media like facebook and linkedin to twitter and this not only in nanotechnology (Kostoff et al., 2006), but also other research realms and E-business (Kanter, 2000). The evolution in this kind of debate is still going on with unprecedented dynamics and is not yet fully understood in all its consequences (Bruns, 2008), (Reifer, 2002) and (Kalman et al., 2002). The hope is, that the easier communication through the internet will invite to a *collaborative* instead of *confronting* modus (Borland & Wallace, 1999). Some advice on how to behave in chats and blog debates on the internet might be useful (Dall'Olio et al., 2011), compare a list of useful websites and databases on biosafety by DeGrassi et al. (Degrassi et al., 2003) and (Burns, 20110801). A list of pertinent websites can be expanded ad libitum, the present state of error of 2011, with all the possible personal bias in (Ammann, 2011).

Informatics and the new ease to access huge amounts of scientific information on the internet causes a democratization effect on the science debate. But this can only then lead to positive developments, if the new flood of information is also well organized and provided people make serious efforts to analyze the available information so that our understanding of complex scientific knowledge can indeed be improved. We arrived in new decades on "culturomics", where cultural shifts and trends can be analyzed with accuracy through the internet (Michel et al., 2010). As Janetzko (Janetzko, 2008) shows, it's not enough to make use of the most common search machines, only professionally organized searches and databases on scientific literature can help and create some limited reliability and sustainability of scientific knowledge. And: clearly, the usual citation clusters among opinion-buddies will not suffice. And it should be emphasized: Electronic ease does not replace the tough job of scholarly reading and *understanding*. It will be a difficult task for the future to divide up clever knowledge accumulation and genuine thinking work among active scientists.

And, a caveat already signaled by Seneca: "*Thoughtful Action creates more wisdom than knowledge accumulation*".

This can be interpreted related to social electronic networking in two ways: On one side, the immense intensification of social networking via the internet creates among other things a new possibility for post publication reviewing and filtering out the really relevant publications and ideas. On the other hand, it hinders systematically the deepening of your own knowledge in an individual way, and be it only by reading every year a dozen or two really relevant book publications. There is a clear danger to get immersed into a shallow and time consuming activity in social networks, admittedly reading the news maybe half a day earlier than in other list-servers. The influence of the internet on social life has been scrutinized also in earlier days by Kraut et al. 1998 (Kraut et al., 1998), claiming already with data that in the sample the internet was used extensively for communication. Nonetheless greater use of the internet was associated with declines in participant's communication with family members in the household, declines in the size of their social circle, and increase in their depression and loneliness. These data were collected in a time when facebook and twitter did not even exist yet. Bonfadelli 2002 also spotted knowledge gaps and explains the theory behind (Bonfadelli, 2002). Such discontinuities have happened in history throughout with the introduction of writing, bookprinting, telephones and transistor radios and mobile smart phones. Whereas Swidler et al. 1994 (Swidler & Arditi, 1994) still has doubts whether the next revolution in (electronic) communication will have an important impact, this question is answered now – in a time when

facebook and mobile improvised television channels have triggered the Arab spring, it is the power of knowledge and the mind which is now spread in minutes and creates amazing persistence, as Ismail Serageldin, the director of the Bibliotheca Alexandrina so clearly communicated to the CNN:

<http://www.youtube.com/watch?v=X6MOKfS1ACI> .

This major shift from paper to electronics is also creating new methods of *quantitative* analysis of science work: see the Scientometrics Wikipedia: <http://en.wikipedia.org/wiki/Scientometrics>. Actually, this newly emerging science can provide with caveats and insights in changes of research priority, reveal citation habit, evaluate journals with new scales etc. (Leydesdorff, 2002, 2008, 2009; Leydesdorff & Wagner, 2009). A typical example is given in the semantic analysis of the coming and going of the Frankenfood myth (Leydesdorff & Hellsten, 2006), with a somewhat surprisingly early and sharp peak of appearances of the word Frankenfood in websites for 1998, followed by a sharp decline to virtually zero two years later.

Fig. 9 Web site pages addressing the 'Frankenfood' and 'Frankenstein food' issues at Monsanto, the *Times*, and the Friends of the Earth Web sites. [jcmc.indiana.edu/vol8/issue4/hellsten.html](http://jcmc.indiana.edu/vol8/issue4/hellsten.html)

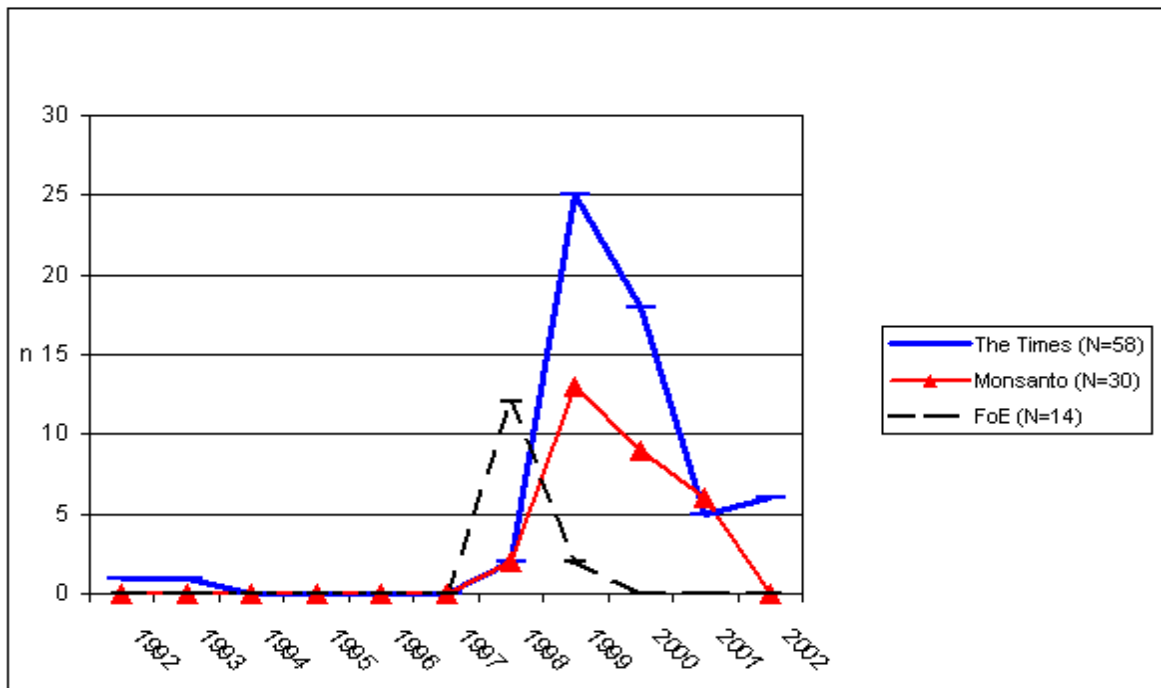


Fig. 10 This figure is confirmed in (Leydesdorff & Hellsten, 2006) with the following statements and figures:



Fig. 12 The cosine map of 100 words used more than 31 times in the 6101 documents on Frankenfoods in 2003 (cosine  $\geq$  0.1) From (Leydesdorff & Hellsten, 2006)

The comments in (Leydesdorff & Hellsten, 2006):

*“Our interpretation of these results is as follows: the decline of the organizing power of the metaphor was rapid in 1999 and 2000 when the metaphors of ‘Frankenfood’ and ‘Frankenstein food’ began to be outdated. Due to its generalized meaning, the metaphor was used increasingly across domains and therefore lost its domain-specificity and the ability to organize distinctions among domains. This might also explain why the NGOs stopped using the metaphor in 2000 (HELLSTEN, 2003).”*  
From (Leydesdorff & Hellsten, 2006)

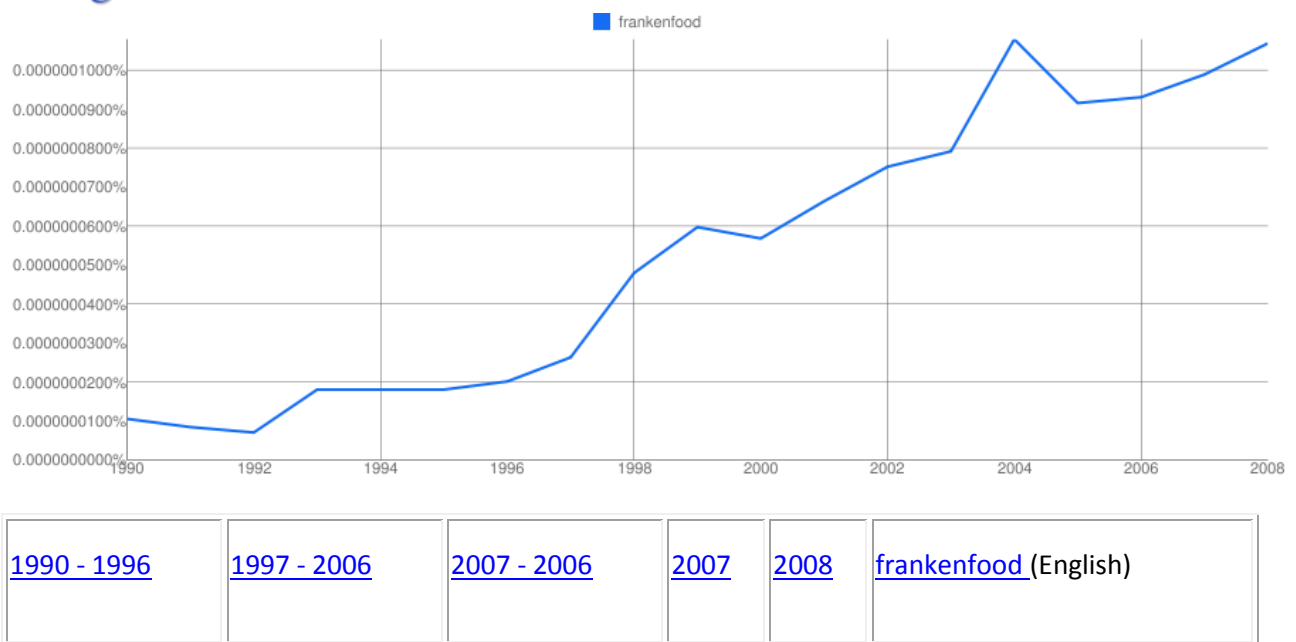
Scientometrics can do much more, (Aizen et al., 2004) have shown the potential of a sophisticated statistical analysis combined with modeling of community interactions in the web: Besides tracking just the description-to-acquisition behavior of users scientometrics can do much more by longer observation periods which offers the chance to make richer inferences about both group and individual user intentions – trends of intruding into human behavior and making conclusions, which are actually beyond Orwell’s imagination. Yet we should have no illusions, since a lot of work and application is already going on in the marketing and advertisement scene, which has also a often manifested interest in knowledge accumulation methods (Cavaller, 2009; Cavaller & Aubertin, 2008). It is somehow amazing to realize that the academic world in most fields of specialization have not yet reached the realms of professional knowledge accumulation and consolidation – not to speak about an efficient way of reaching out from knowledge accumulation to efficient development of new technology. Scientometrics would have the potential to get instrumentalized in research and development, with some good chance to be used also in new peer review processes.

See also the earlier discussion of the term Frankenfood in (Cook et al., 2006): Interestingly enough the analysis of Cook et al. demonstrated, that in the analyzed period 2003 the word Frankenfood was more often used by proponents of GM food than by the opponents:

*A variety of software programs like Wordsmith Tools (Wordsmith Tools, 1996) enable researchers to build and analyze their own corpora, and to compare them with larger corpora such as the British National Corpus of 100 million words. One revealing and particularly useful output from such programs is the concordance, centering occurrences of a particular word in such a way that the linguistic contexts in which it occurred are revealed. Table 1 (from our own newspaper corpus) shows actual uses of the word “Frankenstein,” demonstrating that, contrary to our expectation, the phrase “Frankenstein food” is used more often by proponents of GM to characterize the opposition (“so-called Frankenstein foods,” “lurid warnings about Frankenstein foods”) than by the opposition itself.(Cook et al., 2006),*

A *qualitative* evaluation of science should involve additional elements - see below under peer review in the section 2 on regulation.

Deplorably, important networks are often only known in specific reader clusters, these awareness gaps should be minimized. We need knowledge exchange, jumping over geographical and ideology fences. And for sure, the internet is an ideal instrument for such purposes. Google also offers some good programs for analyzing the worlds literature published in books, see Google Books Ngram Viewer, the example for Frankenfood, this time the source is the scrutinization of millions of books:



[http://books.google.com/ngrams/graph?content=frankenfood&year\\_start=1990&year\\_end=2008&corpus=0&smoothing=3](http://books.google.com/ngrams/graph?content=frankenfood&year_start=1990&year_end=2008&corpus=0&smoothing=3)

Fig. 13 The Google Labs N-gram Viewer is the first tool of its kind, capable of precisely and rapidly quantifying cultural trends based on massive quantities of data derived from a big number of books. Here the keyword frankenfood has been retrieved in the Period from 1990 to 2008 (the latest year possible in Dec. 2011), see also [http://edutechwiki.unige.ch/en/Ngram\\_Viewor](http://edutechwiki.unige.ch/en/Ngram_Viewor)

It shows a steadily growing number of frankenfood mentions in books, a picture, which is different from the analysis of published journal literature by (Leydesdorff & Hellsten, 2006) because both teams used different definitions of the metaphor and filtering of the literature set and different statistical methods.

A downside of internet activities has to be mentioned: Cyberbullying is on the uprise in many fields of social dispute, it has the potential of giving space to veritable keyboard gangsters, as Pelfrey et al. explain with hard data in (Pelfrey & Weber, 2013). The sociological research field of cyberbullying remains to be extended to disputes like genetically engineered crops. The fight has already reached the stage of harsh accusation and even some court cases: Case Prof. Marc Fellous, France (Seppi Wackes et al., 2011; Seralini-Fellous, 20110123) and Case Busamante, Peru (Laurson Lucas, 201002, 20119111). There are also incidences on cyber attacks such as the closing down of the website of the Rothamstead experimental potato field trials (Vaughan Adam, 20120528).

## 2.2. Scientist's education and new developments on the internet

In a successful initiative, Ron LaPorte and his group 'Supercourse' started in 2002 (Laporte et al., 2002a) a new educational internet based system: In his view, Journals do not have an exclusive "right" to science. A publication and a scientific presentation do virtually the same thing—they share scientific knowledge. Publication and presentation have been separate but could "morph" into a single entity. This metamorphosis is taking place and is driven by a juggernaut called PowerPoint, Microsoft's graphics and slide presentation software, and today enriched with more media from Twitter over YouTube to all the numerous blog systems, networking enhanced with RSS etc. More on the Supercourse programme in (Laporte et al., 2006; Laporte et al., 2002b; Linkov, 2006; Linkov et al., 2003; Sa et al., 2003), also in connection with the Bibliotheca Alexandrina in Egypt: (Sauer, 2010) Another possibility on a well organized collection of powerpoint slides is offered for free by the

University of California by Peggy Lemaux and Barbara Alonso, University of California [http://ucbiotech.org/resources/slide\\_archive/index.html](http://ucbiotech.org/resources/slide_archive/index.html). A series of over 100 slideshows is offered by the bibliography of the author, new slide shows are continuously added, they can be downloaded from (Ammann, 20110904). An important new development started 2002 at the Bibliotheca Alexandrina, where a new world center of electronic knowledge is emerging, which is based on thoughtful new structures (Adly, 2009).

Clearly, education in science is in swift change in methods and targeting contents in a more efficient way. It is also of utmost importance, that science education takes into account an important effort in educating young scientists in professional communication methods on a high ethical standard. It is deplorable that educational staff at universities is selected mainly according to their skill in science performance, which is mainly measured in the impact of publication efforts.

### 2.2.1. On biosafety education

Biosafety is today a permanent topic on local, national and international level, and basically, it is good to see educational activity. As demonstrated in this contribution, the topic of biosafety is highly controversial, and so are the views on the various educational activities. The most blatant misunderstandings in biosafety education stem again from the 'Genomic Misconception', which forces authors seemingly to focus on transgenic crops alone, which is scientifically unacceptable as we will see in section 2.4. A symptomatic example on the enumeration of risks related to transgenic crops is given by Craig et al. (Craig et al., 2008): All risks duly mentioned can be attributed just as well to conventional crops. The only difference between modern and conventional breeds can be found in risk mitigation, which is much easier in the case of the transgenic crops. Here just two recent examples related to the successful prevention of upcoming resistant pest insects (a problem arising in all kinds of agricultural management systems): (Tabashnik et al., 2011) and (Huang et al., 2011). It is deplorable, that most biosafety education is still based on the erroneous 'Genomic Misconception', which results automatically into a biosafety risk view focusing on the process of transgenesis instead of working on a product oriented basis. Read more about the 'Genomic Misconception' in section 2.4.

Clearly, science education going through a major shift with the new internet possibilities. The same goes for biosafety education, and it will be very helpful to apply all electronic means to this complex field of knowledge. There is also no excuse to exclude unwelcome scientific publications, since the Web of Science (Web of Science, 2012).

### 2.2.2. Words of Mass Destruction

The sections title is borrowed from an enlightening press analysis from the first half of the year 2003 in Great Britain (Cook et al., 2006), in essence the conclusions revealed that opponents indulged primarily into politics and questionable parallels, the pro-side leaned towards scientific argument:

*"Both in the press and in public reaction, the issue of GM was found to be intimately associated with other political events of the time, notably the invasion of Iraq. Except among experts, there was little awareness of the official national debate and issues were approached in more general terms. Pro-GM characterization of the issues as primarily scientific, both by newspapers and experts, was rejected by the anti-GM press and campaigners, and by the focus-group participants. They assessed the issues in a more global frame, rejecting scientists and companies as unreliable. In addition, they linked both US and British GM policy to the invasion of Iraq, and, by analogy, rejected pro-GM arguments as untrustworthy." (Cook et al., 2006)*

The conclusion of an earlier paper of the same authors Cook et al. (Cook et al., 2004) are clear: 'The scientists think and the public feels': This is the result of 50h of interviews on expert perceptions of the discourse of GM food:

*“Debates about new technologies, such as crop and food genetic modification (GM), raise pressing questions about the ways ‘experts and non experts’ communicate. These debates are dynamic, characterized by many voices contesting numerous storylines. The discursal features, including language choices and communication strategies, of the GM debate are in some ways taken for granted and in others actively manipulated by participants. Although there are many voices, some have more influence than others. This study makes use of 50 hours of in-depth interviews with GM scientists, nonexperts, and other stakeholders in the GM debate to examine this phenomenon. We uncover rhetorical devices used by scientists to characterize and ultimately undermine participation by non-experts in areas including rationality, knowledge, understanding and objectivity. Scientists engage with ‘the public’ from their own linguistic and social domain, without reflexive confirmation of their own status as part of the public and the citizenry. This raises a number of interesting ironies and contradictions, which are explored in the article. As such, it provides valuable insights into an increasingly important type of discourse.” (Cook et al., 2004)*

The table from the word analysis of (Cook et al., 2006) tells the same story:

Ways of characterizing pro-GM	Ways of characterizing anti-GM
Balanced	Polarized
Benefits	Highly selective
Thoughtful	Scaremongering
Calm	Fear
Choice	Hostile
Truth	Hysteria
Evidence	Panic
Open-minded	Emotional
Open debate	Feverish
Objective	Religious
Complex	Irrational
Facts	Lurid
Sound science	Frankenstein
Sensible	Frankenfoods
Informed	Superweeds
Information	Bedevilled
Lucid	Demonized
Understanding	Danger
Reasoned	Genie out of the bottle
Rational	Zero risk
Strength	100% safe
Safe	Extreme views
Solid	Exaggerate
Excellent	Anti-science
Level headed	Inappropriate
Society wants/Society decides	Lack of realism
Public	Does not grasp
Peer reviewed	Accusations
Precise	Cultural norms
Gene insertion	Powerful
Tool	Destructive
Wish	Activist
Impartial	Evangelical
Appropriate	Hard core
Careful	Hot
Experts	Worry
Independent	Uninformed
Legal	Prejudice
Justified	Luddite
Rearrangement of genetic material	Immoral
Consumer wants/Consumer decides	Cherry-picked
Risks minimized	Political agenda
Rewards maximized	Unhelpful
Functional	Unscientific
Nutritional	Inefficient
Cutting edge	Ignorant
Improved	Unjustified
	Unfounded
	Untruth

**Fig. 14 Table 3: Language used by pro-GM newspapers when referring to arguments against GM technology (Cook et al., 2006)**

The wisdom of Shakespeare matches perfectly the imbalance of the public debate mirrored in the press (and TV):

**Evil always fascinates, goodness rarely entertains (Macbeth?, Shakespeare)**

More details and many more elements in this debate on psychology and philosophy see in section 6.



### 2.2.3. Proposal for a website of websites

There are simply too many websites (see 5.1.) and not enough coordination, so there is a need for networking structures among the most important websites, a *network of networks* with all the fancy new buttons available like RRS etc. There should be a place where people see with one glance on the first page what news they can expect on various important sites. It should also not be difficult to add possibilities for an individual choice.

Those website connection activities need professional support with some secretarial/managerial help. We must work out ways that a broad public can easily reach rebuttals on all the myths, facts and benefits in the debate on green biotechnology. It will be not difficult to establish a platform for a better communication among the most important websites – in the field of agricultural biotechnology there are a few very successful ones, but this is not the whole task. We need to look deeper into the theory of networks in order to be really successful, comprehensive reviews demonstrate how complex the networking task really is (Leicht & Newman, 2008; Newman, 2003).

As for now, this is just an idea and needs to be discussed with internet and website specialists. One of the main difficulties will be to establish permanent existence, this is why it would be best to use structures having proofed long years activities and assured permanence, such as ISAAA, the International Service for the acquisition of Agri-Biotech Applications, [www.isaaa.org](http://www.isaaa.org). After all, the leading webmasters and coordinators agree, that it is time to **enhance collaboration through better communication**, see section 5.1. ASK-FORCE. The task on uniting the most relevant websites and blogs should not be underestimated, see the list already given above (Ammann, 2011).

## 3. Developments in risk handling of GM crops

### 3.1. General views on the dialogue related to regulation of GM crops.

The dialogue between scientists and regulators is very complex, as accurately described by Saner (Saner, 2007). This should be a reminder that it's not about facts alone:

*"It should be clear without explanation that each and every rational decision is a combination of facts and values – a decision requires judgment. The agents of judgment are, of course, people, and this leads us to an entirely different interface – that between scientists and policy-makers."*

We should keep this in mind when we concentrate here on the *science* of GM crop regulation. See also the analysis of the debate in 1.1. Read more about philosophy and psychology of the debate in section 5.4. These philosophical thoughts of Saner are at the basis of the discursive methodology for complex decision making processes, (Ammann & Papazova Ammann, 2004; Rith & Dubberly, 2007a; Rittel & Weber, 1973), details see below in this contribution in sections 5.2. and 5.3.

Valid overviews on the regulatory science and tracability related to GM crops have been published by Gasson & Burke (Gasson & Burke, 2001; Phillips, 2003), it is not the intention to repeat these reviews. A comprehensive review of the regulatory system of GM crops of the United States has been published by McHughen & Smyth (McHughen & Smyth, 2008), a critical one on Europe by Morris & Spillane (Morris & Spillane, 2010).

## 3.2. Biotechnology and economics

### 3.2.1. How economics are influencing the GM crop debate

The example of the Flavr Savr Tomato demonstrates, that in earlier times even in Europe GM food was well received, but several factors just made it clear that economic success was missing (Sheehy et al., 1988), (Kramer & Redenbaugh, 1994; Martineau, 2002; Redenbaugh et al., 1994). And regulation of this pioneer work needs to get a new look: with modern screening methods, the gene silencing on the molecular level revealed some surprises (Krieger et al., 2008).

Economics play a very important role in the process of technology acceptance: This can be illustrated with the present day feed import situation in Europe.

First it should be mentioned, that it's the trade policy of Europe still going the wrong way, which causes a lot of difficulties in the transatlantic dialogue: As Graff et al. (Graff & Zilberman, 2004) explain:

*"European policies blocking genetically engineered crops are conventionally attributed to the concerns of European consumers, but they can be attributed to the self-interests of European industry and farmers as well. Biotech policies maintained in the name of consumer interests are helping European chemical firms to slow their losses in the global crop protection market and are helping European farmers differentiate their conventional crops on environmental and safety grounds, maintain their agricultural subsidies and win new non-tariff trade protections."*

The recent development in feed supplies, see Lawrence in the Guardian (Lawrence, 2009) in the EU provides argument, the reports and letters below give excellent examples:

- Food Chain Dossier 2009: <http://www.botanischergarten.ch/Feed/Food-Feed-Chain-Dossier-20090616.pdf>
- DG AGRI feed report: <http://www.botanischergarten.ch/Feed/EC-DG-AGRI-Rep-feed-situation-UnapprovedGMOs-200709.pdf>
- EU Report on Pipeline: <http://www.botanischergarten.ch/Feed/Stein-EU-Report-GMOpipeline-LLP-2009.pdf>
- Letter to the President of the EU Commission Barroso: <http://www.botanischergarten.ch/Feed/Letter-big-Producers-Tolerance-Value-Barroso-20090624.pdf>

Strict labeling and thus a discrimination of European meat from animals fed with GM crops will soon be impossible as a political goal due to *economic* reasons - as it is also scientifically not justifiable (Aumaitre, 2004; Flachowsky et al., 2007).

An interesting thesis with economic arguments is promoted by Paarlberg (Paarlberg, 2006): Today Africa's production of GM crops is exported mainly to other African countries, and this might go on this way in the coming years, so the reasoning that Africans would destroy export opportunities to Europe by developing their own GM crops does not really convince. But in reality there is growing concern: Commercial fear over potential loss of export sales to Europe and East Asia is also a reason for mounting pressure on biosafety approvals in developing countries. Consumer misgivings towards GM food in rich countries combined with restrictive import and labeling policies are prompting GM free agricultural production in developing countries. The long term costs of these negative trends could be enormous (Cohen & Paarlberg, 2002). Good arguments for this view are produced with lots of facts on economics and negative labeling effects of European developed countries, published by Gruère et al. (Gruere et al., 2008b; Gruere & Rosegrant, 2008; Gruere & Sengupta, 2009):

*In this context, the marketing decision of avoiding GM ingredients in food items rapidly became a quality attribute employed in the competition among the retail chains of Europe, Japan and South Korea. A report by the international NGO, Greenpeace, which has encouraged companies to adopt GMfree policies, provides evidence of the widespread adoption of such practices in Europe (Greenpeace, 2007) as follows:*

*Fourteen of these retailers have a policy of not selling GM-branded products under their company name for all European countries. These include Carrefour, Auchan, Sainsbury's, Safeway, Marks & Spencer, Coop Switzerland, Coop Italia, Migros, Big Food Group, Somerfield, Morrison's, Kesko, Boots, and Co-op UK.*

*Seven of these retailers have a non-GM policy for their own branded products for their main markets (mainly in their home countries). These include Tesco, Rewe, Metro Group, Casino, Edeka, Schwarz group, Tengelmann).*

*Out of the top 30 European food and drink producers, 22 have a non-GM commitment in Europe, including Nestle, Unilever, Coca Cola, Diageo, Kraft Foods (Altria), Masterfoods (Mars), Heineken, Barilla, Carlsberg, Dr. Oetker, Arla Foods, InBev (Interbrew), Heinz, Chiquita, Cirio del Monte, Orkla, Ferrero, Northern Foods, Eckes Granini, Bonduelle, Kellogg and McCain. Thirteen of these 22 multinationals have a company-wide non-GM policy beyond Europe. These include Diageo, Heineken, Barilla, Carlsberg, Arla Foods, Dr. Oetker, Chiquita, Cirio del Monte, Orkla, Ferrero, Northern Foods, Eckes Granini, and Bonduelle. (Gruere & Sengupta, 2009)*

Some companies even go beyond banning processed products derived from GM ingredients to include requirements on GM-free animal feed in animal products. Virtually all supermarkets sell only poultry fed with non-GM feeds, whereas the policies for dairy products, beef and pork vary. The usual crude Greenpeace mix of facts and interpretation helped efficiently to push the companies for the European market to go GM crop free (Greenpeace, 2007, 2008). The simple fact of labeling allows opponent NGOs to drive a polemic campaign of pompous “contamination” reports, thus delivering junk science “evidence” that there is some risk involved in the numerous events of minute admixtures of transgenes traces.

In India there is a clear positive trend visible since some years, after some difficulties in the beginning, because local traits had to be created for the many Indian regions and also because there was right from the beginning a black market with illegal cotton traits developing (which often did better commercially than the legal ones. Presently, there are 38 traits of GM cotton in India (ISAAA, 2011)

The whole complex story has been recently summarized by (Sadashivappa & Qaim, 2009):

*“On average, Bt-adopting farmers **realize pesticide reductions of roughly 40%, and yield advantages of 30-40%. Profit gains are at a magnitude of US \$60 per acre.** These benefits have been sustainable over time. Farmers’ satisfaction is reflected in a high willingness to pay for Bt seeds. Nonetheless, in 2006 Indian state governments decided to establish price caps at levels much lower than what companies had charged before. This intervention has further increased farmers’ profits, but the impact on aggregate Bt adoption was relatively small. Price controls might have negative long-term implications, as they can severely hamper private sector incentives to invest in new technology.” (Sadashivappa & Qaim, 2009)*

At the end of the day the profitability of Bt cotton is now uncontested, see comments of Müller-Jung Frankfurter Allgemeine: (Mueller-Jung, 2007)

Also the old wrong connection between suicides of Indian farmers and the introduction of GM cotton in India has been thoroughly falsified (Gruere et al., 2008a; Gruere & Sengupta, 2011). This does not hinder activists like Vandana Shiva from continuing with cheap propaganda linking GM crops with the sad tradition of farmer suicides in India, which started decades before the introduction of GM crops and beginning activities of multinational seed companies. Here two of many graphs from (Gruere & Sengupta, 2011):

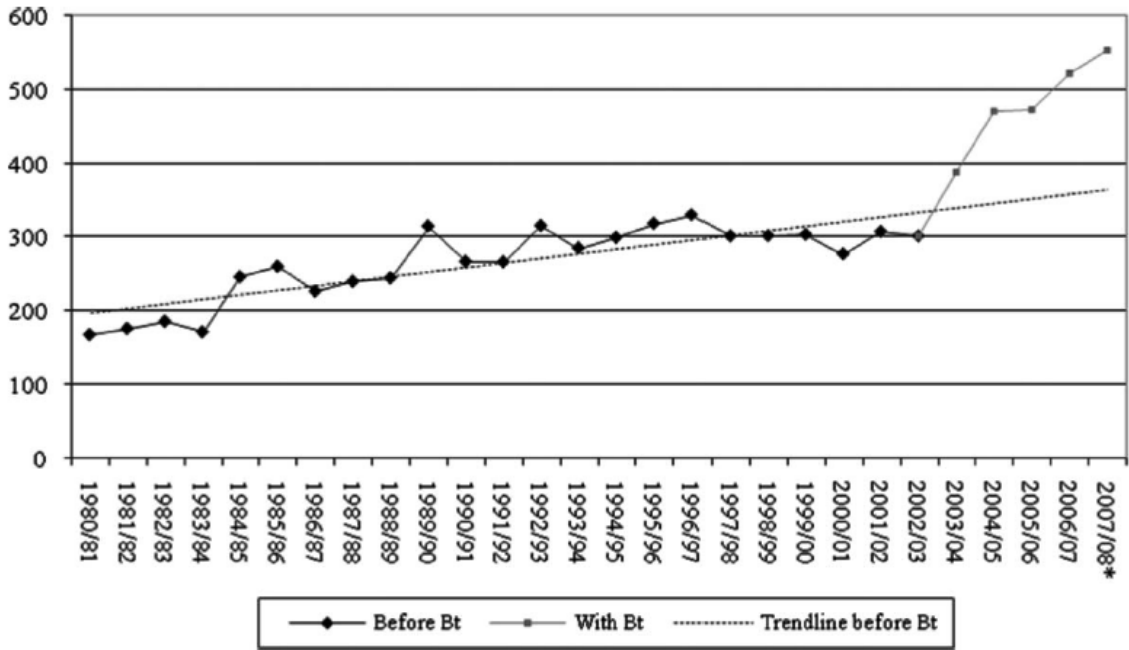


Fig. 15 Average cotton yields in India (kg/ha), 1980–2007. Source: International Cotton Advisory Committee (2008). Note: Data for 2007/08 is an estimate. From (Gruere & Sengupta, 2011)

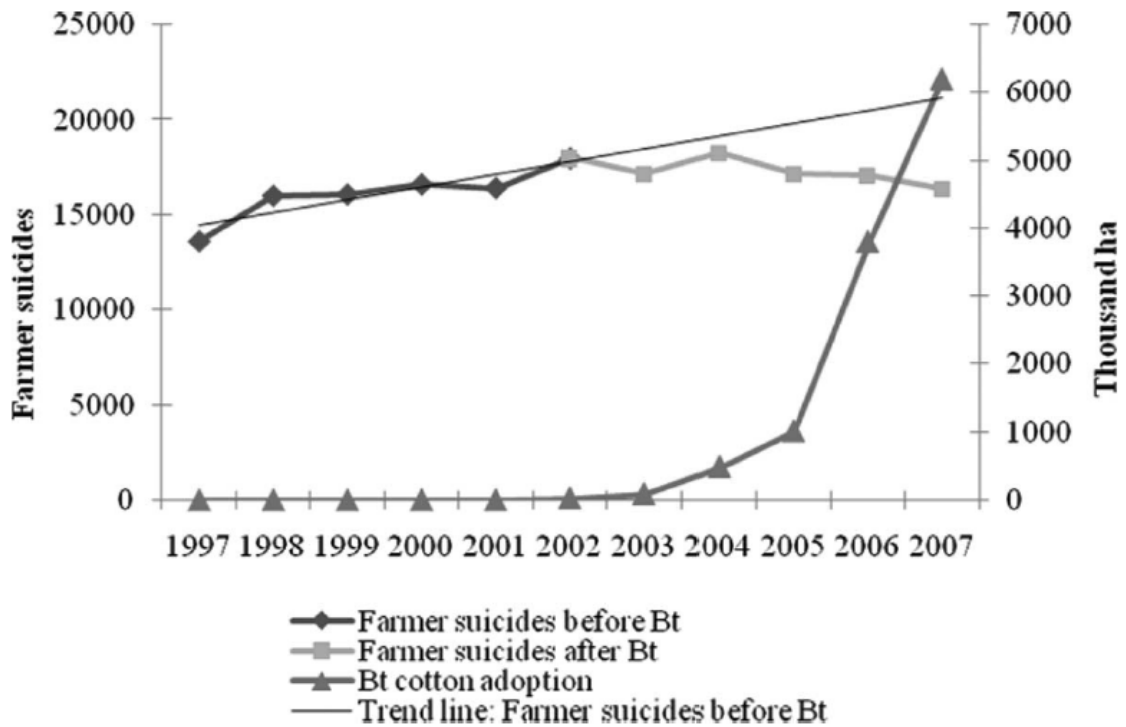


Fig. 16 Farmer suicides and Bt cotton area in India, 1997–2007. Source: Combined data from Table 1 and Table 2. From (Gruere & Sengupta, 2011)

Abstract:

*“Bt cotton is accused of being responsible for an increase of farmer suicides in India. In this article, we provide a comprehensive review of evidence on Bt cotton and farmer suicides. Available data show no evidence of a ‘resurgence’ of farmer suicides. Moreover, Bt cotton technology has been very effective overall in India. Nevertheless, in specific districts*

and years, Bt cotton may have indirectly contributed to farmer indebtedness, leading to suicides, but its failure was mainly the result of the context or environment in which it was planted.” (Gruere & Sengupta, 2011)

From the discussions:

*“The absence of irrigation systems in drought-prone areas (especially in Maharashtra), combined with specialisation in high-cost crops, low market and support prices, and the absence or failure of the credit system, is a clear recipe for failure. It is possible, therefore, that under the conditions in which it was introduced, Bt cotton, an expensive technology that has been poorly explained, often misused and initially available in only a few varieties, might have played a role in the overall indebtedness of certain farmers in some of the suicide-prone areas of these two states, particularly in its initial years. But none of these possible links has been explicitly demonstrated with a sufficiently robust analysis. One implication of this study is the critical need to distinguish the effect of Bt cotton as a technology from the context in which it was introduced. Revealed preferences based on farmer adoption rates and official or unofficial data all point toward the overall success it has had in controlling pest damage and therefore raising average yields in India. In particular, the increasing adoption rate in two suicide-prone states, Andhra Pradesh and Maharashtra, indicates that farmers in these states found this technology economically beneficial.*

*In contrast, marketing constraints and institutional issues may have played a significant role. Our analysis suggests the need for a better extension system, more controlled seed marketing system, anti-fraud enforcement and better information dissemination among farmers in all regions, before the introduction of any costly new technologies like Bt cotton. Farmers should also be encouraged to diversify their farming and non-farming activities to spread the risks they may incur.*

*The second implication is that, as farmer suicides are not new or specific to recent cases or to the introduction of Bt cotton, they point toward the failure of the socioeconomic environment and institutional settings in rural dry areas of India. This has nothing to do with cotton or the use of new technology and would suggest many potential policy changes. In several states, such as Karnataka and Andhra Pradesh, some policy changes have already been proposed. Lastly, much more and better federal and state investment could help prevent the 80 per cent or more other cases of suicides.”*

This does not hinder activists like Vandana Shiva from proclaiming Indian farmers suicides to be the fault of international corporations: (Shiva, 2004) and lately also at a Barilla webinar July 20, 2011 in Milano: <http://www.barillacfn.com/en/biotechnologie>, she does also not shy away from connecting the sad tradition of farmers suicides in India with the emergence of GM crops, despite hard facts as demonstrated above. In the same picture you can see her pompous literature list she gives in her curriculum of “over 300 scientific publications in important journals” – a quick test in the comprehensive database of the Web of Knowledge <http://apps.isiknowledge.com/> reveals some 47 papers, most of them in less important journals and magazines – so much about her scientific achievements. The author was also participating in the webinar (see an extended version of his thoughts in (Ammann, 20111111), the poll after the webinar was slightly positive for GM crops.

A new perspective is open since 2006 for the production of cotton seed (oil for human consumption), seed meal for feed), made possible thanks to the detoxification (gossypol) successfully done by modern breeding including genetic engineering (Sunilkumar et al., 2006), see the latest summary on the matter: (Choudhary & Gaur, 2011):

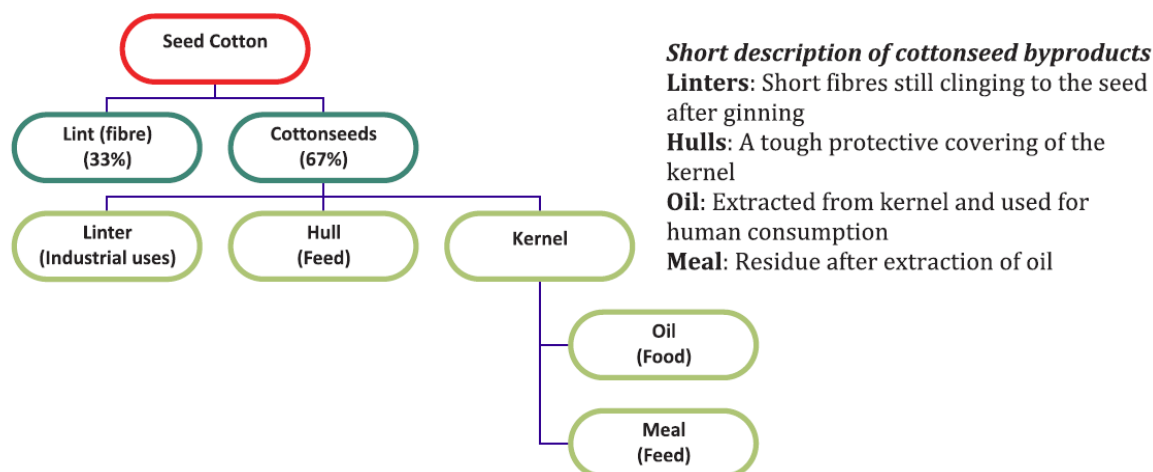


Fig. 17 Cotton Seed Byproducts, from (Choudhary & Gaur, 2011)

This latest development will open new doors for the cotton production and marketing.

### 3.2.2. The political economy of biosafety regulation in agriculture

An in-depth analysis of how politics is influenced by multiple factors of discursive processes, influenced by economics, has been developed by Graff et al. (Graff et al., 2009a). They are giving highly differentiated insights in the network of self-interests with some interesting examples of units influencing in their own interest the debate on GM crops: Opponents of genetically engineered crops and also industrial units fearing losses in pesticide sellings. Often these important socio-economic elements in the regulatory debate are neglected and it seems to be difficult for all the regulatory analysis to bring together socio-economic *and* molecular plant breeding aspects.

**Graff, G., G. Hochman, et al. (2009)** The Political Economy of Agricultural Biotechnology Policies. *AgBioForum* 12, 1-13 DOI: <http://www.agbioforum.org/v12n1/v12n1a04-graff.htm> AND <http://www.botanischergarten.ch/Regulation/Graff-Political-Economy-Policies-2009.pdf>

*"This article develops a political-economy framework to analyze the formation of agricultural biotechnology policies. Going beyond accounts, that largely attribute differences between US and European regulatory environments to consumer attitudes, we consider the impact of what amounts to a Schumpeterian process of "creative destruction" across the entire range of relevant economic sectors and interests. The analysis suggests that in Europe and in some developing countries a "strange bedfellows" constellation of concentrated economic interests (including incumbent agrochemical manufacturers, certain farm groups, and environmental protest activists) act in rational self-interest to negatively characterize GM technology in the public arena and to seek regulations that block or slow its introduction. In contrast, those interests most likely to experience welfare gains from biotechnology are the more diffused and less informed--including consumers and small farmers. The most profound implications of overregulation of agricultural biotechnology are (1) delays in the global diffusion of proven technologies, resulting in a lower rate of growth in the global food supply and higher food prices, and (2) disincentives for investing in further R&D, resulting in a slowdown in innovation of second generation technologies anticipated to introduce broad consumer and environmental benefits." (Graff et al., 2009a)*

Ayal & Hochman (Ayal & Hochman, 2009), started in some intricate experimental setups working on the cognitive processes underlying choice behavior. With a mix of behavioral actions combined with opinion polls they found that people *do not rely on limited arguments only, but tend to integrate all acquired information into their choice processes*. This could explain the delay in such opinion finding and decision making processes influencing politics over years, described in the Gartner hype cycles, see 1.1.

Although this would be an epic theme, we shall concentrate here more on the debate of the *science* of regulation and some discursive elements.

### 3.2.3. Brazil, a case where politics and science positively influence the development and adoption of GM crops

With important contributions of Dr. Lucia de Souza, Vice President of ANBIO, the National Biosafety Association of Brazil <http://www.anbio.org.br/english/index.htm>

Studying the biosafety law of Brazil, the similarities with the European legislation cannot be overlooked: Both regulatory frameworks are process-oriented and are based on the precautionary approach. They obey to strict rules on biosafety assessment for all activities related to rDNA technology. It is a step by step procedure through the different stages of development from fundamental research including field experimentation and ending in commercialization.

#### 3.2.3.1. A closer look at the Brazilian biosafety law in comparison to European legislation

The first biosafety law No. 8.974 was established as early as 1995 (Cardoso et al., 2005).

Cardoso and colleagues describe in detail the beginnings of biosafety regulation and how finally the bioafety law was achieved and reluctantly acknowledged even by opponents (Chamas et al., 1995), but complaining that “science was involved only in a minimal way”, which should be translated into “scientists critical to GM crops were only involved in a minimal way”.

*“The role played by organizations is consolidation, by this field of knowledge by providing an interchange between similar associations in the world and accelerating scientific-technological development is thus fundamental. The model chosen by Brazil for regulating Biosafety procedures for the manipulation of GMOs should be understood and supported by our citizens because it represents a safe way of accepting new technologies and simultaneously to model international standards. Unifying broad and fundamental bases, the social actors try to identify solutions for emerging problems and make efforts to reduce obstacles to a quick and effective application of biotechnological research so that the results are quickly available to society. The work of promoting life and the environment is done by motivating integration of biotechnological advancements and Biosafety, based on good quality of health services, concern with the environment, and dissemination of information for the general public about the decisions made in the governmental sphere. A thorough understanding of the legal and political aspects as well as the information system helps individuals to choose consistently, based on their cultural, familial, and personal values.” (Cardoso et al., 1992)*

Until today the crop biotech scientists have to cope up with considerable resistance, still manifested in 1995, although even opponents reluctantly accepted the new biosafety laws: (Chamas et al., 1995), but complaining that “science was involved only in a minimal way”, which should be translated into “scientists critical to GM crops were only involved in a minimal way”. Also in the year 2000 the same group of critical scientists (Valle, 2000) publish negative statements:

*“The development of agro-industrial processes - food products in particular - through recombinant DNA technology has enhanced the profit prospects of the few big biotechnology companies and of large-scale farmers who have access to the latest technological developments. We thus oppose a moratorium on recombinant DNA technology. Moreover, hasty statements about risk-free transgenics may be misleading in the absence of extensive safety tests (Valle, 2000).*

Later, it was amended by the Provisional Measure No. 2.191-9/2001 at the occasion of establishing the interdisciplinary National Technical Commission on Biosafety (CTNBio, 2005).

The new biosafety legislation has been established in 2005, it left behind a series of “regulatorios” as an obstacle of decision making, an intricate tangle of rules and regulations that only contributed to the bureaucratization process, but not representing in any way a safer process of analysis of GMOs. Relevant modifications were introduced by this new law, these are mainly the following:

*“Regulates items II, IV and V of Paragraph 1 of Article 225 of the Federal Constitution, provides for safety norms and inspection mechanisms for activities that involve genetically modified organisms - – GMOs and their by-products, implements the National Biosafety Council (CNBS), re-structures the National Biosafety Technical Commission (CTNBio), provides for the National Biosafety Policy (PNB), revokes Law no 8.974, of 5 January 1995, and Provisional Measure no 2.191-9, of 23 August 2001, and arts. 5, 6, 7, 8, 9, 10 and 16 of Law no 10.814, of 15 December 2003, and provides for other measures.” (CTNBio, 2005)*

Important was also the establishment of an Information System on Biosafety (SIB), an amended treatment for research and commercial releases, including an advanced discussion of post-monitoring procedures (Melo et al., 2010)

Since then, numerous normative resolutions etc. (CTNBio Normative Resolutions, 2006-2009) have been developed which cover GMO activities, the details in (Oda, 2011). CTNBio is a interdisciplinary and intersectoral body established and managed under the Ministry of Science and Technology and it responsible for making science-based technical assessments of all activities related to genetical engineering including products and an assessment of the commercial conditions of use. The CTNBio approval may be followed by a review from the National Biosafety Council (CNBS) for details in field research, licencing conditions including university research, transport and import conditions, including also other social and economic factors – as this procedure is still pending in the case of the new viral resistant bean, including the basic question whether these clarifications are still necessary.

In summary, on first sight the Brazilian law shows similarities to the European legislation on the selection of regulated molecular processes, but regarding the decision making processes there are considerable differences – which make positive political conclusions in Brazil much easier. Once a safety decision has been taken and positive, it is difficult to stop applications in Brazil, whereas in



Europe a complex decision making process on the political level basically prevents progress. The Brazilian model also reveals a robust participation of public consultation, whereas in Europe the public consultation is delegated to countries and the European Parliament, where the controversies are endless and prevent any decision, see more details in the following subsections!

#### Brazil:

*“Article 3. Under this Law, it shall be considered:*

*V – genetically modified organism - GMOs: an organism the genetic material of which – DNA/RNA has been modified by any genetic engineering technique;”*

And compare some exclusion rules, typically reducing the safety assessments strictly to the process of genetic engineering.

*Article 4. This Law is not applicable when a genetic modification results from the following techniques, provided they do not imply in using a GMO as the receiver or donator:*

*I – mutagenesis;*

*I – the formation and use of animal hybridome somatic cells;*

*III – cellular fusion, including plant cells protoplasm, which can be produced from traditional culture methods;*

*IV – the self-cloning of naturally processed non-pathogenic organisms.*

The same is the case in the European law:

(European Parliament and European Council, 20030922), in the introduction the definition of GMOs is given:

*“In order to protect human and animal health, food and feed consisting of, containing or produced from genetically modified organisms (hereinafter referred to as genetically modified food and feed) should undergo a safety assessment through a Community procedure before being placed on the market within the Community.”*

The intention of this “exclusive” definition is clear in this European Law: it should be restricted to GMOs which are wrongly defined as “genetically modified crops”, a scientifically questionable denomination, since in the strict sense of modern genomic science this means to include all crops and horticultural traits having been modified also by conventional breeding. This kind of now false but routine denomination is an example for the disregard of proper science views in regulation.

This kind of misleading label is incidentally not adopted in Brazil: In the texts it is always word of the “transgênicos”.

*Good hopes can be invested in the activities of EFSA (the European Food Safety Agency) see the official website*

*<http://www.efsa.europa.eu/> and [http://en.wikipedia.org/wiki/European\\_Food\\_Safety\\_Authority](http://en.wikipedia.org/wiki/European_Food_Safety_Authority)*

*The websites show manyfold activities*

*“EFSA was created as part of a comprehensive programme to improve EU food safety, ensure a high level of consumer protection and restore and maintain confidence in the EU food supply. In the European food safety system, risk assessment is done independently from risk management. Of particular interest is the GMO panel for this paper: The Panel on Genetically Modified Organisms (GMO) deals with genetically modified organisms and genetically modified food and feed. The Panel is supported by the GMO Unit. The Panel works independently, openly and transparently to deliver timely scientific advice of the highest standards to support the policies and decisions of risk managers.*

*The Panel carries out its work either in response to requests for scientific advice from risk managers or on its own initiative. It frequently sets up Working Groups involving external scientists with relevant expertise to focus on specific matters and help produce scientific opinions. The Panel itself meets regularly in plenary sessions to discuss work in progress and to adopt finalised scientific opinions. Each opinion results from a collective decision-making process with every Panel member having an equal say.”*

EFSA’s scientific experts give independent advice on food and feed safety to EU decision makers, such as the Commission, the Parliament and Member States. EFSA is also carefully choosing its experts in the panel in order to make sure that their work can be done in strict scientific independence.

There is also critique about the activities of EFSA, questioning the independence of the experts active within the panels, despite the fact that EFSA experts are chosen in an extremely careful scrutiny



procedure to guarantee optimal independence. Also the critique about risk assessment of GM crops is scientifically not convincing and clearly politically motivated, as an example the Greenpeace attack on EFSA related to their opinions of the GM maize MON810 (Cotter & Mueller, 2009), a glimpse in the clearly filtered literature list reveals the paper as a political pamphlet with low scientific merits. Greenpeace and numerous other opponents of the approval of Bt maize got proper and repetitive answers with excellent scientific arguments: (EFSA, 2007a, b, c). The answer of EFSA about its own independence is likewise more convincing (Geslain-Laneelle, 2008) and also on <http://www.efsa.europa.eu/en/edinterviews/edcommentary.htm> and <http://www.allaboutfeed.net/news/efsa-director-we-are-not-there-to-please-everybody-12448.html> EFSA is also following up a painstakingly detailed procedure in the election of scientific experts in order to make sure that EFSA produces truly independent risk assessment based on excellent science. The author would like to suggest, that EFSA is also achieving more independency from political influence of all kinds, including to a certain degree also from the government structures of the European Union.

EFSA has every reason to remain independent as a risk assessor and to stick to the scientific principles of assessing the risk, although it is unfortunate that EFSA is forced to leave out a risk-benefit analysis, based on Article 19 of the Rio Convention on Biological Diversity, which is the official root of the Cartagena Protocol, signed also by the European Union. Needless to say that equally unfortunate is the focus on process oriented risk assessment instead of the usual focus on the process of transgenesis, it is still the Genomic misconception at the root of many calamities in Europe and worldwide related to exaggerated risk evaluation of GM crops – although it has to be admitted that this conforms completely with the Cartagena Protocol. More about the extremely complex decision making procedure in Europe (Brussels) which leads to a stall of development of GM crops in Europe see above.

### ***3.2.3.2. Comparison to the European biosafety legislation***

A comparison of the legislations in Europe and Brazil shows both as rather strict and also in line with the Cartagena Biosafety Protocol Annex III, the decisive difference is that in Brazil there is made a clear distinction between safety decisions and political decision making rules: CTNBio is managed by the Ministry of Science and Technology and it is responsible for making science-based, technical assessments of genetically engineered products including the commercial conditions of use. The CTNBio approval may be followed by a review from the National Biosafety Council (CNBS) in order to examine social and economic factors. One of the important improvements is done on communication: Scientists went out to communicate and explain to the politicians and regulators the biosafety science behind the debate. Thus scientists also approached society opinion leaders, multipliers such as nutritionists, high-schools and journalists. The CNBS is in contact with specific committees, whereas these are lacking in Europe: until lately, the decisions were depending on majority voting rules of the European states, and this caused a lot of confusion and an almost complete stall in decision-making since often (for years) the committee votes were undecided. This is why Commissioner John Dalli in July 2010 opened a debate on delegating some important decisions to the national level: GM crop free zones should be decided independently by the EU member states: (EU-Regulation-GMO-free Regions, 20100713). This caused a lot of critical comments, from the pro and the contra side, (GMO-Compass, 2010).

*(13 July 2010) As expected, the EU Commission decided on 13.07.2010 changes in the legal regulation of green biotechnology. Accordingly, Member States should be able to prohibit the cultivation of genetically modified (GM) crops that*

have been approved EU-wide. As the next step, the EU Parliament and Council of Ministers must agree.

The outcome will again depend on complex negotiations and it is not sure whether Commissioner Dalli and the EU will come to concrete legislative results. And, except for some modest GMO corn cultivation in Spain, the present day acreage of GM cultivars remains disappointingly low. (James, 2009a).

In contrast to the complex and stalled situation on European GMOs, the case in Brazil documents in the last few years successful regulation and commercialization of GMOs:

### ***3.2.3.3. Positive Development in Brazil on GM crops due to a good mix of politics, communication and legislation***

In the period before 2005, the lack of clear GMO regulations and its negative impact on researchers and farmers was described by (Contini et al., 2005a): The following statement, produced by researchers of Embrapa, just before better legislation has taken place:

*“Only soybean has been specially approved in the last three seasons (2002/03, 2003/04 and 2004/05). As there is no consistent information about the benefits of using transgenic seeds in Brazil, the authors made simulations on the basis of the experiences reported by Argentina and the USA. The paper concludes that Brazil could do much better if government had taken the lead to clarify the legal requirements for research and commercial release of genetically modified crops which are still contradictory and unlikely to control any future environmental impact in Brazil.”(Contini et al., 2005b).*

Lucia de Souza, editorial remarks for this section:

*“The new law came under intense debate, but a very important point is the economical importance -in 2003, it was estimated that around six million tons of soybeans (over 10% of the national harvest, expected to reach 49 million tons that year), were transgenic. Of the 53.5 million metric tons of soybeans produced in 2003-2004, official statistics indicate biotech varieties comprised about 12% of the crop; unofficial estimates put the adoption rate as high as 30%. This raised a serious judicial and economic challenge for the country. Destroying millions of tons of illegal beans, to comply with court orders, would cause an estimated loss of \$US10–13 billion in exports considering 10% transgenic. Furthermore, the idea of burning such a huge volume of foodstuffs could lead to unfavorable political consequences for a government that was attempting to implement a large-scale program to eradicate hunger in Brazil (the ‘Zero Hunger’ Program).”*

After a period of spontaneous and sometimes rather uncontrolled commercialization of GM crops in Brazil (Neto, 2003), the recent reports, beginning mainly with the installment of the new biosafety law in 2005 (CTNBio, 2005), (Griffin et al., 2005) show steadily growing acres on GMO crops are documented in Brazil: (Griffin et al., 2005; Marques & Neto, 2007) they also show growing environmental and economic benefits.

In the most recent report of Céleres (<http://www.celeres.com.br/1/english/index.html>) the positive trends in economy and ecology of GM crop cultivation in Brazil (soybeans, cotton, corn) are documented.

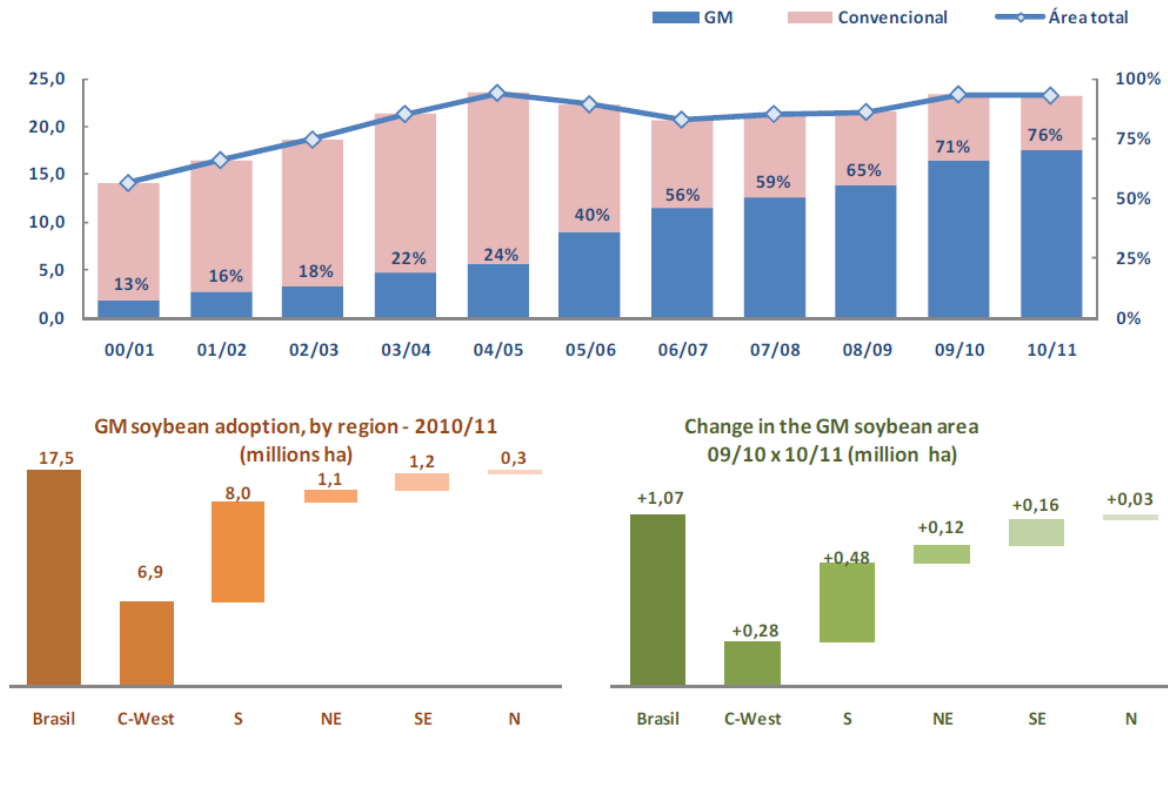


Fig. 18 Source: (Galvao & Celeres, 20100809), see also <http://www.celeres.com.br/1/english/index.html>

"The 1st survey on agro-biotechnology in Brazil for the 2010/11 growing season showed there was a substantial growth in the adoption rate of biotech soybeans, corn, and cotton. The Brazilian farmers are expected to plant 17.2 million hectares with GM soybean cultivars, or 75.6% of the total harvested surface, in 2010/11.

Substantial growth in the adoption rate of biotech soybeans, corn and cotton in Brazil - this is the projection for the 2010/11 growing season based on the first survey on agro-biotechnology in the country by Celeres, an agrobusiness consultancy group.

Highlights of the report estimate that:

Farmers will plant 17.2 million hectares with GM soybean cultivars or 76.6% of the total harvested area

A total of 250,000 hectares will be planted to GM cotton

Summer corn crop will reach a total cultivated area of 7.6 million hectares or 42% of the total area reserved for biotech corn

Total area harvested with biotech corn is expected to reach 7.1 million hectares or 55.6% of the total area.

In another general survey two years earlier, Mendonca-Hagler et al: (Mendonca-Hagler et al., 2008): confirm this clearly optimistic picture, the abstract:

"Biotechnology is a Brazilian priority, and has been recognized for its potential to promote sustainable development. The Government recently announced an ambitious program for Science and Technology, which includes strategies to develop modern biotechnology, continuing three decades of public investments on capacity building and infrastructure, aimed principally at the development of technologies applied to health, agriculture and the environment (MCT, 2008 <http://www.mct.gov.br/>). Research initiatives have focused on genomics, proteomics, genetically modified organisms (GMOs), gene therapy, stem cells, bio-fuels and nanotechnology, among other biotechnological topics. Research projects in Brazil have been mainly developed in public universities and institutions funded by federal and state agencies, with a minor participation from the private sector (Silveira, 2004). Genomics, an area of considerable success in the country, was launched a decade ago by S. Paulo State Research Foundation (FAPESP), with the organization of a virtual institute, called ONSA, comprising several laboratories with the main task of sequencing the genome of the citrus pathogenic bacterium *Xylella fastidiosa* (Frohme et al., 2000; Simpson et al., 2000) The success of this genomic network stimulated biotechnology startup companies and projects with the focus on other genomes, such as sugarcane and coffee, including functional genomics and proteomics. Following in the footsteps of the ONSA network, the Ministry of Science and Technology created a National Genome Project Consortium involving institutions located in the major regions of the country, with the task of sequencing eight microbial and two plant genomes. Recently, they concluded the sequence of *Chromobacterium violaceum*, a bacterium with exploitable properties, such as the ability to produce a bactericidal purple pigment (violacein) and bioplastics (Vasconcelos, 2003). Later on, several states launched their

own genome programs. A group from Rio de Janeiro, part of the Riogene network, recently sequenced the genome of the nitrogen-fixing bacterium *Gluconoacetobacter diazotrophicus*, a sugarcane endophyte involved in enhancing growth of large crops without the addition of nitrogen fertilizer (Magnani et al., 2010; Mendes et al., 2007), see also the websites of EMBRAPA <http://www.embrapa.br/english> and the Ministerio Biotecnologia e Tecnologia <http://www.mct.gov.br/>. Agriculture plays an important role in the Brazilian economy, being responsible for ca. 40% of the exports and employing 20% of the active work force. About one third of the Brazilian GDP comes from agribusiness. Traditionally, this country has been competitive in tropical agriculture, supported by strong research programs on conventional and modern technologies. Intense capacity building initiatives resulted in the formation of a critical mass of scientists working in molecular biology and agricultural sciences (Silveira, 2004). Despite these favorable factors, the adoption of GM crops has been delayed due to intense opposition organized by environmental groups and additional difficulties resulting from a conflicting regulatory framework. In this overview, we address the current status of Brazilian biosafety legislation, and discuss the perspectives for the development of molecular biotechnology in Brazil."

(Mendonca-Hagler et al., 2008) pointed to the actual basis of the Brazilian success in farming GMO crops: The science and its positive communication was key. This is confirmed in a recent editorial in Nature, (Nature Editorial, 2010), interestingly enough with the same emphasis as above on gene sequencing projects which are the basis of independent biotechnological research and development in Brazil. Several start ups came after the project: Allelyx, Canavialis und Scylla. Besides, it gave experience and in working with collaboration among several research intitutions making a consortitium. It gave confidence of the scientific capacity. The success with this project mostly funded by FAPESP inspired on more scientific development/research funding

### 3.2.3.5. First homemade GM crop in Brazil approved

Also the latest success of approving regulatory decisions is symptomatic for the positive biotech climate in Brazil: The first fully in Brazil developed transgenic crop has been approved for commercialization, published in 2007: (Bonfim et al., 2007), see also (Neto, 2003) . The press release of the president of AnBio (National Biosafety Association) Leila Oda emphasizes also the socio-economic importance of this approval: (Oda, 2011).

*"Besides being the **first 100% national transgenic technology**, there will be a very positive impact on a crop that is predominantly grown by small producers," said Oda, who is also a former president of CTNBio. "Benefits are many for both farmers and for the many millions of Brazilian consumers." The seed of genetically modified (GMO) beans was developed by the Brazilian Agricultural Research Corporation (**Embrapa**), a public research institution linked to the federal government. Oda also noted that, in Brazil, beans are a crop of great social importance, produced mainly by small producers, with about 80% of production in acreage properties with 100 hectares or less. Besides, beans are one of the main foods consumed by Brazilians, and the main source of vegetable protein, iron and many vitamins. "This approval represents a great relief to producers, since the golden mosaic virus causes up to 85% loss of bean crops in Brazil, an amount that could feed up to 9 million to 18 million more people", says Oda. Brazil is the world's largest beans producer and consumer. World production of beans is over than 12 million tons." (Oda, 2011)*

See also YouTube <http://www.youtube.com/watch?v=bl8RWHnZftY>

Another recent knowledge source on the viral resistant bean has been published on the website of Biofortified by (De Souza, 20111018):

*"Why are virus-resistant beans so important:*

*Beans are highly nutritious and one of the most important legumes consumed by over 500 million people in Latin America and Africa. In Brazil it is regularly an indispensable item of the everyday diet, often combined with rice and eaten by all social classes in all parts of the nation. They are found in a great variety of types with different sizes, colors and tastes consumed throughout the country. Perhaps, the most typical Brazilian dish is the "feijoada", a black beans stew. The local consumption is around 16 kg per person every year. Given its high protein (15 to 33%) content besides B vitamins and minerals as iron, calcium and phosphorus, beans provide a high nutritional value meal. Moreover, beans are the major source of protein for the economically disadvantaged." (De Souza, 20111018).*

AnBio,(AnBio Brazil, 2011) the Brazilian NGO dealing with biosafety including GM crops, has lots of activities running, among them in schools at secondary level with a special website for highschoools including a biology contest: <http://www.anbiojovem.org.br/obb/index.php?mod=home&ID=> . For

more information about the multiple efforts in educating the public, see Traynor et al. (Traynor et al., 2007). Besides AnBio there is also an industry funded group active in biotechnology communication with the public <http://www.cib.org.br/index.php> under the direction of Alda Lerayer [http://www.cib.org.br/sec\\_executiva.php](http://www.cib.org.br/sec_executiva.php) called Conselho de Informações sobre Biotecnologia with numerous activities and providing scientific literature on the website.

Numerous local media covered the bean approval. As a result, it's not only the anti-biotech groups communicating, there were lots of scientists, farmers, who undertook important efforts such as CTNBio, (Ministry of Agriculture) using even modern communication tools such as twitter <http://twitter.com/#!/CTNBio> to counterbalance the anti-propaganda.

For example from Xico Graziano, published at the newspaper Estado de Sao Paulo:

*"The numbers do not lie, but liars produce numbers. The phrase, attributed to Itamar Franco, applies to the detractors of transgenics. Contrary to its release by CTNBio, the opponents advertise dangers that were never proven, tout to disbelieve in science. Invent reasons, shouting old discredited slogans against biotechnology.*

In fact, the Brazilian transgenic crops developed by Embrapa broke the jaw of those who always accused the genetic engineering to serve the multinationals and favor large producers. They lost thus the easy axis of the ideological "neomarxist" discourse by anticorporate stance mixed with pseudoscience.

And farmers in Brazil those days complain in newspaper interviews that they have to wait that long for the approval process of highly useful crops. See a newsflash in Portuguese on <http://www.youtube.com/watch?v=bl8RWHnZftY>.

The latest summary has been published by a Brazilian farmer: (Dijkstra, 2011):

*"A new development holds great promise both for Brazil's small farmers and its malnourished people. One of my country's favorite national dishes is rice and beans. Low-income consumers depend on it as a staple food and small farmers depend on it because their livelihood comes from growing the ingredients.*

*Yet a deadly parasite makes the work difficult. In Brazil, white flies attack our beans, spreading the golden mosaic virus, which can devastate whole fields of crops.*

*Advances in biotechnology now offer a solution. Brazilian farmers will have the opportunity to grow beans that are genetically modified to resist the disease, giving them the strength they need to fight off the threat. The health of farmers will improve, too. Until recently, their most effective tool for crop protection had been weekly applications of insecticide. With this new technology, that is not necessary any more." (Dijkstra, 2011)*

### 3.2.3.6. Opposition against GM crop introduction not convincing, basically not successful

There is no use of going into a broad survey on the Brazilian opponent's activities and reports, you encounter usually fact free actionism and pamphlets with propaganda and sometimes including blunt lies – a pictorial glimpse into the scare campaigns of Greenpeace may suffice:

<http://www.flickr.com/photos/greenpeacebrasil/4014661006/>

Instead, we concentrate here on some symptomatic biosafety science debates: Here just a typical example published by a medical group (not linked in any way with environmental toxicology research): The publication of (Paganelli et al., 2010a) demonstrates on how science is distorted in order to make a negative and totally unfounded point against glyphosate: This paper produces negative toxicological effects on clearly doubtful experimental protocols: Those experimental *Xenopus* frog embryos were *injected* with glyphosate, as mentioned in the introduction:

*"We show here that sublethal doses are sufficient to induce reproducible malformations in *Xenopus* and chicken embryos treated with a 1/5000 dilution of a GBH formulation (equivalent to 430  $\mu$ M of glyphosate) or in frog embryos **injected with***

**glyphosate alone (between 8 and 12 µM per injected cell).** GBH treated or glyphosate injected frog embryos showed very similar phenotypes, including shortening of the trunk, cephalic reduction, microphthalmia, cyclopia, reduction of the neural crest territory at neurula stages, and craniofacial malformations at tadpole stages.”

This absurd experiment methodology contradicts all internationally agreed rules on environmental toxicology testing, as described and cited in detail in: (Chassy & Parrott, 2009).

But opponents are well organized on an international level, and promptly, the Paganelli paper is cited in many of those reports, here just one example: (Antoniou et al., 2010a). In this extensive report, dozens of papers are cited which do not match the high quality standards of biosafety science, they are cited because they produce negative results related to modern soybean agriculture. An example on how the authors do not even shy away from distorted reporting of published results:

*“Very few studies directly examine the effects of GM foods on humans. However, two studies examining possible impacts of GM RR soy on human health found potential problems.*

*Simulated digestion trials show that GM DNA in GM RR soy can survive passage through the small intestine and would therefore be available for uptake by the intestinal bacteria or cells (Martin-Orue et al., 2002). Another study showed that GM DNA from RR soy had transferred to intestinal bacteria before the experiment began and continued to be biologically active.(Netherwood et al., 2004). These studies were not followed up. GM proponents often claim that GM DNA in food is broken down and inactivated in the digestive tract. These studies show that this is false.”*

Actually, if you read the above Newcastle study properly, you notice, that the GM DNA is completely decomposed in the colon, the only traces measurable were found in fresh, undigested stomach probes of human ileostomist patients. Reading the summary alone shows the blatant incorrectness of the comments: Two previous studies, after careful reading, reveal the same results (Martin-Orue et al., 2002; Netherwood et al., 1999). The conclusion therefore: the interpretation of (Antoniou et al., 2010a) is false, as confirmed in the latest publication of the Newcastle research team:

*“The transgene did not survive the gastro-intestinal tract of human subjects fed GM soya.”*

The Antoniou study (Antoniou et al., 2010b) with its selective citing of flawed studies treated as “high quality science” is not alone, other colleagues come up with more pseudoscience: As an example the absurd frog experiment of Paganelli et al. (Paganelli et al., 2010a) is commented here: The study relies on totally unrealistic high concentrations of Glyphosate applications to frog embryos, and on top of this, the environmental glyphosate pathway remains obscure: (Mulet, 2011; Palma, 2011; Saltmiras et al., 2011), the answer given by the senior author of (Paganelli et al., 2010b) is weak and scientifically misses the critical points of the experiment: (Carrasco, 2010).

The most recent publication of Carrasco is a clear signal of the ideological position of the author (Carrasco, 2011): as strange as it sounds, he tries to make a link between the old Nazi ideology of Eugenics and the massive use of glyphosate (and the virtual human mortality rate related, without any reproducible relationship to facts).

The latest myth is created by a former Purdue Scientist Don Huber stating (without direct of evidence or publication for the latest scare story on unknown diseases plaguing soybean cultures) that glyphosate resistant plants could be the reason for upcoming new infection problems – this has been rebutted with good scientific arguments by (Camberato et al., 2011):

*“ The claim that herbicides, such as glyphosate, can make plants more susceptible to disease is not entirely without merit. Research has indicated that plants sprayed with glyphosate or other herbicides are more susceptible to many biological and physiological disorders (Babiker et al., 2011; Descalzo et al., 1996; Johal and Rahe, 1984; Larson et al., 2006; Means and Kremer, 2007; Sanogo et al., 2000; Smiley et al., 1992).”*



A recent publication cleans up with all the myths about toxicity of Glyphosate, there are some telling tables included for comments on the major Anti-Glyphosate publications: (Williams et al., 2011): The summary may suffice here, more see in section:

*“Glyphosate is the active ingredient of several widely used herbicide formulations. Glyphosate targets the shikimate metabolic pathway, which is found in plants but not in animals. Despite the relative safety of glyphosate, various adverse developmental and reproductive problems have been alleged as a result of exposure in humans and animals. To assess the developmental and reproductive safety of glyphosate, an analysis of the available literature was conducted. Epidemiological and animal reports, as well as studies on mechanisms of action related to possible developmental and reproductive effects of glyphosate, were reviewed. An evaluation of this database found no consistent effects of glyphosate exposure on reproductive health or the developing offspring. Furthermore, no plausible mechanisms of action for such effects were elucidated. Although toxicity was observed in studies that used glyphosate-based formulations, the data strongly suggest that such effects were due to surfactants present in the formulations and not the direct result of glyphosate exposure. To estimate potential human exposure concentrations to glyphosate as a result of working directly with the herbicide, available biomonitoring data were examined. These data demonstrated extremely low human exposures as a result of normal application practices. Furthermore, the estimated exposure concentrations in humans are >500-fold less than the oral reference dose for glyphosate of 2 mg/kg/d set by the U.S. Environmental Protection Agency (U.S. EPA 1993). In conclusion, the available literature shows no solid evidence linking glyphosate exposure to adverse developmental or reproductive effects at environmentally realistic exposure concentrations.”(Williams et al., 2011)*

The above examples of misleading statements and publications of the opponents lead in a logical way to the following chapter on the quality of scientific papers.

But lets close this Brazil chapter with a more optimistic element: There are first signs that Brazil is getting active in the foreign politics related to GM crops by helping the Bill and Melinda Gates Foundation to boost its programs on modern agriculture in Sub-Saharan Africa (Gates & Gates, 2011).

Nature has published an account on the Brazilian bean development (Toleffson, 2011), but opponents raised the question on whether the bean has gone through a scientifically convincing biosafety testing phase (Nodari, 2011): But this is answered by Embrapa and CTNBio properly:

*“Nodari, a former member of CTNBio who has long questioned transgenic crops, says that the commission improperly granted EMBRAPA’s request for confidentiality regarding key aspects of the genetic engineering. “We don’t know what we will be eating tomorrow in Brazil,” he says.*

*Current members of the commission have aggressively defended their decision. In a media interview after the decision last month, Edilson Paiva, president of CTNBio, said that Nodari and other opponents of genetic engineering are taking an ideological position aimed at “promoting fear and uncertainty” as they demand that scientists provide the impossible: guarantees of absolute safety.*

*EMBRAPA says that it must keep core information about genetic insertions confidential, to allow it to patent the work. The details will help the agency to develop bean varieties that are resistant to the golden mosaic and similar viruses, says Aragão, who is a member of CTNBio but abstained from the decision on the beans.*

*Aragão notes that safety analyses showed no reason for concern regarding the beans. He says that whereas some other GM crops produce unfamiliar proteins that could in theory cause an allergic reaction when eaten, the GM pinto bean produces only small snippets of RNA, tailored to react with and neutralize RNA from any invading virus. Herve Vanderschuren, a biotechnologist at the Swiss Federal Institute of Technology in Zurich, adds that plants naturally produce similar RNA snippets to defend themselves from viral attack, **and there is no evidence that this common molecular warfare is dangerous to humans.**(Toleffson, 2011)*

## 4. On the Quality of Scientific Publications

### 4.1. Peer review in the biosafety science debate on regulation

Before we start talking about regulation, a word on the science debate shall precede, which depends on the process of peer review, but it may be flawed in many ways, although there is no real good



alternative in sight, despite some attempts to change this situation like the proposal to involve respected science journalists. But there are objections: journalists might become part of the system (Fransen, 2007) and give up indirectly their strict impartiality and neutrality – which is maybe anyway an illusion. Or it might be, that they may simply not have the scientific expertise as demonstrated recently in a contribution of a science journalist in *Nature* (Waltz, 2009), extensive critical comments in ASK-FORCE contribution on the Rosi-Marshall publication on aquatic insects, see (Ammann, 20111002). More comments about this study below). It should also be admitted, that a fresh look of a “greenhorn” might reveal new aspects of the GMO battle.

The quality of biotechnological research is also influenced by the research environment offered to students and is evaluated in a differentiated way for Europe by Reiss et al. (Reiss & Lacasa, 2007). Peer review is a very fragile instrument and needs constant inquiry, as demonstrated also on the wikipedia website on the subject of peer review [http://en.wikipedia.org/wiki/Peer\\_review](http://en.wikipedia.org/wiki/Peer_review). It should also be seriously considered, that the present day peer review system is basically “faith based”, as described with convincing details by (Linkov et al., 2006). By criticizing bad science, we also have to seriously consider the cultural context including respect of traditional knowledge, avoiding any impression to give way to cultural colonialism (Dickson, 2012).

A trend towards a magazine style is documented for some important journals as *Nature* and others, the facts show, that the percentage of externally peer reviewed articles has dropped dramatically, facts will be given in a forthcoming publication of R. Laporte, F. Linkov and K. Ammann.

A telling graph is given in the new publication of (Leydesdorff & Bornmann, 2011), demonstrating that the journal *PNAS* beats *Nature* and *Science* clearly in numbers of citable publications:

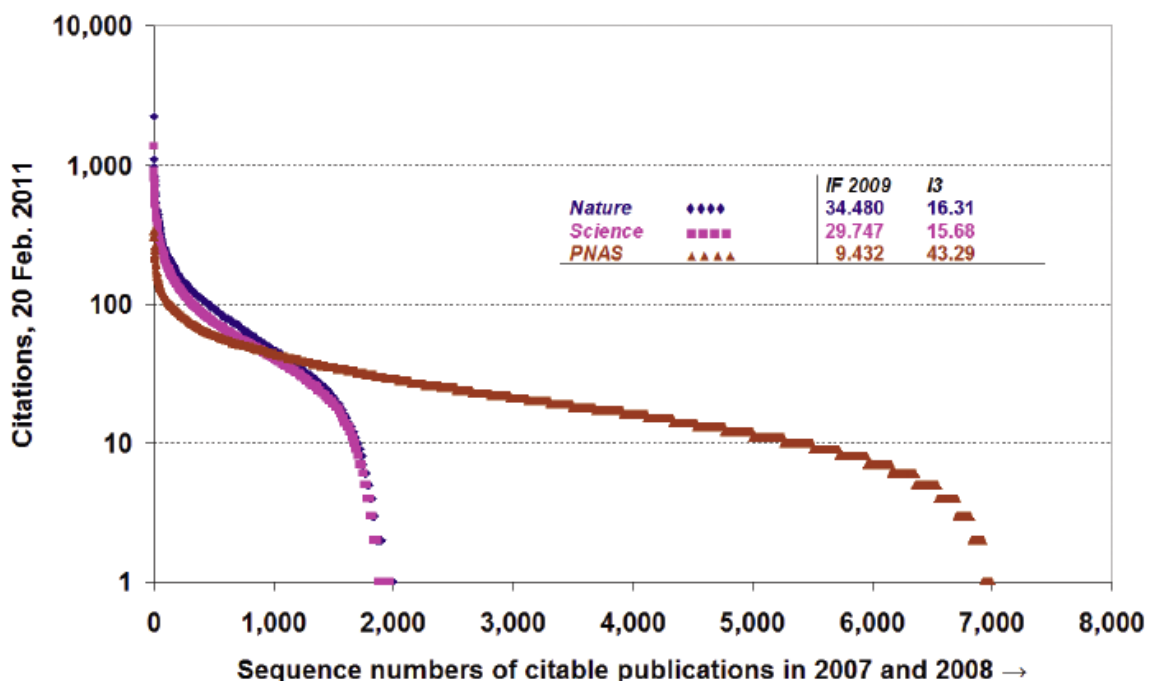


Fig. 19 Log-scaled citation distributions for the citable publications in 2007 and 2008 in *Nature*, *Science*, and *PNAS*; downloaded at the Web of Science on February 20, 2011. [Color figure can be viewed in the online issue, which is available at [wileyonlinelibrary.com](http://wileyonlinelibrary.com).] (Leydesdorff & Bornmann, 2011)

We should also include a new element in the reviews and evaluation of science as proposed by Lubchenco (Lubchenco, 1998): the scientific community should formulate a new *Social Contract for science*.

*"This contract would more adequately address the problems of the coming century than does our current scientific enterprise. The contract should be predicated upon the assumptions that scientists will (1) address the most urgent needs of society, in proportion to their importance; (2) communicate their knowledge and understanding widely in order to inform decisions of individuals and institutions; and (3) exercise good judgment, wisdom, and humility. The paper concentrates, according to the zeitgeist of the publication date, too much on environmental issues alone, today we should put into the center of our science strategy debates **humanity as a whole – and this means to take care of the most urgent needs, namely to work on the eradication of hunger.**"*

However, this process should not be mollified on the costs of hard science. The line between science and pseudo-science is often difficult to draw.

An interesting new aspect has been introduced by the Supercourse Group with Faina Linkov and Ron LaPorte: (Linkov et al., 2007). It is true that quality control of internet texts need rethinking, and it is also important to analyze in a critical way peer review of print material: Their comments can be summarized as follows: High quality internet distributed lectures are not basically different from written science publications, they also must be documented and references properly. A further element could be a method of quality management introduced originally for the industry by Edwards Deming Wikipedia of Edward Deming [http://en.wikipedia.org/wiki/W. Edwards Deming](http://en.wikipedia.org/wiki/W._Edwards_Deming), who very successfully taught management and quality control also in Japan in the fifties.

Two more initiatives should be mentioned here, they can be summarized under a kind of *post-publication peer review*.

#### 4.1.1. Faculty of 1000 system

With a total of nearly 84'000 articles reviewed by May 2011, the system has accumulated an important body of comments, see <http://f1000.com/> , the comments are following a certain scheme, but really critical sentences are not foreseen, the system is now linked to The Scientist and provides helpful orientation about important publications. Some examples have been evaluated by the author (Ammann, 2007b). As a result, the system, now worked on by some 4000 chosen experts, provides still a kind of positive selection system.

#### 4.1.2. Frontiers of Science

Frontiers of Science has been developed over two years in consultation with scientists and other faculty, as well as with students and postdoctoral fellows, to address manifest intellectual, logistical, and pedagogical issues, see <http://www.sciencecore.columbia.edu/s2.html> and <http://www.fos-online.org/>

#### 4.1.3. Peerage of science literature

Peerage of Science is a growing community of hundreds of scientists from 27 countries, united to fix peer review. Peerage of Science is a web service for automatically controlled, standardized, rigorous, fully anonymous scientific peer review. The service offers Authors a way to focus on science, Reviewers a way to directly benefit from the work they do, Editors a way to proactive, efficient and less time-consuming decisions, and Publishers a competitive advantage. Funders, institutions and society as a whole benefit from better use and allocation of resources via better evaluation of science.

Peerage of Science Ltd is a company in Jyväskylä, Finland, founded, owned and governed by scientists. Proud to be a different company, the primary purpose of Peerage of Science is to "foster

and develop the practice of science, as well as the conditions, societal standing and evaluation thereof, while promoting the interests of the researchers registered as users of the Company's services". (Akst Jef, 2012; Peerage of Science, 2012)

#### 4.1.4. Corporate influence in science

It is normal and essential in all kinds of economies, that corporate life influences science, since successful corporation performance depends on genuine innovation, translating innovation into products which can be sold with enough revenue in order to survive as a company.

On 6 October 2009, Hans Küng, Josef Wieland and Klaus Leisinger presented the Declaration of a NEW GLOBAL BUSINESS ETHOS at the United Nations in New York (Kueng Hans et al., 2009)

Although coming from a pharmaceutical company like Novartis, multinational seed companies will (or should) most likely join. More details on the Business Ethos Declaration see in section 6.5.1. p. 88. Such efforts are important, because there is a constant pressure of undue influence on scientific papers, although resisted successfully by most researchers, but the influence of multinational (in this case pharmaceutical) companies can be hidden but nevertheless powerful:

An example of such influence by units sponsoring scientific journals has popped up in Australia: See the debate around the withdrawal of six Australia based Elsevier "fake" journals sponsored by the pharmaceutical industry, see the statement of Elsevier's CEO Michael Hansen (Hansen, 2009) and (Goldacre, 2009; Smith, 2003b, 2005). This kind of influence might still be under control, and peer review is usually functioning in an unbiased way - but the difficulties are deep-rooted, and it's a constant fight for quality, as is summarized comprehensively by Scott (Scott, 2007), see also the summary of a conference of corporate influence on science: (Greenberg, 2003).

It is a cheap and intellectually intolerable slogan of opponents of genetic engineering in agriculture when they discredit researchers for their relationships with industry, since the great majority of researchers all over the world act as independent persons, although sometimes also funded by industry. The sole quality criteria on science are transparency in applied methods agreed upon by the science community and the reproducibility of the data, more on corporate ethics see below in section 6.

In the "dangerous" waters of corporate influence, we need renewed efforts of scientometric analysis, as given earlier in a report of bio-era: (Graff & Newcomb, 2003). The top part of table 5 reveals the few really successful seed companies in relation to the top universities with agricultural research regarding R&D: The calculation rules for the table below:

*"The four R&D measures are weighted equally. For example, having 10 percent of industry patents is just as significant as having 10 percent of commercialized products. Share of industry R&D output = (share of industry patents + share of industry patent citations + share of industry field trials + share of industry commercialized products) / 4." (Graff & Newcomb, 2003).*

*The top 35 R&D organizations in agricultural biotechnology*

RANK	PARENT ORGANIZATION	SHARE OF INDUSTRY R&D OUTPUT
1.	Monsanto	29.82%
2.	Du Pont / Pioneer	10.98%
3.	Bayer / Aventis	10.14%
4.	Dow	5.81%
5.	Syngenta	5.80%
6.	Savia / Seminis	2.57%
7.	USDA	2.38%
8.	BASF	1.71%
9.	Cornell University	1.25%
10.	Stine Seed Farm Inc	1.15%
11.	Florigene	1.08%
12.	University of California	1.05%
13.	Exellix	0.98%
14.	Iowa State University	0.91%
15.	Rutgers University	0.83%
16.	University of Guelph	0.79%

Fig. 20 Table 5, upper part, with a ranking of biotech companies and universities in the United States, from (Graff & Newcomb, 2003), calculation rules above.

It is fact that Corporations contribute to the development of plant sciences heavily. A check in the Web of Knowledge in January 2012 shows, that over time some 8300 publications in peer reviewed journals have been authored or co-authored by scientists with an address at the Monsanto Seed Company.

#### 4.1.5. More on the quality of scientific publications

Coming back to the peer review on the quality of scientific papers, all the above statements do not mean to say goodbye to the factual and methodological scrutiny per se – even after a paper is already published. With a focus on the GM food safety research Chassy & Parrott (Chassy & Parrott, 2009) summarize the criteria on how to judge whether a food study is believable or not: (a) Making sure the samples tested are comparable samples. (b) Testing composition to make sure the tests and controls are comparable. (c) The need for an acceptable balanced and nutritious diet. (d) Why the dose is important. (e) What statistics do and don't tell us. (f) The importance of peer review and scientific publication, (g) Guidelines for dealing with conflicting information. (h) Ethical considerations. A very important additional point is emphasized by Kostoff (Kostoff, 2002): "Multiple technical experts should average out individual bias and subjectivity".

Several blatant examples of peer review not properly done are, among others, discussed in ASK-FORCE (with some additions related to recent publications, all cited in the renewed blog (Ammann, 20110921), but all the examples enjoy high popularity on the websites of opponents to GM crops.

## 4.2. Debate on the Quality of Publications:

### 4.2.1. The case of Bt endo-toxins detrimental to aquatic organisms

See comments in ASK-FORCE blog No. 3 on (Rosi-Marshall et al., 2007): (Ammann, 20120724) (including also the latest publications of (Tank et al., 2010). The study has been criticized heavily by (Beachy et al., 2008) and (Parrott, 2008), the main points of critique, summarized in a letter to the editor of PNAS (McHughen et al., 2007): No indication about the nature of Bt toxin, nor any data about its origin. Unscientific extrapolation from lab to field experiments, suppression of an important

result of fig.3: low toxicity of normal Bt toxin levels for aquatic organisms etc. It is good to know that the authors of the original study admitted some mistakes in their reply: (Rosi-Marshall et al., 2008) *“Growth of trichopterans can be affected by many factors, including nutritional quality of food resources. As we stated (3), we paired “Bt” and “non-Bt” materials on the basis of nutritional quality (carbon:nitrogen ratios and lignin content). The use of isogenic hybrids would have resulted in food resources of different nutritional quality (4) and Cry1Ab content, and this would have confounded the experiments. We cannot fully disregard the unlikely possibility that some other leaf constituent was responsible for observed differences between the “Bt” and “non-Bt” treatments. However, we argue that the presence or absence of Cry1Ab protein is the most likely explanation for observed differences in trichopteran growth and mortality. We encourage others to pursue further research to develop a broader body of knowledge on the effects of Cry1Ab protein on aquatic insects.*

*We agree that extrapolation from laboratory experiments to ecosystems is unjustified without supporting evidence from field measurements. We (Rosi-Marshall et al., 2007) presented several lines of evidence suggesting that Cry1Ab-containing materials could potentially affect headwater stream ecosystems: (i) inputs of corn pollen and detritus to streams were documented and quantified, (ii) trichopterans collected from streams contained pollen in their guts or often were found associated with decaying corn detritus, and (iii) laboratory feeding trials indicated trichopterans are susceptible to the effects of Cry1Ab. **Further study may reveal that the potential for detrimental effects is not realized in situ in streams or that effects are limited spatially or temporally and thus may not outweigh the benefits associated with the planting of Bt corn—only further study will reveal whether this is the case.** Regarding the concern of (Beachy et al., 2008) and (Parrott, 2008) that the final sentence of our abstract overstated the conclusions of the paper, we agree that the sentence should have articulated the potential for ecosystem-scale consequences within streams, rather than suggesting that such consequences were observed in situ.*

*Lastly, (Beachy et al., 2008) imply that our publication and statements therein could “cause significant damage.” We are unsure what Beachy et al. believe to have been significantly damaged. We argue that the wise use of any new technology requires a full understanding of both the benefits and the potential costs. In the case of corn genetically modified to express the Bt  $\delta$ -endotoxin, the environmental costs appeared not to have been fully assessed, and we believe the studies we reported (3) contribute to a better understanding of potential effects on aquatic ecosystems.” (Rosi-Marshall et al., 2008)*

And they repeated also in the second study the statement that detrimental effects of the Bt toxin on aquatic organisms are not confirmed and thus tuned down the interpretation from the first study: (Tank et al., 2010).

*“The question of whether the concentrations of Cry1Ab protein we report in this study have any effects on nontarget organisms merits further study.”*

#### **4.2.2. Flawed experiments with mice and Bt crops in Austria prematurely launched**

The case of the Austrian mice experiments supposedly affecting fertility after some generations (Velimirov et al., 2008). The report was never published in a peer reviewed journal, but it was launched on the political pressure of the Austrian ministry prematurely. After lots of public and scientific debate, which caused serious and unfounded damage to the image of Bt crops, the study results were distributed on hundreds of websites of GM crop opponents. Greenpeace launched populist slogans that “eating this Bt maize would be a new innovative way of birth control”. But critique came up, and since there was no publication in a peer reviewed journal available, the rebuttals were not published in journals either. The whole bitter debate is summarized extensively in two ASK-FORCE blogs: (Ammann, 20100407). In this ASK-FORCE blog there are all the massive contradictions against the Velimirov-Study summarized.

The EFSA-rebuttal from 2009 may suffice here, with the final conclusions again fully rejecting the study: (EFSA-Opinion, 2009)

*“In conclusion, the EFSA GMO Panel considers that the information available for maize MON810 addresses the scientific comments raised by Member States and that maize MON810 is as safe as its conventional counterpart with respect to potential effects on human and animal health. The EFSA GMO Panel also concludes that maize MON810 is unlikely to have any adverse effect on the environment in the context of its intended uses, especially if appropriate management measures are put in place in order to mitigate possible exposure of non-target Lepidoptera. Moreover, the EFSA GMO Panel advises that pest resistance management strategies continue to be employed.”*

See also the comments of Ammann in (Sinha, 2009):

*“Studies that look at non-obvious risks are a welcome addition to the literature, say critics, but poorly conducted studies do more harm than good. “It’s just bad science,” says Ammann. “There are a lot of scientists producing these studies in a very sloppy way. They bolster public fear yet do nothing to resolve conflicts or move the field forward.” And:*

*“But the authors aren’t to blame, says Klaus Ammann, emeritus professor at the University of Bern in Switzerland. They are merely the latest victims of what has become the political gerrymandering of science to bolster and support anti-GM sentiment in Europe. “The Austrian government had exhausted all legal avenues to ban cultivation of GM crops,” Ammann says. “The Ministry of Health decided to avoid the peer-review process and announce study results at a conference, hide the data from scientists, and let the activists run amok with the help of uncritical media.” Indeed, in the ensuing months the Austrian government has backpedaled. The Ministry of Health responded to a request to interview Zentek or other authors with the following: “We asked the scientists to reevaluate their statistical analysis. Additionally the external evaluation will soon be started. I kindly ask you to wait with your proposal until the reevaluation is completed.” (Sinha, 2009)*

The subsequent official retraction done by the Austrian Government itself is hidden in an European Commission Health and Consumers Directorate-General Summary Record of the Standing Committee on the Food Chain and Animal Health from October 19, 2008: European Commission Health and Consumer Directorate-General, Summary Record of the Standing Committee on the Food Chain and Animal Health Held in Brussels October 19, 2008: (EFSA, 20091019):

***“Miscellaneous***

*Long-term reproduction studies on mice*

*The delegation of Austria informed the Committee about the last developments regarding a study entitled “Biological effects of transgenic maize NK603xMON810 fed in long term reproduction studies on mice” that was financed by the Austrian Federal Ministry of Health, Family and Youth and the Ministry of Agriculture, Forestry, Environment and Water Management with a view to examine effects of the stacked GM crop NK603xMON810 in different models (MGS, RACB) of long-term feeding studies. This study was already discussed in the Committee on 16 December 2008 and it was considered that it did not allow to draw conclusions on the investigated GM maize.*

*The delegation of Austria indicated that the contracted researchers still failed to deliver a satisfactory report on this study, especially with respect to the statistical analysis of the data, and that the Austrian Ministries do not expect anymore to receive such a report.*

*For the sake of transparency, raw data that were provided by the researchers were made available to EFSA and Member States.*

*Despite the difficulties encountered with this specific research project, the Austrian delegation reiterated its interest in establishing an adequate model for long-term feeding studies.” (EFSA, 20091019).*

With some astonishment the author reads in this retraction text, that “the delegation of Austria indicated that the contracted researchers still failed to deliver a satisfactory report on this study, especially with respect to the statistical analysis of the data, and that the Austrian Ministries do not expect anymore to receive such a report.” This statement was published in a time when the Austrian government must have received the second draft of the report with rectified statistics – which was accompanied by comments that negative effects described in the original version could not be verified due to revised statistic analysis (oral communication of Prof. Zentek).

**4.2.3. The example of a biased review on the biosafety of GM food: Dona et al. 2009**

The review by Dona & Arvanitoyannis (Dona & Arvanitoyannis, 2009) would never have passed a serious peer review, and for sure it would not pass tests designed by Tang et al. (Tang et al., 2009), which can detect biased filtering of citations and words: According to Tang et al it is important to distinguish between *subjectivity classification* retrieved from opinionated and factual statements, and combine it with a multi-class *sentiment classification* and to get a better scale by using neutral training examples. An extensive, but still not complete scientific analysis on (Dona & Arvanitoyannis, 2009) has been placed in ASK-FORCE with critical comments: (Ammann, 20110909).

This paper of Dona & Arvanitoyannis, published in “Critical Reviews in Food Science and Nutrition” by the internationally well known editorial house Taylor & Francis, needs to be critically commented for a multitude of reasons:

In a first overview, the reader will find a lot of mostly unconfirmed concerns about the safety of foods derived from GM crops, the citations are extremely filtered in a way to construct a negative picture on GM crops, and the review authors seem to lack proper knowledge about the field of food safety research as a whole – or worse: they perform purposeful literature filtering, which can also be called fraud. They also publish numerous paragraphs as their own writings, whereas they are just taken by copy-paste from other publications, and worse: those placatory passages are selected from papers with a negative bias and with notorious contents, which have been rebutted recently and for the majority even some years ago. Most of those rebuttals they do not cite are written by the best authorities in the field, well publicized and easily obtainable in the internet or in libraries from the best peer reviewed journals. Thus Dona et al. give the uninformed reader the wrong picture, as if the food safety situation in 2008 would still be precarious. This is simply not the case and in summary this is a blatant example of scientific distortion of the overall picture in this field of scientific research on food safety.

The text in (Ammann, 20120807) gives some examples, always supported by peer reviewed literature, which is available in abundance. It is hard to understand that Taylor & Francis let pass such a low quality review with numerous errors, and it is even harder to understand that major efforts in food safety research are simply ignored in this review, or mentioned in a misleading way, such as giving only the outlook and summary comment on one of the major efforts ‘ENTRANSFOOD’ in the European research on food safety: Citing only (Kuiper et al., 2004), which concentrates on some future research efforts, gives the erroneous picture, that ENTRANSFOOD came to the conclusion that food safety is not yet secured with the GM crops. But if you make the effort of reading the *major official summary* of ENTRANSFOOD (Konig et al., 2004), agreed upon by all researchers participating in this huge project, then you easily fall on their major conclusion:

*“In conclusion, the food safety assessment paradigm as described in this paper, under which any differences in the new food are identified and any hazards and risks characterized, relative to the conventional food or product, clearly establishes whether the test food derived from a GM crop is as safe as the conventional counterpart. It can even be argued that foods from GM crops are better characterized than other non-regulated plant-derived foods, due to the additional rigor in the current regulatory requirements and testing regime compared to that for conventionally-bred crops.”*

It should be mentioned, that this summary is based on an impressive number of joint research papers which have been carefully coordinated in their conclusions by a consortium of the most renowned researchers in food safety today.

Under the treacherous title: ***Potential Effects on Human Health resulting from the use of Viral DNA in Plants p. 167*** the authors set right from the beginning a negative tone:

Based on a publication managed by the same publisher Taylor & Francis (van Ho et al., 2000) the review authors are parroting the notoriously alarmist and often refuted opinion views of Mae van Ho and her colleagues from the ISIS institute, they do not cite the original source (van Ho et al., 1998) and avoid to reveal to the reader, that those papers have been rebutted properly and in detail ever since by some of the most renowned virologists (Hull et al., 2000; Morel & Tepfer, 2000) see also the comments of Chris Leaver in (Hodgson, 2000). Here the abstract of (Hull et al., 2000), which is actually sufficient:



*“The 35S promoter, derived from the common plant virus, cauliflower mosaic virus (CaMV), is a component of transgenic constructs in more than 80% of genetically modified (GM) plants. Alarming reports have suggested that the 35S promoter might cause accidental activation of plant genes or endogenous viruses, promote horizontal gene transfer, or might even recombine with mammalian viruses such as HIV, with unexpected consequences. In this article, we discuss the properties of CaMV and the 35S promoter and the potential risks associated with the use of the promoter in GM plants, concluding that any risks are no greater than those encountered in conventional plant breeding.” (Hull et al., 2000).*

Besides many more points (horizontal gene transfer, toxicity of GM foods) clearly contradicted in the ASK-FORCE blog, and there is also a published very detailed rebuttal of the Dona review as a letter to the editor in the same review journal by (Rickard, 2010), the introduction:

*From the scientific perspective, we are very surprised and disappointed with the publication of Dona – Arvanitoyannis 2009 in Critical Reviews in Food Science and Nutrition. The obvious bias against GM crops and the companies that develop this technology, as represented throughout this work, is unexpected and inappropriate for a publication in a scientific journal, as are the many unfounded assertions and inaccurate citations that pervade the text. Strong bias is clearly illustrated in the first sentence of the abstract which begins “As genetically modified (GM) foods are starting to **intrude** in our diet...” (emphasis on “intrude” added). This unfounded bias is further exemplified on page 169: “... Because companies try to hide information about the health impacts of GM.” And the choice of vocabulary across the document (e.g. on pages 164 and 172) the use of the word “contaminated” and “contamination”, respectively, with regard to foods with GM crops). Such statements are clearly inflammatory, and at a minimum, demand the same critical review and body of supporting evidence as other assertions made in scientific works.*

*While the number of unsubstantiated claims by Dona et al. are too numerous to catalog here, we provide the following examples of claims in sequential order that are not supported by science, and offer for review applicable literature to support each of those points. (Rickard, 2010)*

And then it goes on with dozens of critical remarks, point by point, in the end you realize that this review is rather an unscientific propaganda pamphlet and has little scientific merits.

#### 4.2.4. Example from the pseudo-debate on glyphosate toxicity

(Williams Amy Lavin & deSesso John M., 2010) have scrutinized the main bulk of recent literature making false claims on Glyphosate toxicity: The case of the experimental papers of Malatesta (Malatesta et al., 2005a; Malatesta et al., 2003; Malatesta et al., 2008a; Malatesta et al., 2002a; Malatesta et al., 2002b; Malatesta et al., 2001; Malatesta et al., 2008b; Malatesta et al., 2005b; Malatesta et al., 2002c) have been critically reviewed by Williams and deSesso, from the poster the extract (considered by the author as a crystal clear review, actually, as short as it is, this is the way, peer review should be done):

*“Critical evaluation of the above studies uncovered a number of major methodological flaws or deficiencies. To ensure that the observations reported from a stereologic morphometry study are representative of the entire organ, procedures must be followed so that the images used for analysis are selected in an objective and unbiased manner (Weibel Ewald R. & B.P. Bolender, 1973; Weibel Ewald R. et al., 1969) These procedures include the following:*

**1. Study designs fail to control for possible litter effects.**

*The methods by which offspring were selected for study and the number of litters from which they were derived are not reported. Further, nothing in the studies’ methods suggest that potential litter effects were controlled. When littermates are assigned to the same treatment group in a study, they should be considered a single experimental unit for purposes of statistical analysis (Festing Michael F.W., 2006; Holson & Pearce, 1992) Ideally, however, offspring should be randomly selected from multiple litters such that each member of the treatment group is derived from a different litter and each individual animal can be considered a separate experimental unit for statistical analysis.*

**2. Methodological procedures were inadequate to ensure an unbiased, quantitative assessment.**

*In the studies of Malatesta et al., the a priori selection of micrographic field locations and regions of the organ to be photographed is not described. Although one report refers to, “randomly selected electron micrographs,” the numerical size of this pool of images is not stated. In other cases, the information provided seems contradictory. Overall, the methods descriptions provided in the study reports suggest that micrographs were not taken or selected for examination in a truly random manner and that an insufficient number of micrographs were analyzed.*

**3. Methods for statistical analysis were inappropriate.**

*Anywhere from 2 to 10 animals per treatment group, with a median of 3 animals per group, were examined at any one time point. Additionally, only 10–20 micrographs per animal were examined. These 10–20 micrographs are not considered*

*independent measures because they come from the same animal. Furthermore, if the animals in the test groups were littermates (as seems likely), then the measures from these individual animals would also not be considered independent. This suggests that the statistical methods used in the analyses were inappropriate (i.e., the highly dependent nature of the observed measures makes it unlikely that any of the findings reported would have reached statistical significance). In (Magana-Gomez et al., 2008) the standard errors reported for body weight gains and food consumption rates were exactly the same for both groups (Table 4). Standard errors for feed conversion rates and protein efficiency measures were also the same for both groups. Such findings are highly improbable.*

Nevertheless, in most of Malatesta's publications the door about the real reasons of the effects (true or not) are still in question. This does not hinder some opponents to cite Malatesta as blaming directly the transgenesis of the Soybeans tested: The conclusions in (Malatesta et al., 2008a)

*"This study demonstrates that GM soybean intake can influence some liver features during ageing and, **although the mechanisms remain unknown**, underlines the importance to investigate the long-term consequences of GM-diets and the potential synergistic effects with ageing, xenobiotics and/or stress conditions." (Malatesta et al., 2008a)*

The case of numerous claims on serious toxicity effects related to glyphosate are refuted: In a major review paper (Williams et al., 2011) many of the recent glyphosate bioassessment literature has been critically reviewed, the result is that glyphosate alone does not cause any problems.

It is important to also reproduce two tables giving the results of scientific scrutiny of the papers of a range of papers scrutinizing glyphosate, in most cases with some surfactant substances included:

The conclusions are clear and count the recent scaremonger wave against glyphosate, readily taken up by some European governments without a shred of scientific evidence:

### **Summary—Biomonitoring Data**

The body of biomonitoring data available for glyphosate is limited at this time. Nevertheless, the data reviewed herein clearly show that the degree of systemic glyphosate exposure that occurs as a result of normal application practices is exceedingly small, often below the limits of detection (especially for those not intimately involved in the application process). In fact, the highest systemic dose estimated from these studies was 0.004 mg/kg (Acquavella et al. 2004), a value 500-fold below the daily oral reference dose for glyphosate of 2 mg/kg/d (U.S. EPA 1993). These findings indicate that the risk of substantial exposure as a result of glyphosate application practices is minimal at best.

#### *Conclusions*

*An extensive, in-depth analysis of the available scientific literature provides no apparent evidence to indicate that exposure to glyphosate is associated with the potential to produce adverse developmental and reproductive effects in humans. While the body of epidemiological data for glyphosate is fairly limited, and none of the available studies (with the exception of Sanin et al. 2009) were designed specifically to assess the potential effects of glyphosate exposure, data as a whole reveal no developmental or reproductive health disturbances associated with exposure. In contrast to epidemiological data, the database of animal studies for glyphosate is relatively robust, including studies of mice, rats, and rabbits exposed to glyphosate, various glyphosate-based herbicidal formulations, the major glyphosate environmental breakdown product AMPA, and POEA surfactants included in some Roundup-branded herbicides. All guideline-compliant studies reviewed found no marked effects of glyphosate treatment on reproductive health or the developing offspring at non-maternally toxic doses (Holson 1990; 1991; IRDC 1980a; 1980b; Knapp 2007; 2008; Reyna 1990; Schroeder 1981). It should be noted that while a number of non-guideline-compliant studies claimed adverse developmental effects associated with glyphosate exposure (Beuret et al. 2004; Dallegrave et al. 2003; Dariuch et al. 2001; Yousef et al. 1995), these investigations suffer from numerous inadequacies in design, which makes substantiation of their conclusions problematical. Furthermore, these studies all used commercially formulated glyphosate-based herbicides rather than pure.*

*Thus, findings reported in these studies cannot be definitively assigned to glyphosate exposure. Similarly, review of the available mechanistic data related to glyphosate fails to find a plausible MOA by which glyphosate may be able to induce adverse developmental or reproductive outcomes. It should be noted, however, that the body of available studies suffers from numerous design inadequacies, particularly with regard to the type of test agents used (commercially available*

*glyphosate-based herbicides versus pure glyphosate). Furthermore, other than hypothesizing possible MOA, these data provide little relevant information that can be used in a human health risk assessment.*

*Finally, a review of the limited body of available biomonitoring studies shows that, via reasonably anticipated exposure routes, human exposure to glyphosate is likely to be well below the daily oral reference dose for glyphosate of 2 mg/kg/d, as set by the U.S. EPA (1993). These data show that, regardless of any potential developmental and reproductive hazards that may be alleged based on misinterpretation of results from animal and mechanistic studies, the levels of glyphosate to which humans are likely to be exposed are far below the range of doses considered to be safe by the U.S. and other regulatory agencies worldwide. In conclusion, a thorough evaluation of the available data demonstrates that exposure to environmentally relevant glyphosate concentrations is not anticipated to produce adverse developmental or reproductive outcomes. It should be noted, however, that the body of available studies suffers from numerous design inadequacies, particularly with regard to the type of test agents used (commercially available glyphosate-based herbicides versus pure glyphosate). Furthermore, other than hypothesizing possible MOA, these data provide little relevant information that can be used in a human health risk assessment.*

*Finally, a review of the limited body of available biomonitoring studies shows that, via reasonably anticipated exposure routes, human exposure to glyphosate is likely to be well below the daily oral reference dose for glyphosate of 2 mg/kg/d, as set by the U.S. EPA (1993). These data show that, regardless of any potential developmental and reproductive hazards that may be alleged based on misinterpretation of results from animal and mechanistic studies, the levels of glyphosate to which humans are likely to be exposed are far below the range of doses considered to be safe by the U.S. and other regulatory agencies worldwide. In conclusion, a thorough evaluation of the available data demonstrates that exposure to environmentally relevant glyphosate concentrations is not anticipated to produce adverse developmental and reproductive effects in humans.”(Williams et al., 2011)*

**TABLE 11.** Mechanistic Studies Assessing the Potential Endocrine-Disrupting Effects of Exposure to Glyphosate and Glyphosate-Based Formulations

Study	Basic experimental design	Findings
Petit et al. 1997	Recombinant yeast system expressing the estrogen receptor (ER): Estrogenic potential of various chemicals, including $10^{-8}$ to $10^{-4}$ M glyphosate, tested in yeast cells expressing the rainbow trout ER linked to a <i>lacZ</i> reporter gene; cells treated to test agents for 4 h.	Glyphosate did not demonstrate estrogenic activity.
Lin and Garry 2000	Estrogen-responsive MCF-7 cells: Response of MCF-7 cells to Roundup or glyphosate exposure assessed; cell proliferation after a 7-d exposure period in presence and absence of steroid growth factor-deficient FBS examined by flow cytometry; cell viability and apoptosis examined after 72 h of incubation by flow cytometry and propidium iodide.	Cell proliferation increased with exposure to both Roundup and glyphosate, but response was similar with and without FBS, suggesting it was mediated through a nonestrogenic pathway; no cytotoxicity or apoptosis observed due to glyphosate exposure.
Meulenberg 2002	Displacement of estradiol ( $E_2$ ) from human sex hormone binding globulin (SHBG): Displacement of tritiated $E_2$ from SHBG by different concentrations of various test agents (including glyphosate) measured in vitro.	Glyphosate reported to have shown ambiguous results for $E_2$ displacement from SHBG.
Xie et al. 2005	Rainbow trout vitellogenin assay: Ability of 0.11 mg/L glyphosate and other herbicides to induce vitellogenin expression in trout assessed.	Glyphosate was not found to have estrogenic activity in this assay.
Kojima et al. 2004	Human $ER\alpha$ , $ER\beta$ , and androgen receptor (AR) binding: More than 200 pesticides were tested for agonist or antagonist activity at human $ER\alpha$ , $ER\beta$ , and AR transfected into Chinese hamster ovary cells; $\leq 10^{-5}$ M glyphosate tested.	Glyphosate was not noted to affect hormone binding in any of the receptor subtypes tested.
Walsh et al. 2000	Steroidogenic acute regulatory (StAR) protein synthesis: Impact of Roundup (with 180 g/L glyphosate) and other herbicides on steroidogenesis in MA-10 Leydig tumor cells was assessed by measuring progesterone production by radioimmunoassay; levels of StAR mRNA assessed using Northern blots.	20–100 $\mu\text{g/ml}$ Roundup, but not pure glyphosate, caused a significant dose-dependent decrease in progesterone production; 25 $\mu\text{g/ml}$ Roundup did not influence overall protein levels, but decreased levels of StAR mRNA.
Levine et al. 2007	Inhibition of progesterone production in MA-10 mouse Leydig cells: MA-10 cells were exposed for 2 h to Roundup with and without glyphosate, as well as to various surfactants; the hCG-stimulated increase in progesterone production was measured following incubation; impact of surfactants on StAR protein levels was assessed by Western blot on hCG-stimulated and nonstimulated MA-10 cells; impact of treatment on mitochondrial membrane function was determined by JC-1 cationic dye.	Exposure to surfactants, as well as to Roundup with and without glyphosate, was associated with a decrease in hCG-progesterone production, decreased expression of the StAR protein, and a decrease in mitochondrial membrane function.
Richard et al. 2005	Aromatase activity and mRNA levels in JEG3 cells and placental and equine testicular microsomes: Aromatase activity in JEG3 cells treated 1 and 18 h with 0.2–2% Roundup (or corresponding concentrations of glyphosate) measured by radioimmunoassay; aromatase mRNA expression measured by RT-PCR. Aromatase activity in microsomes from full-term placentas and equine testes also assessed upon 15 min exposure to Roundup or glyphosate.	JEG3 cells: 0.2–2% Roundup has significantly greater impact on cell viability than glyphosate of corresponding concentrations; aromatase activity significantly increased at 1 h and significantly decreased at 18 h after exposure to 0.01% Roundup; aromatase mRNA also decreased at 18 h following Roundup exposure; $\leq 0.8\%$ glyphosate for 1 or 18 h had no effect on aromatase activity. Microsomes: Aromatase activity decreased at $>0.05\%$ Roundup and $>0.5\%$ glyphosate. <i>Concentrations of Roundup and glyphosate used in this study are not environmentally relevant.</i>

(Continued)

TABLE 11. (Continued)

Study	Basic experimental design	Findings
Benachour et al. 2007	Aromatase activity in JEG3 and human embryonic kidney 293 cells and placental and equine testicular microsomes: Cell viability and aromatase activity following 1, 24, or 48 h of treatment with 1–2% Roundup or equivalent concentrations of glyphosate assessed as above; cultures treated in either serum-containing or serum-free media.	293 Cells were more sensitive than JEG3 cells; cells in serum-free media were more sensitive than those in serum-containing media; Roundup was substantially more cytotoxic than glyphosate; Roundup decreased aromatase activity in microsomes in temperature-responsive manner. <i>Concentrations of Roundup and glyphosate used in this study are not environmentally relevant. Also, the pH values of the test agents were not adjusted appropriately.</i>
Casnier et al. 2009	Aromatase activity and anti-estrogenicity in HepG2 cells and anti-androgenicity in MDA-MB-453-kb2 cells: Aromatase activity following 24 h of treatment with glyphosate or 1 or 4 herbicide formulations; anti-estrogenicity and anti-androgenicity assessed following 24 h of treatment with same test compounds; incubations done in serum-free media.	Herbicide formulations inhibited aromatase activity and exhibited dose-dependent antiestrogenic and antiandrogenic activity; results were not proportional to glyphosate concentration of formulations; $\leq 0.3\%$ glyphosate has no effect on aromatase or estrogenic activity; androgenic activity altered by glyphosate, but not in dose-dependent manner. <i>Results with glyphosate alone suggest no endocrine modulating activity. Results with formulations confounded by presence of surfactants and other ingredients.</i>
Hokanson et al. 2007	Gene expression in MCF-7 cells: Gene expression following 18 h of exposure to 0.001–0.1% of a glyphosate-containing herbicide was assessed by DNA microarray and RT-PCR.	Treatment altered gene expression, but of seven genes selected for further study, dysregulation was confirmed by RT-PCR for only three. <i>Because a herbicidal formulation was tested, findings cannot be specifically attributed to glyphosate. Also, no evidence indicates that these changes were mediated through endocrine-disruption.</i>
Paganelli et al. 2010	Neural crest cell marker expression in <i>Xenopus laevis</i> embryos: Expression of various neural crest cell markers following exposure of 2-cell stage embryos to 1/5000–1/3000 dilutions of Roundup Classic or injection with 500 pg glyphosate.	Treatments reduced neural crest cell marker expression and appeared to be associated with cranial malformations; possible involvement of retinoic acid pathway hypothesized. <i>Glyphosate solution was not pH-adjusted and was injected into embryos, making relevance to environmental exposures questionable.</i>

Nevertheless many opponents consider Malatesta's papers to support their own negative view on glyphosate, another proof that moral self-licensing can lead to imprecise analysis of scientific papers.

A review with 436 full text links of some important Glyphosate literature has been summarized in (Ammann K., 20121216)

Finally we all have to consider that critique on peer review should not be exaggerated, D. Ploegh's warning about unnecessary additional lab experiments demanded by peer reviewers should be carefully considered (Ploegh, 2011).

*The result of this discussion: it will be necessary to call for new, internet based methods to create a more efficient peer review system. A nucleus of such a system is given in Ron La Porte's supercourse system <http://www.pitt.edu/~super1/> .*

It will also be worthwhile to think about post publication review see the section on peer review.

More material is given in a draft blog on the glyphosate debate:

#### 4.2.5. Caveat about pseudo-balance of views in the GM debate

A caveat at the end of this paragraph on peer review is appropriate: Although it is in principle necessary to ask ethical questions, we should first concentrate on the scientific assessment of a professional peer review strictly following a factual agenda such as (Chassy & Parrott, 2009; Chassy, 2009) are demanding. Only then, when this filter has been passed successfully, then it is important to go into ethical and socio-economic questions.

But as often, it is the farmers and the market regulating efficiently – and – no surprise – they follow quite naturally socio-economic principles. It is wrong to mix scientific and ethical questions as de Melo et al. and Inteman et al. are asking for (de Melo-Martin & Meghani, 2008; Intemann & de Melo-Martin, 2008), the result is then to erroneously accept for discussion a paper like the one of Seralini et al. (Seralini et al., 2007b), a paper which has been seriously and repetitiously criticized on a factual basis by EFSA (EFSA, 2007a, b, c). Such papers should not be seen as a publication which takes into account a “balanced view”, because they are flawed in the first place. Papers from the laboratory of Seralini are unfortunately often cited as done by *independent* scientists with the function of important whistleblowers, which is not very convincing: Digging into the financial support of Seralini and his CRIIGEN lab is highly interesting, You realize that they also receive funds which come from opponents of GMO technology, such as Sevene Pharma, commercializing homeopathic products which claim to detoxify various toxic products (Imposteurs, 2011) and more: CRIIGEN has been created with the financial support of the retailer Carrefour which has also contributed financially to certain studies of Seralini and his group. Interestingly enough, Carrefour, the second largest food distributor in the world, sells its own brand of “GMO-free” products... Source: (Kuntz, 2011b). For more details about ethical questions see section 5.4. But it should also be seen here that the main argument of the quality of scientific papers is not who actually financed the research, but one should scrutinize the methodological and scientific quality of the papers. It is rather simplistic to split the science paper world into two halves with a contrasting financial background.

It is not only ironic, but truly sad that a colleague of ours, Marc Fellous, has been convicted by a French court to have accused Gilles Eric Seralini for not being a neutral scientist anymore (taking money from Greenpeace, which is a fact). Interestingly enough Fellous has not been convicted by the same court because he is accusing Seralini for publishing bad science...(Kuntz, 2011b; Sachs, 2005; Sachs et al., 2007, 2009). See also more material about the case Seralini-Fellous in (Seppi Wackes et al., 2011).

## 5. GM- and non-GM-crop differences over-estimated, the ‘Genomic Misconception’.

### 5.1. Early phase of risk assessment

In the wake of molecular breeding, in particular with the first successes of “gene splicing”, the safety debates started soon after the discovery of the DNA structure by Watson & Crick (Watson & Crick, 1953a, b; Wilkins et al., 1953), followed by the Asilomar Conference (Berg et al., 1975; Berg & Singer, 1995) - see also some historical accounts (Chassy, 2007; Friedberg, 2007; Klug, 2004). The fascination about the novelty of transgenesis was justified, but also overwhelming, and the many unforeseen scientific breakthroughs following were unprecedented in the history of molecular biology.

Unfortunately, the enthusiasm also lashed back in an overacting in risk assessment, when the first GM crops went into production. The debate on how GM crops should be regulated started very early



with an emerging divide between regulation in the US and Great Britain, including later the whole of Europe (Bennett et al., 1986; NRC (National-Research-Council), 1989). Some more traces of early disputes about regulatory decisions in the US and in Great Britain can be seen in letters to Nature in 1992: (Lehrman, 1992; Mundell, 1992). Some support tighter regulation including field biosafety assessments, others fear strangulation of biotechnology research. During the wake of the Cartagena Biosafety Protocol most countries adopted (around 2003) the European way of risk analysis of genetic engineering, emphasizing process oriented regulation and rejecting product oriented regulation.

The seemingly absolute novelty of genetic engineering on the molecular level has been contested already in the early days of molecular biology in the 1930s and 1950s with the discovery of cellular systems for genome restructuring discovered with the classic papers of McClintock (McClintock, 1930, 1953) and with later commentaries of Fedoroff (Fedoroff, 1994; Fedoroff et al., 1995), also summarized under 'natural genetic engineering' (Lewin, 1983; Shapiro, 1997), see also the rich and continuing collection on the topic of natural genetic engineering by David Tribe. In a recent opinion paper, Fedoroff et al. are emphasizing again the process-agnostic approach, which is a world wide scientific consensus since decades, but regulatory agencies (targeted in this paper particularly: EPA, Environment Protection Agency of the US) are just turning a deaf eye to science about such fundamental questions and erroneous views (Fedoroff et al., 2011)

## 5.2. Molecular processes similar in natural mutation and transgenesis

Genetic engineering has been brought into evolutionary perspective of natural mutation by authorities such as Werner Arber: his view remains scientifically uncontested that molecular processes in transgenesis and natural mutation are basically similar (Arber, 1994, 2000, 2002, 2003, 2004). In two recent papers, Werner Arber (Arber, 2010, 2011) re-emphasized those similarities on a broader organismal and evolutionary basis: The abstract:

*"By comparing strategies of genetic alterations introduced in genetic engineering with spontaneously occurring genetic variation, we have come to conclude that both processes depend on several distinct and specific molecular mechanisms. **These mechanisms can be attributed, with regard to their evolutionary impact, to three different strategies of genetic variation. These are local nucleotide sequence changes, intragenomic rearrangement of DNA segments and the acquisition of a foreign DNA segment by horizontal gene transfer. Both the strategies followed in genetic engineering and the amounts of DNA sequences thereby involved are identical to, or at least very comparable with, those involved in natural genetic variation.***

*Therefore, conjectural risks of genetic engineering must be of the same order as those for natural biological evolution and for conventional breeding methods. These risks are known to be quite low. There is no scientific reason to assume special long-term risks for GM crops.*

*For future agricultural developments, a road map is designed that can be expected to lead, by a combination of genetic engineering and conventional plant breeding, to crops that can insure food security and eliminate malnutrition and hunger for the entire human population on our planet. Public-private partnerships should be formed with the mission to reach the set goals in the coming decades. " from (Arber, 2010).*

The same claim is made with a more organismic view by Hackett, an overview on the regulatory problems of transgenic salmon:

Based on a rich literature, the most important publications come from Werner Arber, Nobel Prize 1978 (his papers cited above) and Henry I. Miller (the first regulator scientist in the USDA): (Miller, 1981, 1996, 2001a, b; Miller, 2002; Miller, 2003; Miller & Conko, 2004), the author has pre-published on the internet webpage ASK-FORCE a summary of what he calls the 'Genomic Misconception' with lots of details: (Ammann, 20110909).



The same claim of high similarity on the molecular process level between natural mutation and transgenesis is made in the comparison of selection and transgenesis in fish breeding by (Hackett, 2002). According to Hackett, the bottom line is that mutation and addition/loss of new genes is not uncommon in animals; it occurs naturally during evolution and various combinations of alleles are selected in different environments, leading to sub-speciation and genetic diversity. Transgenics represent an almost negligible addition to this natural variation; however they just are carefully screened, selected, and cared for. Hackett questions the differences between transgenesis and normal genotypic variations in natural populations. Fish breeders have learned to integrate transgenesis into genomic changes through domestication (Devlin et al., 2001) and (Devlin et al., 2009).

The rate of natural genetic mutation and the resulting increases in certain gene expression in human genetics, where mutations of nearly every sort have been catalogued (Crow, 1997) cannot be underestimated. In particular, gene duplication events occur at rates of up to one per 10,000 individuals. Moreover, the levels of gene expression can vary more than 30-fold as a result of single base mutations in regulator regions (Myers et al., 1986).

It is therefore no surprise that a natural transgene species has been discovered in a widespread grass genus (Ghatnekar et al., 2006). An extensive overview on “natural transgenic organisms” is given in the excellent blog of David Tribe GMO pundit on natural transgenics:

<http://gmopundit2.blogspot.com/2005/12/collected-links-to-scientific.html>

A new possibility to see *RNA steering protein synthesis* has recently been found by (Garrett & Rosenthal, 2012) This is clearly another epigenetic process, another possibility that the genome can react to environmental pressure:

*“Here we present evidence that RNA editing can respond to an external pressure: temperature. While still maintaining the basic K<sup>+</sup> channel plan, octopus can make fast closing versions, and the extent of their expression can be graded. A basic question that remains is whether octopuses use editing for rapid acclimation or longterm adaptation. For each possibility, the biochemical mechanisms that impart temperature sensitivity to the editing process would be different.” (Garrett & Rosenthal, 2012)*

An excellent recent summary of the regulatory situation related to the process of transgenesis is given by Weber et al.: (Weber et al., 2012). Although focusing on the case of stacked transgenes, the conclusions also relate to traits with single transgenes:

*“Because the molecular mechanisms leading to genomic changes are found in both non-GE and GE plants, and because there is no evidence or biological explanation to suggest that crops with different genome structures (e.g. type or amount of repetitive DNA) differ in genome stability, there is no reason to expect that the genome of a GE stack is less stable than that of a non-GE plant or of a GE plant containing a single event. Accordingly, the frequency of potential protein changes and the evolution of novel protein functions should not differ between a GE crop, whether a single event or stacked, and its non-GE version. Importantly, it should be noted that any rare recombination occurring between common regulatory (e.g. promoter) sequences in two transgenes will not yield a hybrid protein, since the common sequences are not part of the coding region (Fig. 2). Therefore, other than changes due to the transgene products, the risks of introducing new food hazards are no different from the risks associated with traditional breeding (Conner & Jacobs, 1999).”*

Figure 2 from (Weber et al., 2012)

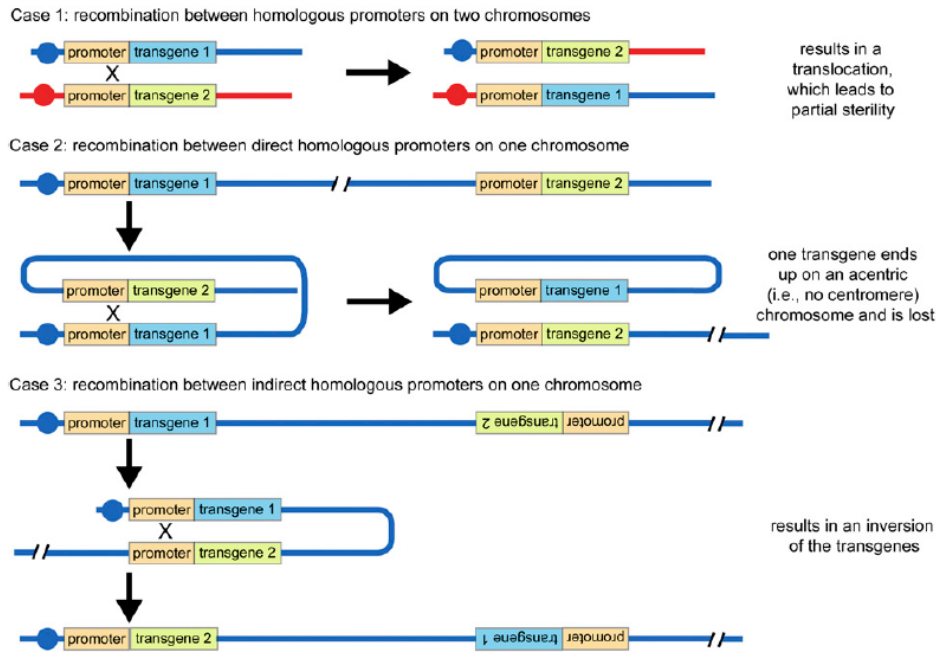


Fig. 21 Recombination between homologous DNA sequences has been proposed as a cause of both translocations and inversions. Three cases (recombination between homologous promoters on different chromosomes, between homologous promoters in direct orientation on one chromosome, and between homologous promoters in indirect orientation on one chromosome) are shown, and their results are indicated. Figure two from (Weber et al., 2012).

### 5.3. Conventional breeding with more genomic disturbances than transgenic crops

Recent publications demonstrate, that transgenesis e.g. has less impact on the transcriptome of the wheat grain than traditional breeding (Batista et al., 2008; Baudo et al., 2006; Ricroch et al., 2011; Shewry et al., 2007), (more details with figures in (Ammann, 20110909) and (Ammann, 2008, 2009b)).

One should also take into account, that many of the conventional breeding methods such as colchicination (Awolaye et al., 1994; Barnabás et al., 1999) and radiation mutation breeding (Reynolds et al., 2000) can be obviously more damaging to the genome, and it is in addition not possible to clearly define what impact the un-targeted process could have caused. Or, on the other hand, as (Molnar et al., 2009) have demonstrated that irradiation-induced wheat - *Aegilops biuncialis* intergenomic translocations will facilitate the successful introgression of drought tolerance and other alien traits into bread wheat. In their review (Schouten & Jacobsen, 2007b) criticized the biased statements of (Latham et al., 2006; Wilson et al., 2006) who focus in an unjustified manner on transgenesis alone when describing unwelcome mutations. It has to be acknowledged after all that repair mechanisms on the DNA level are powerful (Baarends et al., 2001; Dong et al., 2002; Morikawa & Shirakawa, 2001). It is thus not logical that opposition within organic farming towards genetic engineering is now expanding also to some of those conventional breeding methods, some go even so far as to reject marker assisted breeding – symptomatic for the organic agriculture scene, this trend is based on the myth of “intrinsic integrity of the genome” (Lammerts van Bueren et al., 2002; Lammerts van Bueren et al., 2003), for which term it is not possible to find a proper scientific definition, which inevitably should be based on comparisons (Ammann, 2008). The addition of

rejected breeding methods would ultimately lead to an absurd situation, where most of the modern time traits would have to be rejected and breeding would be forced to virtually start from scratch.

Basically, many of the first generation GM crops should be today subject to a professional debate on *deregulation*, and there is good and sturdy reason to state that many of these GM crops should not have been treated in such a special way in the first place, they can be compared in their risk potential to many crops created with traditional methods.

*This should not be misunderstood as a plea for general deregulation of GM crops, rather for a strictly science based risk based regulation and clearly for a shift from process based regulation towards product based regulation.*

### **5.3.1. The case of miRNA of plants found in human blood**

A sidenote on the recent discovery of miRNAs of rice genome origin in the blood of Asian population: A paper of Zhang is seen as a breakthrough in our knowledge on interkingdom relations between plant and animal genomics: (Zhang et al., 2011). First data, obtained with modern genomic analysis, demonstrate the surprising finding that exogenous plant miRNAs are present in the sera and tissues of various animals and that these exogenous plant miRNAs are primarily acquired orally, through food intake. MIR168a is abundant in rice and is one of the most highly enriched exogenous plant miRNAs in the sera of Chinese subjects. In addition, these findings demonstrate that exogenous plant miRNAs in food can regulate the expression of specific target genes in mammals. (On general terms, microRNA is a long time and widespread research topic, Google Scholar reveals over 10'000 entries on this subject, Web of Knowledge over 22'000 publications).

The finding of Zhang et al. could lead to erroneous conclusions that horizontal gene transfer is possible also for the antibiotic resistance genes and even for genes expressing Bt toxins into mammals and humans, and one can see already that opponents to genetic engineering take advantage of the news by clear mis-interpretation of the results: They use it as an argument for the unforeseen risks of the technology, see the comments of anonymous scientists in GMwatch (GMwatch, 20110921):

*"The study is yet another nail in the coffin of the already discredited 'safety assessment' process for GM foods in the EU and elsewhere. These assessments do not consider the effects described." (GMwatch, 20110921)*

This rather naive statement is typical for the thinking of GM crop opponents. Numerous blogs and websites followed this opinion without any scientific merits such as the piece published by Ari LeVaux in The Atlantic (LeVaux Ari, 20120109). This article triggered an extensive debate published in The Atlantic, and there are two published rebuttals which sets the record straight: (Petit Charlie, 20120110) and (Ropeik David, 20120111). Another excellent rebuttal has been put on the Biology Files: (Willingham Emily, 20120109). Excerpt:

*"First, the headline: **The Very Real Danger of Genetically Modified Foods**. I read the Cell Research paper. I can't find mention of GMOs in it. I don't find mention in the paper the the rice miRNA in question derives from a genetically modified rice strain. So, I don't see that this headline appropriately represents the science here. Then there's the dek: "New research shows that when we eat we're consuming more than just vitamins and proteins. Our bodies are absorbing information, or DNA." That's not what this research shows. It shows that the body takes up a specific rice miRNA when people consume it. Not DNA or "information." The lede leaves out a crucial modifier: the word "rice": "Chinese researchers have found small pieces of ribonucleic acid (RNA) in the blood and organs of humans who eat rice." Actually, miRNAs are present in the blood and organs of...all humans, whether they eat rice or not. I think the writer here means "small pieces of rice ribonucleic acid." There is then a series of claims about what the research implies, including, mysteriously, that it will help us learn how some "herbal medicines function." The original paper makes no mention of herbal medicines, although some research indicates that "natural agents" can alter **expression of human miRNA**. Also among the potential implications described in the piece is, "And it reveals a pathway by which genetically modified (GM) foods might influence human health." That's an enormous*

leap to make from "one rice miRNA in blood and tissues influences activity of one human protein." A number of steps would be required for a GM food to exert a similar effect, none of which have been investigated yet. These steps include identifying that the modified sequence in the target food either also encodes a miRNA sequence or interacts with its expression or, later in the gene-to-protein process, somehow evades normal miRNA regulation thanks to this change. Then suddenly, there's Monsanto and a strange effort to explain the central dogma of molecular biology (**DNA-->RNA-->protein**) using a pizza/pizza restaurant analogy that involves the "DNA" knowing what kind of pizza "it wants," although in truth, the cell is the entity in charge of which parts of the DNA it uses. The central dogma, a linear representation of how a cell copies DNA into RNA and then uses the RNA copy instructions to build proteins, is too simple for what we know today about how cells regulate protein expression. But the core dogma remains intact, including that DNA serves as the template for making RNA." AND

"The article makes a number of other scientific errors, including in a bold pull quote claiming, "The Chinese RNA study threatens to blast a major hole in Monsanto's claim. It means that DNA can code for microRNA (*italics mine*), which can, in fact, be hazardous." No. That's not what the Chinese study "means." It's not news that DNA encodes RNA of all kinds. It encodes the messenger form that carries the copy of the code. It encodes the ribosomal form that is a component of ribosomes, the cell factory workers that take the code copy and use it as an instruction book for building proteins. It encodes the RNAs that bring those factory workers the molecular blocks the cell uses for building proteins. And it encodes miRNAs. This latest paper does not carry the meaning that DNA encodes miRNAs--that's a longstanding part of the Central Dogma, ironically, and not news. Nor does it threaten in any discernible way to "blast a hole" in much of anything. As I noted, the study opens a door." (Willingham Emily, 20120109)

The most thorough analysis of the Zhang paper comes from Monsanto (active already for some years in research on miRNA): (Sachs Eric, 20120110), excerpt:

"It is important to remember that humans regularly consume plants that contain small RNAs. Recent research by Ivashuta et al. (2009, *Food and Chemical Toxicology* 47:353–360) (Ivashuta et al., 2009) demonstrated that many existing plant RNA's share sequences with human genes. Further, humans regularly consume animal derived foods with mammalian miRNAs with 100% identity to human genes. Despite the routine ingestion of plant and animal small RNAs, no impacts on human gene regulation or health have been reported. Treatment of disease via oral ingestion of RNA-based medications has not been accomplished despite more than a decade of effort by the pharmaceutical industry. Systemic suppression of specific target genes in humans has not been possible with oral administration of small RNAs, even when using RNA constructs specifically designed to achieve gene suppression and when employing modified RNAs to enhance stability. This is an important area of research, but given what is known about the ubiquitous nature of RNA in all whole foods and about the unsuccessful efforts to develop oral RNA pharmaceutical products, much more information is needed before it can be concluded that dietary miRNAs regularly have any meaningful impact on mammalian or human gene regulation. Importantly, the author's state: "It is unlikely that such high concentrations of mature plant miRNAs can be achieved in serum, plasma, and organs of humans or animals via food intake." Based on the available information, the results with the abundant MIR168a are not sufficient to support a broad conclusion that plant miRNAs present in food are part of a common and general mechanism for "cross-kingdom" regulation animal genes."

Selected additional comments:

- Of the many thousands of plant miRNAs, only a small number are found in human or animal blood.
- The absence of most plant miRNAs in serum indicates:
  - Absorption may be selective;
  - Only some miRNAs in foods have properties which allow them to survive in foods, the GI tract, and serum;
  - Only relatively abundant miRNAs are present at high enough levels to be detected;
  - Or some combination of these factors.
- The findings with MIR168a may represent a rare or unique case, resulting from the uncharacteristically high abundance of MIR168a in rice and disproportionate absorption and/or preservation of MIR168a in combination with the high homology (gene sequence match) to LDLRAP1.
- The loss of MIR168a effects occurred with less than a 10-fold reduction in diet concentration, indicating that this phenomenon is highly dose-dependent. The ability to observe this phenomenon may be related to the high-dosing regimens employed

Additional statements related to mRNA come from official institutions from Great Britain:

The Advisory Committee on Novel Foods and Processes from the United Kingdom (ACNFP Minutes, 20111215):

#### 8. Micro RNAs ACNFP/104/5

The Committee was asked to consider a recently published article that reported the discovery of stable plant microRNAs in mammalian (including human) serum and plasma. This suggested that these miRNAs are capable of surviving passage through the mammalian gut and being absorbed through the gut wall into the bloodstream. The most abundant of these miRNAs, which is present at high levels in rice, was also shown to influence mammalian gene expression.

The Committee found this paper extremely interesting in terms of the interaction between the food constituents of plants and their influence on the human body, while emphasizing that this was an entirely natural phenomenon and that people have always consumed these RNA molecules as part of their diet. Members agreed that a number of the findings were unexpected and these findings needed to be confirmed by other research groups.

**In terms of the risk assessment of GM foods, miRNAs produced by GM plants would be no different from those produced ordinarily by non-GM plants, but researchers need to be aware of the results of this work and follow up studies need to be monitored to assess their implications.** There are currently no applications for authorization of GMOs expressing miRNAs, but current GM risk assessment guidelines should be adequate to cover any future application of this technology in the production of GM plants.

The Committee was informed that the paper was due to be discussed at a meeting of the Advisory Committee on Releases to the Environment in early December.

**ACTION:** the Secretariat to keep the Committee informed of any developments. (ACNFP Minutes, 20111215)

The Advisory Committee on Releases to the Environment from Great Britain also comes to non-alarming conclusions (ACRE Minutes, 2011):

#### 10.3 Exogenous plant MIR168a specifically targets mammalian LDLRAP1: evidence of cross-kingdom regulation by microRNA ACRE/11/INF15

This paper, published in *Cell Research*, had been identified by ACRE members as presenting interesting but as yet, uncorroborated results and conclusions. The committee noted that its relevance would be primarily for diet and health. The paper reports the first evidence that small regulatory RNAs, called microRNAs, produced by plants can regulate gene expression in mammals. The researchers detected plant-derived microRNAs produced in the blood and tissues of humans and other plant-eating mammals. One particular microRNA, MIR168a, which is present naturally in high concentrations in rice and cruciferous vegetables was found to inhibit a protein that helps to remove low-density lipoprotein ('bad cholesterol'). The researchers acknowledge in their paper that these findings are surprising.

ACRE considered that animal and plant material containing these molecules has been part of the human diet for hundreds of thousands of years and that humans have therefore evolved in the presence of such molecules. The committee noted that the current regulatory pipeline does not include any GMOs that have been modified to produce microRNAs. There are GM plants that have been developed using antisense technology. This generates small silencing RNAs. ACRE considered that current risk assessment procedures were appropriate for addressing possible risks to the environment on a case by case basis.

A member of the secretariat for the Advisory Committee on Novel Foods (ACNFP) attended the meeting and informed ACRE of the discussion that had taken place during the ACNFP meeting on November 24th. Both committees agreed that further work would be needed to validate the findings and that they would track the issue with interest

**Action:** ACRE to keep apprised of research in this area and to coordinate with the ACNFP as necessary. (ACRE Minutes, 2011)

Comments related to possible regulatory follow-ups:

1. Opponent writers mix up in a unscientific way various categories of transgenes and thus arrive to produce unjustified scare stories.
2. Scientific progress inevitably calls for adaptation of risk assessment methodology compared to the present day regulatory rules as they stand, as long as we are hypnotized on process oriented biosafety assessment
3. When we would finally agree to product oriented risk assessment by accepting the 'Genomic Misconception' to be rejected and by following a process-agnostic and 'de minimis' strategy of assessing risks (Durham Tim et al., 2011)

It should be a matter of simple scientific consensus that biosafety assessment has to adapt in methodology with the progress of genetic engineering: on one side, Zink Finger and TALEs methods (details see 1.2.4 and 1.2.5.) with all their precision and elegance are prone for simplified risk

assessments after detailed studies.

Also the technologies using small RNA molecules will undoubtedly encourage risk assessment researchers to adapt to appropriate methods of analysis, as already proposed by (Auer & Frederick, 2009):

*“In the future, the predictive ERA process will need to be flexible and adaptable for analysis of the next generation of crops engineered using RNAi and HD-RNAi. As a first step, regulatory agencies and risk analysts need to become familiar with the science of RNAi and its application to plant biotechnology. A concerted effort is needed to develop a pool of expertise to ask the right questions about potential hazards and exposures, to ensure that relevant data are collected and to characterize uncertainty in risk assessments.*

*Regulators will have to evaluate the design and implementation of research protocols for laboratory experiments and confined experimental field trials. Scientific questions will need to be answered about off-target effects, non-target effects and the impact of genetic mutations and polymorphisms. Understanding the stability, persistence and half-life of small RNAs in various aquatic and terrestrial ecosystems will be essential for the characterization of exposure pathways. New diagnostic tools will probably be required for the identification and quantification of small RNAs for a range of purposes, including crop identity preservation, monitoring and segregation. Ideally, these tools should have a low detection limit and a high degree of specificity for each RNAi crop, while being relatively inexpensive, functional under field conditions and operable by individuals with diverse backgrounds and training. With all this in mind, it should be possible for stakeholders, regulators and citizens to develop policies and ERA frameworks for RNAi and HD-RNAi crops.” (Auer & Frederick, 2009)*

It is correct that small RNA molecules are a common phenomenon (Heisel et al., 2008; Ivashuta et al., 2011; Ivashuta et al., 2009) *considered* and used for GM plant improvements, as suggested by (Auer & Frederick, 2009). And it is also correct that the risk assessment of GM crops up to now does not specifically include the effects described by Zhang et al.. i.e. that small miRNAs are obviously passing mammal stomach environments and can be integrated in the organism and even be active genetically. This seems to be routine in the evolution of life (and undoubtedly calls for verification and further studies). And the question arises whether we should *automatically* include in the risk assessment small miRNAs, the answer should be **no**: rather it should be another reason to switch European and UN-Risk assessment to product oriented mood (or, as Durham et al. (Durham Tim et al., 2011) call it: “process-agnostic” view - following the conclusions drawn in section 7, based on Section 2.4. here about the ‘Genomic Misconception’.

#### 5.4. Dissent over differences between GM- and non-GM crops causes transatlantic regulatory divide

This actually includes a critical questioning about some basic rules of the United Nations Convention on Biological Diversity (CBD): transgenic crops of the first generation should not have been *generally* subjected to regulation purely based on the *process* of transgenesis alone; rather it would have been wiser to have a close look at the *products* in each case, as John Maddox already proposed in 1992 in an editorial in Nature (Anonymous, 1992). This is also the view of Canadian regulators (Andree, 2002; Berwald et al., 2006; Macdonald & Yarrow, 2002), where the *novelty* of the crop is the primary trigger for regulation. This transatlantic contrast has been commented by many (Bennett et al., 1986; Kalaitzandonakes et al., 2005; Ramjoue, 2007a, b; Snyder et al., 2008; Thro, 2004), and although for many years a solution and mediation seemed to be too difficult, contrasts can be overcome:

In a letter to the executives of the Convention on Biological Diversity (CBD), the Public Research and Regulation Initiative (PRRI)

[http://www.pubresreg.org/index.php?option=com\\_docman&task=doc\\_download&gid=490](http://www.pubresreg.org/index.php?option=com_docman&task=doc_download&gid=490) is asking for a scientific discussion in order to exempt a list of GM crops from the expensive regulatory process for approval, here only the final statement:

*“Bearing in mind that the **method of transformation itself is neutral**, i.e. that there are no risks related to process of*

*transformation, PRRI believes that there are several types of LMOs and traits for which - on the basis of the characteristics of the host plant, the functioning of the inserted genes and experience with the resulting GMO - it can be concluded that they are as safe as its conventional counterpart with respect to potential effects on the environment, taking also into account human health. “*

Unfortunately, there was no substantial reaction from the leading Cartagena organizers.

To be quite explicit once more, this does not mean to exempt transgenesis from biosafety assessment as a whole, but it should say that “several types of LMOs and traits, where the inserted genes demonstrate in large scale commercialization (of course after risk assessment done in due course) can be deemed as safe as conventional counterparts according to several years of beneficial agricultural practice, should be exempt under article 7.4 of the Cartagena Protocol for further expensive and time consuming risk assessment and regulatory procedures. This motion has now officially been repeated by PRRI (Public Research and Regulation Initiative at the occasion of the COP10-MOP5 negotiations in Nagoya, Japan, see the interventions on the website [www.pubresreg.org](http://www.pubresreg.org) with recent additions.

In a recent paper, an indiscriminate continuation of food biosafety research is questioned on the basis of all the above arguments by Herman et al. (Herman et al., 2009) with good reason:

*“Compositional studies comparing transgenic crops with non-transgenic crops are almost universally required by governmental regulatory bodies to support the safety assessment of new transgenic crops. Here we discuss the assumptions that led to this requirement and lay out **the theoretical and empirical evidence suggesting that such studies are no more necessary for evaluating the safety of transgenic crops than they are for traditionally bred crops.***

## 5.5. Perspectives for solutions, an attempt for a synthesis of divergent views in previous sections 5

### 5.5.1. Perspectives within the Cartagena Protocol are very difficult to achieve

- a) Failed proposals on the re-establishment of the roster of experts for the CBD  
 These new perspectives create hope, that solutions can be found: Even within the difficult and for GMOs totally negative legal environment of the Cartagena Protocol there are some slim possibilities, although the author has attended most of the COP-MOP conferences in the past years, helping PRRI (Public Research and Regulation Initiative, [www.pubresreg.org](http://www.pubresreg.org)) to make substantial moves – mostly in vain. As an example the fruitless attempts (since 2006!) should be mentioned to re-establish the scientific committee which exists on the paper, but which has no power and is blatantly inactive, see the letter of PRRI written to the committee, not having any substantial followup: (PRRI, 2006-2010).
- b) Failed attempt to submit proposals for exemption based on the paragraph 7.4 of the Cartagena Protocol  
 In a first phase some of the widespread transgenic crops like transgenic maize with the Cry1Ab endotoxin could be exempt from regulation. This is indeed possible according to art. 7.4 in the Cartagena Protocol. In COP-MOP5 2010 in Japan (Fifth meeting of the Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 5), 11-15. 10. 2010 Nagoya, Japan <http://bch.cbd.int/protocol/meetings/>) it should be possible, to amend the protocol with the introduction of a dynamics which allows to start the regulatory process with an initial phase focusing on the process of transgenesis, first following procedures proposed for non-target insects by (Raybould, 2010; Romeis et al.,



2008).

Indeed, in COP10-MOP5 in Nagoya October 2010, PRRI [www.pubresreg.org](http://www.pubresreg.org) has made a request for the exemption of widely adopted GM crops such as certain Bt maize traits of the endotoxin type of Cry1Ab, see the original text as read at the plenary meeting in Nagoya: PRRI Statement on exemptions MOP5: (PRRI, 20101012):

*“Third, there is an underlying misperception that there are demonstrated cases of adverse effects. This is incorrect. Over the last 15 years GM crops have been planted over a billion hectares by tens of millions of farmers in the developing and developed world. These crops have been grown in numerous different environments, and they have been consumed in billions of meals. The substantial scientific evidence accumulated shows that there are **no** verifiable reports of any adverse effect to environment or human health.*

*The Strategic plan includes an indicator “Number of reports to the BCH on the identification of LMOs or specific traits that may have adverse effects”. Such an indicator makes little sense, because it is never possible to rule out that any organisms, LMO or non LMO, may have adverse effects. What is crucial is the question whether they are likely or unlikely to have adverse effects, and PRRI proposes that the strategic plan includes these two questions. PRRI is ready to submit examples of categories of LMOs of which the risk assessments and accumulated evidence indicate that they are unlikely to have more adverse effects on biodiversity or human health than their non modified counterparts, and that consequently those LMOs can be exempted from the AIA procedure on basis of article 7.4 of the Protocol.”*

Unfortunately, there were no substantial reactions coming from the responsible of the Cartagena Protocol, except some quickly written “approving” formal letters without any substance.

- c) PRRI undertook also over the years numerous substantial initiatives in all the plenary MOP sessions with the goal to support public research by questioning the exaggerated regulatory costs, which automatically exclude public research followed by applications, just one example of an official letter submitted to the CBD authorities: (PRRI, 20101011). The reasons for an almost total failure are obvious:

The vision of PRRI is that in future it should also be possible to shift the focus on the product, making it possible to abbreviate the regulatory process wherever possible and feasible – but this would mean substantial and deepgoing debates on the regulatory structures of the Cartagena Protocol. The ultimate goal of new regulatory concepts should be to minimize obstacles for new and urgent necessities in crop development, such as Swaminathan and Raven are proposing (Kesavan & Swaminathan, 2008; Raven et al., 2006).

The author remains pessimistic, since the whole cumbersome process of legal changes in the Cartagena Protocol is also systematically hindered by a strong anti-GMO lobby, having made its way through the institutions to higher and powerful positions within the Cartagena administration quite successfully, starting from MOP1 all the way up through MOP5, thus influencing negatively all change of regulatory appeasement and lowering regulatory costs. Unfortunately, the recent overview of the European legislation on GM crops does not generate much optimism either: (Plan & van den Eede, 2010).

- d) A further negative trend is triggered by a growing community of risk assessment researchers, who have a vested interest to keep the pot cooking, examples can be downloaded at the website of GENOK [www.genok.com](http://www.genok.com) and also from the website of the Third World Network <http://www.twinside.org.sg/> with its intricate mixture of activist statements and questionable and peer reviewed scientific contributions. Other similar examples supporting this view can be downloaded over the Freiburger Oekoinstitut <http://www.oeko.de/> and on the website of ENSSER, European Network of Scientists for Social and Environmental Responsibility <http://www.ensser.org/>
- One could easily cite dozens of exaggerated statements on potential risks of GM crops,

typically enough they notoriously come from scientists with a vested interest in getting more biosafety research funds and also from scientists from other fields of research in social and philosophical sciences.

Here just one example from the Federal Ethics Committee on Non-Human Biotechnology (ECNH), which presented at a press conference from December 2011 a report on safety requirements for GM crops (EKAH, 20111212) clearly overstepping the competence of the Ethics committee by making statements on environmental and food safety, issues which are taken care of by the sister committee, the Federal Committee for Biosafety (SECB). Three examples from this committee: all (based on insufficient knowledge in natural sciences):

*Based on epistemological thoughts the committee (composed of philosophers and social scientists) comes to conclusions which run against an overwhelming scientific body of knowledge, that GM crops can never be safe. This of course triggered press comments stating that GM crops are unsafe.*

*The committee claims that epigenetic and and pleiotropic effects may occur in GM crops, obviously ignorant of the fact that all plants can show such effects, whether transgenic or not.*

*On the question of the author related to the 'Genomic Misconception' at the press conference where the cited report has been presented, nobody of the committee was informed about this new regulatory development.*

A critique has been issued on the blog of Internutrition by Jan Lucht (Lucht Jan, 2011).

### 5.5.2. A conceptual framework is proposed by IFPRI/ISNAR in 2002

The International Service for National Agricultural Research (McLean et al., 2002), a careful evaluation of process-based versus product-based triggers in regulatory action can also lead to a merger of both seemingly so contrasting concepts into a legalized decision making process on which trigger should be chosen in a case by case strategy:

*"Process-based triggers are the rule in almost all countries that have developed national biosafety regulatory systems; there are exceptions, however, where the novelty of the trait determines the extent of regulatory oversight and not the process by which the trait was introduced. While such a product-based approach to defining the object of regulation is truest to the scientific principle that biotechnology is not inherently more risky than other technologies that have a long and accepted history of application in agriculture and food production, it is less prescriptive than process-based regulatory systems."*

Many of the debates on those two concepts suffer from a lack of clear-cut definitions, it will be important to have a close look at the *Canadian regulatory system* and the definition of PNTs (Plants with Novel Traits). In Canada, the trigger for risk-assessment is the *novelty* of the plant rather than the *methods* used to produce it. The difficulties start there, where a clear definition of PNTs is needed to come to a decision: It means that plants produced using recombinant DNA techniques, chemical mutagenesis, cell fusion, cis-genics or any other in-vitro technique leading to a novel trait, need to undergo risk assessment in the Canadian system. No wonder the Canadian definition of novel traits is rather wordy, but remains broad minded:

*"A plant variety/genotype possessing characteristics that demonstrate neither familiarity nor substantial equivalence to those present in a distinct, stable population of a cultivated seed in Canada and that have been intentionally selected, created or introduced into a population of that species through a specific genetic change."*

Conclusions:

*There can be no doubt that product-based regulatory approaches are truest to the scientific principle that biotechnology is not inherently more risky than other*

*technologies that have a long and accepted history of application in agriculture and food production.*

The scientific assessment is summarized by Health Canada as follows:

**Scientific Assessment**

Scientific evaluators, with individual expertise in molecular biology, toxicology, chemistry, nutritional sciences and microbiology, assess the following:

[http://www.hc-sc.gc.ca/sr-sr/pubs/biotech/reg\\_gen\\_mod-eng.php](http://www.hc-sc.gc.ca/sr-sr/pubs/biotech/reg_gen_mod-eng.php)

*development of the modified organism, including the molecular biological data that characterizes the genetic change; composition of and nutritional information about the GM food compared to a non-modified counterpart food; the potential for production of new toxins in the food; the potential for causing allergic reactions; microbiological and chemical safety of the food; the potential for any unintended or secondary effects; key nutrients and toxicants; and, major constituents (for example, fats, proteins, carbohydrates) and minor constituents (for example, minerals and vitamins).*

The product oriented regulation is also less prescriptive than process-based systems, see for more details McLean et al. (McLean et al., 2002).

### 5.5.3. New Regulatory View: De minimis Framework for New Crops

In a recent AgBioForum electronic paper, Tim Durham, John Doucet and Lori Unruh Snyder (Durham Tim et al., 2011) propose a new way of regulation of GM crops (which the author wants to see extended to all kinds of new crops traits): Basically, they agree to see risk embodied in the end product and not in the methodology per se, just as many other people proposed before, see section 2.4. The proposal here, amended by the author, takes up the idea to correct the ‘Genomic Misconception’ and wants to overcome the difficulty of handling the precautionary principle (which strictly legally seen is the ‘Precautionary Approach’ (Sunstein & Zeckhauser, 2011). It is often taken as a mantra by fundamentalist opponents to freeze development of modern breeding. There is a possibility to reframe the Precautionary Approach (PA) towards emphasizing more the “burden of proof” (van den Belt & Gremmen, 2002). Critique on the PA has been based on a survey among a broad spectrum of scientists from various epistemic cultures by (Boeschen, 2009; Boeschen et al., 2006). It is time to follow up the regulatory debates with a better systems approach:

The concept of epistemic cultures and their strategies of evidence-making should be investigated more explicitly with respect to other risk policy fields. The analysis of hybrid regimes of knowledge should be deepened by looking at the complex interactions between institutional, discursive and practical rules affecting risk assessment. In a discursive structure this should be undertaken as a medium term project, see section

We need a pragmatic preliminary examination of new breeds in order to follow a ‘*de minimis framework*’, so that we do not have to widen in an unnecessary way regulation to all new breeds independent of the method of genomic alteration.

The author agrees with most content of (Durham Tim et al., 2011) and here we need just to emphasize the new idea on the *de minimis framework*, not without amending it immediately below:

*"In this manuscript we synthesize a number of the aforementioned policy reforms with our own.*

*Firstly, regulators should adopt a **method-agnostic approach**, and focus on relevant ecological and biochemical characters of the end product.*

*Moreover, **any risks associated with GM should be assessed relative to their antecedent peers**. This demands a performance-based framework to replace the prescriptive, one-size-fits all approach.*

*Moreover, the precautionary principle, as invoked in the current regulatory scheme, is scientifically indefensible. It should be **replaced with a flexible de minimis approach**, which avoids the allocation of resources to address negligible risks for nominal or nonexistent gains in safety.*

*In addition, we believe that **current regulations place an acute overemphasis on hypothetical (and often unmeasurable) risks**, while downplaying the advantages. In effect, this accentuates the what-if scenarios of the risk assessment calculus at the expense of demonstrable benefits.*

*It is critical that the latter receives appropriate weight in the decisionmaking continuum. Indeed, (Conner et al., 2003a; Conner et al., 2003b) suggested a regulatory reform that would juxtapose the costs of inaction with the costs of action. We believe that such an inclusion, though difficult to encapsulate in the risk evaluation equation, is a critical consideration."*

It is appropriate to copy here the two illustrative figures given in (Durham Tim et al., 2011) and then give comments about amendments of the proposal (actually a rapprochement to the Canadian regulatory system).

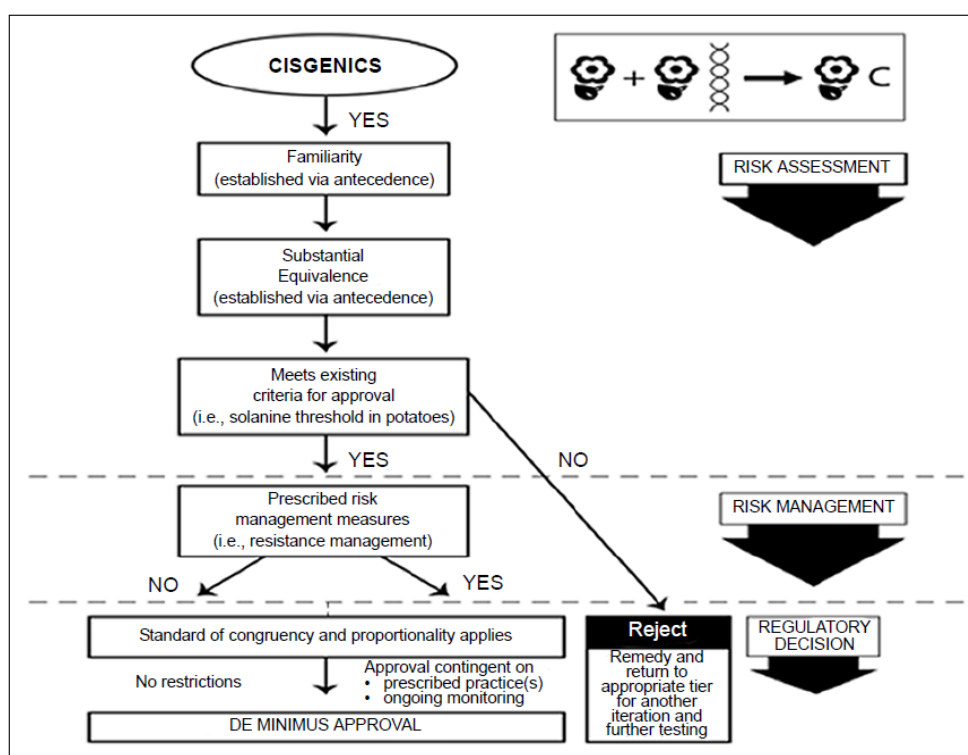


Fig. 22 Proposed framework for the regulation of cisgenic articles. Cisgenics is generally conferred *de minimis* status, given the intrinsic nature of the genetic material and phenotypic reproducibility with conventional breeding. The process is partitioned into three stages: risk assessment, risk management, and regulatory decision.

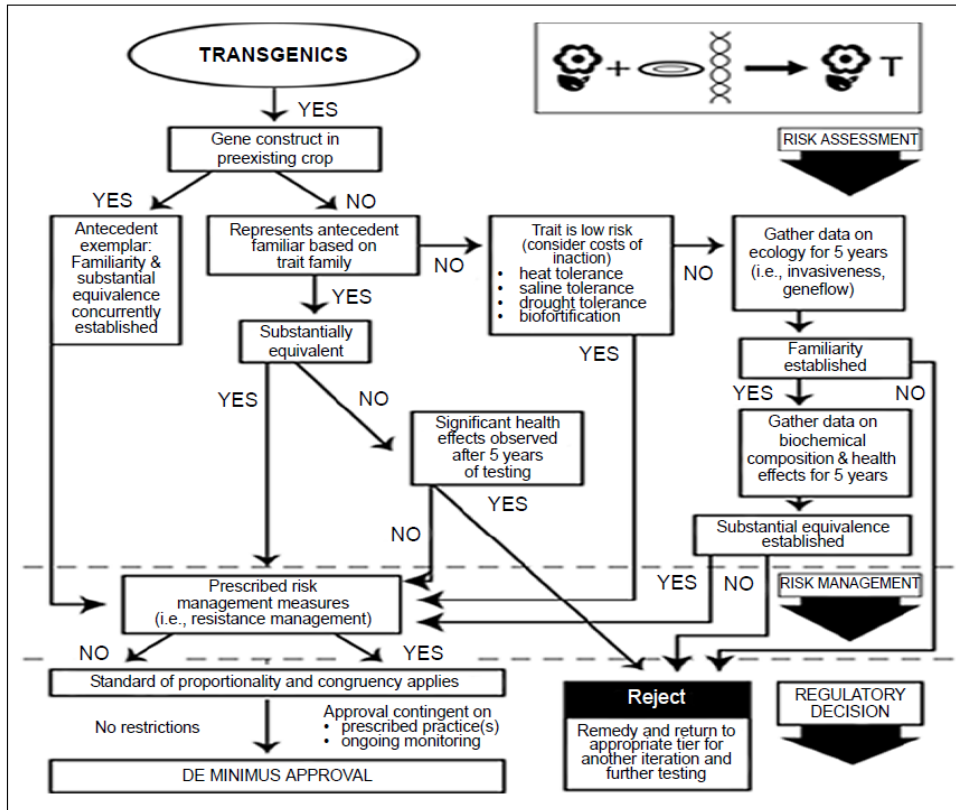


Fig. 23 Proposed framework for the regulation of transgenic articles. Given the extrinsic nature of the introduced gene(s), evaluation is a composite of multiple factors, including: preexisting gene constructs, antecedence, familiarity, substantial equivalence, and the costs of inaction. When necessary, this framework accommodates a nested conventional evaluation with potential advancement to *de minimis* standing.

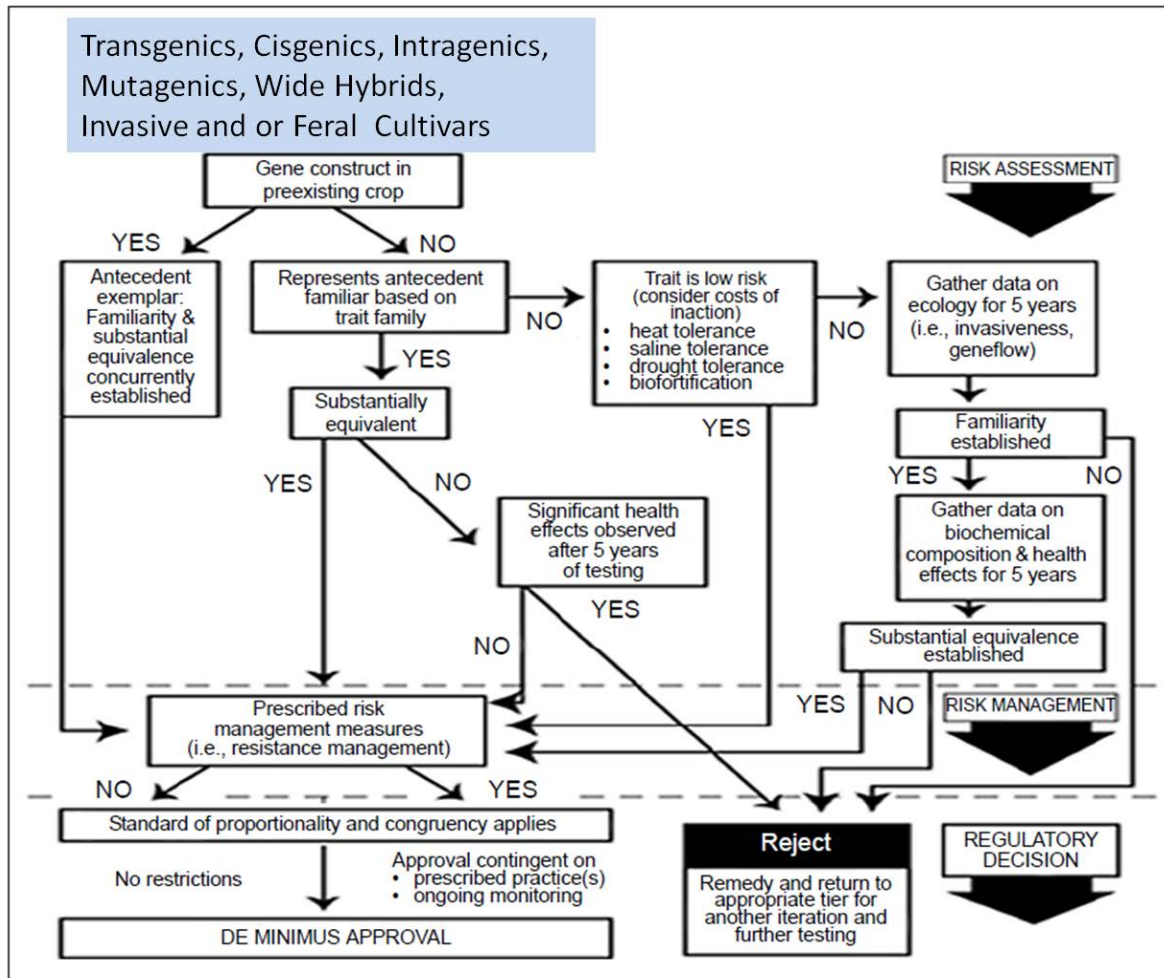


Fig. 24 Same figure as in No. 13 and 14, but with the inclusion besides transgenic plants: Cisgenics, Intragenics, Mutagenics (mutated with gamma radiation or chemicals), wide Hybrids and invasive or feral cultivars. After (Durham Tim et al., 2011), amended by K. Ammann 2011.

According to (Durham Tim et al., 2011) three outcomes are possible under a *de minimis* stream:

- (a) fast-tracked deregulation, Art. 7.4 of the Cartagena Biosafety Protocol allows for exemptions.
- (b) fasttracked deregulation with prescribed risk management measures (such as non-Bt “refuges” to minimize insect resistance); and
- (c) a nested conventional risk assessment with potential advancement to *de minimis* standing, with or without prescribed risk management measures.

What we need in future is a new index of potential risks, built in the same way as the one we have developed in a Dutch-Swiss-Irish effort on geneflow, see (Flannery et al., 2005) (Ammann et al., 2005; Ammann et al., 1996, 2000).



## 6. The costs and lost benefits of overregulation

### 6.1. The issue

The Cartagena Protocol on Biosafety (CPB) has now been adopted by 157 parties

<http://www.cbd.int/biosafety/signinglist.shtml>. It still builds on the principle that GM crop plants might bare risks in contrast to the conventional crops, objective of CPB:

<http://www.cbd.int/biosafety/articles.shtml?a=cpb-01>. 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 insights have proven the contrary, as shown in ASK-FORCE AF-9 (Ammann, 20110909) on the molecular basis of transgenesis. This results in maintaining the concept of an asymmetric risk assessment of innovation of GM crops. The possible exemption of widespread GM crops in Art. 7.4 (Cartagena Protocol on Biosafety, Article 7: <http://www.cbd.int/biosafety/articles.shtml?a=cpb-07>) is not even considered officially up to now. See about the numerous mostly fruitless interventions of PRRI, [www.pubresreg.org](http://www.pubresreg.org) in section 2.5.1.

### 6.2. Overview

Its time to relax regulatory rules, as summarized with good detail by Jaroslav Drobnik (Drobnik, 2008):

*“There is enough experience gained during 10 years of genetically modified (GM) crops application to seriously evaluate the ratio of risk to benefit and reduce the existing regulation in Europe. It does not evaluate benefit and the risk of the alternative situation when GM crops are not used. The precautionary principle is applied only to GM crops application, never to alternative solutions of, e.g., pest control. The Eurobarometer 2005 shows how propaganda inseminates public opinion with shameful nonsense. Voices asking for change of this politics come from the European Parliament, British ACRE, EuropaBio, even from Commission, scientists and other European sources, but also from Africa and other developing countries.” (Drobnik, 2008)*

Drobnik is also co-author of a White Book with Frantisek Sehnal: (Sehnal & Drobnik, 2009)

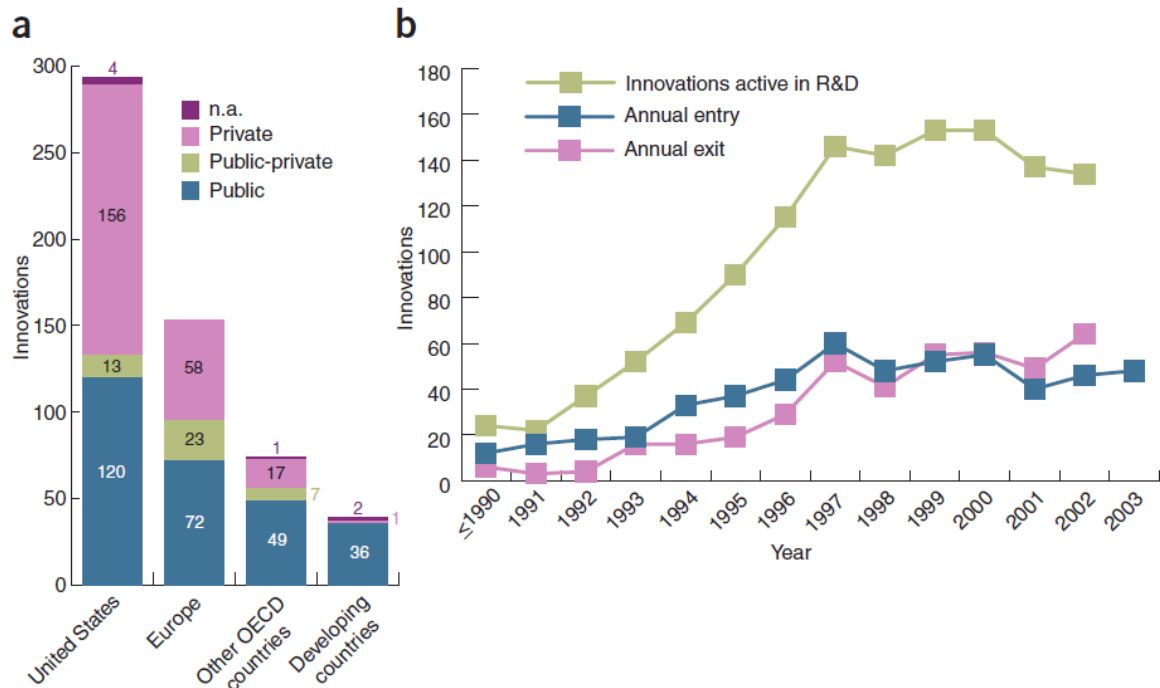
Their conclusions about the European GM crop regulation are crystal clear and very negative

*“EU regulation is largely based on prejudice and political calculus  
GMO regulation similar to that of narcotics, poisons and explosives sends a message to the public that the products of biotechnology pose a comparable level of danger to human and animal health;  
Current GMO regulation restricts the farmers and restrains agricultural productivity, decreases EU competitiveness in the global market, and in the long run endangers the environment.” (Sehnal & Drobnik, 2009)*

### 6.3. Costs and lost benefits worldwide and Europe

An excellent summary graph is given in (Graff et al., 2009b) in fig. 9b: 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.





**Fig. 25 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. Fig.1 from (Graff et al., 2009b).**

“Commentary from Table 1 in (Graff et al., 2009b): “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.” (Graff et al., 2009b)

In a recent publication (Miller & Bradford, 2010) document the same dramatic negative trend for speciality GM crops is demonstrated:

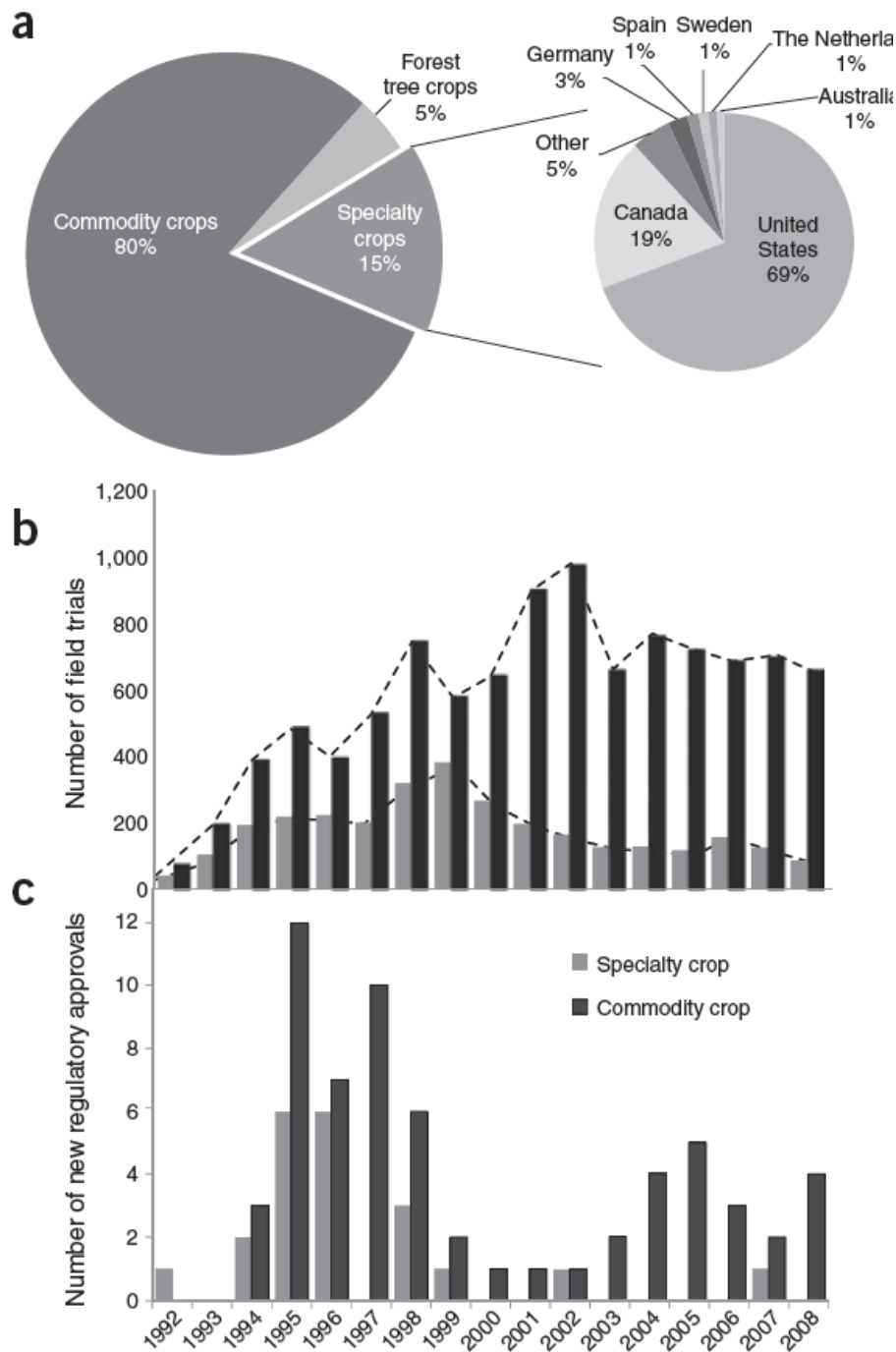


Fig. 26 Field trials and regulatory approvals. (a) Using the UNU-MERIT database, field trials conducted in 24 developed countries between 2003 and 2008 were separated on the basis of commodity, forest tree or specialty crop. From this, the specialty crops were further subdivided based on the country in which the field trial was conducted. (b) The numbers of field trial permits acknowledged or issued in the United States are plotted by year for commodity crops and specialty crops. (c) The 84 unique transgenic events that have been granted regulatory approval by one or more countries are plotted by year of approval. If the year of approval varied among countries, the first year of regulatory approval granted by any agency for a given event was used. From (Miller & Bradford, 2010).

## 6.4. Difficult European decision processes for approving GM crops, a mix of political obstacles and high complexity of EU administrative structures

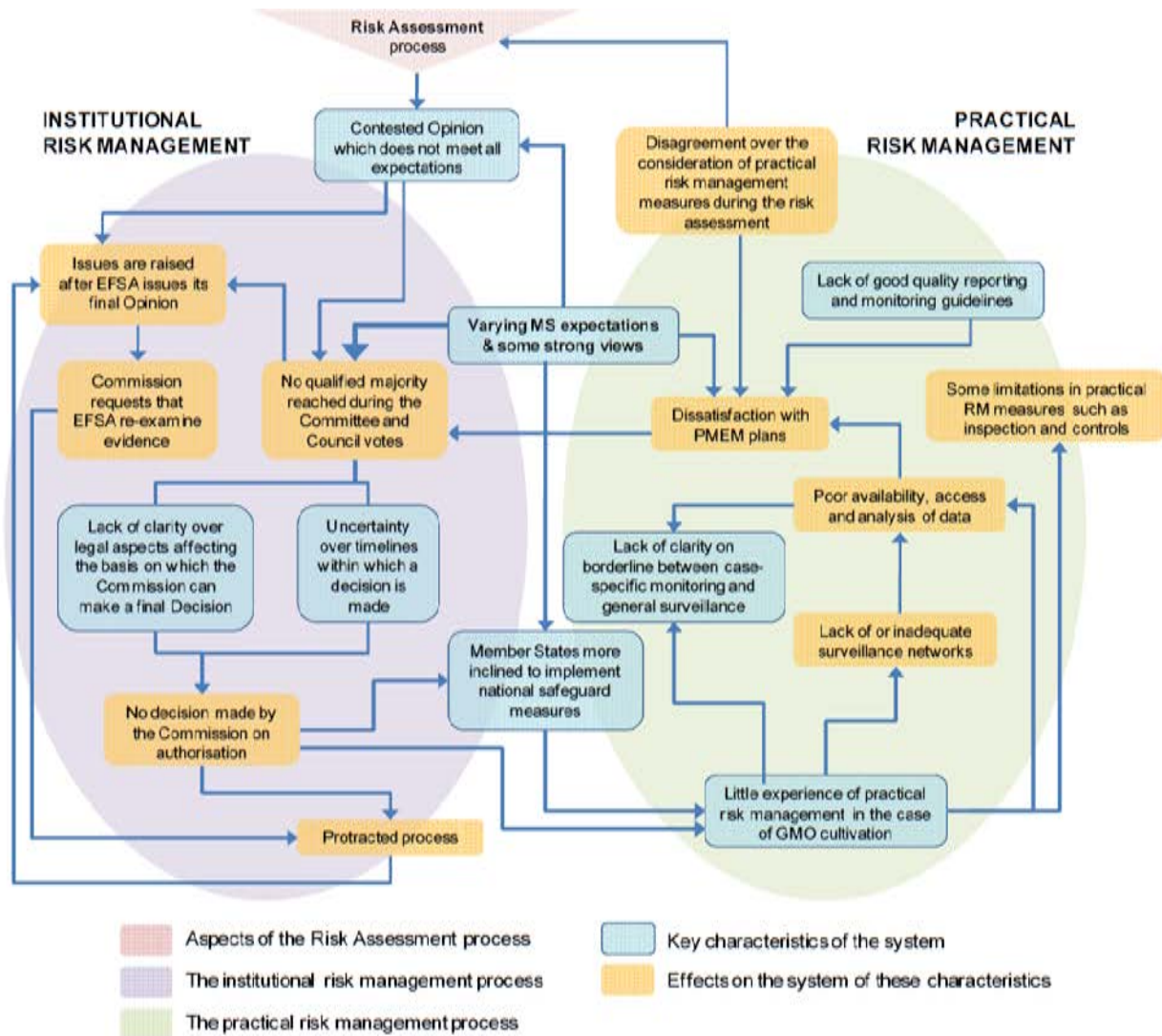


Fig. 27 System map of the principal issues, challenges and feedback loops in the risk management component of the legislation (from (EPEC-SANCO, 2011))

The comments from the EPEC-SANCO – Report (EPEC-SANCO, 2011) (fully supported by the author) show the nearly unsurmountable difficulties of European Regulation, due to a disorganized mix of politics and wrong risk conception of GM crops, all this contrary to the food and environmental safety experience worldwide.

**Frustration with the implementation of the framework** is concentrated on the risk management stage, and in particular on the absence of decisions. As discussed earlier in the report, the risk assessment process is the cause of some unhappiness among Member States and other consultees (Chapter 5 discusses options that would fine-tune the process and bring more resources into the system to increase its capacity). Nonetheless, consultees' frustration with the risk assessment phase is modest compared to that caused by the risk management stage. The research conducted for this study suggests that it is the lack of decisions, whether positive or negative, that is of particular concern.

The system for making decisions on whether or not to authorise cultivation has demonstrated a form of regulatory paralysis: Firstly, when the Commission has put forward a draft Decision on cultivation to a vote, Member States have been unable to reach a qualified majority (the same situation applies for all other uses, although there have been slightly more votes in

favour in those cases). The lack of qualified majority is mainly attributed to the polarised views within and among Member States and a significant number of abstentions;  
 Secondly, the Commission has chosen not to issue a final Decision itself (though a decision on the Amflora potato was issued in March 2010) or not proceed with proposals to the Council where the votes were inconclusive (in the case of maize 1507 and Bt-1161). Five GMOs have received favorable Opinions for cultivation from EFSA62, on which only the potato has progressed to EU authorization. This situation gives rise to comments, heard repeated in consultations, that the legislative framework is not being implemented as intended. Empirically, the risk management aspects of the framework as implemented are not efficient, transparent or, in aggregate, fit for purpose. **Consultees agreed that the current situation with GMO authorizations in Europe is not sustainable.**

The full extent of the GM crop development pipeline can be evaluated in websites like the Information Systems for Biotechnology alone from the U.S.A., there are (23. Oct. 2009) 14204 notifications with 1586 full field release permits registered in this Database, ISB: Information Systems of Biotechnology: Field Test Releases in the US: <http://www.isb.vt.edu/cfdocs/fieldtests1.cfm>

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 probably more accurate because?) it yields very positive results: (Morandini, 2008, 20071211)

*“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.**”*

A summary of the Lombardia maize case has also been published in Nature Biotechnology: (Marshall, 2007a). Unfortunately, the original research report is still not published, it is “resting” in an Italian government draw – a clear case of political censoring.

The present day regulatory “cropping 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, 2009a) (Ronald & Adamchak, 2008) and (deRenobales-Scheifler, 2009) – in short words: Gene Peace instead of Greenpeace....

## 6.5. 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, 2009a; 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 are 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 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 Zambia by Andrew Apel in GMobelus:

<http://www.gmobelus.com/news.php?viewStory=234> , where the Norwegian Government has partly sponsored a 400'000\$ laboratory, for which GENOK 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 characterizes GM crops as poisonous. The Norwegian GENOK is a well known anti-biotech NGO, with a very negative attitude towards GM crops, not shying away from spreading myths on allergy caused by pollen of transgenic maize in the Philippines, this is documented in the controversy between GENOK and Rick Roush:

<http://www.botanischergarten.ch/Allergy/Traavik-Roush-Philippines-controversy-2004.pdf>, also supported in favour of Genok without a shred of evidence by John Vidal from the Guardian:

<http://www.guardian.co.uk/science/2004/feb/27/gm.science> . 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", as reported by SciDev Net

[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](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) .

Indeed, it is rather ironical, that many of the biosafety educational efforts undertaken by organizations highly critical to transgenesis, is turned into the 'contrary': the biotechnological methods introduced in those countries are now also used for research and development of GM crops. A comprehensive report on agricultural biotechnology by Alhassan (Alhassan, 2002) demonstrates, that high regulatory hurdles would hinder a reasonable development of modern agriculture in Africa.

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; Ramessar et al., 2010; Raybould, 2010; Shelton, 2003).

## **6.6. The Golden Rice development hampered through over-regulation for 12 years! 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 consequences as documented in <http://www.agbioworld.org/biotech-info/topics/goldenrice/index.html> and in (Bradford et al., 2005b; 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., 2007b; Stein et al., 2008; Stein et al., 2007a; Stein & Qaim, 2007; Stein et al., 2006, 2007b). The initiator of the Golden Rice Ingo Potrykus project complains bitterly about the unjustified delays due to over-regulation in a Nature article: (Potrykus, 2010b)

Specifically related to the developing world: we should refrain from the old myths that international corporate companies are dominating the field in Africa – 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. The Asian farmers will also be able to multiply seeds without paying royalties. The homepage of the project is the main information source <http://goldenrice.org/>. 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.”*

A bibliography of 1921 publications of the Golden Rice and Biofortification demonstrates the importance of this field of research and biopolitics (Ammann K., 20120102).

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

Conclusions drawn by Ingo Potrykus (Potrykus, 2010a), the creator of the Golden Rice:

*“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.”*

As a whole, the new, well documented review paper of Adenle (Ademola A, 2011) delivers overwhelming evidence that GM crops are urgently needed in the developing world:

*“The world needs fast and reliable solutions to fast growing population and the problems of hunger, malnutrition, ravaging diseases, poverty and global warming crisis. One of ideal technological innovations such as GM technology can be part of solutions to these problems. It is imperative to understand that GM technology cannot establish its ground if continuously faced with the baggage of constraints as discussed above. Moreover, it is not surprising to gather from a variety of literatures that most developing countries lack capacity building and still struggling with the establishment of biosafety system that can facilitate GM field trials and commercial release of GM products. Some of the challenges associated with the development of modern biotechnology still boil down to the fact that individual country government and international organisations have not clearly identified a coherent strategy and enabling policy instrument to deal with the problems.*

***While some progress have been made on GM technology in terms of research and development, capacity building, and biosafety regulation in developed countries and a few developing countries, concerted effort is still needed to make it an accessible technology for every country.”*** (Ademola A, 2011).



## 7. The dispute between scientists and opponents today

### 7.1. The role of some activist NGOs in the debate

#### 7.1.1. Overview of NGO opponent activities

There is a continuous need for dialogue with regulators, the public and specifically consumers, since the new technology emerging from modern life science is affecting all aspects of human life, including food, reproduction etc. We do have an unfortunate trend towards irrational and anti-science argumentation in the GM crop dispute, as clearly diagnosed by (Taverne, 2005a) in his book “The March of Unreason), see also (Durant, 2005; Taverne, 2005b).

This said we should not create misunderstandings: There is no room for appeasement politics today when it comes to the activist NGOs like Greenpeace and Friends of the Earth, or websites like the Institute of Science in Society (I-SIS) and GM-Watch. Those professional organizations have proven repetitiously not to be interested in peer reviewed science in a debate on the science and the socio-cultural issues. They rather rely on un-confirmed reports in order to follow their own ideological and commercial interests. Any rational discourse with such organizations would be very welcome, but needs to be based on the latest peer reviewed science. Their usual tactics is to appeal on fear. A good example from Greenpeace has been described on the EFB forum website <http://www.efb-central.org/index.php/forums/viewthread/13/> about baseless accusations that 1600 sheep have died from feeding Bt cotton leaves. An critique on the distorted picture on Indian cotton cultivation by NGOs is given by Herring (Herring, 2008b) with lots of figures, facts and extensive documentation.

Another blatant example of junk science has been launched recently by Greenpeace on You Tube “Genetic engineering: The world's greatest scam?” <http://www.youtube.com/watch?v=1H9WZGKQeYg> full of misinformation and hatred against multinational seed companies. Another recent example is the baseless accusation against a national franchise chain Bakers Delight, telling customers they soon would be eating bread made from genetically modified wheat. There are many more examples to document this kind of professional framing of the public towards a negative attitude against genetic engineering of food crops, see section 6.2.

We are also confronted with violence - activities clearly documented and justifiably named and pursued as terrorism (Marris, 2006). Also in Europe there are regularly occurring field destructions (Atkinson & Urwin, 2008), which hamper seriously biosafety research – what an irony! Eco-terrorism is not confined to Europe, problems of such kind also are very real in the United States (Leader & Probst, 2003):

According to the Federal Bureau of Investigation (FBI), the Earth Liberation Front, together with its sister organization, the Animal Liberation Front (ALF) has committed from 1997 to 2003 more than 600 criminal acts that have resulted in more than \$43 million in damages. Moreover, attacks have been perpetrated in virtually every region of the US against a wide variety of targets.

Recently, Greenpeace destroyed government field research in Australia (Finkel, 2011) and defended the act of eco-terrorism with very thin arguments – and promptly lost lots of supporters and sympathy: Even some old friends and supporters of Greenpeace (but not all) distanced themselves from the action: (Bettles, 2011). A list of field destruction actions in Europe has been compiled by Marcel Kuntz (Kuntz, 2011a). This list, far from being complete, demonstrates that activists have lost their moral compass in recent years: (Da Silva, 2011; Gough, 2011). A philosophical and psychological explanation of those new violent phenomena see under section 6, the moral self licensing (Miller & Efron, 2010). As a whole, Greenpeace has lost many friends with the Australian action of destroying field research: (Farr, 20111209).

One of the best rebuttals of cheap anti-GMO propaganda coming in attractive book editions, widely distributed in international events by the author Jeffrey Smith (Smith, 2003a, 2007) has been published on the internet by Bruce Chassy <http://academicsreview.org/reviewed-content/genetic-roulette/> , it is actually a scientific comment section by section, based on the best available peer reviewed literature.

A recent very negative balance sheet has been published by Ben Pile in Spiked: (Pile Ben, 20110912)

More chagrin emerges from the mounting pressure from within the academia, where for instance German university leaders in Giessen ordered to cease field research on GM crops which is unwelcome in the eyes of the extremists, (Miller, 2008) and there are serious complaints about the difficult atmosphere for biotech researchers in Germany (Rauschen, 2009).

### 7.1.2. The Bt Brinjal battle in India

Another symptomatic row is presently taking place in India, related to the approval of Bt brinjal, where activists in a desperate attempt to stop the regulatory approval of Bt brinjal with outrageous and completely unfounded rumors like: GM brinjal will render the soil sterile. But contradictions have been posted as well, the most recent and comprehensive summary report published by Kameswara Rao (Rao, 2010), see also his recent interview on the much criticized Biotech Bill of India, which he defends (Rao C.K., 20111222). The report from 2010 is a review of massive evidence for the safety of Bt Brinjal and the detrimental heavy use of pesticides for the production of conventional Brinjal and it contains no less than 231 detailed comments. Instead of going into such details, here the final comments of a Wall Street Journal article of C.K. Rao: (Rao C.K., 20100303)

*“If anything, the Indian government should be cheering on this kind of innovation. The country’s version of Bt Brinjal was developed by a public-private partnership—just the type Delhi wants to encourage. Mumbai-based Maharashtra Hybrid Seed Company (Mahyco) obtained rights to the Cry 1Ac gene from Monsanto. Mahyco then collaborated with Tamil Nadu Agricultural University at Coimbatore and the University of Agricultural Sciences at Dharwad in Karnataka to develop the specific local Bt varieties. The company also set up similar arrangements with the Indian Institute of Vegetable Research at Varanasi, the University of Philippines, Bangladesh Agricultural Research Institute and a private seed company, Dhaka-based East West Seeds. The project was funded by the U.S. Agency for International Development and managed by Cornell University. In spite of all this effort, Mr. Ramesh played to the activist campaign that alleged products are toxic and allergenic, harm related species, and negatively impact ecology and biodiversity—among many other false claims. Bt Brinjal is neither toxic nor allergenic and is safe to the nontarget organisms and the environment. In fact, it greatly reduces the cultivation expenses on the use of synthetic pesticides, and thus the risk from synthetic chemicals to the farmers, consumers and the environment. It vastly enhances the marketable yield of healthy vegetables, benefiting millions of farmers and consumers.*

*Some members of government understand these proven facts, including members of the Prime Minister’s Economic Advisory Council and the Ministers for Agriculture, Science and Technology and Human Resources—all of whom have voiced concern in recent days.*

*The government’s stand has created huge regulatory uncertainties for no valid scientific reason or environmental concern. No innovator can afford to develop any biotech crop with an uncertain approval process that is divorced from science. Delay*

*in the commercialization of Bt Brinjal will promote its clandestine cultivation, as it has happened with Bt cotton in Gujarat, and elsewhere. This is not in the best interests of India, nor its people.” (Rao C.K., 20100303).*

Another important report has been published by B. Choudhary as ISAAA Brief No. 38: (Choudhary, 2009). Another extensive scientific report has been conveyed by the involved industry, approved by an impressive range of experts: (Genetic Engineering Approval Committee, 20091008). There is also the concern, that Bt Brinjal could be consumed as vegetable in raw condition over long time, a concern, which is dismissed by a comment from Bruce Chassy and Ronald Herring (Chassy Bruce & Herring Ronald, 20120115): The final comments:

*“No amount of experimentation can prove absolute zero risk, but that is what is demanded of GM foods. If we were to reject all new food ingredients because there was no prior record of long term consumption we would never produce new food ingredients would we? That may be the object of this line of questioning which asserts our food is perfectly fine now so no changes should be made because who knows what harm they may do after years of chronic consumption. Absent evidence or a reason to expect a specific effect to occur, the question about unknown long term effects is really a denial that science can be used to assess and manage risks. We do not and cannot prove things are safe, what we do is demonstrate that there are no known unacceptable risks and no reason to believe adverse effects would occur. Questions such as we are dealing with here can be used to derail any new technology.” (Chassy Bruce & Herring Ronald, 20120115)*

In the whole Brinjal debate, the aspect of *dramatic reduction of pesticide use* should not be forgotten: Kolady et al. (Kolady & Lesser, 2008) report from field trials with GM eggplants a pesticide reduction by 52% that will result in a saving of US\$ 130/acre for hybrid growers and US\$ 53/acre for growers of open pollinated traits. There are dozens of papers confirming the benefits caused by Bt Brinjal related to pesticide use: (Basu & Pramanik, 1968; Hamilton & Lashomb, 1996; Krishna & Qaim, 2008; Kumari et al., 2002; Mathur & Jain, 2006; Mishra et al., 2009; Ntow et al., 2009; Roy et al., 2006; Shahid et al., 2009; Sheu & Chen, 2009; Sing & Sing, 2005). And most interesting details in (Krishna & Qaim, 2007)

*“As indicated in earlier studies (George S. et al., 2002; Rashid M.A. et al., 2003) , eggplant in South Asia is being cultivated with excessive quantities of plant protection chemicals. In our survey, farmers were spending in Indian money Rs. 3570/acre (1 US\$ = Rs. 44) on insecticides, 64% of which was intended to control ESFB. On average, for a crop of 180 days, 2.34 kg/acre of active ingredients are applied in 30 sprays. Farmers are well-aware of associated health-hazards and negative externalities: 25% had experienced one or more forms of health impairments associated with agro-chemical use during the previous season” (Krishna & Qaim, 2007)*

It is ironic, that one of the main arguments for proponents of the Bt Brinjal moratorium in India is now seriously questioned. There was the seemingly clear evidence on a crop biodiversity center for Brinjal in India which called for extra protection of indigenous genomes. But recent extensive genomic analysis has clearly demonstrated that Brinjal is originating in Africa (Weese & Bohs, 2010), this view is also supported by historic evidence (Hanur, 2011; Wang et al., 2008). Nevertheless indigenous Indian Brinjal needs protection, since a long standing tradition of Brinjal culture produced some 1000 Indian traits, but with good measures it should be possible to achieve this goal, since gene flow can be controlled, see the recent debate in Current science: Some concern on biodiversity is manifested (Samuels, 2011a, b; Samuels & Shanmugam, 2011), other authors claim that those problems can be handled and balanced out against the massive benefits in reducing pesticides (Bokolial, 2011; Hanur, 2011), casting some more realistic light on the biodiversity question. In the whole Brinjal debate, the aspect of dramatic reduction of pesticide use should not be forgotten: Kolady et al. (Kolady & Lesser, 2008) report from field trials with GM eggplants a pesticide reduction by 52% that will result in a saving of US\$ 130/acre for hybrid growers and US\$ 53/acre for growers of open pollinated traits. However there are authors like (Yadugiri, 2011) who develop a scary picture of

Bt brinjal, by taking up without scientific scrutiny flawed papers on Bt brinjal health problems like the ones of (Seralini et al., 2009) which is criticized by the overwhelming majority of the food safety scientists and (Aris & Leblanc, 2011) who were using inadequate methods – this means that the sensational findings of Aris et al. of Bt toxin in human blood are a total fake – and - the conclusions of Yadugiri are based on dubious science as a whole.

Finally, it should be mentioned, that activists also raise mythical emotional issues such as that Bt brinjal would affect the use of brinjal in traditional medicine in India. In fact such an argument is being extended to several other crops also, but the arguments are merely hypothetical, as C.K. Rao has shown (Rao, 2011). In his words, this highly exaggerated view, unsubstantiated by reference to Ayurvedic sources, propagates a dangerous myth. The issue was sensationalized by the activists to disproportionate emotional levels and immediately taken up by the MoEF (Ministry of Environment and Forestry), as a potential arrow in his quiver to shoot down *Bt* brinjal.

The conclusion for this contribution on the brinjal debate in India is again, that the ‘Genomic Misconception’ (Ammann, 20120706) in regulation plays again a very unfortunate role. If India would achieve a shift from process oriented regulation to a product oriented regulation, then *automatically* conventional Brinjal would be included in the risk assessment, and again *automatically* the devastating and massive use of pesticides to grow ‘healthy’ conventional brinjal would be included in the risk assessment, and the case would be solved in clear favour of the Bt brinjal, see section 7.

This is exactly the mistake described above which is also made by David Andow in his report (Andow David, 2010) on the biosafety of Brinjal: His exclusive focus on the risk aspects of GM brinjal is scientifically untenable. A careful analysis of this paper, which also had a major impact in the regulatory scene of India and which is cited by name and excerpts twice in the report to the Indian parliament (India-Parliament-Ag-Committee, 20120807), reveals this kind of misconception: In the sections on gene flow the author ignores the fact, that hundreds of traditional varieties exist in the Indian agricultural traditional system without any remarkable hybridization over extremely long timespans, on the contrary, they co-exist without difficulties over centuries. In the erroneous view of the ‘Genomic Misconception’ the exclusive focus on coexistence with GM crops is unreflected and automatic, without scientific justification.

Even worse is the fact, that in the whole study of David Andow, dealing with traditional brinjal crop, there is no documentation on the exorbitant and proven unhealthy use of pesticides in traditional brinjal growing, as described above. A product – oriented biosafety view would automatically correct such basic errors. The result is astonishing: Although David Andow is correctly citing a lot of literature and gives an in-depth analysis of possible and hypothetical biosafety concerns of Bt Brinjal, nevertheless, he does not tell the whole story, thus missing a very important part of the biosafety assessment of modern AND conventional Brinjal breeding. A truly scientific assessment of Bt brinjal has to be done in *a product oriented strategy*, which means clearly that agriculture and food safety of conventional brinjal has to be taken into account in a balanced way. This had been explicitly stated without the theoretical correct background of the genomic misconception by Bokolia in his attempt to come to a consensus in the Brinjal battle: (Bokolia, 2011): Simple common sense leads to product oriented regulation as the Canadians do it for years, see the summary papers (McHughen & Smyth, 2008; McHughen et al., 2012; Smyth et al., 2012).

## 7.2. Insight in the worldwide activities of the Protest Corporations, Finances

As an exemplary dispute, you can also follow the exchange of letters between the Public Research and Regulation Initiative (PRRI) and Friends of the Earth (FoE) (PRRI, 2006), Friends of the Earth still owes an answer to PRRI in the correspondence.

Some of those anti-GMO activist groups get hefty funding from governments in the EU as documented accurately by Andrew Apel and his GMobelus website: Europe's massive funding of world-wide activism, compare also his recent article on the same subject, focusing also on global aspects: (Apel, 2010b), p. 637:

*"The sums of money diverted to these organizations are substantial and in Europe consist heavily of public funds. Perhaps the greatest beneficiary in this category is the Friends of the Earth (FOE). In 2006 alone, the FOE, directly and through member/affiliate/partner groups, was earmarked to receive roughly 790 million s from European governments. These governments appear to provide nearly all of its annual income (Apel Andrew, 20080824). Members of the European Parliament have called this diversion of public funds 'grotesque' and 'anti-democratic', and said that it amounts to government 'paying to have itself lobbied to take actions which, in the main, it would wish to take anyway'(Banks Martin, 20070817; Cox Simon, 20071206). Even so, the sums diverted to the FOE are commensurate with the magnitude of the financial and political interests which benefit from its advocacy, and the influence of the FOE is not restricted to Europe. The organization now claims to be 'the world's largest grassroots environmental network, uniting 77 national member groups and some 5,000 local activist groups on every continent' (Friends of the Earth, 20120124). The vast majority of the FOE's affiliate groups are found outside the EU, which means that Member States of the EU are paying the FOE to advertise the anti-biotech message around the world." (Apel, 2010a).*

The table below from (Apel, 2010a) demonstrates that large finances are involved in the GM battle. It also reveals nicely that one of the most powerful lobbyists against Agrobiotechnology is the organic farming industry with a gigantic financial vested interest. The saddest points are made by Andrew Apel when focusing on the developing world:

*"In fact, it appears that the greatest money to be made by restricting access to agricultural biotechnology is made by intentionally keeping it out of the hands of those who need it the most – that is, by the organic industry. By linking political and financial interests in environmentalism, GMO testing, segregation and traceability, international trade and threatened disruptions, premiums for functionally identical goods, retailing, advertising, popular media and government subsidies for NGOs, the organic industry is able to monetize restrictions on agricultural biotechnology at nearly every point in the political/financial chain of interests." (Apel, 2010a).*

**TABLE 1**

<b>Comparison of financial interests in restricting agricultural biotechnology</b>	
Organic industry sales, international	40,000
Sales of GM seeds, international	6800
Premiums paid for non-GM soy, EU	3409
Payments to Friends of the Earth (FOE) and affiliates, EU	1171
Payments to US groups opposed to GM	600
Supermarket advertising (eight largest supermarkets in UK)	575
Testing for GM content, US and India (excludes EU market)	318

Figures are annual, US\$ millions.

Table 1 from (Apel, 2010a)

The current set of arguments of GM crop opponents is often a mix of anti-American, anti-global, post-modern and even anti-science notions, (Borlaug, 2000), a strategy which has now been taken over very successfully by NGOs like Greenpeace and Friends of the Earth as global actors. These leading protest forces have helped, particularly in Europe, to build up a post-modern negative picture of biotechnology as a whole (Hemming, 2006). In this light it is easy to act as ‘opinion leaders’ with pseudoscientific arguments. The feedback mechanisms through the media and a network of citations of all the flawed stories make it possible for the global opponents to maintain confirmation of negation mechanisms. We are in a situation where the opponents already try to claim victory, penetrate highest political levels in governments and international organizations like the United Nations, some produce strikingly flawed reports on GM crops.

An analytical article about media and NGO activities in New Zealand has been published by Motion & Weaver (Motion & Weaver, 2005): by attracting media attention through dramatic protests Greenpeace risks to jeopardize its reputation. The abstract:

*“The challenges of attracting positive media attention are likened to a contest in which various organizations attempt to promote and circulate their version of events; however, this is particularly difficult when attempting to circulate less established, unpopular or critical knowledge. Although complying with, and managing, news values is an important starting point, the need to move beyond news values to consider the commercial values and realities of media organizations is highlighted. In this paper, a case study is undertaken of the Greenpeace media relations in New Zealand when a proposed controversial expiry of a moratorium to release genetically modified organisms into the environment. The predicament for Greenpeace is that in attracting media attention through dramatic protests it risks jeopardizing its reputation as a credible news source that can influence the framing of news stories. Insights are offered into the need for organizations to understand and manage the story or knowledge to be circulated and comply with contradictory news values.”*

Related to this paragraph on NGOs it is necessary to write a word on the press: newspapers and other media usually are mirroring what is important in the public debate, and the NGOs are clever in manipulating both the public and the press, after all, it is easy to provoke with fear and scaremongering and the majority of journalists of all calibers are also committed to their own product, position and its commercial situation.

A classic example is the coming and going of the Frankenfood Myth see fig. 3 and [http://en.wikipedia.org/wiki/The\\_Frankenfood\\_Myth](http://en.wikipedia.org/wiki/The_Frankenfood_Myth). Interestingly enough, this myth had its sharp peak in the press statistics around 1998 (see fig.3) and since then it has vanished from the headlines (Leydesdorff & Hellsten, 2006) as a major buzz word.

Those mechanisms have been precisely described by Burke for the situation in Great Britain some years ago (Burke, 2004). But it is also clear that in the last 5 years more balanced voices appear in the press, although there is no room to extend this topic here, just one recent example from the London Financial Times may suffice (Blas, 2009).

A final most recent example is the claim of C. Then from Greenpeace blaming cultivation of Bt corn for the spread the Western Bean Cutworm in the US corn fields: In a simplistic way Then and his co-authors blame GM crops for massive damage in the US corn fields (Then Christoph et al., 2010). In a rebuttal on many detailed items Hutchinson et al. (Hutchison William D. et al., 2011) come to the following conclusion:

*“In conclusion, although Then (2010) attempted to fault transgenic Bt corn for the geographical spread of western bean cutworm into eastern North America, historical records indicate that the insect had an extensive range west of the Missouri River, and considerable eastward spread had begun before the widespread adoption of Bt corn. Many factors, operating alone or interacting (Table 1), may have played a role in this biological phenomenon. The evidence is conclusive — the*

*western bean cutworm is neither a “new plant pest” nor “caused by genetically engineered corn” as stated by Greenpeace Germany.” (Hutchison William D. et al., 2011).*

Despite of the dubious quality of these reports of [www.testbiotech.org](http://www.testbiotech.org) are very popular in Germany, Switzerland and also Austria. Then is a frequent speaker at events organized by opponents in the European Parliament in Brussels, invited by Corinne Lepage chair of the Agriculture and former president of anti-GMO organization CRIIGEN, see her polemic statement related to the Séralini controversy: (LePage Corinne, 20120925).

### 7.3. The “GM crop battle” in Nature, the dispute among scientists, about the use of strong language

First, let us not forget some words of Antony Shelton (Shelton, 2003), the most important words can translate into a slogan: “Quality of science must back up personal opinions”, the abstract:

*“In agricultural biotechnology there are roles and responsibilities of scientists, scientific journals, the public media, public agencies, and those who oppose or advocate a specific technology and serious consequences for science in general when those roles and responsibilities go awry. Scientists may feel the pressure of competition, especially in an academic setting. Personal views may continue to decide which issues one will work on, **but the quality of science must back up those personal opinions**. Common sense tells us that scientific inquiry and the publication and reporting of results to the scientific community and general population should be performed with high standards of ethical behavior, regardless of one’s personal perspective on agricultural biotechnology”*

One of the arising problems is, that there has been recently a tendency to mollify peer review for the sake of giving space to politically correct so-called “critical views” of genetic modification of crops, with some blatant examples of flawed pseudo-critical papers having passed for publication in highly respected scientific journals – a few examples have been commented by (Miller et al., 2008). Some of those papers just passed due to flawed peer review, others passed despite rejection by some peer scientists, obviously for the sake of a so called “balanced” public debate (and – for the promotion of the journal) see as an example the rather thin justifications of the editor in chief editor of Lancet Richard Horton to go ahead with the publication of Pusztai’s rat experiments (Horton, 1999a, b, c; Horton, 1999d; Horton, 1999e). More details about this controversy see in ASK-FORCE on Pusztai (Ammann, 20120514), it is an anatomy of the case on 49 pages on the Pusztai affair, which had an unfortunate and big influence on the regulatory climate on GM crops in Great Britain and the world.

It is only between 2005 and 2011 that a certain fatigue of new negative arguments against GM crops is developing, and it is interesting to note that opponents, in lack of real negative health and environmental effects, now shift their emphasis on negative arguments in socio-economics realms. There are hardly any new issues in food safety and environmental impact to be dealt with in the last few years. This might also be the reason why in a desperate routine of repetitious ‘negative’ GM crop stories get into journals, often also on rehashed events which have been clearly rebutted scientifically many years before. Those ‘news stories’ often pass uncontested and get printed in “news”-media due to a mix of short memory effects of uninformed editors and readers of all kind, or worse: they are purposefully repeated by activists counting on short memory of press and public.

A strange effect should also be mentioned, that scientists, who defend good science in biosafety research, sometimes get blamed because they use straightforward language when criticizing flawed papers. A paper on such debates has been published by Nature (Waltz, 2009), see the comments in a contribution of ASK-FORCE (Ammann, 20120724) on a paper on aquatic organisms supposedly harmed by Bt toxins of GM maize by Rosi-Marshall (Rosi-Marshall et al., 2007) and (Tank et al., 2010). There are several controversial hints in this Nature story put forward by science journalist Emily



Waltz, who is neither specialized nor experienced in the hot scientific regulatory debate on GM crops, suggesting that to criticize flawed papers with “strong language” is detrimental to the progress of scientific research. This statement was supported by interviewed writers such as Ignazio Chapela (famous for starting the controversy of the Mexican gene flow of transgenic maize with a letter to Nature (Quist & Chapela, 2001), which later turned out containing insufficient evidence for publication (Campbell, 2002), see the latest summary in (Pineyro-Nelson et al., 2009). Another interview Waltz conducted in the cited Nature piece with David Schubert, who tries as a pharmacist to give advice in biosafety rules of GM food, and with his strong anti-corporate mood publishes fraud accusations against pro-GMO scientists (Schubert & Tribe D. comments, 2006). Both interviewees Chapela and Schubert defend independent scientific whistle blowing, but themselves they have a proven negative agenda about GM crops see more controversy papers: (Bradford et al., 2005a; Bradford et al., 2005b; Schubert, 2005). In the meanwhile, several letters to the editor of Nature have been written commenting the feature of Emily Waltz in Nature, they are all cited in (Ammann, 20111002), the majority is not supporting her thesis.

Incidentally: Strong language has been used before in the history of science, remember some really bitter and hefty disputes about the history of discovery of the double helix structure of DNA between Watson and Crick (Friedberg, 2007), who both later made their peace again.

Other numerous examples of a fight out in the open are documented about evolution when Darwin proposed his revolutionary ideas. Two citations of strong language may suffice: In a debate on natural selection (Punnett, 1928) writes on a dispute with William Bateson:

*“By these admission almost the last shred of that teleological fustian with which Victorian philosophy loved to clothe the theory of evolution is destroyed. Those who would proclaim that whatever is right will be wise henceforth to base this faith frankly on the impregnable rock of superstition and to abstain from direct appeals to natural fact.”*

Another clear example of sharp and relentless scientific controversy on evolutionary biology with strong language has been described in detail by Strick (Strick, 1999), among the numerous juicy examples:

*“His [Bastian’s] tone was sharp in response to Huxley’s public accusations that his technique was sloppy (a much more high-powered attack than Huxley ever adopted in private when attempting to correct young scientists). Huxley replied with an equally sharp tone, now saying sweepingly that “what Bastian got out of his tubes was exactly what he put into them,” i.e. contaminants”.*

And one last word about strong language: The word “abuse” has been printed by Nature in the Battlefield paper (Waltz, 2009) very prominently in the subtitle, when attacking a group of authors including me who criticize flawed papers in the GM crop debate with blunt, but still polite words – what an irony! – And to be quite clear: no complaints from my side....

More on the psychology and philosophy of the often harsh dispute on biotechnology, agriculture and food see section 5.4.

#### 7.4. Reports on negative effects of modern breeding methods in food and environmental safety do (or should) not pass strict scientific procedure rules and peer review

If researchers would follow strict procedural rules, the world of scientific biosafety debate would be far less complex, here a few papers standing for such in fact uncontested rules: (Chassy et al., 2007; Chassy & Parrott, 2009; Chassy, 2002; Duan et al., 2010; Miller & Bradford, 2010; Potrykus, 2010b; Raybould, 2010; Romeis et al., 2008; Shelton et al., 2009b) It is fact, that for some years basically no new arguments against agricultural biotechnology (in particular clearly related to transgenesis) on an agronomic base can be put forward for the most widespread crops, which have run through multiple regulatory processes in many countries.

This should not mean, that transgenic crops are completely free of problems, but it is fact that a comparison with conventional crop problems reveals these are minor and manageable in a more efficient way – and – they are not directly related to the transgenesis. One of the basic mistakes of GM crop criticism is the unilateral focus on the risks of transgenes inserted, instead of comparing in a fair and scientific (holistic!) way with conventional cropping (Broer et al., 2011), this text should be read as a direct rebuttal to (Taube et al., 2011), who is making this basic error of focusing in its critique on GM crops exclusively on the transgenesis.

Still: A growing number of herbicide tolerant weeds are emerging: (Duke & Powles, 2009; Green & Owen, 2010; Johnson et al., 2009; Vila-Aiub et al., 2008). (Powles, 2008) rightly points to the monotonous fields of glyphosate resistant soybean landscapes, where the herbicide tolerant weeds emerge more rapidly:

*“Indeed, in spite of longterm use, the evolution of glyphosate-resistant weed populations in non-GRC, burndown systems has been very limited. Thus, functionally competent gene traits endowing glyphosate resistance are relatively rare and not easily enriched in plant populations.(Powles & Preston, 2006), (Neve, 2008). This is why glyphosate is a remarkably robust herbicide from a resistance avoidance viewpoint. However, as reviewed above, it is clear that, where there is very intense glyphosate selection without diversity, glyphosateresistant weed populations will evolve. In particular, the evolution of glyphosate-resistant weed populations is a looming threat in areas where transgenic glyphosate-resistant crops dominate the landscape and in which glyphosate selection is intense and without diversity.”(Powles, 2008)*

But it is also fact that the emergence of glyphosate resistant weeds is happening on a much slower pace than with conventional herbicides (Mikulka & Chodova, 2000), and such negative trends can be corrected easier with modern breeding methods: (Green, 2009; Green et al., 2008)

Some critical science journalists question the strategies and behavior of the global opposition players. In a kind of last bid questionable reviews are published, either containing lots of negative *assumptions* (Hilbeck & Schmidt, 2006) and also dealing with wrong toxico-analytical concepts resulting into an exaggerated risk assessment for non-target insects as the lacewings promoted by Hilbeck et al. (Hilbeck et al., 2000; Hilbeck et al., 1998, 1999) and contradicted clearly in Romeis (Romeis et al., 2004). Other examples of questionable eco-toxicological conclusions have been drawn by producing or reviewing flawed data or statistics, or drawing questionable conclusions, see the debate on Ermakova’s flawed rat experiments: (Marshall, 2007b), more details in a contribution to the ASK-FORCE (Ammann, 20120712). Typical other examples, recognizable on filtered citation lists are Dona et al. and Seralini et al. (Dona & Arvanitoyannis, 2009; Seralini et al., 2007a). Seralini conducted his experiments in disrespect of the internationally approved rules of biosafety

experiments established by the OECD (OECD, 1998a, b) and also he avoids the citation of certain contradicting peer reviewed references. Many of those papers have been or will be treated in ASK-FORCE (Ammann, 20110921), where you can read about new or recently updated ASK-FORCE contributions, for more details see section 5.1.

It also must be said (remember Saner's statements at the beginning of this section), that vested interests can be spotted with some biosafety researchers, who are in need of research grants and thus tend to paint a negative picture on biosafety, they symptomatically have difficulties to distinguish between the 'nice-to knows' and the 'need-to knows.' Example: see the ASK-FORCE contribution (Ammann, 20111002) on the publication of (Lovei et al., 2009), a paper which is flawed in several ways. It has been completely rebutted by Shelton et al. (Shelton et al., 2009a), the questions asked in the Lovei paper are irrelevant for Bt maize cultivation, since the Bt-toxin-technology is overwhelmingly beneficial for the majority of non-target insects (Candolfi et al., 2004; Duan et al., 2008; Marvier et al., 2007; Naranjo, 2009; Wolfenbarger et al., 2008). One of the major flaws of the Lovei paper is that they used low quality prey for their laboratory feeding studies. A thorough analysis of risk assessment research has been recently published by Raybould (Raybould, 2010): We need to carefully distinguish between basic ecological research and purposeful and targeted risk assessment research which concentrates on the real *agronomic risks* and needs (Ammann, 2005; Ammann et al., 2004).

The question and negative answer given in the letter of the Public Research and Regulation Initiative (PRRI) to the Secretariat of CBD (PRRI Public Research and Regulation Initiative, 20090914) is fully justified, *and PRRI stands ready to expand on the points made in this letter.*

*"1. Are there LMOs or traits that have caused adverse effects?"*

**No.** *Since the first application of genetic modification in the 80s, many thousands of field trials have been conducted with GM organisms (to date mostly plants), and since 1996 many hundreds of millions of hectares have been planted with GM crops by many millions of farmers and consumed by hundreds of millions of consumers in developed and developing countries, without any verifiable reports of adverse effects on the environment or human or animal health.*

*In fact, taking a broader look, experience with those GM crops has shown environmental and socio-economic benefits in terms of increases in yield, significant reductions in use of pesticides, fossil fuels and soil erosion, less mycotoxins in grains, as well as increased farmers health and income."*

Final remarks: Coming back to the first statement of Saner (Saner, 2007) given under 2.1.: Value laden scientific activity cannot be avoided, but minimized - if you refrain to work with flawed data, with filtered citation lists and with reviews pontificating on negative assumptions. The only remedy is to work with high quality data produced in a methodologically transparent way following international agreement.

It is appropriate, to end this rather pessimistic section with a positive note, not free of irony: As (Gupta, 2010) recently stated, there is hope that the introduction of strict biosafety rules in the Cartagena Protocol, originally aiming at a slowing down or even at stopping the transboundary movement (and indirectly development) of GM crops, now seems to turn into its contrary:

*"Through analyzing the dynamics of GMO-related information disclosure to the global Biosafety Clearing House (BCH), I argue that the originally intended normative and procedural aims of disclosure in this case to facilitate a GMO-importing country's right to know and right to choose prior to trade in GMOs are not yet being realized, partly because the burden of BCH disclosure currently rests, ironically, on importing countries. As a result, BCH disclosure may even have market-facilitating rather than originally intended market-regulating effects with regard to GMO trade, turning on its head the intended aims of governance by disclosure."*

Other flagrant examples of biased reviews are published by José Domingo (Domingo, 2000, 2007; Domingo & Giné Bordonaba, 2011). His 2011 view on the safety of GM food is based on a clearly selective choice of cited literature.

## 8. Debate improvements: What can we do to enhance the situation?

With the upcoming molecular biology and its impact on human society we encounter again the problem of complexity of scientific knowledge. This complexity in molecular science is indeed growing to heights hard to imagine, and it is a veritable obstacle in the difficult discourse on green biotechnology and modern agriculture. On the other hand, there is justified criticism on the “Deficit Model” of science communication, see section 1.3. and the writings of Sturgis (Sturgis & Allum, 2004), but nevertheless it is the scientists important task is to bring science to the public and vice versa (section 4.4.). On a philosophical level, they must confront the task in the spirit of resolving the conflict between direct realism and perceptual consciousness: An accurate account of this complex epistemological dispute is given in a debate between Susanna Siegel (Siegel, 2006) and A.D. Smith (Smith, 2006) for which there is no room here for extemporation, for the following reason: The debate can be resolved indirectly by adopting a *discourse model of the second generation*. An important feature of this new second generation discourse claiming respect for different kinds of knowledge, including scientific knowledge (see section 5.3 for details).

Foremost, it is important for both sides to *shift from pro-reactive to proactive mode*. This does not automatically mean to filter away negative views on GM crops or traditional breeding and to organize a eulogy on the benefits of different kinds of agriculture, the pro-active mode should actually engage a new mode of debate, which is more discursive, more structured and definitely concentrates on a solution oriented and open-end decision making process. It’s time for action – as far as a strict scientific view is allowing this. There are several websites working hard on sorting out the strictly science oriented messages in biotechnology, as mentioned below. We should not, as it often happens, in our struggle against the negative pseudo facts focus on the risk alone and thus trap ourselves in a negativistic perspective.

Rather we should address in a balanced way also the obvious (or lost) benefits. But this alone will not provoke a turnaround. This shift must be embedded in a discourse with concerned people and organizations and it must clearly oppose untruthful strategies of the global protest corporations and thus also refrain from using the same counter tactics. One of the appropriate organizations for this activity will be the two platforms: (1) Public Research and Regulation Initiative PRRI [www.pubresreg.org](http://www.pubresreg.org) run by public researchers and (2) also the European Federation of Biotechnology <http://www.efb-central.org/>, so that public science will get a more important place in the international regulatory debate (but also where private seed companies are not fundamentally battled in a naïve neo-Marxist scheme). In many meetings strictly based on science and organized by PRRI both platforms are well received. The project outline can be described as follows:

### 8.1. ASK-FORCE organization and related websites

There is a flood of papers which cast doubt on the GM crops already regulated in many countries. Most (if not all) of these papers are written in a bad quality, either with flawed methodologies not

internationally agreed upon, or with conclusions which are not supported by the data (Lovei et al., 2009), rebutted by (Shelton et al., 2009a), details see in (Ammann, 20111002). There are also many reviews published, in a scientific style, but unfortunately either with a strongly biased set of references or with unsupported assumptions and doubtful conclusions – contradicted by peer reviewed publications often not cited. In some cases, the flaws are more hidden: Experimental data are achieved on clearly theoretical schemes, working with outdated Bt maize and non-target butterflies which have in their biology in nature no connection to maize fields: (Felke et al., 2010). It is therefore important to set the record straight and to try to rebut at least the most important and blatant cases.

Within an EU project with Marc van Montagu and Piet van der Meer, which has been granted to PRRI a blog was launched with the name ASK-FORCE on the PRRI website [www.pubresreg.org](http://www.pubresreg.org) with the secretarial help of Kim Meulenbroeks (until 2008) and presently Zuzana Kulikova. A list of about 130 items (Ammann, 20090911) has been compiled with international help and will be entered step by step in the grid of the following 6 sections.

(1)General (2)Human & Animal Health (3)Environmental Safety (4)Agriculture (5)Public Perception (6)Developing Countries.

Up to now, 11 contributions have been published on the internet, links and contributions see (Ammann, 20110921), they are all reviewed by the experts of the steering committees of Public Research and Regulation Initiative and the European Federation of Biotechnology, some also by the Experts united in the blog community of AgBioWorld <http://www.agbioworld.org/>. All three lists contain some of the best specialists on green biotechnology from all around the world for reviewing and commenting.

In order to become more pro-active, we need to develop forward looking strategies. It is up to the scientists to ask questions to the opposition, and in particular to the professional distorters of the scientific facts. This must escalate into public campaigns if (what is to be expected) those specific questions are ignored. Carefully built contacts with science writers are important here, as a help for networkers a selected list is given here

<http://www.ask-force.org/web/ASK-FORCE-Summary/Contacts-ASK-FORCE-2011.pdf>

## 8.2. Long term discourse and decision making processes

Let me first be quite clear that I think a dialogue with the professional protest corporations is, as a rule, a waste of time (specifically Greenpeace and Friends of the Earth, not to mention some other organizations). Their only interest is to keep the pot cooking and make sure that the population remains in a state of fear. They should be addressed with a confrontational strategy, which is included in ASK-FORCE. Often such NGOs get the willful help of the press, which acts according to the old proverb (Macbeth, Shakespeare) *“evil always fascinates – goodness rarely entertains”* (Freeland, 20070504), see also the arguments produced by Andrew Moore (Moore, 2006). While some press products concentrate on mirroring public concerns, a press more or less close to boulevard strives to foster its marketing with the help of sensational headlines, creating stories which sell better, but indirectly they are exacerbating the problems. We are also not going to talk about a special discourse, as described by Erjavec (Erjavec & Erjavec, 2009) related to the politics of the EU

commission. What we are aiming at is a fresh look at the regulation of GM crops after all. There are a lot of NGOs critical about GM crops which could be involved in this project, such as the British

Nevertheless we have to address all segments of the public with its concerns, feelings and interests. And the discourse we are going to concentrate on is solution oriented. This should be done according to the discursive rules of the management strategies of the second generation, the *Systems Approach* (see under 5.3.). As a basic reference with description and citations see the classic book of Churchman (Churchman, 1979). If we follow some ground rules, this should not be too complicated:

### 8.3. The Second Generation Systems Approach as a new decision making process

Instead of making questionable concessions (example: “let’s not talk about transgenic crops” as often done by Nestlé and Unilever, with notable exceptions (Carney & Brabeck-Lemathe, 20110903) within these two companies!), the dialogue should be organized in an atmosphere of ‘*Active Listening*’ (Rogers & Farson, 1957) and understanding - in which, apart from the strict rules of scientific argumentation we should send signals that the new technologies also trigger socio-economic and cultural feedbacks. This will be the key to solve *Wicked Problems* (Conklin, 2005), which contain also socio-cultural elements besides a set of hard, often contradictory facts (Rittel & Weber, 1973).

In his usual cynic precision, George Bernard Shaw defined the ultimate problem in the dialogue between scientists and lay people: “*Every profession is a conspiracy against the laity*”.

The new discourse is not about the usual stakeholder meeting, rather it is about instigating modern planning processes of the second generation in evidence based but open ended decision making processes. This *Systems Approach of the second generation* contrasts to linear planning with pre-determined targets and dominating deontic thinking (e.g. of the industrial corporations and government agencies), it contrasts also to *the Systems Approach of the first generation* (Example: Apollo moon landing with clear target).

#### 8.3.1. The rationale of new management and decision making processes

*“Some problems are so complex that you have to be highly intelligent and well informed just to be undecided about them.”*  
Laurence J. Peter (Peter & Hull, 2009)

These new strategies should dissolve the traditional stakeholder concept in favor of a much more efficient system respecting *different kinds of knowledge* and other rules (such knowledge differentiation is also known from learning processes, which are related to our decision making dynamics (Blackmore, 2007).

There are more practical reasons to employ into the Systems Approach and its concept of different kinds of knowledge as Zwart (Zwart, 2007) rightly emphasizes: Ever since we have realized that the low number of human genes (approximately 22'500) cannot be interpreted as a narcissistic offence, since organisms are so highly complex, including the emerging consciousness of our human brain, genomics takes us now beyond a genetic deterministic understanding of life, this must have consequences for societal research and debate as well. Policies for self-improvement will increasingly rely on the use of complex interpretation. *Therefore, the emphasis in our discourse must shift from issues such as genetic manipulation and human enhancement to issues involved in governance of*

*novel forms of information*. The same can be said on the side of agriculture. Ikerd (Ikerd, 1993) develops with the means of the systems approach a more holistic picture of agricultural management.

(Fairclough, 2009) as a linguist gives an in depth and critical analysis on discourse related to globalization with lots of facets and again with a totally different set of terminology, he also presents negative examples of discourse: Objectivism treats globalization as simply objective fact, which discourse may either illuminate or obscure, represent or misrepresent. In the Churchman systems approach there is no such thing as an objective approach, rather it is *objectivation*. Ideologism focuses upon how particular discourses of globalization systematically contribute to the legitimation of a particular global order which incorporates asymmetrical relations of power such as those between and within countries.

Scoones et al. (Scoones, 2008) come to similar conclusions as the Churchman school, but this time related to agricultural policy: the paper explores the national and transnational character of mobilization against GM crops in India, South Africa and Brazil in the ten-year period to 2005. The paper argues for a better understanding of national political and economic contexts which must be taken into account, alongside on how the GM debates articulate with other foci for activism and the complex and often fragile nature of alliances that make up activist networks. It is important to understand that the debate about GM crops has become a much wider one: about the future of agriculture and small-scale farmers, about corporate control and property rights and about the rules of global trade see also the new report of the Royal Society (Royal-Society, 2009). In sum, a debate should not just focus on the pros and cons of a particular set of technologies – after all, they have proven safe, - it's more about politics and values and the future of agrarian society. Again we see the plea for the complexity of '*wicked problems*' to be solved.

The downside is that those planning processes of the second generation are time consuming and need a careful and tedious procedure in developing the most important and difficult *zero-step* – before such decision making can be started. It also implies an exchange of knowledge between the parties beforehand, in order to minimize *hidden agendas*. It also must be emphasized that those decision making processes do not lead necessarily to a pre-defined goal, they are often *open-ended* and demand flexibility among the discourse participants, who need to remain open-minded.

The more questions we are asking the more answers are possible and vice versa. Limitations of technological solutions are always hidden in the open ecological and social systems: Just compare the (in)famous case of DDT sprayings in the past (Tren & Bate, 2001; Weissmann, 2006; WHO, 2005). Today it is clear that with linear planning DDT has been banned for ecological and health reasons, not considering the wider argument field of malaria prophylaxes: This inconsiderate DDT ban has caused millions of malaria deaths in Africa. Today, reasonable domestic use of DDT has again lowered the malaria threat measurably.

Constraints in possible secondary effects in ecology should be examined carefully: This is well demonstrated in the case of the Monarch larvae being killed by Bt-Maize-Pollen, the result of a laboratory study published in Nature ( Losey, 1999) where the subsequent press interpretation got way out of proportion – even though the author Losey himself warned about the limitations of this small lab study. Would researchers have asked the farmers, they would have been able to say that feeding time of the young larvae do rarely overlap with the time of pollen shed of maize, and that the plants the Monarchs are feeding upon are fiercely fought as a weed. Subsequent field studies



revealed that there is no problem arising from extensive Bt maize planting for the monarch larvae (Gatehouse et al., 2002).

In order to tackle wicked problems you need to go through *an extensive process of argumentation*, also called objectification, not to be mixed up with an "objective approach" to the problem.

There is rational planning, but there is no way to start to be rational, one should always start a step earlier, since there are important trends and facts which will make straightforward rational thinking and acting in solving wicked problems useless. It is not the theory component, but rather the political component of the knowledge, which determines the vector of the action. This is the *zero-step* so important in the publications of Horst Rittel (Rith & Dubberly, 2007a; Rittel & Weber, 1973).

As an example: The fact, that experts can be wrong and farmers know better in certain situations in agriculture because they are better observers out in the field and because they are very experienced in traditional knowledge (Ammann, 2007c).

The knowledge needed in solving wicked planning problems is not concentrated in a single head. It is absolutely essential to let all partners be involved in the problem solution process, which includes part of the population (mainly farmers organisations and consumer organisations), the Governmental Regulators, the Non-Governmental Organisations, the Life Science Companies and the Scientists. There is no monopoly of knowledge. Having illustrated the difficulties in solving wicked problems, we need a new approach in problem solving, in order to avoid the pitfalls of ignoring bottom up feedbacks.

You only can keep to this rule if you are also following another important rule: All partners in the planning process have to avoid hidden agendas, which is certainly eased by a minimum amount of respect paid to each other partner. Nobody should be criticised for speaking up in his own interest.

A caveat: It would be naive to just believe in the discursive capacities of the civil society, on the contrary: as Gerhards (Gerhards, 1997) has shown, that Habermas' support for the discursive model is based on the assumption, that actors of the civil society argue much more discursive and on a higher level of rationality than other collective actors do. But empirical results show that actors of the civil society are maybe even less discursive than other actors.

It is primarily the paradox of rationality which has been severely underestimated in the systems approach of the first generation when tackling *wicked problems*.

### **8.3.2. How to Solve Wicked Problems in Biotechnology and the Environment**

What we need in such cases is an action oriented approach. Risk Assessment and Management must be seen as a planning strategy of the second generation in developing a professional framework for *decision making*.

Strategies have to be developed to recognise the consequences of our doing on one side, and to specify our knowledge on the other side. This knowledge has to be gained step by step and case by case: If we want to clearly distinguish our present state knowledge from appropriate decisions to be made *not* based on our views and opinions, we need to go through the following steps.

- What is the problem?
- What do we want?
- What are the alternatives?
- How do we compare them?
- How can we reach the solution?

All participants need to keep in mind that there are *various types of planning knowledge* (arranged according to the 5 questions asked above):

Examples given here are lumped together as simple keyword-illustrations, taken out of their context in real planning examples, they cannot be regarded as an example of a realistic situation, this would be exactly the task of a planning process of the second generation.

*Factual knowledge* is the knowledge of what actually happens (quantitative data or empirical, observational data). Gene flow species by species / region by region / facts about insect resistance in agriculture.

- *Deontic Knowledge*, the very important knowledge of what ought to be. The knowledge about new crops which enhance agricultural production / new agricultural techniques to avoid erosion / new biological approaches to fight insect pests etc.
- *Explanatory Knowledge* explains why things are so or why certain effects will happen. Here already you start to determine the direction of the solution. The way Bt proteins are acting on specific pest and beneficial insects / what are the main reasons of unwelcome erosion effects / mechanisms of vertical gene flow / mechanisms of resistance development.
- *Instrumental knowledge* on how to steer certain processes, on how to achieve certain goals, knowledge which needs to be balanced against regulation and safety. The way how to build Bt and other genes into crops and how to stabilise them / how to avoid vertical gene flow / how to avoid unwelcome soil erosion / how to avoid early upcoming pest resistance.
- *Conceptual knowledge* which would allow avoiding conflicts before they pop up. This is the knowledge about complex situations, taking into account all previous kinds of knowledge and also weighting them against arguments coming from open ecological and societal systems. Concepts about transgenic crops compatible to the ideas of a sustainable agriculture. Lawyers and judges also may work with this kind of procedural knowledge.

You need to go through an *extensive, time consuming process of argumentation*, also called objectification, not to be mixed up with an "objective approach" to the problem. The hopes of this process are:

- to forget less, to raise the right issue
- to look at the planning process as a sequence of events
- to stimulate doubt by raising questions, to avoid short-sighted explicitness
- to control the delegation of judgement: Experts have no absolute power, scientific knowledge is important, but always limited.

There is no such thing as 'scientific planning'.

- Solving practical problems as to develop sustainable transgenic crops cannot be dealt with by "scientification of planning". Dealing with wicked problems is always political because of its deontic premises (means that you have to involve knowledge what ought to be) and because

we deal with traditional knowledge. Science only generates factual, instrumental and in the best case explanatory knowledge.

- The planner (here the manager of an action plan) is not primarily an expert, but a "*mid-wife of problem solving*", a teacher more than a doctor. Moderate optimism and careful, seasoned disrespect, casting doubt is a virtue, not a disadvantage of an action plan manager.
- The planning process of wicked problems has to be understood as an *argumentative process*, it should be seen as a venture (or even adventure) within a conspiracy framework, where one cannot anticipate all the consequences of plans.
- Systems methods of the *second generation* are trying to make this deliberation explicit, to support it and to find means in order to make this process more powerful and to get it under better control *for all participants*. Methods like the computer based argument mapping systems of can be helpful (Conklin, 2003).
- It helps making such processes more successful, if they are conducted in the spirit of the *Symmetry of Ignorance* (Fischer, 2000) – this is the secret of the active listening which often leads to acceptable outcomes and trust.

This seems to be a rather theoretical approach with lots of restrictive rules, but actually it is on the contrary an opening for much more freedom in dialogue. Also it is more practical and efficient in creating results and contrasts with the traditional stakeholder concept where hidden agendas prevail in often disguised authoritarian structures. Such discursive processes are described in detail (Ammann, 2004; Ammann & Papazova Ammann, 2004; Rith & Dubberly, 2007a, b; Rith et al., 2007; Rittel, 1984; Rittel & Weber, 1973; Rittel & Webber, 2005; Schmidt et al., 2004). A comprehensive and voluminous monograph on risk related debate methods has been published by Ortwin Renn (Renn, 2008), see especially the texts related to risk communication with essays 7 and 8 and section 8 on risk participation with numerous references, but notably lacking completely the papers on the 'Systems Approach' of the Churchman/Rittel/Webber school.

In a French paper by Moirand (Moirand, 2003) the origin of negatively connoted words in the debate on GM crops like 'contamination', 'pollution', 'Frankenfood' etc. are clearly relating to negative events like BSE, dioxin scandals and of course Tchernobyl etc., thus explaining new words like 'mad soya' and 'mad colza' in the media. Moirand concludes that a new type of discourse is needed, but – as well as Renn (Renn, 2008) – does not refer to the very pragmatic and promising systems approach of Churchman and Rittel.

There are many more schools promoting discourse and new decision making processes, also in specialized journals, only a few can be summarized here for space reason: (Beer, 2004; Bogner, 2010; Bonfadelli et al., 2002; Chen, 1975; Chiapello & Fairclough, 2002; Clark, 2000; Fairclough, 2009; Feldman & Lowe, 2008; Galtung & Ruge, 1965; Gaskell et al., 2000; Huang & Newell, 2003; Irwin, 2006; Iyengar et al., 2009; Moirand, 2003; Motion & Leitch, 1996; Newman, 2003; Priest et al., 2003; Renn, 2006; Saner, 2007; Schuman & Presser, 1980; Vaughan, 1995; von Grebmer & Omamo, 2007).

More readings about communication schools are available in book publications: British views on science communication: (Bennet & Jenkins, 2011), German views by Renn: (Renn, 2008), Rittel (Rittel, 1992) and Protzen and Harris (Protzen & Harris, 2010), American views by Churchman: (Churchman, 1979) and a more general view on the history of talking Biotech by Osseweijer

(Osseweijer, 2006c). There are several books written on the history of communication, such as Poe: (Poe, 2010) and (Rogers, 2002).

### 8.3.3. More on successful discursive processes:

To be clear: there are probably hundreds of other approaches to solve debate problems, but they should be evaluated according to their professional and philosophical background – too many superficial methods, often combined with high costs and false promises, are ballyhooed, accompanied by rather cheap animation methods applied by mediators who have no clue about the contents and the history of the debate to be solved. A broad overview on discursive methods in Environmental debates is given by Ortwin Renn and his school (Renn et al., 1997) (still only a small selection, nota bene without a single mention of the American-German Churchman-Rittel School which is treated here in section 5).

Another promising view on discursive processes, nicely underpinned by philosophical preciseness, has been published by M. Calkins (Calkins, 2002). Calkins shows that with a thorough analysis of the arguments of proponents and opponents a first important step is made towards a more indepth mode of the debate. Although the proposals of combining casuistry with a virtue ethics remains still theoretical, the views could be adapted and included in the systems approach debates of the second generation in order to solve wicked problems (see previous sections).

But lets see what the systems approach (not always labeled this way in the below examples) might look like in the real world of discourse:

See Patrick Moore's practical examples of decision making processes solving environmental and sustainability problems in forestry, consult his own website Green Spirit <http://www.greenspirit.com/index.cfm>. These processes need time: Patrick Moore (Moore, 2000a, b; Moore, 2002b) has gone successfully through such processes in the difficult task of reconciliation between the needs of timber production and environmental constraint, he needed months of debate to come to reasonable decisions.

Another good example on how group discourses have good learning effects, has been described by Snyder et al. (Snyder et al., 2008): Although the U.S. government has assured stakeholders of their safety, the EU continues to be an outspoken opponent. This can largely be attributed to a lack of trust in the regulatory process, and especially a cynical perspective on the underlying science and institutions that govern approval. Such disparities were illustrated in 2003 when the United States donated GM maize to aid African countries stricken by famine. Under purported EU threats, negative propaganda by NGOs and stressing retaliatory trade sanctions, African officials refused the aid. An examination of this episode contrasts the potential discord between those affected and those who formulate government policy. Using resources from both sides of the debate, this scenario summarizes the pertinent issues regarding EU's refusal to the import of transgenic crops. A group discussion and debate protocol was developed for facilitating small group and entire class consideration of the scenario while strengthening student critical thinking skills.

It helps, if you prepare carefully scenarios before people start the process, a method which has been successfully applied to the reconciliation processes in South Africa after abolishing apartheid by Adam Kahane as one of the principal mediators (Kahane, 2004). He also followed another wise rule:

Should only people participate in such processes who are part of the problem. Another excellent example of long term discourse is described in many aspects by von Grebmer et al. (von Grebmer & Omamo, 2007):

*“By working collectively the process will be more open, transparent, inclusive and accountable, and sensitive to the normative dimensions of the issues critical to the participants. The themes and processes outlined in this article set the stage for the discussions, internally and between countries, that will shape the policies of agricultural biotechnology in the region. If the dialogue can frame the discussion and be enriched by the information generated from actions taken, it can sustain the interest and commitment of the stakeholders, and more successfully direct biotechnology toward reducing hunger and poverty in the region.”*

There are too many scientists remaining in the ivory tower, shying away from public debates. They fear to lose their independence, a fear which is not only unfounded, but actually it's the contrary: remaining in the academic ivory tower means having lost your independence, since science is not an art per se, its full of importance for society and humanity. A strong plea in this direction is coming from (Schenkel, 2010). Although science should remain at the heart of invention and the drive to make our lives better, scientists, instead of always having “the answers” ready, should not be afraid to engage in a contradictory evidence-based mode. A solution is offered by (Janssen et al., 2000) through a professional connection between university research and private sector companies.

In one of the most successful examples of long term discourse the author participated as an invited expert in a public hearing in 2000. Strikingly, it was done without the theoretical load described above, but with lots of financial and logistic help from the New Zealand Government, in particular from the Royal Commission on Genetic Modification. A report was finalized after a 14-month inquiry into the risks and benefits of genetic modification. It heard from over 400 experts, including scientists, environmentalists and ethical specialists. It considered more than 10,000 public submissions and heard the view of many others during a series of public meetings and workshops around New Zealand.

The Royal Commission's major conclusion was that New Zealand should proceed cautiously with genetic modification (GM) but not close the door to the opportunities offered by the new technology <http://www.mfe.govt.nz/issues/organisms/index.html> . Still, the discourse is continuing now: Again, it is visible that the discourse is less confrontational and may lead to innovative solutions in the future (Rogers-Hayden & Campbell, 2003):

*“The debate about genetic modification (GM) can be seen as characteristic of our time. Environmental groups, in challenging GM, are also challenging modernist faith in progress, and science and technology. In this paper we use the case of New Zealand's Royal Commission on Genetic Modification to explore the application of science discourses as used by environmental groups. We do this by situating the debate in the framework of modernity, discussing the use of science by environmental groups, and deconstructing the science discourses evident within environmental groups' submissions to the Commission. We find science being called into question by the very movement that has relied on it to fight environmental issues for many years. The environmental groups are challenging the traditional boundaries of science, for although they use science they also present it as a culturally embedded activity with no greater epistemological authority than other knowledge systems. Their discourses, like that of the other main actors in the GM debate, are thus part of the constant re-negotiation of the cultural construct of 'science'.” (Rogers-Hayden & Campbell, 2003)*

(Motion & Doolin, 2007) describe with accuracy the discursive dynamics about the Royal Commission GMO debate, not sparing critical remarks for both parties – for more comments see section 5.3.3.1.

However, this process should not be mollified on the expense of hard science. The line between science and pseudo-science is often difficult to draw.

Finally, an extensive thesis paper of 578 pages on the regulation history of Australia should be mentioned here, it is also full of refreshing, independent views, the weak part is on how biosafety of GM crops is perceived, it is lacking scientific scrutiny of important peer reviewed publications (Gogarty, 2005). The whole detailed description of gene technology and its regulation, including the debate between opponents and proponents, is strictly focusing on the process oriented view of transgenesis, no word of the Canadian-US-view on product oriented regulation, including the fact, that natural mutation and transgenesis are based on the same molecular processes, see the section 2.4 about the ‘Genomic Misconception’.

#### 8.4. How to take science to the people, how to take people to science?

Although this is not the main thrust of the paper, it is important to consider science communication in the broad sense of taking science to the people, those who have in the majority no education in science, and for sure not in the complex matters of molecular sciences. It is of utmost importance to bridge the gap with all kinds of strategies and methods.

This review concentrates mainly on the debate within science and their professional opponents, but it is impossible to keep the debate restricted to those players, since they all try to influence public opinion – and – they are themselves (hopefully...) influenced by the public opinion in all aspects.

The importance of the topic is demonstrated alone by the literature inquiry in the Web of Science: under the keyword combination of “science communication” some 55’000 items are popping up, reduced to reviews (5000 references) and further on to agriculture – only a few, a bit more on biotechnology. Some examples of publications worthy to be read, such as new efforts to explain the genetic code as suggested by (Nelkin, 2001).

(Sinemus & Egelhofer, 2007) state clearly, that the deficit model does not work alone: As long as scientists take to heart the statement of Loren Eiseley: *“It is frequently the tragedy of the great artist, as it is of the great scientist, that he frightens the ordinary man.”*

*“What makes it difficult is not only the complexity of innovative technologies, but equally the need to communicate them efficiently to lay people. The journalist’s role is to be a mediator between the public and the scientific community, trying to inform the public about scientific “news” in a comprehensible manner. Reality, however, often looks different. Journalists often are unable to clearly understand how “science” works. By the same token, scientists frequently struggle to communicate clearly in a manner that is accurate, but also positive, exciting and fascinating to journalists and lay people alike. Scientists lack the experience and knowledge of media’s basic rules, language, timing, and priorities. In a worst-case scenario, unfounded scares and concerns result in the general public, especially when it comes to hotly debated innovations such as in agricultural biotechnology. Therefore, science cannot rely on or appeal to, journalists’ understanding. In contrary, researchers should become more proactive, engage in public discussions and learn how to deal with the media.”(Sinemus & Egelhofer, 2007)*

New attendance and focus on science communication is often triggered by remarkable, catastrophic events such as the nuclear accident at Chernobyl in 1987. The dispute between scientists from the nuclear industry, the press and the public is extensively reviewed by (Gamson & Modigliani, 1989). Their conclusions are also meaningful for the biotechnology debate:

**Conclusion** — *We live in an era where most policy debates relevant to science and emerging technologies are not simply technical issues. Rather, they are collectively decided at the intersection of politics, values, and expert knowledge. Under these conditions, sophisticated public outreach and engagement are essential to overcoming perceptual gridlock on climate change, for encouraging public acceptance of the teaching of evolution in schools, for meaningfully involving the public in societal decisions about plant biotechnology and nanotechnology, or for effectively engaging with stakeholders and a wider public on almost any issue.*

*Yet public communication and engagement should not be conceived of as simply a way to “sell” the public on the importance of science or to persuade the public to view scientific debates as scientists and their allies do. To apply sophisticated approaches such as framing or deliberative forums to achieve these ends falls back into the trap of deficit model thinking and undermines longer term efforts at building trust, relationships, and participation across segments of the public. (Gamson & Modigliani, 1989)*

Frank Burnet, emeritus Prof. from Bristol, who left the university ivory tower to become a professional communicator, delivers the most important lesson, namely that its your *personality*, your own thoughts honestly conveyed which are in all kinds of circumstances creating the most powerful messages to the people, it is suggested to visit the very informative website [www.frankburnet.com](http://www.frankburnet.com) .

*“The overall picture, therefore, is that there are many publics and their attitudes to science and technology are subtle and complex. A very significant percent combine being both fascinated by scientific phenomena and the natural world with considerable distrust of the motives of scientists. It does not appear to be the case that greater knowledge of science equates to increases public sympathy for science and scientists as was pointed out by Jon Turney in “To know science is to love it” and little evidence to suggest that knowing the science behind say genetic engineering, re-assures the public that it will be responsibly applied in society.*

*Given what is now known it could be seen as surprising that a very substantial amount of the effort to communicate science is still focused on convincing people that science is amazing, something which the great majority already believe. However, the fact that so much of the communicating is done by Universities as part of recruitment activity may go some way to explaining this apparent paradox.” (Burnet, 2010)*

Frank Burnet promotes in a very convincing way an informal learning scheme which is elegantly adaptive to the complex, ever changing situations with different learning topics opposed to highly diverse publics:

**The aim therefore is according to Frank Burnet (and many others) to move away from one way communication models and use two way models that reduce or eliminate the extent to which there is a sender and receiver relationship between the scientific community and the public.**

For both communication models there is an oft quoted Chinese proverb that neatly sums up the relative effectiveness of different approaches to getting people to learn, it is:

- I hear – I forget
- I see – I remember
- I do – I understand

The school of Churchman-Rittel (see section 5) is actually taking up the communication tactics of Burnet, but using a different set of words with often very similar meaning (there are hundreds of communication schools, many use totally different sets of wordings, but with a high degree of overlapping meanings. The structure of discourse described in section 5 is, also according to their proponents Churchman and Rittel not a recipe with fixed advice, it is on the contrary an openminded system, giving room to all the so successful spontaneity and genuinity of the approaches described by Frank Burnet (and certainly many other gifted communicators on the scene).

Sections 4.4 and 5 should not be misunderstood as a description of strict rules to be followed, so to say for a guarantee of communication success. Clearly there are multiple possibilities which lead to success – unfortunately there are also many possibilities which lead to major communicative mishaps or even disasters.



A final word from Nick Brown et al., (Brown & Michael, 2001) should be addressed to the scientists:

*“The root of the problem is not the public’s trust in science but science’s trust in the public. Every practising scientist knows and appreciates the uncertainties in which ‘facts’ are steeped – that facts are limited, provisional, revisable and unlikely to remain cocooned in certainty for very long. However, there has been a pervasive institutional ethos that this uncertainty should not be revealed to ‘outsiders’. Indeed, it takes great courage to believe that such uncertainties would not damage science if made public. Moreover, it would take a vault of spectacular dimensions to imagine that science might, in fact, benefit if its uncertainties were laid bare to public scrutiny on a more transparent basis.” (Brown & Michael, 2001)*

## 9. Remarks about the Psychology, Spirituality and General Philosophy of the GMO Debate

Clearly, we need a thorough reshuffling of our basic principles in how to solve wicked problems, as described in section 8. The disadvantage of the discursive strategy in solving wicked problems is that you need to go through an extremely difficult zero phase in building up consortium structures of people willing to come to solutions in an open end manner instead of fighting each-other.

The problems of this zero phase cannot be underestimated, as already stated earlier:

*There is rational planning, but there is no way to start to be rational, one should always start a step earlier, since there are important trends and facts which will make straightforward rational thinking and acting in solving wicked problems useless. It is not the theory component, but rather the political component of the knowledge, which determines the vector of the action. This is the zero-step so important in the publications of Horst Rittel (Rith & Dubberly, 2007a; Rittel & Weber, 1973).*

But there are more debate elements, which can be only summarily addressed here: We need to incorporate more basic understandings of debate processes *and* world views. A short, by far not comprehensive enumeration of such viewpoints is given here. They can cover large sections of science activities (often denied or ignored by hardliners of fact-believing researchers and fundamentalist opponents). The whole field of evaluating psychosocial and cultural factors affecting the perceived risk is rather complex, and there are only a minority of publications covering in a balanced way the hard facts of natural sciences and the data on psychosocial and cultural factors. There are a multitude of surveys like Finucane & Holup (Finucane & Holup, 2005), dealing comprehensively with psychosocial and cultural factors, but treating negligently the natural science part of risk factors on the natural science side. On the other side, there are publications like Kvakkestad et al. (Kvakkestad et al., 2007) promoting the scientists view on the public debate on GM crops by organizing polls with metric data, suggesting that the hard science should be restructured in order to include public views on controversial technologies, but this has been proven impossible with the examples of the citizens conferences on genetic engineering, leading to no solutions with a few exceptions. Many books have been written on this topic of section 6 - here only a few important elements of the public debates – apart from the usual battle on facts described earlier in this contribution:

### 9.1. Moral Self Licencing

(Merritt et al., 2010) describe with accuracy, how psychological processes can lead over moral self licensing to freeing persons to be bad, with the original intention to be good. Indeed, past good deeds can liberate individuals to engage in behaviors that are immoral, unethical, or otherwise problematic – even to adopt violent action, behaviors that they would otherwise avoid for fear of feeling or appearing immoral.

According to Miller & Effron 2010 (Miller & Effron, 2010) licensing feelings can liberate people to express morally problematic attitudes that those who do not feel licensed are inhibited from expressing. The field of moral self licensing has been often researched, as can be seen in the pertinent literature lists of (Merritt et al., 2010; Miller & Effron, 2010; Monin & Miller, 2001). According to Monin et. Al. 2001 (Monin & Miller, 2001) p. 33, the desire to avoid being prejudiced does not manifest itself only in the hesitancy to express non-egalitarian attitudes. Sometimes it can actually lead to the granting of preferential treatment to minority members. This so-called reverse

discrimination occurs when actors fear that treating a minority member as they would a majority member could be attributed to prejudice. Although the author sees good potential in research on moral self licensing in the difficult field of the GM crop debate with all its regionally differentiated minorities and majorities, the case needs to be explored along those lines first.

But Moral Self Licensing is not confined to the domain of prejudice. Jordan et al. 2011 (Jordan et al., 2011) investigated the licensing effects of helpful behavior. This licensing effect seems not to be driven by simply feeling proud of one-self: writing about a past accomplishment did not affect participants' intentions to help.

(Motion & Doolin, 2007) describe with accuracy the discursive dynamics about the Royal Commission GMO debate, not sparing critical remarks for both contrahents – for more comments see section 4.1.

*“This article analyses the discursive practices of scientists engaged in controversial science in their narrated accounts of encounters with activists. It explores what happens when scientific credibility and authority are challenged in a public debate on the benefits and risks of such science. The aim is to understand how scientists discursively negotiate and make sense of their encounters with activists, the range of subject positions they claim, and how power is implicated in identification with the public. The article shows how scientists counter emotional appeals, utilizing both scientific and public identities respectively to legitimate the epistemic and moral authority of science and to marginalize opposing activists. It is argued that a unitary view of scientific identity is inadequate. Rather, in times of public challenge and controversy, scientists may utilize a multiplicity of subject positions to achieve identification with public interests. The discursive construct, public interest, is interpreted as a contested discursive space and a discursive resource for influencing public opinion.”*

However, this kind of multiplicity of subject positions (which acts like an antidote to exaggerated moral self licensing) should also be respected by the activists. The most successful activist organizations like Greenpeace and Friends of the Earth rather follow a very successful policy of influencing the public through feeding press agencies with filtered information of flawed pseudoscience and sometimes even with straightforward untruthful information, only to mention the propaganda hoax placed for years on their website: that a single person needs up to 9kg of Golden Rice to fulfill the daily needs of Vitamin A supply, whereas it is clear for a long time that 50g to be cooked are enough. On a more subtle way, false argumentation is often blaming negative effects to the transgenes of modern crops, whereas in most cases it is the wrong agricultural management to be blamed. Here just one example: the one-sided paper of Taube (Taube et al., 2011) which criticizes the report of the “Deutsche Forschungsgemeinschaft” (Broer et al., 2009) as being much too positive about GM crops, but making the mistake of focussing on transgenes when discussing negative environmental effects of GM crops. This wrong perspective has been successfully rebutted by Broer (Broer et al., 2011). Actually, the thinking of Taube et al. reminds of moral self licensing, since those authors are relating negative effects in agriculture to transgenesis without any hesitation and reflection.

The phenomenon of moral self licensing can also lead to violent behavior, as it is emerging in a growing number of field destructions, especially in Europe, details see in section 4.1.

An interesting view on ethics in science is given by (Johnson, 2010): Anticipatory ethics as a new approach that integrates ethics into technological development.

Still, it is not done with criticizing a one sided technology-acceptance view without respecting the economic facts as done by (Jansen & Gupta, 2009). The reality calls for an integration of all realms of knowledge, combining modern technology with the good side of participative breeding (with its parallel learning processes in science and traditional knowledge (Millstone et al., 2010; Slingerland et

al., 2006)) including a well documented critique on exaggerated risk assessment legislation (Peng, 2011).

Moral rebels can be found in both here described discursive parties, those supporting modern agrobiotechnology and those opposing it, and both are at risk of being rejected (Monin et al., 2008) by various parties and factions.

## 9.2. Framing processes, social movements and epistemic brokers

As a conceptual term, “frames” are interpretative storylines that communicate what is at stake in a societal debate and why the issue matters

Within sociology, not only has the framing concept been applied most extensively to the substantive study of social movements and collective action, but according to Benford et al. 2000 (Benford & Snow, 2000) the interest in framing processes in relation to the operation of social movements has animated an increasing amount of conceptual and empirical scholarship resulting into an extensive literature. Combined keywords framing and discourse yield nearly 2500 references in the Web of Sciences. Framing topics can be found in all fields of conflict, they develop in a variety of processes, including discursive internal and external dynamics.

Ron Herring in his thoughtful analysis of the GM crop battle pointed to the framing processes within social movements dealing with issues in biotechnology as a main psycho-social process: (Herring, 2008a):

*“Social framing of transgenic crops as ‘unnatural’ and ‘anti-developmental’ has obscured variations that matter biologically. Regardless of trait, genetic event or cultivar, all products of agricultural rDNA technology have been lumped together in one ominous category: GMOs. GMOs in turn were framed as incompatible with other plausible frames — sustainability and development. The diagnostic element of this frame identified special dangers from novel organisms: the biosafety problem. Prognostic framing put bioproperty at odds with the science of assessing the safety of new technologies: potential threats could not be authoritatively evaluated because multinational corporations had strong proprietary interests in the results of trials. Because testing was done under corporate auspices, the science could not be trusted. Furthermore, bioproperty would permit multinational firms to control the world food supply, and to dominate and exploit farmers through patents and, most alarmingly, ‘terminator technology’ — gene use restriction technology (GURT) — that, in theory, renders transgenic plants sterile<sup>32</sup>. The motivational frame follows logically: caring for personal safety, for powerless victims of exploitation in the third world and for ecological integrity all necessitate opposition to GMOs, perhaps even militancy. (Herring, 2008a)*

Especially in Europe the unfortunate authoritative and negativistic cementing (framing) of the GMO was successful, and parallel to it the UN Cartagena Protocol was taken hostage by transnational activists right from the beginning, and, as demonstrated in section 2.4 on the ‘Genomic Misconception’, negative framing created scientifically unjustified adverse biosafety policy outcomes, resulting into various political dynamics such as eco-imperialist attitudes of Europe against many countries of the developing world. Amazingly enough the opposition activism succeeded in achieving a bifurcation between food and other applications: It was not in their (own) interest to mobilize opposition against drugs that often involve rDNA technology. Even global trade has not been segregated around GM drugs, although the use of rDNA technology is common in pharmaceuticals, and indeed is much supported by public opinion in Europe (Gaskell George et al., 2006).

One of the main triggering elements to turn around the GM crop and food debate to the negative has been the virtual terminator gene issue with the typical distortion of the science behind it. There are only a few rare original publications available for the patented idea by the main inventor Mel Oliver: (Norsworthy & Oliver, 2001; Oliver, 2002; Oliver et al., 2004; Oliver et al., 1998, 1999; Oliver & Velten, 2001). In clearly exaggerated concerns lacking molecular and ecological knowledge, the

technology was shunned (Shand, 2002) with weak arguments. The RAFI campaign was initially very successful and Monsanto was impressed by the huge potential negative impact of this so successful negative framing and wrote in a letter to the Rockefeller foundation (Shapiro, 1999) pledging not to develop the terminator technology further on, for which they acquired the patents through a finally approved purchase of Delta Pine Land (Falck-Zepeda et al., 2000).

The terminator hysteria is a classic case of framing the technology exclusively to the potential difficulties of monopolizing seed production, a truly artificial problem which can be avoided with a few simple measures. Indeed, the RAFI campaign starting in a now defunct website in Canada, was very successful particularly in India by channeling the thoughts to a negative image of the technology:

The operation “Cremate Monsanto” combined anti-corporate arguments in a clever way with the sad tradition of Indian farmers suicides, but was finally unsuccessful because thousands of farmers adopted the Bt technology by massive illegal regrowing and breeding of Bt cotton seeds in the “cottage campaign”, see many details in (Herring, 2006). The latest publication of Gruère et al. (Gruere & Sengupta, 2011) debunks the connection between GM crops and farmers suicides for good. Even today (2011) the terminator gene scare pops up regularly in public debates, promoted by activists as a killer argument, although there is not as single crop existing in research greenhouses or in production fields with this original technology. It does not hinder until today the Indian Activist Vandana Shiva from still spreading the old propaganda slogans: (Shiva, 2004), see also the Barilla webinars from July 2011 (Shiva, 20110720) and (Ammann, 20111111). Actually, some aspects of the technology “control of plant gene expression” invented by Oliver et al. (see above) can be seen very positively since they offer possibilities to control gene flow.

Still, already in 1999 Ismail Serageldin (Serageldin, 1999) called for a more reasonable view on terminator technologies, which could well have a future in agriculture:

*“Take the so-called Terminator Gene Technology. The Consultative Group on International Agricultural Research (CGIAR), which sponsors a global network of 16 international agricultural research centers, has announced that it will not release any germplasm that contains technologies that would prevent smallholder farmers from holding and replanting seeds (21). Instead, CGIAR centers are pursuing the apomictic gene to assist smallholders to replant hybrid varieties (22). But it is legitimate to study the sophisticated terminator technology, and learn from it, or seek out possible benign applications, such as a platform that would bond novel transgenes in desirable varieties, preventing their escape through unwanted gene flow.” (Serageldin, 1999)*

The term “epistemic brokers” coined by Ron Herring (Herring, 2010) can be used for activists who professionally continue the framing processes with public relation means – the summary of his paper, produced from his presentation at the conference on invitation of the Vatican Academy of Sciences in 2009, the summary does not need further comment:

“Unlike some global contentions – abolition of slavery, or universal franchise, for example – the rift over rDNA crops is not about ultimate values. Improvement of farmer welfare and enhanced sustainability of agriculture are universally valued goals. However, means to those ends are politically disputed; that dispute depends on alternative empirical stories about biotechnology, sometimes even alternative epistemologies. Opposition revolves around two fundamental dimensions: bio-safety and bio-property. There is convergence of these dimensions around exceptional risk and vulnerability to corporate control of farmers, but these are analytically separable questions of fact. This paper concentrates on bioproperty. Epistemic brokers have successfully established knowledge claims that simultaneously undermine the case for rDNA technologies as potential contributors to development and motivate opposition. **Epistemic brokers command authority from their positions at junctures of networks, enabling the screening, weighting, theorizing and diffusion of contentious empirical accounts. In contentions of low information, high information costs and diffuse anxiety, these claims provide cognitive support for opposition to ‘GMOs’.** Specifically, claims of patents, monopoly corporate control and terminator technology have diffused to and from India in global networks. Though effective in transnational advocacy networks, these claims have proved either false or inconsistent with dynamics on the ground.” (Herring, 2010)

### 9.3. The science of fear

In a comprehensive book Gardner is giving a review of the topic (Gardner, 2008, 2009) the author explains, why we fear things we shouldn't and put ourselves in greater danger. Fear is of course a big topic in psychology, just a few points helping reflection: A source of learnful citations is Michel de Montaigne (Montaigne & Frame, 1958):

*"I fear nothing more than fear", and:*

*"There is no other [passion] whatever, which carries our judgment away sooner from its proper seat" (qu'il n'en est aucune, qui emporte plustost nostre jugement hors de sa deue assiete)" (Montaigne & Frame, 1958)*

And Montaigne cites Ennius through Cicero:

*"Then fear drives out all wisdom from my mind"*

The chapter on the chemistry of fear is the most interesting one of the book for our purpose: A differentiated, but critical view on the seminal book of Rachel Carson brings more balance in the debate on toxicology, human medicine and agriculture. The global ban on DDT is criticized, more about the DDT story in section 5.3.1.

A great majority of people do not know that any plant in nature contains hundreds of cancer causing chemicals, and it's the old rule of the Bernese medic Paracelsus about the dosage which decides on alarming toxicity levels. As Gardner rightly states:

*"Unfortunately, there are lots of activists, politicians and corporations who are not nearly as interested in persuing rational risk regulations as they are in scaring people. Even more unfortunate, Gut will often decide with the alarmists. That's particularly true in the case of chemicals thanks to a combination of Gut's intuitive toxicology and the negative reputation have in the culture." (Gardner, 2008, 2009)*

You have only to replace "chemicals" by "GM crops" to come back to the point of our section.

### 9.4. Semiotic views on Nature

Semiotics is not purely a matter of philosophical and scientific theorization (Bouissac, 2011). It is also a culture of inquiry, exploration, and discovery. It is a state of mind which prompts us to question what we take for granted, to break away from disciplinary fences, and to connect dots which had seemed so far unbridgeable. In real life there is no experience of space (or nature) that cannot be described as a feeling: familiarity, boredom, arousal, anxiety, and many other kinds of fleeting affective moments. Space (or nature) is indeed primarily subjective. It takes some intellectual effort to construct a detached approach to nature.

In a broad overview, researchers from New Zealand have, based on a broad survey, summarized among many other topics the semiotic relationship between the term Nature and how people understand it and how this does reflect on their view about biotechnology (Coyle et al., 2003). Their conclusion:

*"We argued in this chapter that the acceptance/rejection of new biotechnologies is highly dependent on the way we perceive nature, the way we understand our place in nature, and how these impact upon the way people draw the boundaries between what is natural and unnatural. Whilst there are many competing and complimentary versions of nature, a fairly consistent view was that natural spoke of things that are unmodified, unchanged. That natural predates sprays and chemicals, hence existing in a space-time of the traditional. Yet, whilst nature is increasingly seen as a dynamic, complex ecosystem, this perspective somehow conflicts with the idea of traditional nature." (Coyle et al., 2003)*

and

*“The boundaries participants drew between what was natural and unnatural were not necessarily in the same place as their peers.*

*These boundaries were far from absolute and were dependent on differing conceptions of just what nature was. Nature was a multifaceted construction, with overlapping meanings that were used in different contexts. “ (Coyle et al., 2003)*

The consequences from this small semiotic excursion: the debate on genetic modification has truly many facets in the popular views.

This semiotic perspectives (there would be many more of this kind) might help to understand the European impasse in GM crop regulation Helge Torgersen (Torgersen, 2004) is complaining about:

*“... risk and its perception is a social phenomenon rather than a scientifically determinable factor”*

A final word comes from Leonardo da Vinci, it is appropriate here, and there is some logic in this: Leonardo da Vinci was also the first European thinker who has also merits for his discovery of the real age of the earth and thus the future Darwinian evolution view through his vast knowledge in geology:

**“Although nature commences with reason and ends in experience it is necessary for us to do the opposite, that is to commence with experience and from this to proceed to investigate the reason”.**

Leonardo da Vinci

## 9.5. Science, Ethics, Moral, Religion and Spirituality

There have been published recently many books and papers on Ethics of Science and also the Ethics of Corporations, this is hardly the space to give a comprehensive summary. Dealing with the debate on GM crops and biotechnology, we focus on a few selected topics:

### 9.5.1. Corporate Ethics

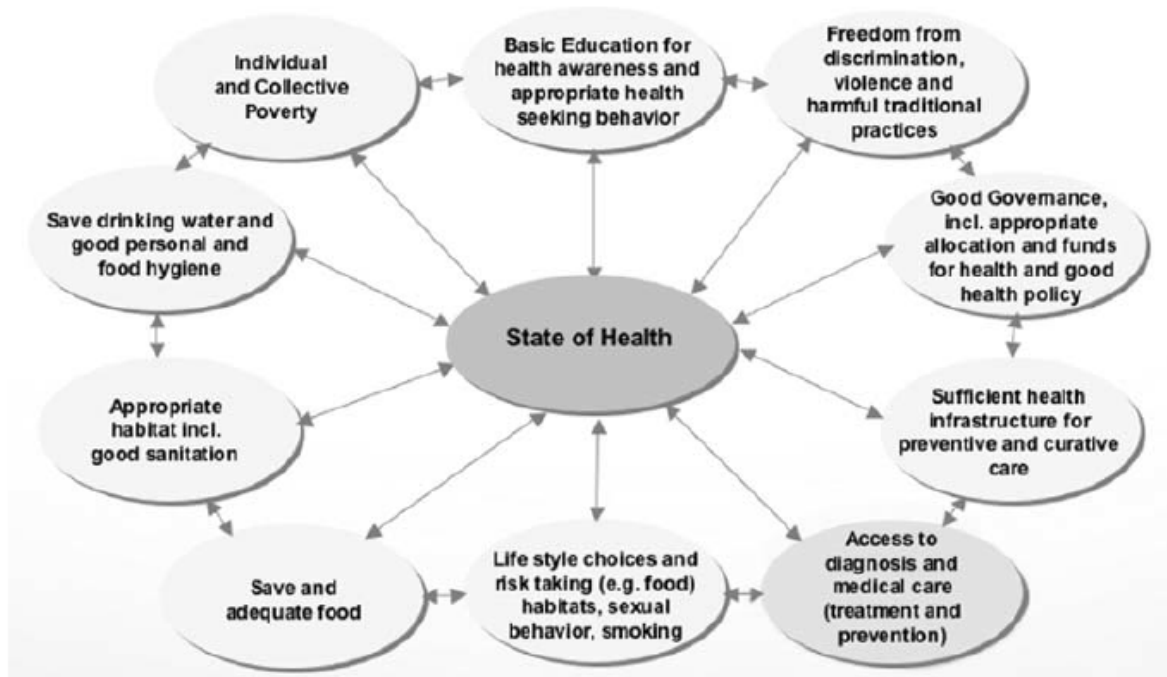
A broad overview on corporate ethics – although in the field of pharmaceuticals – but with obvious parallels to agrobiotechnology has been published by Klaus Leisinger from the Novartis Foundation: (Leisinger Klaus, 2009), instead of giving a written comment, the following figure 19 below tells properly the story on the complexity of the case.

In 1993, the Parliament of the World’s Religions in Chicago adopted the World Ethos Declaration (Kueng Hans & Kuschel Karl-Josef, 1993), drafted by the Swiss theologian Hans Küng. The Declaration identified four ethical principles that are shared across all cultures and religions: Non-violence and respect for life; justice and solidarity; tolerance and truthfulness; finally equal rights and partnership between men and women.

16 years later and in the midst of a global economic crisis, a manifesto has been published which is based on the World Ethos Declaration (Kueng Hans & Kuschel Karl-Josef, 1993) but adapted to the economic sphere (Kueng Hans et al., 2009). The main authors were Hans Küng and Josef Wieland, a business ethicist; the Novartis Foundation was involved through Klaus M. Leisinger as a peer reviewer and commentator. The Global Business Ethos Declaration outlines five universally acceptable principles and values: humanity; non-violence and respect for life; justice and solidarity; honesty and tolerance; and mutual esteem and partnership.



## Poverty and Health: A Vicious Circle



Novartis Foundation for Sustainable Development

Fig. 28 The mere perception of disease – its acceptance or non-acceptance – and the eventual demand for traditional or modern health services place the world’s poor at a further disadvantage. In a disease-ridden social environment, poverty-related illness becomes a ‘normal’ part of everyday reality and rarely results in demand for appropriate health services – even where available. Last but not least gender discrimination can pose life-threatening obstacles for seeking appropriate healthcare. And yet, as poor health is not only a consequence of poverty but also a cause, the poorest would benefit most from health improvements: an individual’s state of health determines their ability to work, his or her labor productivity, and therefore earnings. And income level determines almost all other elements of living standard.<sup>31</sup> For poor people, the health of their body and mind is a critically important asset – often their only asset. And vice versa: People’s abilities to manage their own lives, to develop their assets, and to learn and make use of their skills and knowledge all depend heavily on their state of health.

Just add to fig. 19 hunger to the word illness and food to medicine, and you will arrive to an appropriate scheme for any seed corporation with a few more amendments.

In an interesting paper (Meghani & Kuzma, 2011) address the often encountered phenomenon of the “*revolving doors*”: Often, at the end of their industry tenure, key industry personnel seek employment in government regulatory entities and vice versa. This could a) adversely impact the confidence of the public, b) this may result into policy decisions in favour of the industry and c) it virtually guarantees the industry a voice in the policy making process although other stakeholders may not enjoy the same important influence. On the other hand, the authors see predominantly the positive side of this situation:

The review process lacks credibility because, at the very least, it is procedurally biased in favor of industry interests. The authors argue realistically, that prohibiting the flow of personnel between regulatory agencies and industry would not be a satisfactory solution to the three problems of public trust and just representation. To address them, regulatory entities must reject the traditional notion of objectivity. Instead they should adopt the conception of objectivity developed by Sandra Harding (Harding, 2003, 2004) and re-configure their regulatory review on the basis of it. That will ensure that

a heterogeneous group of stakeholders is at the decision-making table. The fair representation of interests of different constituencies in the review process could do much to inspire warranted public confidence in regulatory protocols and decisions. This is, obviously without that the authors are aware, a perfectly matching plea for a professional discursive procedure as suggested by the author extensively in section 5 with numerous literature references. See specifically the remarks about the rationale of discursive processes and objectivation in section 5.3.1.

Nevertheless, this does not hinder fundamentalists to launch petitions addressed to President Obama such as ‘Cease FDA ties to Monsanto’, (Flock Elisabeth, 20120130) with the usual polemic arguments: When Taylor’s appointment (formerly Monsanto) to the FDA was announced, it was criticized by consumers and consumer advocates across the U.S. One such critical consumer advocate, Jeffrey Smith, who campaigns against genetically modified foods, wrote on his blog at the time: “The person who may be responsible for more food-related illness and death than anyone in history has just been made the US food safety czar. This is no joke.”. Indeed, this is no joke, because what Jeffrey Smith is always doing – by actually combining in the usual way baseless accusations related to the safety of GM crops with the argument of the revolving doors. About the low quality of Jeffrey Smith’s pseudo-scientific arguments against GM crops just go to <http://www.academicsreview.org> and read the extensive rebuttals.

Reconciliation of the conflict between opponents and the corporations is possible, but needs professional methods such as the discursive approaches described here in section 5.

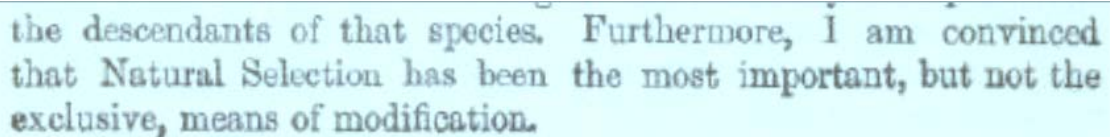
### **9.5.2. Emotional Consciousness, Neo-Darwinism, a new moral landscape and beyond.**

The neural model on how cognitive appraisal and somatic perception interact to produce qualitative experience (D’Esposito, 2007) should be supported, since ignoring scientifically informed philosophical reflection leads not only to bad philosophy but also to bad science. In another paper, (Thagard & Aubie, 2008). Thagard et al. analyze emotional consciousness and bring it into the neural model of how cognitive appraisal and somatic perception interact to produce qualitative experience: They combine in an “Emocon Model” all the aspects of emotion and consciousness. It includes neural representations of the world, of the body, and of other neural representations. It has all the most important brain areas known to be involved in positive and negative bodily responses to stimuli, and also includes the dorsolateral prefrontal cortex which is capable of complex inferences about the social significance of a wide range of information. The authors see emotion not just a perception of bodily states, nor just as a cognitive appraisal of one’s overall situation. Rather, an emotion is a pattern of neural activity in the whole neural system, including inputs from bodily states and external senses. Thus, the “Emocon Model” shows how to combine somatic perception and cognitive appraisal into a single system that transcends the century-old conflict between physiological and cognitive theories of emotions.

However, this does not imply that we can reduce all the processes leading to knowledge, opinions and emotions simply to neural and biological mechanisms, since the result of decades and centuries of knowledge production is involved in a highly complex process producing culture in time and space.

It is also not done with introducing biologicistic and neo-positivist views on knowledge production as Dawkins et al. are doing: No doubt Darwin provided a thrilling and (nearly) complete explanation of his bottom-up evolutionary scientific world view, and maybe it is correct or at least a good approximation to say with Dawkins that “Darwin made it possible to be an intellectually fulfilled atheist” (Dawkins, 1986). Dawkins followed the path of many atheists and involved Darwinian

evolutionary vision and tried to give proof, based on Darwin's precise observational evidence and including also an enormous amount on molecular evidence, that there is no need for God. As a consequence, he made a plea to get rid of religion as a whole and some of his predecessors and followers like (Huxley Thomas Henry, 2004) to cast spirituality altogether. Also Dawkins introduced his evolutionary view about the world without design and replaced culture in all its aspects from art to history with a poorly defined term *mnem* in order to comply better with a living world structure steered solely by molecules (Dawkins, 1996, 2006) and (Dawkins, 1976, 2006). Neo-Positivism or logical positivism came in again with Richard Dawkins (Dawkins Richard & McKean Dave, 2011), Sam Harris (Harris Sam, 2005) and Michael Shermer (Shermer, 2011a, b) and many more. Darwin himself is narrowed down by them to a 'Darwinist' – most conspicuously by Thomas Henry Huxley (Huxley Thomas Henry, 2004), a process pupils apply with more orthodoxy to their own masters, although often the master himself had a broader view (on evolution), (Ammann, 20091115). Indeed, it was Darwin himself who amended the introduction of his 6<sup>th</sup> edition of the *Origin of Species* in a very significant way: He distanced himself from being narrowed down to "variation" (which is the modern mutation) and "selection" with the very last sentence of the introduction p.4 (the last one he edited himself before he died).



the descendants of that species. Furthermore, I am convinced that Natural Selection has been the most important, but not the exclusive, means of modification.

Fig. 29 From Darwin, *Origin of Species*, 6<sup>th</sup> edition with additions, corrections 1876 (Darwin, 1876), last sentence of Introduction

It is true, that Sam Harris in his recent book on moral landscapes (Harris, 2010) makes impressive pleas to give science a better chance to talk about moral, in order to help to avoid the many negative outcomes of un-reflected progress, or to fall into the trap of moral self-licensing. Sam Harris tells us in an impressive way, that morality, like rationality implies the existence of certain norms, that is, morality does not merely describe how we tend to think and behave; it tells us how we *should* think and behave. It may well be time to reconsider an old principle, namely that human knowledge and human values can always be kept apart. We need to invent new concepts and combine science and morality as Harris suggests.

A final remark: the abyss and philosophical chaos of the debate on *creationism* is left out here, since it refers to a small minority of fanatics and pseudo-orthodox people (Arda, 2009; Shostak S. (rev) and Isaak Mark, 2008 and 2004; Yahya, 2001) – and yes – deplorably, those narrow minded people refer notoriously and literally to religion, the Bible, the Koran, both wonderful historic and philosophic accounts which are deplorably also full of 'unbelievably' violent stories and arcane advise, but which should not be understood as the truth word by word, but rather seen in their historical *and* regional context. Here just the latest abominable example from the USA: (Grant Rob, 20120127): 6 of 8 Senators voted for the introduction of creationism as a topic in the school lessons, obviously a cheap move to get re-elected.

For our topic here, it is important to acknowledge that the risk-benefit debate on genetic engineered crops it is based on a pattern of neural activity in the whole neural system, including inputs from bodily states and external senses. Many of us are working on a highly complex cultural network in time and space with all its uncalculable elements as emotions, art, trends, etc. Finally, the author

agrees to the widespread view of an ‘Einsteinian religion’ (Ravichandran & Dawkins, 2006) of the great and eternal ‘Unknown’ and thus can also see the ramifications into spirituality and religion in all its diversity. The combination of rational perception and spiritual world also opens the perspective that religion and spirituality can be reconciled with modern science, hence religion and spirituality do not a priori contradict modern breeding in agriculture. (H.H. Dalai Lama & Norman Alexander, 2011; Kueng Hans, 1998). It is also important and maybe surprising to many readers, that the present day church organizations with a worldwide span often have a positive relationship built on solid theological advice with modern biotechnology, see the following sections 6.5.3 to 6.5.6.

Let us finish with a famous proverb of Einstein, which is wrongly abbreviated to “science without religion is lame, religion with out science is blind”, rather the following paragraph from Einstein 1954 needs to be read in full context (Einstein Albert et al., 1954), cited from

*“ Though religion may be that which determines the goal, it has, nevertheless, learned from sciences, in the broadest sence, what means will contribute to the attainment of the goals it has set up. But science can only be created by those who are thoroughly imbued with the aspiration toward truth and understanding. This source of feeling, however, springs from the sphere of religion. To this there also belongs the faith in the possibilitiy that the regulations valid for the world of existence are rational, that is, comprehensible to reason. I cannot conceive of a genuine scientist without that profound faith. This situation may be expressed by an image: science without religion is lame, religion without science is blind. (Einstein Albert et al., 1954)*

### 9.5.3. Conference of the Catholic Vatican Academy of Sciences.

In 2009 the Vatican Academy of Sciences organized an international Conference on Transgenic Plants for Food Security in the Context of Development. The results were published in an open source volume in Elsevier’s Journal of New Biotechnology (Potrykus & Ammann, 2010b). It contains also a conference statement with some theological elements (Potrykus et al., 2010), justifying in the context of modern Darwinian evolution a progressive way of molecular plant breeding, some pertinent citations:

*“During the course of the meeting, we surveyed recent advances in the scientific understanding of novel varieties of genetically engineered (GE) plants, as well as the social conditions under which GE technology could be made available for the improvement of agriculture in general and for the benefit of the poor and vulnerable in particular. The spirit of the participants was inspired by the same approach to technology that Benedict XVI expressed in his new Encyclica, in particular that ‘Technology is the objective side of human action, Cf. John Paul II, Encyclical Letter Laborem exercens, 5: loc. cit., 586-589. whose origin and raison d’être is found in the subjective element: the worker himself. For this reason, technology is never merely technology. It reveals man and his aspirations towards developement, it expresses the inner tension that impels him gradually to overcome material limitations. Technology, in this sense, is a response to God’s command to till and to keep the land (cf. Gen 2:15) that he has entrusted to humanity, and it must serve to reinforce the covenant between human beings and the environment, a covenant that should mirror God’s creative love’. Caritas in veritate, § 69.”*

#### **And about faith, scientific reasons and ethics:**

*“For a believer, the point of departure for the Christian vision is the upholding of the divine origin of man, above all because of his soul, which explains the commission that God gives to human beings to govern the whole world of living creatures on the earth through the work to which they dedicate the strength of their bodies guided by the light of the spirit. In this way human beings become the stewards of God by developing and modifying natural beings from which they can draw nourishment through the application of the methods of improvement: ‘God has sovereign dominion over all things: and He, according to His providence, directed certain things to the sustenance of man’s body. For this reason man has a natural dominion over things, as regards the power to make use of them’ (Thomas Aquinas, Summa Theologica, II-II, q. 66, a. 1 ad 1). Thus, however limited the action of humans may be in the infinite cosmos, they nevertheless participate in the power of God and are able to build their world, that is to say an environment suited to their dual corporeal and spiritual life, their subsistence and their wellbeing. Thus new human forms of intervention in the natural world should not be seen as contrary to the natural law that God has given to the Creation.*

Indeed, as Paul VI told the Pontifical Academy of Sciences in 1975, (cf. Paul VI, Address to the Plenary Session of the Pontifical Academy of Sciences of 19 April 1975, Papal Addresses, Vatican City 2003, p. 209) on the one hand, the scientist must honestly consider the question of the earthly future of mankind and, as a responsible person, help to prepare it, to preserve it for subsistence and wellbeing, and eliminate risks. Therefore, we must express solidarity with the present and future generations as a form of love and Christian charity. On the other hand, the scientist also must be animated by the confidence that nature has in store secret possibilities that are for human intelligence to discover and make use of, in order to achieve that level of development which is in the plan of the Creator. Thus, scientific intervention should be seen as a development of physical or vegetal/animal nature for the benefit of human life, in the same way that ‘many things for the benefit of human life have been added over and above the natural law, both by divine law and by human laws’: (St. Thomas Aquinas, *Summa Theologica*, I-II, 94, a.5. Cf. loc. cit. ad 3.)” (Potrykus et al., 2010)

#### 9.5.4. World Halal Forum, Sharia Compliance and Islam

Two recent international conferences on the position of Islam towards modern agriculture yielded positive views: The **World Halal Forum 2010** (World Halal Forum, 2010) sought to begin discussions on the Islamic stance of Genetically Modified Food. At the end of the workshop panelists and participants unanimously agreed to the following statement:

##### Resolution

- A. Biotech crops and products have undergone intensive food and environment safety tests and are acceptable in the Islamic world as Halal, provided the sources are Halal.
- B. Biotechnology awareness building strategies that would encourage and improve public participation in the decision-making process on biotechnology-related issues.
- C. Biotechnology awareness and education programs need to be established by private and public sectors to increase biotechnology perception in the country.
- D. The role of Islamic scholars (Ulama) in scientific discussions involving the developments of biotechnology, in particular the production of food derived from genetically modified crops must be enhanced.”(World Halal Forum, 2010)

The second international conference on the highest possible theological level on the **Sharia Compliance** related to GM food came to positive conclusions: (Sharia Compliance, 2010)

The summary:

- “1. Islam and science are complementary and Islam supports beneficial scientific innovations for mankind. Modern biotechnology and genetic engineering are important developments that merit promotion in all OIC Members. Regulatory measures should facilitate the acceptance and use of GM products particularly by Muslims. Genetic modification and GM products are Halal as long as the sources from which they originate are Halal. The only Haram cases are limited to products derived from Haram origin retaining their original characteristics that are not substantially changed.
- 2. Modern biotechnology and genetic engineering are methods of plant improvement and intrinsically are not different from other plant improvement techniques from the shariah point of view.
- 3. In ensuring food security, our Islamic obligations require us to urge all Muslim countries, governments, international organizations and research institutions, to support research and development and use of modern biotechnology, genetic engineering and their products.
- 4. Because of their positive impacts on agriculture and the urgency of food security for Muslim Ummah, promotion of modern biotechnology and genetic engineering are considered "Fardhu Kifayah" (collective obligation) and should not be neglected from the Shariah point of view.
- 5. Public awareness and education on modern biotechnology and genetic engineering, demand continuous interaction between the Islamic scholars, scientists and the general public.
- 6. Transparent and complete scientific information should be available for the interested stakeholders for informed decision making.”(Sharia Compliance, 2010)

#### 9.5.5. Jewish Religion and Kosher Food

According to Ariel Haro von Mogel and her mentor Jordan Rosenblum it is also possible to find modern positive arguments on the biotechnology revolution related to **Kosher laws within the Jewish religion** (Haro von Mogel, 20111221). Surprisingly enough, the orthodox jews are clearly in favour of genetic engineering: The reasons are rooted in important religious principles: First, there is no fear over “playing God.” They regard themselves as “co-creators” with God in improving the natural world. Psalm 115:6 reads ‘the heavens are the heavens of God’ yet ‘the earth he has given to the sons of man.’ Second, the Torah and the Talmud has nothing in it that directly or indirectly



forbids genetic engineering. In addition, for orthodox jews follow strictly *pikuach nefesh* – the solemn duty to save human souls: so – if genetically engineered food (the Golden Rice) can save human lives – then it must be supported.

In contrast to this positive view, the liberal jews in secular societites seem to be more subjected to framing against GM crops by public attitudes. This is why a more liberal interpretation of Jewish laws is reluctant to accept transgenesis (Regenstein et al., 2003) – but it does not go as far as outright rejection.

#### 9.5.6. Amish Farmers from Lancaster County, Pennsylvania, USA.

It seems to be a more widespread phenomenon that representatives of conservative religious views have less problems accepting modern breeding technologies than liberal representatives. The author remembers his own intervention 1998 in Lancaster county N Washington, where he met **old order Amish farmers**, (Mennonites) and conducted a spontaneous debate on GM crops lasting about 2 hours. The friendly entertainment ended with an invitation to the Monsanto company to help out with transgenic seeds to start cultivation of modern crops on their own land. Interestingly enough the Amish farmers name is related to the family name Ammann of the author, since it was Jacob Ammann, who founded 1642 the Mennonite Anabaptist community which was subsequently named Amish after him (Ammann K., 2004; Ammann K. & Truth about Science, 1999). Part of the Amish community near Lancaster still grows transgenic crops today

A survey of 1997 shows with good data of the same region in Lancaster county and elsewhere, that Amish farmers show in the practice of using fertilizer and pesticides only slight differences from conventional farming (Blake et al., 1997). Neverthelss the majority is proud to maintain the organic label, which should not be too difficult for marketing image reasons anyway.

An overview on the three main monotheistic religions Judaism, Islam and Christianity on public views on GM food technology is given by (Omobowale et al., 2009): They conclude that indeed public views on GM crops are partly influenced by those three religions, however, there are several other interests competing with this influence, such as media, environmental activists, scientists and the food industry.

#### 9.5.7. Environmentalism as a Religion

Presently, a lot of people live a seemingly agnostic life, but in fact they believe in a new surrogate religion you can call with Michael Crichton a new kind of environmentalism (Crichton Michael, 20120121). A manuscript on the cultural roots of environmentalism can be downloaded from the internet (Vogel David, 2001), the conclusions should be taken cum grano salis, but are nevertheless interesting here, especially within the focus on Protestantism:

##### *“Conclusion*

*The case for a casual linkage between Protestantism and dark green environmentalism is strongest in the United States, where one can trace actual historical links between individuals with Protestant backgrounds and the development of American environmentalism. In the cases of the United States, England and Germany, 19th century romanticism provides an historical link between Protestantism and contemporary dark green environmentalism. In other rich countries, the connection may be through post- materialism, which is more prevalent in historically Protestant countries and of which dark green environmentalism may be regarded as one expression. In other countries, the influence of Protestantism may be through capitalism itself: the world’s wealthiest and oldest industrial countries – and thus the nations with the strongest bourgeois cultures – are disproportionately Protestant.*

*There is no reason to assume that the connection between Protestantism and dark green environmentalism is equally strong in all Protestant/dark green countries or that it operates through identical mechanisms. The same is true of the role of religion in shaping environmental politics and policies in light green countries: it may be more important in some countries than in others. In the one country which is an exception to the strong relationship between Protestantism and dark green environmentalism, namely Austria, religion is clearly less important than culture: Austria may be dark green as a function of its Germanic heritage. In this context, it is worth noting that two-thirds of the population of dark green Switzerland – a pluralist nation in which Catholics slightly outnumber Protestants – are Germans.*

*Correlation is not of course causality and the claim that a nation's religion has shaped its pattern of environmentalism must remain speculative. Nevertheless, contemporary environmentalism does appear to have an important cultural dimension and understanding the religious roots of a nation's culture can contribute to our understanding as to how its citizens and policy-makers have responded to the contemporary emergence of environmentalism. There is no reason to assume that the connection between Protestantism and dark green environmentalism." (Vogel David, 2001)*

It was Guth et al. (Guth et al., 1993), building on many previous studies, to show in his comprehensive overview that Religion can influence attitudes towards environmentalism: In Table 3 p. 380 you can read about considering environmentalism as the most important problem by the following issue clusters: Christian Left 47%, Pro-Life Liberals 40%, Christian Center 27%, Traditional Right 10%, Christian Right 3%. These patterns are clear and striking: Environmentalism is part and parcel of a liberal/religious/political worldview. This is why the protest corporates have more success in the negative agenda setting against GM crops with scaremonger stories about industrial agriculture being bad for the environment.

Environmentalism has grown into a new religion, particularly among people who have problems with the church and with traditional religious activities, but are not ready for blunt atheism (consciously or subconsciously): Michael Crichton, by all means not denying that the earth needs an enhanced environment in many ways, points to a common, widespread shift towards environmentalism as a new religion (Crichton Michael, 20120121): The parallels between Judeo-Christian beliefs and Environmentalism are perfectly laid out with some embarrassing clarity:

*"Today, one of the most powerful religions in the Western World is environmentalism. Environmentalism seems to be the religion of choice for urban atheists. Why do I say it's a religion? Well, just look at the beliefs. If you look carefully, you see that environmentalism is in fact a perfect 21<sup>st</sup> century remapping of traditional Judeo-Christian beliefs and myths. There's an initial Eden, that pesticide-free wafer that the right people with the right beliefs, imbibe a paradise, a state of grace and unity with nature, there's a fall from grace into a state of pollution as a result of eating from the tree of knowledge, and as a result of our actions there is a judgment day coming for us all. We are all energy sinners, doomed to die, unless we seek salvation, which is now called sustainability. Sustainability is salvation in the church of the environment. Just as organic food is its communion, that pesticide-free wafer that the right people with the right beliefs, imbibe. Eden, the fall of man, the loss of grace, the coming doomsday---these are deeply held mythic structures. They are profoundly conservative beliefs. They may even be hard-wired in the brain, for all I know. I certainly don't want to talk anybody out of them, as I don't want to talk anybody out of a belief that Jesus Christ is the son of God who rose from the dead. But the reason I don't want to talk anybody out of these beliefs is that I know that I can't talk anybody out of them. These are not facts that can be argued. These are issues of faith. And so it is, sadly, with environmentalism. **Increasingly it seems facts aren't necessary, because the tenets of environmentalism are all about belief.** It's about whether you are going to be a sinner, or saved, whether you are going to be one of the people on the side of salvation, or on the side of doom, whether you are going to be one of us, or one of them." (Crichton Michael, 20120121)*

In a way, the whole book of Dick Taverne (Taverne, 2005a) is a brilliant epistle against the new fundamentalism, especially the chapter 6 on the rise of Eco-Fundamentalism p. 132. – it is introduced with an appropriate citation from Friedrich Nietzsche: Convictions are greater enemies of truth than lies. Interestingly enough, Dick Taverne introduces Ernst Haeckel with his strong evangelical streak, who is seen by many as a founder of a new religion of environmentalism. Many ecologists reject the anthropocentric view of the world. Ecologists typically express a mystical unity of Mankind and Nature and claim that the birth of science brought a mechanistic, rapacious and inorganic attitude towards nature. Taverne (Taverne, 2005b) indeed describes also Greenpeace as an organization with a clear attitude towards religious fundamentalism: During a hearing of a committee of the House of Lords on regulation of transgenic crops, its director was asked: "Your opposition to the release of GMOs (genetically modified organisms), that is an absolute and definite opposition... not one that is dependent on further scientific research?" He replied "It is a permanent and definite and complete opposition" (House-of-Lords, 1999) .



### 9.5.8. Pseudo-Religious Environmentalism; Agroecology as Mantra

The eco-imperialist attitude towards farmers in the developing world should be seen critically by (Paarlberg, 2000, 2006, 2008; Paarlberg, 2009a, b; Paarlberg, 2010). He, and many other authors cast doubts on the frequent claims (and this is supported by this author), that agro-ecology-based production strategies would be better for smallholder farmers than solutions including modern breeding, a claim which is not supported by data: The fact is, that some 80% of farmers from the developing world who have adopted GM crops are smallholder farmers making considerable economic profits with the technology (Brookes & Barfoot, 2007) and (Qaim & Stein, 2009a, b; Qaim et al., 2007a)).

The numerous papers by Miguel Altieri (a selection: (Altieri, 1989, 1999, 2000a; Altieri, 2002; Altieri & Letourneau, 1982; Altieri et al., 1983; Altieri & Nicholls, 2003; Altieri & Rosset, 1999; Altieri & Toledo, 2011) offer tempting concepts on agro-ecology with some good elements and ideas, but they are not based on hard production data. Except for one publication (Altieri, 2000b) with focus on production but lacking sufficient details to allow verification, his concepts are more wishful thinking than agricultural reality. Other notorious and often cited examples of seemingly positive yield results by applying agro-ecological methods (even a doubling of yield is claimed) come from Jules Pretty: (Pretty et al., 2011; Pretty et al., 2005). They are efficiently debunked by (Phalan et al., 2006).

- a) *There is a strong selection bias towards successful projects.*
- b) *Methods used to measure changes in yields, water and pesticide use, and carbon sequestration are poorly explained, and therefore, hard to reproduce*
- c) *Crucially, the study lacks adequate controls, thereby failing to show that it is the introduction of resource-conserving practices which is responsible for reported increases in yield and sustainability.*
- d) *The extent to which these practices provide greater net benefits to farmers than conventional techniques is unclear.*

In the answers to the critique of Phalan, Pretty et al. (Pretty et al., 2006) basically admit the weakness of their study, but offer the excuse of unreasonably high costs to overcome the flaws in field data gathering. Nevertheless, Miguel Altieri seems to be 100% convinced that his way is the right one, otherwise it would be hard to understand why he helps fundamentalists to occupy research areas near Berkeley, hindering ag-biotech research with the false accusation, that it is supported by corporate money and he also supports the demonizing of biotech maize: (Brooks, 20120511).

The reasons for such righteous and stubborn interpretation of agroecology are deep sitting in pseudoreligious views:

Presently, a lot of people live a seemingly agnostic life, but in fact they believe in a new surrogate religion you can call with Michael Crichton a new kind of environmentalism (Crichton Michael, 20120121). A manuscript on the cultural roots of environmentalism can be downloaded from the internet (Vogel David, 2001), the conclusions should be taken cum grano salis, but are nevertheless interesting here, especially within the focus on Protestantism:

#### *“Conclusion*

*The case for a casual linkage between Protestantism and dark green environmentalism is strongest in the United States, where one can trace actual historical links between individuals with Protestant backgrounds and the development of American environmentalism. In the cases of the United States, England and Germany, 19th century romanticism provides an historical link between Protestantism and contemporary dark green environmentalism. In other rich countries, the connection may be through post-materialism, which is more prevalent in historically Protestant countries and of which dark green environmentalism may be regarded as one expression. In other countries, the influence of Protestantism may be*

*through capitalism itself: the world's wealthiest and oldest industrial countries – and thus the nations with the strongest bourgeois cultures – are disproportionately Protestant.*

*There is no reason to assume that the connection between Protestantism and dark green environmentalism is equally strong in all Protestant/dark green countries or that it operates through identical mechanisms. The same is true of the role of religion in shaping environmental politics and policies in light green countries: it may be more important in some countries than in others. In the one country which is an exception to the strong relationship between Protestantism and dark green environmentalism, namely Austria, religion is clearly less important than culture: Austria may be dark green as a function of its Germanic heritage. In this context, it is worth noting that two-thirds of the population of dark green Switzerland – a pluralist nation in which Catholics slightly outnumber Protestants – are Germans.*

*Correlation is not of course causality and the claim that a nation's religion has shaped its pattern of environmentalism must remain speculative. Nevertheless, contemporary environmentalism does appear to have an important cultural dimension and understanding the religious roots of a nation's culture can contribute to our understanding as to how its citizens and policy-makers have responded to the contemporary emergence of environmentalism. There is no reason to assume that the connection between Protestantism and dark green environmentalism.” (Vogel David, 2001)*

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towards nature. Taverne (Taverne, 2005b) indeed describes also Greenpeace as an organization with a clear attitude towards religious fundamentalism: During a hearing of a committee of the House of Lords on regulation of transgenic crops, its director was asked: "Your opposition to the release of GMOs (genetically modified organisms), that is an absolute and definite opposition... not one that is dependent on further scientific research?" He replied "It is a permanent and definite and complete opposition" (House-of-Lords, 1999) .

### 9.5.9. Reconciliation of Science, Religion and Spirituality

Religion, and especially their historic documents cause unfortunate misunderstandings, which root creationism and refusal of evolutionary dynamics of nature, views which are still not overcome, despite the renaissance, Da Vinci and Darwin. It is indeed baffling, that even in modern churches as the Lutheran and the Catholic Church these views still linger undercover: Nobody 'should interfere with God's creation', and such statements are not only abundant in the Bible Belt of the Southern United States, but also part of the English Royalty seems to favour medieval views with His Royal Highness, the Prince of Wales:

*"The Prince says that genetic engineering "takes mankind into realms that belong to God and to God alone", and raises ethical and practical considerations. "Apart from certain highly beneficial and specific medical applications, do we have the right to experiment with and commercialise the building blocks of life? We live in an age of rights - and it seems to me that it is time that our Creator had some rights too." , Prince of Wales, London Times.*

Already in 1998 Charles, Prince of Wales indulges into hostilities against modern agriculture, actually an obvious propaganda piece "The seeds of disaster" in favor of his own organic farm (Charles Prince-of-Wales, 1998).

It should also be possible to think and act in relation to the **reconciliation of religion, science and spirituality**, since it will be an important element besides the ratio of science, the ethics of our societal activities and the emotional elements in human life. But it will be difficult to separate the cheap esoteric chaff from the precious seeds of true spirituality, as Helmut Reich's writings demonstrate (Reich, 2008).

In his detailed and rich review on the dialogue contents and actors in fostering the dialogue between science and religion (extended into religion, spirituality and theology = RST), he also warns about extreme positions promoted by Dawkins and Sam Harris, pleading instead for long enduring and difficult (and professional) dialogues between parties with a dedicated will to understand each-other positions:

*"Both science and RST can potentially contribute to the amelioration of problems in humanity's current situation, especially if they recognize each other and collaborate closely and each is supported in what it does best. Science (and economics) can fight illness, hunger, and poverty, and RST can provide meaning and additional motivation as well as potentially harmonize the two sexes, contemporaneous generations, reason and emotions, body and spirit, ethics and action, life stages, the temporalities (past, present, future), private and public life, individuals and those around them, nature and culture, the human community and the cosmos (Saroglou 2006). Both together provide knowledge about the world and beyond and potentially can help to take appropriate action. The task of the science-and-RST dialogue is to clarify and detail these potentialities and spread the results, ideally worldwide, in view of actions that would benefit humanity's survival. To do so requires an opening up of present activities, a reorientation toward some kind of nonprofit marketing, and the building up of a worldwide learning and collaborating community that includes everyone, a community that broadens and applies new insights as well as modes of behavior and action." (Reich, 2008)*

A truly **synthetic view on world religions and science philosophy**, full of innovative thoughts is produced by a Sri Lanka philosopher Susantha Goonatilake. She brings together the major world

religions (specifically Buddhism) and philosophies in a probably unique manner: (Goonatilake, 2006), remaining critical about future developments, but mainly optimistic, including biotechnology and modern genetics: A few cited paragraphs:

*"In Buddhism, this elimination of the sense of self sets one free. The realization that the self is a process means that the future becomes open-ended." AND "The Buddhist analysis also suggests a moral compass for the future of merged knowledge streams; such a perspective includes a profound moral code of altruism, and it is not entirely farfetched to think that these principles could also apply to future scenarios."* AND by involving one of the most important philosophers of our century (F. Varela), she continues:

*"A study which evokes some of the same philosophical approaches in charting the future technology is (Varela Francisco J. et al., 1992), The Embodied Mind. They propose a bridge between the mind as conceptualized in science and the mind of everyday experience, through a dialogue between Buddhist meditative practice and cognitive science. The approach was applied to a variety of themes in neuroscience and cognitive psychology, artificial intelligence and evolutionary biology. In doing so, they approach what we considered as the three lineages, namely the internal flow of our thoughts (the culture within the minds), the flow of genes (evolutionary biology) and the flow of 'artificial thoughts' (artificial intelligence). Varela and his colleagues evoke the flow patterns that one observes internally through Buddhist meditation and find here the key to tackling the other two realms. They tackle the problems of non-self and of everflowing streams, and describe the dynamics of the three lineages. Their discussions are located in specific debates with the research communities in these three areas. They reject the subject-object dichotomy that arises in different forms in all the three lineages."*

Goonatilake's courageous views of the future are of breathtaking optimism and faith in human future abilities:

*"If in the future we will be constructed and reconstructed – from biology, culture and artifact what should be our epistemological, philosophical, ethical, and subjectively felt guiding principles? If 'we' would then be 'cyborgs' and hybrids, what should the interiority of robots, of constructed hybrids be as they navigate reality and tunnel through time in our lineages?"*

*The person is not a 'what' but a process, a thought in line with Buddhism's view that the universe's components are in a state of impermanence, of ceaseless movement; nothing is durable or static. Being is only a snapshot in the process of becoming, lasting only the length of one thought." (Goonatilake, 2006).*

This view is in blatant contrast to the texts produced by the following two authors (not deeply involved in Buddhism, but heavily pre-occupied with negative views on genetic engineering, thus in both cases demonstrating a clear abuse of pseudoreligious opinions: In (Epstein Ron, 2001) the simplistic parallel between potential bioterrorism and the peacefulness of Buddhism is described as an 'unsurmountable contradiction'. In (Wachowicz, 2005) an unexperienced and clearly biased author collects all the potential and unconfirmed risks of genetic engineering and compares it to an unreal and idealistic picture of Buddhism.

There are of course those, who, as ***atheists of various kinds***, would like to get rid of religion as a whole, some even would like to cast spirituality altogether as late descendants of positivism like Richard Dawkins (Dawkins Richard & McKean Dave, 2011) and Sam Harris (Harris Sam, 2005). Darwin himself was narrowed down by them to a "Darwinist", a common process pupils apply to their own masters, although often the master himself had a broader view on evolution compared to his later pupils, see my contribution to the Darwin Conference 2009 in the Bibliotheca Alexandria of the British Council (Ammann, 20091115).

On the other hand it would be a great misunderstanding when in this difficult dialogue between science and spirituality the road of the LOGOS should be lost, as Pope Benedict XVI states (Benedict XVI - His Holiness, 2006)

*"Not to act reasonably, not to act with logos, is contrary to the nature of God", said Manuel II, according to his Christian understanding of God, in response to his Persian interlocutor. It is to this great logos, to this breadth of reason, that we invite our partners in the dialogue of cultures. To rediscover it constantly is the great task of the university."*

### 9.5.10. Need for new World Visions: Culture of Question.

But in reality, dialogue and understanding within and between religions and various kinds of spirituality are not enough: We must endeavor new fields of thought, as done by my wife Biljana Papazova Ammann (Papazova Ammann, 2010), a Bulgarian born Philosopher with roots in the schools of Muntjan and the one of Rittel.: We need indeed to build up a new culture of questioning:

*“What do we need as visionaries: Progress or Development? This is my question today, as I deal with the topic of Biovisionaries here in the Library of Alexandria. I ask this question because I am convinced that we need to **build a new culture of questioning**. We need a culture orienting itself by authentic questions. How can we develop taste and the ability to distinguish between those questions which are cognitive, statement- oriented and those which are authentic, close to life and to people? What is more important: cognizance or decision for action? How can we move between Statements and Questions? Statements reflect the need to understand the world. But they are the result of past experience and are often contained in frameworks which are coined by society. They may even protect old routines which hinder innovation. Questions, in contrast to statements, can transform our judgements and prejudices. Questions give birth to energy for new orientation, for a more conscious future. This orientation towards the future, towards vision provokes those choice-questions, and they alone will open the way for an urge to change the world. Visions need people who are free! The quality of freedom is inherent in the question. We must strive for this quality through choice-questions. If we cannot befriend these choice-questions with science, it will disengage from the questioners and will not be human science anymore. Thus we need a new humility of thinking – as it has been wonderfully defined by the German philosopher Heidegger: “The question is the devoutness of thinking.” (Papazova Ammann, 2010)*

This might open new pathways of coming to solutions, beyond the rationality of discourse processes, embedded in a new world view.

## 10. Conclusions:

### 10.1. Doubts and no illusions about the continuation of a dialogue, unless a long term discourse is organized in a professional way

As a whole, in the debate on modern agriculture the solution may be found in professionally organized long lasting discursive processes, where different kinds of views are not only tolerated, but fully integrated. Unfortunately, discourses between natural science and social science (both used in a broad sense) are rare, unilateral approaches prevail: Strongly opinionated papers often claim the missing acceptance of modern agricultural technology with good justification of statistics and facts, but their authors forget over this battle a more holistic view in seeking the difficult balancing act between traditional and modern agriculture, and do not have the skills of talking to people with little knowledge in molecular biology in a way to be understood.

Only a multifaceted dialogue over a considerable time span will lead to results. The internet scene is developing fast and new communication software tools are available now, so careful scrutiny for such a network of networks need to be done first, and the big players like Google and competing networks should be consulted as well.

Personal experience in dialogue with many networkers reveals that sometimes important links are only known in specific clusters, these lacunas should be closed for many reasons – see section 1.3. Knowledge exchange, jumping over national and ideological fences and coordination will be a follow-up effect, without even declaring it to be the goal of such activity. As for now, this is just an idea and needs discussed with internet and website specialists. After all, the leading webmasters and coordinators agree, that it is time to ***enhance collaboration through better communication***.

ASK-FORCE can contribute to this process in making sure, that professional peer reviewed risk assessment papers are fed into the dialogue processes and in ideally fed into a life decision making process with relevant participants.

### 10.2. Urgency for a call of a major change in trade and regulation of modern agriculture, some insights from examples from Africa

As a result of neo-colonial trade policy (hidden protection measures through import rejection of GM products from developing countries) and also due to often missing research infrastructure, agricultural production in developed countries shows dramatic differences compared to emerging economies of Africa, as illustrated by fig. 2 below from the report of the Royal Society (Royal-Society, 2009).

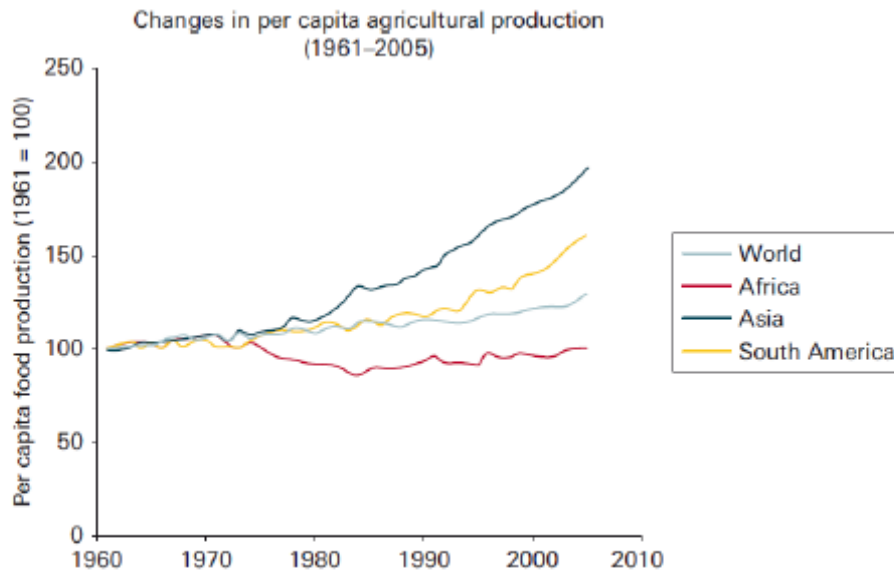


Fig. 30 Changes in per capita agricultural production from the (Royal-Society, 2009)

A lot of work remains to be done if we want to realistically ameliorate the situation. Innovative concepts need to be introduced, always with the focus on local conditions and human development, including both technological and socio-economic innovation.

The trade policy of Europe is still going the wrong way of protectionism, which causes a lot of difficulties in developing countries: As Graff et al. (Graff & Zilberman, 2004) explain: *“European policies blocking genetically engineered crops are conventionally attributed to the concerns of European consumers, but they can be attributed to the self-interests of European industry and farmers as well. Biotech policies maintained in the name of consumer interests are helping European chemical firms to slow their losses in the global crop protection market and are helping European farmers differentiate their conventional crops on environmental and safety grounds, maintain their agricultural subsidies and win new non-tariff trade protections.”*

In another paper Graff et al. (Graff et al., 2009) get even more explicit:

*“The analysis suggests that in Europe and in some developing countries a “strange bedfellows” constellation of concentrated economic interests (including incumbent agrochemical manufacturers, certain farm groups, and environmental protest activists) act in rational self-interest to negatively characterize GM technology in the public arena and to seek regulations that block or slow its introduction.*

As early as 1997 Guasch et al. (Guasch & Hahn, 1997) described precisely the dilemma between high regulatory costs and the urgent need to enhance agricultural production in the developing world – but it did not help – on the contrary, it got worse.

More recent papers document the growing regulatory costs (Antle, 1999; Bernauer et al., 2011; Kalaitzandonakes et al., 2007), Bernauer documents also high protection costs against vandalism in a Swiss field experiment case of more than one million Francs. Kalaitzandonakes tables show regulation costs between 4 to 15 million dollars for well know transgenic traits in Maize and Soybeans. For major commodity crop estimates for global adoption go as high as 100 million dollars. The growing costs are clearly correlated to anti-science campaigns (Miller, 2009). Poorer nations turn to publicly developed crops, the expensive commodity crops of big seed companies are not popular (Cohen, 2005). Anyway most companies prefer fostering humanitarian projects in those countries (Miller-Wallstreet, 20120518).



A new and comprehensive initiative is coming from an workshop of ICGB (Biosafety Unit; International Centre for Genetic Engineering and Biotechnology) in Mauritius on GMO communication strategies for the future (Racovita et al., 2013), an excellent documentation for the countries of Sub-Saharan Africa that things are moving, documenting the different adoption speeds in particular countries, but missing the important point of the change to product-oriented regulation (as most papers on regulatory strategy do, see e.g. (Birner Regina & Linacre Nicolas, 2008), the summary:

*In tackling agricultural challenges, policy-makers in sub-Saharan Africa (SSA) have increasingly considered genetically modified (GM) crops as a potential tool to increase productivity and to improve product quality. Yet, as elsewhere in the world, the adoption of GM crops in SSA has been marked by controversy, encompassing not only the potential risks to animal and human health, and to the environment, but also other concerns such as ethical issues, public participation in decision-making, socio-economic factors and intellectual property rights. With these non-scientific factors complicating an already controversial situation, disseminating credible information to the public as well as facilitating stakeholder input into decision-making is essential. In SSA, there are various and innovative risk communication approaches and strategies being developed, yet a comprehensive analysis of such data is missing. This gap is addressed by giving an overview of current strategies, identifying similarities and differences between various country and institutional approaches and promoting a way forward, building on a recent workshop with risk communicators working in SSA.*

Despite recent more positive trends in African agriculture, we should not forget the obstacles and downsides (Anderson Kim & Bruckner Markus, 2012), making a decisive change even more urgent. The authors

*“...find a statistically significant and sizable negative effect of relative agricultural price distortions on the growth rate of Sub-Saharan African countries. The fixed effects estimates yield that, during the 1960-2005 period, a ten percentage points increase in distortions to relative agricultural prices decreased the region’s real GDP per capita growth rate by about half a percentage point per annum.”*

One figure from this new report illustrates the complexity and dynamics of foreign aid:

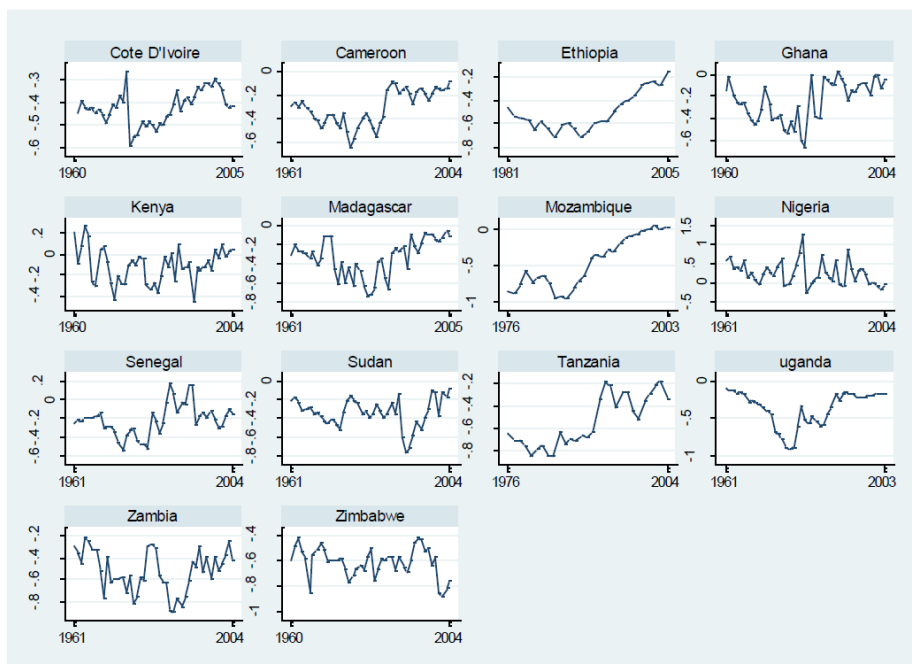


Fig. 31 Time-Series Plots of the Relative Rate of Assistance, Fig. 1 from (Anderson Kim & Bruckner Markus, 2012)

### 10.3. Product oriented regulation i.e. de minimis regulatory strategy,

should be widened to all new breeds in a **process-agnostic way** and be evaluated according to the following scheme (after a stepwise tripartite pre-evaluation still to be developed):

Regulators should adopt a **method-agnostic approach (i.e. a product-orientated approach)**, and focus on relevant ecological and biochemical characters of the end product.

**Any risks associated with GM should be assessed relative to their antecedent peers.** This demands a performance-based framework to replace the prescriptive, one-size-fits all approach.

The precautionary approach, as invoked in the current regulatory scheme, is scientifically indefensible. It should be **replaced with a flexible de minimis approach**, which avoids the allocation of resources to address negligible risks for nominal or nonexistent gains in safety, see last item on stepwise evaluation system.

In addition, we believe that **current regulations place an acute overemphasis on hypothetical (and often unmeasurable) risks**, while downplaying the advantages. In effect, this accentuates the what-if scenarios of the risk assessment calculus at the expense of demonstrable benefits.

Widening regulation to all new breeds it is necessary to **introduce a new stepwise evaluation system**, taking into account risk levels related to the environment and food and also evaluating the questions of co-existence. Long term monitoring should be introduced in cases of new, potentially unknown risks.

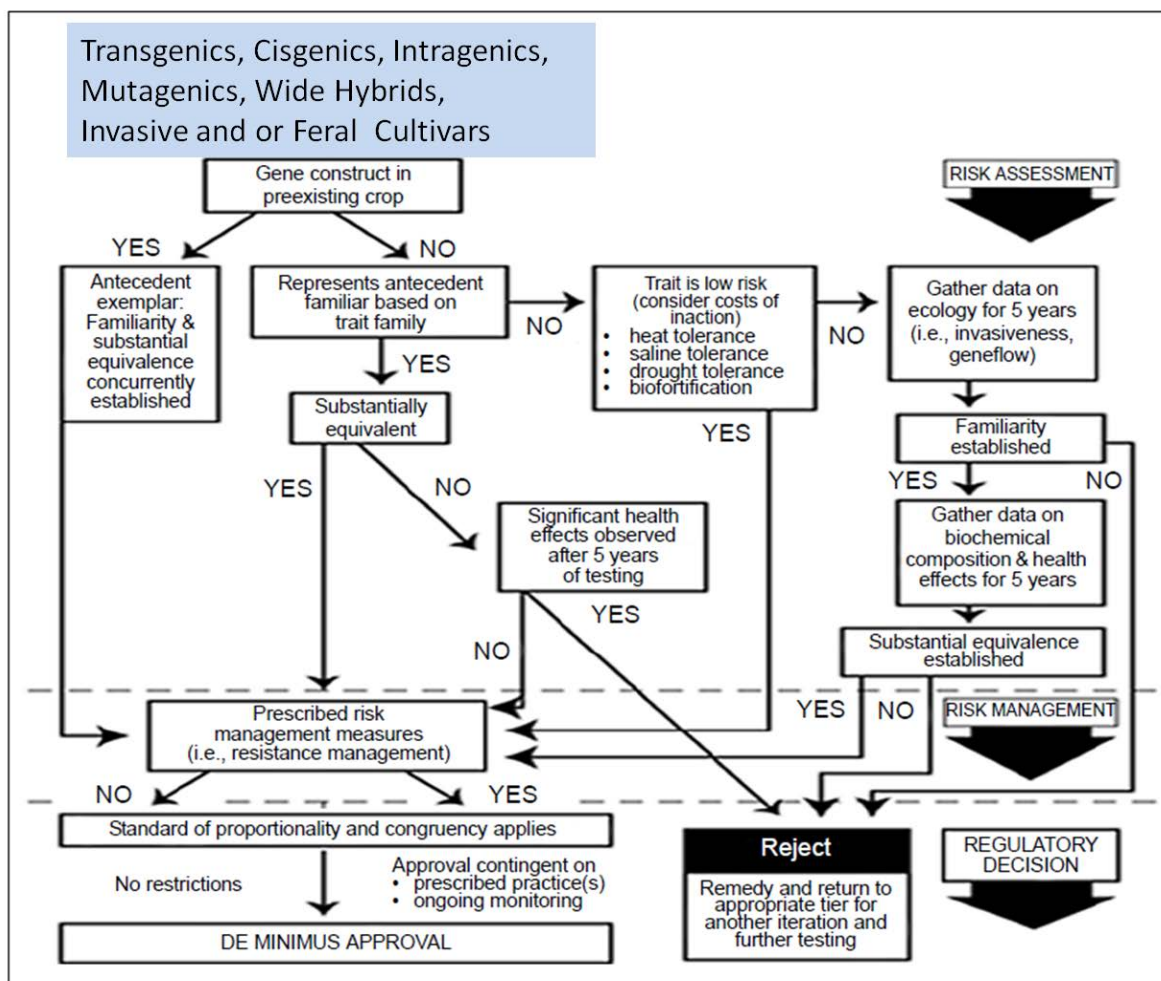


Fig. 32 Same figure as 15, amended from No. 13 and 14, but with the inclusion besides transgenic plants: Cisgenics, Intragenics, Mutagenics (mutated with gamma radiation or chemicals), wide Hybrids and invasive or feral cultivars. After (Durham Tim et al., 2011), amended by K. Ammann 2011. The scheme needs amendment also for the three general risk-levels to be assessed as helping scale.

On a broader scale the following risk assessment on environmental potential impacts could be merged with the above proposed de minimis procedures: (Sanvido et al., 2011b) provides the latest general system for the development of a revised procedure of risk assessment and management. Also from this view it is clear that the biosafety regulation worldwide (including the sacrosanct Cartagena Protocol will have to be viewed as a system in urgent need of thorough revision.

We should start a long term discourse on biosafety of new traits with the help of a new international institution. This also may be a composite of several existing ones such as some important National Academies and the International Service for the Acquisition of Agribiotech Knowledge (ISAAA) <http://www.isaaa.org/> , together with the United Nations Industrial Development Organization (UNIDO) <http://www.unido.org/> , the International Centre for Genetic Engineering and Biotechnology (ICGEB) <http://www.icgeb.org/home.html> , the European Federation of Biotechnology (EFB), <http://www.efb-central.org/index.php/Main/C4> , the International Union of Biological Sciences (IUBS) <http://www.iubs.org/> and the Public Research and Regulation Initiative (PRRI) [www.pubreserg.org](http://www.pubreserg.org) and the International Society for Biosafety Research (ISBR) <http://www.isbr.info/> to name only a few, the list may have to be expanded.

A summary of the Genomic Misconception behind the erroneous process-oriented regulation is published in (Ammann, 20120706), see a summary of the concept in Section 2.4. above.

From Sanvido et al. (Sanvido et al., 2012), amended

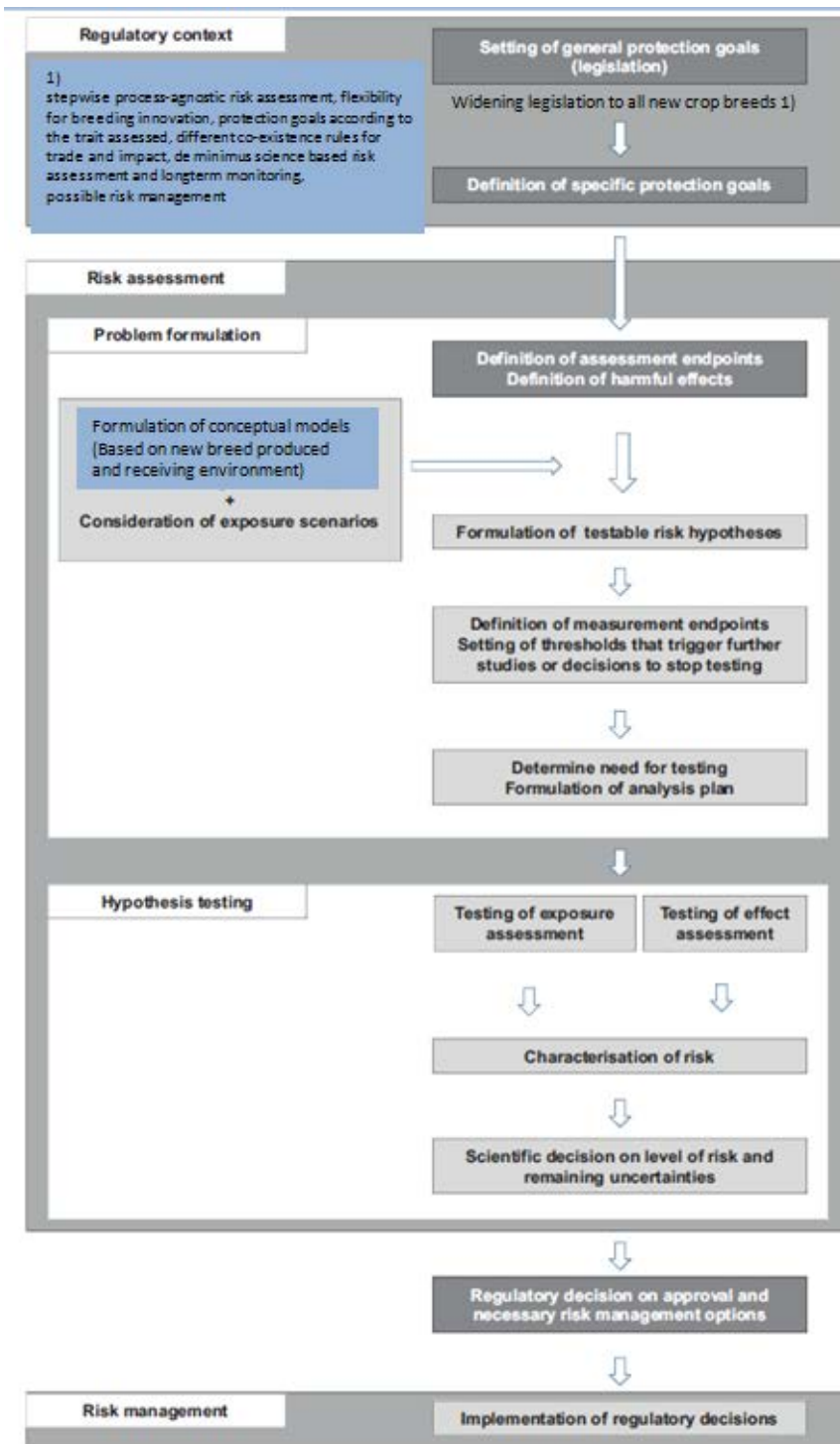


Fig. 33 Schematic diagram representing the main components of the risk analysis of genetically modified crops. Dark shaded boxes depict policy activities that should be carried out by policy-makers or risk managers. Light grey boxes depict science-based activities that are to be conducted by risk assessors (adapted from (EPA, 1998); (Nickson, 2008; Wolt et al., 2010), amended by K. Ammann, avoiding the Genomic Misconception by introducing a process-agnostic vision, together with the de minimis approach in mind. After (Sanvido et al., 2011b) amended by K.Ammann

Just for additional information the original schemes cited in caption of Fig. 21:

EPA figures: <http://www.ask-force.org/web/Regulation/EPA-Figures-1-2-1998.pdf>

Tom Nickson: <http://www.botanischergarten.ch/Regulation/Nickson-Planning-Stress-2008.pdf>

Jeff Wolt et al. <http://www.ask-force.org/web/Regulation/Wolt-Problem-Formulation-Environmental-Risk-2010.pdf>

And not to forget: Figures p.71ff in the Field Testing GMOs of the National Research Council (NRC (National-Research-Council), 1989)

## 10.4. Possible Solution: the Canadian regulatory system with future amendments

There is no reason to re-invent the wheel, for reasonable risk assessment strategies we better have a close look at the Canadian process-agnostic approach, focusing on the novelty of products among the new crops, a comprehensive review paper on Canadian regulation of GE crops comes from Smyth and McHughen 2008. (Smyth & McHughen, 2008)

*The advent of genetically modified crops in the late 1980s triggered a regulatory response to the relatively new field of plant genetic engineering. Over a 7-year period, a new regulatory framework was created, based on scientific principles that focused on risk mitigation. The process was transparent and deliberately sought the input of those involved in crop development from non-governmental organizations, industry, academia and federal research laboratories. The resulting regulations have now been in place for over a decade, and the resilience of the risk-mitigating regulations is evident as there has been no documented case of damage to either environment or human health. (Smyth & McHughen, 2008)*

The two authors describe in detail how Canadian regulators deal with an assessment system fully taking care of the hurdles, when you leave the simplistic path of focusing on the process of transgenesis: The fully science based and still pragmatic regulatory system is now for over a decade in place with uncontested success (this has not been the case in the mid and late nineties in Canada, read about the regulatory difficulties described by (Belem, 1999; Smith Barry et al., 1996) in detail!):

Clearly, the product oriented regulation brings along a major change, including the difficulty as conventional crops have to be taken into account. The challenge was now to find a pragmatic way to avoid that all new crops have to undergo expensive and laborious risk assessment. Canadian regulators have found solutions: They based regulations on the end product that is established, not the process used to create the product. They developed over a seven years period a new classification of plants by creating a new regulatory system focusing of “Plants with Novel Traits” (PNTs), the heart of a process – an agnostic decision making system which is now in place successfully since a decade. The process is transparent and deliberately sought the input of those involved in crop development from non-governmental organizations, industry, academia and federal research laboratories. These plants selected for closer regulation are classified as PNTs, they are modified either via genetic engineering or mutagenesis, in addition these PNTs also those that do *not* have a history of production and safe consumption in Canada: The procedure is described in detail in the Directive Dir2000-07: Conducting Confined Research Field Trials of Plant with Novel Traits in Canada, published by the Canadian Food Inspection Agency (CFIA, 2004a). Before any experimental field release, the Canadian authorities are carefully evaluating environmental safety with the following steps, details see Directive 94-08 Assessment Criteria for Determining Environmental Safety of Plants With Novel Traits by the Canadian Food Inspection Agency (CFIA, 2004b). The novelty and automatically the details of modern transgenic crop breeding is described with great precision, which is lacking in any other international regulatory legislation.

1. *“The potential of the plant to become a weed or to be invasive of natural habitats.*
2. *The potential for gene flow to wild relatives.*
3. *The potential for a plant to become a plant pest.*
4. *The potential impact of a plant or its gene products on non-target species.*
5. *The potential impact on biodiversity” (CFIA, 2004b)*

And related to the herbicide tolerant canola crops:

*“Because of the above definition and the subsequent assessment categories, every herbicide-tolerant variety application that the CFIA receives is treated as a PNT, regardless of the technology used to create the herbicidetolerant variety. Although there are very few crop varieties approved with stacked traits (corn, cotton and potato), a herbicide-tolerant variety that has additional traits stacked with it, such as drought tolerance, would be given consideration for variety approval under the following CFIA directives:*

1. *Directive 94-08: (CFIA, 2004) Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits.*
2. *Directive 95-03: (CFIA, 2009) Guidelines for the Assessment of Novel Feeds: Plant Sources.*
3. *Directive D-96-13: (CFIA, 2010) Import Permit Requirements for Plants with Novel Traits, and their Products.*
4. *Directive 2000-07: (CFIA, 2004a) Guidelines for the Environmental Release of Plants with Novel Traits within Confined Field Trials in Canada.*

*Using these directives, the CFIA assesses all PNT variety applications for environmental release and use as animal feed. It is no longer possible to obtain split approval for a crop variety in Canada, where the crop would be approved for use as animal feed but not human consumption. Figure 2 provides a flowchart of the CFIA’s regulatory process. In Stage 1 of the development of a new PNT variety that is intended for unconfined environmental release and/or use as a livestock feed, the plants are required to be grown in a contained facility (i.e. glasshouse or laboratory growth chamber). Growing conditions in these types of facility follow biosafety guidelines that have been established by Health Canada and the Medical Research Council. Research institutions may develop and require that codes of practice be followed in addition to the above.” (Smyth & McHughen, 2008)*

However, some rDNA developed plants are not PNTs, which creates some confusion for crop developers. This differs from the US regulatory system. Most jurisdictions trigger regulatory scrutiny for every new rDNA insertion into a plant’s genome, but the Canadian CFIA triggers regulatory scrutiny *only* when a plant acquires a new trait, even if it is not a product of rDNA. Plants developed using traditional breeding, not rDNA, have occasionally triggered regulatory review for expressing novel traits, as in a recent case a bred barley trait with low phytate levels. (Edney et al., 2011; Edney et al., 2007). Decades ago the zero-erucic acid oilseed rape, a clear PNT according to modern definition, would be subject to regulation today – a breakthrough in the sixties for oilseed rape as feed (Ofori et al., 2008). In the introductory phase it caused some concern about deer overfeeding with the new variety, but obviously the animals adapted soon.(Inglis et al., 1992).

It is also important to read a clarification related to the term ‘substantial equivalence’, which has been used in an unscientific way to single out transgenic from non-transgenic plants, as (Smyth & McHughen, 2008) explain in detail:

The CFIA states that ‘... a plant with a novel trait is one that is not “substantially equivalent” to existing plants of the same species cultivated in Canada ...’ (CFIA, 2005b: p. 1); however, this is incorrect, as the progeny of approved PNTs are not considered to be novel. The Royal Society report was widely criticized in the scientific community, partly because it assumes a priori that transgenic plants are suspect, and so suggests that scientific evidence must be presented to prove them safe. This is faulty on two points: first, there is no scientific reason to suppose that plants developed using rDNA are any more risky than plants developed using other technologies; and, second, science cannot prove something safe. Health Canada, on the other hand, states that ‘... substantial equivalence is not to be used as a decision threshold and GM-products should be subject to a rigorous scientific assessment of their potential for causing harm ...’ (Health Canada, 2001: p. 1). In fact, Health Canada goes on to identify that substantial equivalence is not uniformly applied in federal regulations. Ultimately, although substantial equivalence for PNTs was not defined within the developing regulations, some form of it has been practiced by the regulators.

An overview of the Canadian regulatory system in the table below shows a clear and feasible structure on who is doing what, it is from this table clear that Health Canada tests all Novel Foods according to the Food and Drug Act, i.e. still the “traditional” process oriented way.

**Table 1** Legislation governing biotechnology

Agency	Product	Act
Canadian Food Inspection Agency (CFIA)	Plants with novel traits	Seeds Act
	Novel fertilizers and supplements	Fertilizers Act
	Novel livestock feeds	Feeds Act
	Veterinary biologics	Health of Animals Act
Environment Canada	All animate products of biotechnology for uses not covered under other federal legislation	Canadian Environmental Protection Act (1999)
Health Canada	Novel foods	Food and Drug Act
	Pest control products	Pest Control Products Act

**Fig. 1** Legislation governing biotechnology in Canada, from (Smyth & McHughen, 2008), the source: (Health Canada, 2006a)

*“To date, in Canada, most commercialized genetically engineered plants have been considered to contain novel traits, and therefore have been assessed for safety. However, the approach used by the CFIA does not mean that all PNTs are developed through genetic engineering. Novel traits can be developed through various techniques (other than genetic engineering), such as mutagenesis, somaclonal variation and other forms of what, in other countries, are considered as ‘traditional’ breeding. Canada does not use the breeding process as a trigger for regulation, but instead focuses on the features of the product.” (Smyth & McHughen, 2008)*

The procedures foreseen are the following ones (Smyth & McHughen, 2008)

- 1.** *The potential of the plant to become a weed or to be invasive of natural habitats.*
  - 2.** *The potential for gene flow to wild relatives.*
  - 3.** *The potential for a plant to become a plant pest.*
  - 4.** *The potential impact of a plant or its gene products on non-target species.*
  - 5.** *The potential impact on biodiversity (CFIA, 2004b).*
- Because of the above definition and the subsequent*

The table below explains the first procedures in detail (CFIA, 2007), a simplified similar figure in (Smyth & McHughen, 2008):



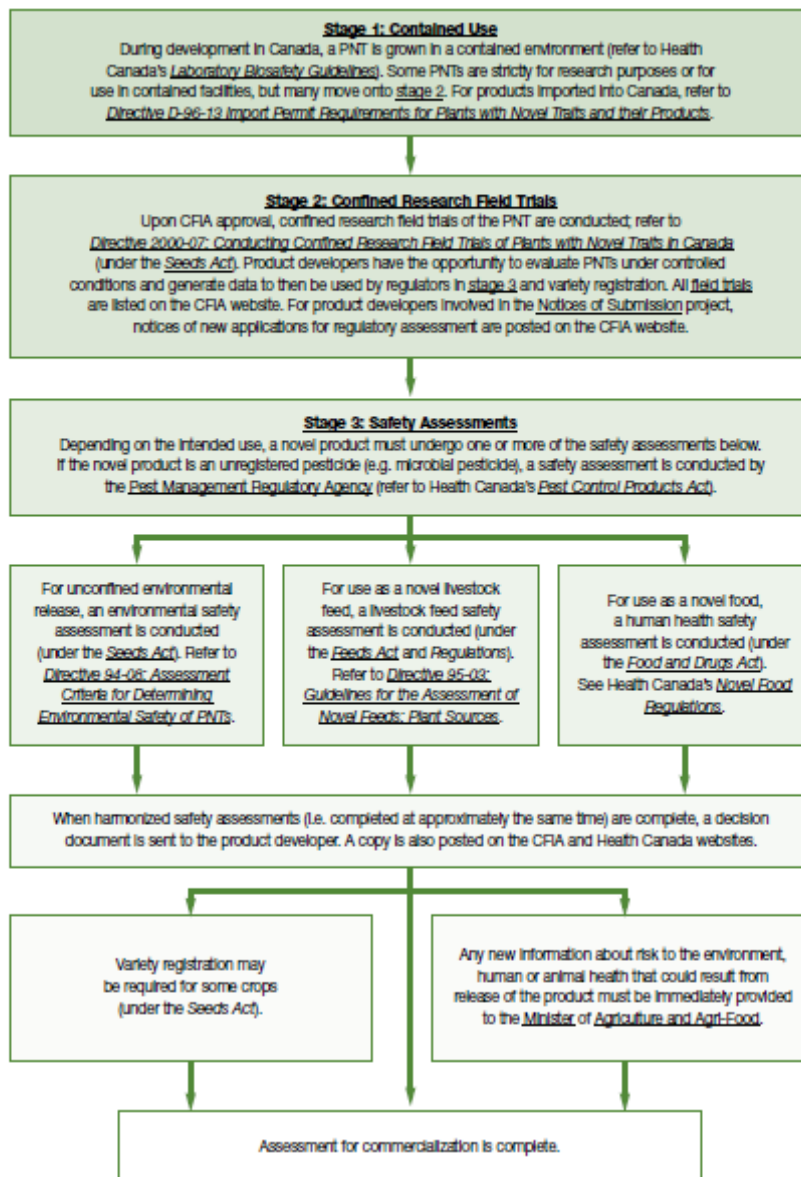


Fig. 34 Regulation of Plants with Novel Traits (PNTs) and/or Novel Livestock Feeds Derived from Plants in Canada (Figure 1 in: (CFIA, 2007). A simplified figure in: Regulation of plants with novel traits in Canada. Source: (CFIA, 2006), see simplified fig. 2 in (Smyth & McHughen, 2008)

Unlike the Canadian Food Inspection Agency (CFIA) the Canadian Health Agency is testing all transgenic products with focus on processes (Health Canada, 2006a).

- "Foods resulting from a process not previously used for food.
- Products that do not have a history of safe use as a food.
- Foods that have been modified by genetic manipulation, also known as genetically modified foods, GM foods, genetically engineered foods or biotechnology-derived foods."

A clear downside of the Canadian regulatory system is lacking harmonization between the three agencies involved in the decision making process: Canadian Food Inspection Agency, Canada Health and Canada Environment. Canada Health also has established directives for environmental safety assessment of GMOs, but harmonization with the Canadian Food Inspection Agency is still under way

and delayed and the websites from 2007 are no more found with active links as cited in (Smyth & McHughen, 2008), there are more details commented there.

It is interesting to note that the Canadian regulatory system respects properly done approval processes from other countries. The definition of scientific criteria for the assessment of risks of PNTs needs to be improved. However, non-novel GM crops have to undergo regulatory scrutiny also in Canada, and Smyth & McHughen would certainly support the letter petitions of PRRI to the Cartagena Protocol organization for a limited exemption of well known and well regulated GM crops (PRRI, 20090914, 20120516) and address this request also to the Canadian regulatory organizations.

The time has come to re-assess the regulatory system in its scientific details, although the success in properly regulated novel traits in GM canola, soybean and maize has been considerable up to now. The comments of (Smyth & McHughen, 2008) are similar to the complaints of their European colleagues:

*“The rigours of the regulatory requirements, in terms of the cost of conducting the studies necessary to gather sufficient data to meet the demands of the regulators for aspects such as gene flow, allergenicity and toxicity, are pushing public researchers out of the variety development industry. Public research institutions have limited budgets and simply do not have the finances to undertake the expensive research required to satisfy regulators. The concern within the seed development industry is that the commercialization of new traits will only be performed by large multinational seed developers, thereby having a potentially large negative impact on the continuing development of crop varieties that are best situated for Canada, such as canola. There is justified concern about the increase in regulatory requirements for GM crop varieties, as this increase in regulation is not justified by any increase in risk.” (Smyth & McHughen, 2008).*

For more details and insight it is recommendable to visit the websites of the Canadian Food Inspection Agency CFIA <http://www.inspection.gc.ca>, Health Canada [www.hc-sc.gc.ca](http://www.hc-sc.gc.ca) and Environment Canada [www.ec.gc.ca](http://www.ec.gc.ca) and some additional references selected: (CFIA, 2010, 2012a, b, c, 20120206; Environment Canada, 1999a, b, c, d, e). See also the latest book edition on the same subject: (Wosniak Chris A. & McHughen Alan, 2012).

One also has to realize, that the Canadian regulatory system is working smoothly up to now (some flaws described above causing unnecessary delays in approvals), not only because it sticks to product-oriented regulation, but according to (Prince, 2000) it maybe even more important that the agency has changed to a more entrepreneurial character within the Canadian administration, making the whole structure definitely more efficient:

*“The CFIA has gathered together most of the Canadian government’s food inspection expertise and regulatory activities. It has a workable organizational design as a departmental corporation, with elbowroom in which to innovate on the administrative and management side. A major asset of the agency is its strong core of scientific and technical employees, reinforced by multiple linkages to scientists and scientific organizations across Canada and around the world. Reinventing government is about politics as much as administration, and the present age is one of continuities as well as discontinuities in public policy and management.” (Prince, 2000).*

This pragmatic diagnosis in the light of product-oriented regulation is logically not welcome to an author like (Andree, 2002), who argues in a more negative way citing activists like Jeremy Rifkin, who care more about politics than science.

There are many manifestos on re-installing science in modern agriculture from Academies and other scientific bodies, as a recent collection of Piero Morandini demonstrates: (Morandini Piero, 2012)

The example from the ABIC conference in Cologne 2004 (Ammann & Salamini, 2004) calls for the use of unbiased information in law-making and politics, the support of R&D to foster innovation in plant

genetic engineering and the elimination of unnecessary, currently existing hurdles in laws and regulations concerning these technologies.

There should be no illusions, the search for a more science based regulatory system needs hard work for months, needs an international perspective in times of growing globalization, which counts also for the opposition of GMOs, it may even take years to come and can only be solved with modern discursive methods of the second generation (Ammann, 2007a; Ammann & Papazova Ammann, 2004), it is also necessary to make use of proposals of regulatory innovation from people experienced in regulatory science: (Sanvido et al., 2008, 2009; Sanvido et al., 2011a; Sanvido et al., 2011b; Sanvido et al., 2012) and (Durham Tim et al., 2011) to give a few examples.

### **10.5. Call for new, biotechnology promoting international institutions for the establish of new regulatory de minimis rules for new breeds.**

This debate should not be abused for a new, fancy and expensive regulatory system per se, on the contrary, what we need is a regulation in a perspective for a development of new useful agricultural products (Juma, 2011a, b, c). In this situation we need truly innovative thought and leave the usual paths. This is also confirmed by the fact that the author of this chapter has followed most of the MOP conferences of the Cartagena Protocol and clearly experienced the futility of numerous letters and floor interventions in order to move things to a more reasonable regulatory system.

Beyond the open end discourse over many years it is still doubtful, whether the deeply entrenched negative agbiotech framing process can be overcome within the present international institutions such as the Cartagena Protocol on Biosafety or the onesided defensive European biosafety legislation (running mainly in protectionist mode). It will be even more difficult to introduce the product oriented regulation.

This is why Harvard Professor Calestous Juma, the former executive director of the UN Convention on Biological Diversity, proposes to create a new independently financed international body: (Juma, 2011c) and comment: (Ridley Matt, 20111210), see also (Juma, 2011a, b). He does not hide his clear disappointment about the global structures responsible for the promotion and regulation of agricultural biotechnology:

*“The 1992 Earth Summit created the UN Convention on Biological Diversity (CBD) to promote the conservation and sustainable use of biological diversity as well as foster equitable sharing of the benefits of biotechnology. Yet for two decades this treaty has curtailed the use of genetically modified organisms (GMOs) in agriculture, even though the greatest threats to biological diversity are deforestation and invasive species. This is mainly because only 8 of the 196 national focal points for the CBD, which are located in environmental ministries, are not hostile to biotechnology. The role of the scientific community at these CBD meetings is often limited to negotiating texts that have been drafted by government officials and international civil servants with the intent of smothering agricultural biotechnology.” (Juma, 2011c)*

Calestous Juma’s conclusions related to Africa are also the ones for this review:

***The time has come for the scientific community to advance a new generation of international organizations that expressly promote scientific cooperation — agencies that can help foster technological cooperation for Africa’s economic transformation.***

**And:**

***African countries should break the logjam by creating an “International Institute for Biotechnology.” The new institute would be created under a charter signed by governments and other invited agencies. The legislative authority should come from the government agencies, private enterprises, universities, scientific associations, farmers’ groups, and others charged with advancing biotechnology and allied fields. The agency would help African countries adopt biotechnology strategies enabling African farmers and the population at large to benefit from the world’s wealth of scientific and technological knowledge. (Juma, 2011c)***

This new institutions, primarily born out of Africa, including more developing countries, together with a coalition of Asian, South American and North American countries could then start with a new legislation and regulatory system (see sections 2.5), which is building on a balanced, science based view on new breeding methods, leaving room for the fast new developments coming, and since it should be based on a product oriented regulation, it might be unfortunately not possible to initiate this major change in regulation within the present day international biosafety institutions.

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