GENOMIC MISCONCEPTION.

A fresh look at the biosafety of transgenic and conventional crops:
a plea for a process agnostic regulation

Klaus Ammann, Bern University, Switzerland

klaus.ammann@ips.unibe.ch

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ABSTRACT AND HIGHLIGHTS

The regulation of genetically engineered crops in Europe and within the legislation of the Cartagena Biosafety Protocol is built on false premises. The claim was (and unfortunately still is) that there is a basic difference between conventional and transgenic crops, despite the fact that this has been rejected on scientifically solid grounds for many years. This contribution collects some major arguments for a fresh look at regulation of transgenic crops; they are in their molecular processes of creation basically no different from conventional crops, which are based in their breeding methods on natural, sometimes enhanced mutation. But the fascination and euphoria of the discoveries in molecular biology and the new perspectives in plant breeding in the 1960s and '70s led to the wrong focus on transgenic plants alone. In a collective framing process the initial biosafety debates focused on the novelty of the process of transgenesis. When early debates on the risk assessment merged into legislative decisions, this wrong focus on transgenesis alone seemed uncontested.

The process-focused view was also fostered by a conglomerate of concerned scientists and biotechnology companies, both with a vested interest at least to tolerate the rise of the safety threshold in order to secure research money and to discourage competitors of all kinds. Policy minded people and opponent activists without deeper insight in the molecular science agreed to those efforts without much resistance.

It is interesting to realise, that the focus on processes was uncontested by a majority of regulators, this in spite of serious early warnings from important authorities in science, mainly of US origin. It is time to change the regulation of GM crops towards a more science based, process-agnostic legislation.

Although this article concentrates on the critique of the process-oriented regulation, including some details about the history behind it, there should be no misunderstanding that there are other important factors responsible for the failure of this kind of process-oriented regulation, most importantly: the predominance of politics in the decision making processes, combined with the lack of serious scientific debates on regulatory matters within the European Union and also in the Cartagena system; the obscure and much too complex decision making structures within the EU; and the active, professional, negative and intimidating role of fundamental opposition to GM crops on all levels dealing with flawed science, which can also be seen parallel science published by 'independent' scientists.

- GMO regulation is built on false premises in the EU and the Cartagena biosafety protocols.
- Molecular processes of transgenesis and natural mutation are similar
- It's Time to change GMO regulation towards a science based product oriented legislation
- Some legislations like the one from Canada rely on Novel crops, conventional or GMOs

1. THE SCIENTIFIC BASIS OF THE PROCESS-AGNOSTIC REGULATION

Genetic engineering has been brought into the evolutionary perspective of natural mutation by authorities such as Werner Arber: his view, already published in 1990 and downloadable from SCOPE (Arber, W, 1990) remains scientifically uncontested, namely that molecular processes in transgenesis and natural mutation are basically similar (Arber, W, 2001). In three recent papers he re-emphasised those similarities on a broader organismal and evolutionary basis (Arber, W, 2010a, Arber, W, 2011a, Arber, W, 2011b)

Arber notes (Arber, W, 2002):
"Interestingly, naturally occurring molecular evolution, i.e. the spontaneous generation of genetic variants, has been seen to follow exactly the same three strategies as those used in genetic engineering. These three strategies are:

(a) small local changes in the nucleotide sequences,
(b) internal reshuffling of genomic DNA segments, and
(c) acquisition of usually rather small segments of DNA from another type of organism by horizontal gene transfer."

Fifteen years of intensive biosafety research have diminished those concerns considerably as mentioned by many specialists, including the Public Research and Regulation Initiative (PRRI) in several letters to the European and International regulatory agencies; as an example a letter from September 14, 2009 see (PRRI, 20090914) , which also insists on a process-agnostic regulation of genetically modified (GM) crops. Until now the reaction of the authorities on the European and international level has been clearly insufficient.

There is proof of political pressure from green activists and parties (Young, FE & Miller, HI, 1989) for this process-based regulation, astonishingly enough excluding also forced mutagenesis for example. Since the first establishment of the process focus in GM crop regulation in the early 2000s, a very strong lobby with important influence at the European and the UN level has fought for even tighter regulation related to the marketing of genetically modified (GM) crops. The regulatory rules have been strengthened continuously due to political pressure, not just in the EU but also in other countries such as India, for example. (Ricroch, AE, et al., 2011a, Taverne, D, 2011). The "precautionary principle" has acquired the status of a doctrine in EU regulation, but actually should be 'renamed' to its original legal term "precautionary approach" with its clearly different and more open minded meaning (McHughen, A, 2007, Morris, SH & Spillane, C, 2008, Sunstein, CR & Zeckhauser, R, 2011). According to Durham et al. process- agnostic regulation needs to be considered seriously in the future (Durham Tim, et al., 2011), and should furthermore also include a *de minimus* approach. The authors call for more balance in regulation: whereas only a minimal number of GM crops received approval in the US going through excessive regulation, thousands of non-GM crops have been cleared with little, if any regulatory scrutiny, clearly a situation not in balance with actual experience in a risk comparison between transgenic and conventional crops based on hard field data.

Understanding the molecular basis of the process-agnostic regulation also makes it easy to accept the fact that transcriptomic disturbance in transgenic crops is less important than in conventional crops, for which numerous papers gave evidence (Batista, R, et al., 2008, Batista, R & Oliveira, MM, 2009, Batista, R & Oliveira, M, 2010, Baudo, MM, et al., 2006, Baudo, MM, et al., 2009, Conner, AJ & Jacobs, JME, 1999, Jiao, Z, et al., 2010, Kogel, K-H, et al., 2010, Montero, M, et al., 2011, Ricroch, AE, et al., 2011b, Ricroch, AE, 2012, Shewry, PR & Jones, HD, 2005, Shewry, PR, et al., 2006, Shewry, PR, et al., 2007, Tenea, GN, et al., 2012, Torgersen, H, et al., 1998), and lately also by (Herman, RA & Price, WD, 2013), combined with a hefty, uncompromising call for a thorough revision of GM crop regulation. Many comparative lab and field experiments with GM crops versus conventional crops neglected in the past the natural variation of all crops no matter what breeding method has been applied. Results are often more influenced by natural variation and as demonstrated, even more than genomic variation of transgenic crops (Batista, R & Oliveira, MM, 2009, Batista, R & Oliveira, M, 2010). However, precise transcriptomic analysis has also revealed the non-uniform distribution pattern for differentially expressed genes of transgenic rice Huahui 1 at different developmental stages and environments (Liu, Z, et al., 2012) – which clearly demonstrates that the learning process in molecular genomics will go on – and will prove that regulation of GM crops needs more science based flexibility. It should however be clear that the new results of (Liu, Z, et al., 2012) have no direct relation to biosafety issues. Because of the persistence of the Genomic Misconception myths are also growing that GM crops have more unintended effects than conventional crops. This has been disproven by important publications and reports such as the book from the National Academy of Sciences (NAS National Academy of Sciences, 2004), clearly stating:

"In contrast to adverse health effects that have been associated with some traditional food production methods, similar serious health effects have not been identified as a result of genetic engineering techniques used in food production. This may be because developers of bioengineered organisms perform extensive compositional analyses to determine that each phenotype is desirable and to ensure that unintended changes have not occurred in key components of food."

However, there are exceptional cases like that on GE peas from Australia, which seemingly showed altered structure and immunogenicity, so that the research team decided on a precautionary level not to pursue the case for food applications. (Prescott, VE, et al., 2005). The case is often cited by opponents as a clearly negative, unexpected incidence, but recently a study has been published demonstrating that genetically modified Alpha-Amylases are not specifically allergenic to the tested mice: (Lee, R-Y, et al., 2012).

Another research trend reveals that epigenesis has to be taken into account seriously: The processes might be involved in resulting into genomic differences due to external stress situations:

It should also be made clear that food as a result from GE or conventional crop breeding shows the same metabolic complexity, so that reductionist conclusions will always fail (Keurentjes, JJB, et al., 2006).

2. HOW THE GENOMIC MISCONCEPTION WAS EVOLVING

In the wake of molecular genetics, Oswald T. Avery and colleagues (Avery, OT, et al., 1944) wrote about their historic discovery of DNA as the molecule uniquely associated with the storage and transfer of genetic information between different strains of bacteria (see the comments of Lederberg about the importance of this discovery (Lederberg, J, 2000)).

The biosafety debates started soon after the discovery of the DNA double helix structure by Watson and Crick (Watson, JD & Crick, FHC, 1953a, Watson, JD & Crick, FHC, 1953b, Watson, JD & Crick, FHC, 1953c), and Wilkins (Wilkins, MHF, et al., 1953), the history of the groundbreaking discovery is treated in Glickstein, Olby and Vasil (Glickstein, NM, 1995, Olby, R, 2003, Vasil, I, 2008) and the major account in Watson and Tooze (Watson, JC & Tooze, J, 1981). The justified euphoria also led to impressive perspectives about the new possibilities to manipulate living organisms. Later, Cohen et al. (Cohen, SN, et al., 1972, Cohen, SN, et al., 1973) discovered successful ways of 'gene splicing' by the construction of new biologically functional plasmids in vitro through joining cohesive-ended plasmid DNA molecules of entirely different origin. The same authors also predicted that these general procedures could be used for the insertion of specific DNA sequences from prokaryotic or eukaryotic chromosomes or extra-chromosomal DNA into independently replicating bacterial plasmids. These transfer methods have been constantly refined and made more efficient and safer (Fraley, RT, et al., 1983, Potrykus, I, 1991, Witkowski, J, 1988). Another breakthrough was initiated by more and more efficient DNA sequencing methods, starting with Sanger et al. (Sanger, F, et al., 1973) and continued by Maxam & Gilbert and Smith & Birnstiel. (Maxam, AM & Gilbert, W, 1977, Smith, HO & Birnstiel, ML, 1976). A recent insight and overview on the next generation sequencing methods is given by Ansorge: (Ansorge, WJ, 2009) and Delseny (Delseny, M, et al., 2010).

In a first debate phase, biosafety concerns were predominant among a majority of leading scientists. Under the impression of the many unknowns in the pioneer phase, concerned scientists called for an international conference on biosafety related to recombinant DNA (Singer, M & Soll, D, 1973), which was then organised by an international committee. The well attended conference took place in Asilomar, California with the task to discuss potential risks of the new technology (Berg, P, et al., 1974, Berg, P, et al., 1975, Berg, P & Singer, M, 1995, Fredrickson, D, 2001, Rogers, M, 1975). According to Norton Zinder (Zinder, N, 1986) the US debate can be divided up into (1) the Asilomar period (1974-76), (2) and the period of 'recombinant DNA wars' (1976-78), summarised in (Zilinskas, RA & Zimmerman, BK, 1986) and (3) the subsequent détente period.

The times of the *'recombinant DNA wars'* were accurately reflected by the first very strict guidelines issued by the National Institutes of Health (NIH), but they did not mark the end of the discussions (Norman, C, 1976). The critical first phase is also well mirrored by a letter from EMBO to the NIH (EMBO, et al., 1976); concerns were numerous but the letter also warns against further tightening of the safety rules, in particular those on containments for diverse experiment risk levels.

According to Mark Cantley (Cantley, M, 1995) the US debate, starting with full speed in 1976, made step by step good progress, and entered after the hefty debates from 1976 to 1978 into a period making use of a rapidly growing molecular insight, and consequently replacing unfounded concerns with confirmed and precise science, thus easing the conflicts in a period of détente.

"A major feature of the debates in the US was the progressive development of a well-organized, articulate and balanced response by the scientific community. The leading role was played by the American Society of Microbiology (ASM), but many other professional associations of biological and medical sciences joined with ASM in a broad alliance, through semiformal linkages via their executive officers, and widespread networks capable of providing rapid responses." (Cantley, M, 1995).

But it should also be made clear that the US debate suffered from many problems, as the ASM expressed strong criticism on the debate at hearings in November 1977 (Halvorson, HO, 1977a, Halvorson, HO, 1977b)

"The apparent intemperate rush to establish legislation to regulate recombinant research without first consulting with the appropriately qualified scientific and medical experts, the need to understand that early allegations concerning recombinant DNA research were characterized by uncontrolled imagination and excessive claims by individuals who lacked knowledge of infectious disease, and the need for minimal interim legislation to extend appropriate guidelines to all recombinant DNA activities regardless of funding source." (Halvorson, HO, 1977a, Halvorson, HO, 1977b)

Solutions were achieved thanks to an open and earlier debate, also due to the fact that authorities and congress in the US demonstrated a remarkable ability to learn at the same speed that scientific knowledge was growing. Deepening molecular insight enabled a better understanding of transgenesis. This was more dynamic in the US, and earlier than in Europe, not due to better science, but because of the more adequate discursive structures. Another important difference in this opening transatlantic divide is hidden in the differences of major political structures, i.e. between the USA with its powerful centralized regulatory structures and contrasting to those a much less centralized regulatory structure in the EU, with hampered decision making processes and debate structures, clearly diagnosed as obscure, too complex and deeply dysfunctional by a new study done by independent experts for DG Sanco (EPEC-SANCO, 2011) The result of major delays, in some cases for years, in the approval of GM crops are obvious (EuropaBio, 2013ff).

Finally, the US came to a solution in regulation of GM crops which holds up in its main lines until today, due to the efforts in the regulatory system, as summarized by (Tooze, J, 1978).

2.1. SOME REASONS WHY THE 'GENOMIC MISCONCEPTION' WAS ERRONEOUSLY MAINTAINED IN EUROPEAN REGULATION AND THE CARTAGENA PROTOCOL ON BIOSAFETY

A) EUROPE, THE DEVELOPMENT OF THE TRANSATLANTIC DIVIDE WITH THE UNITED STATES

Support for a process-agnostic view (today followed by only a few countries like the USA and Canada) has been published in official letters of European scientists, including 16 Nobel Prize laureates, in which they warned against a legislation targeting the process (transgenesis) alone and not the product itself (its traits), a regulatory erroneous principle which can be called *'Genomic Misconception'*. The scientists unanimously stated, the full text coming from (Cantley, M, 1995), bold from the author:

"Dear Mr. President,
In the fourth week of May the European Parliament will debate in Plenary Session a subject which is of vital importance for the future development of science in Europe, namely the three Commission proposals for Council Directives on biotechnology. The Council will decide on this matter at the beginning of June.
Recombinant DNA is a method in biology, without which modern research in this field is not possible. It allows small and well defined changes to be introduced into the genomic set-up of an organism. More than 90% of research and production use non-pathogenic and safe organisms. There are well established and internationally accepted safety standards which have been followed by a community of about one hundred thousand researchers in the past 15 years. The EC Commission has proposed three Council Directives, based on this experience. In principle there is no scientific justification to single out a technique for regulation instead of basing it on the properties of the generated organisms. Consequently, the proposal on 'Worker Protection' relates to 'Exposure to Biological Agents' irrespective of the method by which these agents may have obtained their characteristics. The proposals on"Contained Use" and"Deliberate Release" of genetically modified organisms are in line with already existing OECD recommendations and the guidelines o f a number of major countries, such as the USA and Japan. ***Amendments have been proposed which are based on unfounded fears rather than on scientific risk assessment.*** *They are both impractical and widely inhibitory to the progress of knowledge and its responsible beneficial applications. We refer in particular to those tabled by the rapporteurs for the Environment, Public Health, and Consumer Protection Committee. as well as those accepted additionally in the same committee.*
We would therefore appeal for your support for the Commission's proposals, un-amended in this important debate." From (Cantley, M, 1995)

Unfortunately, European authorities did not consider the timely recommendations of the Nobel laureates, and they also ignored advice by the US National Academy of Sciences as early as 1987 (NAS National Academy of Sciences, et al., 1987) with a clear message in favour of a process-agnostic view in regulation, based strictly on the general insights in molecular processes:

"There is no evidence that unique hazards exist either in the use of R-DNA techniques or in the transfer of genes between unrelated organisms", AND
"The risks associated with R-DNA engineered organisms are the same in kind as those associated with the introduction into the environment of unmodified organisms and organisms modified by other genetic techniques." AND
"Assessment of the risks of introducing R-DNA-engineered organisms into the environment should be based on the nature of the organism and the environment into which it will be introduced, not on the method by which it was modified."

The subsequent consolidated report of the US Academy of Sciences from 2000 (NAS National Academy of Sciences, et al., 2000) explicitly maintains this process-agnostic view, widening the perspective to health and environmental risks involved and admitting that research lacunas should be covered in the future:

"Although the same scientific arguments can be made for the risks posed by conventional pest-protected plants, which are not subject to regulation under the coordinated framework, lack of experience with transgenic pest-protected products and public concern with these products constitute practical reasons for not granting a categorical exemption to transgenic pest-protectants derived from sexually compatible species."

Unfortunately, it did not have any impact on European regulation, despite numerous publications in the US:
According to Cantley (Cantley, M, 1995) these developments were watched with growing alarm by scientific and industrial circles, in Europe and elsewhere in the world. In several publications in important science journals (indeed hard to overlook) the Commissioner of the US Food and Drug Association (Young) and his special assistant (Miller) had explicitly criticised the EU Commission's proposed Directive on field release. on three grounds (Young, FE & Miller, HI, 1987a, Young, FE & Miller, HI, 1987b, Young, FE & Miller, HI, 1987c) and cited below (Young, FE & Miller, HI, 1989):

- *"the underlying premises on which it was based;*
- *the risk of a regulatory approach that would hinder research and development;*
- *the possible use of its provisions to erect non-tariff trade barriers to foreign products."*

Developing the first point, they noted that:

"The directive is focused on the regulation of "genetically modified organisms (CMOS)", which are defined as those manipulated with only certain recently developed techniques, including recombinant DNA. Thus the directive preferentially singles out for stringent regulation the newest techniques of genetic manipulation that enable the most precise and predictable genetic changes. This is at odds with the broad consensus that these newest techniques represent a clear refinement, an improvement on conventional techniques of genetic manipulation that enhances the precision and predictability of the effects of intervention.
Such GMOs are clearly not a functional category. and most certainly not one correlated to risk." (Young, FE & Miller, HI, 1989)

The first scientist organising GM crop regulation in the US, Henry I. Miller, criticised strongly over many years and with dozens of publications in science journals the focus on transgenesis in regulatory procedures (for a selection see (Miller, HI, 1994a, Miller, HI, 1994b, Miller, HI, 1995, Miller, HI, 1997, Miller, HI, 1999, Miller, HI, 2002, Miller, JK & Bradford, KJ, 2010)), all blatantly ignored by the European authorities. There would be many more early voices stating the same, such as Halvorson (Halvorson, HO, 1977a, Halvorson, HO, 1977b).

Regulatory authorities in Europe and the UN (conceiving the Cartagena Protocol on Biosafety) obviously decided right from the beginning to ignore scientific information supporting the process-*agnostic* regulatory approach. They went instead for a strong focus on the process of transgenesis, thus following the British approach from 1978. They followed earlier advice from EMBO, the European Molecular Biology Organization, which followed a cautious strategy, not mentioning the genomic misconception problems (EMBO, et al., 1976).

A second letter by Nobel Prize Laureates pleading against the focus on the process of transgenesis was again blatantly ignored by the European authorities (more details can be found in Cantley 1995 (Cantley, M, 1995) and in the Czech White Book (Sehnal, F & Drobnik, J, 2009)). From the same White Book source: no wonder, that a clear statement against process oriented regulation by a major research association EMBO was also systematically ignored.. The 40th meeting of the Council of EMBO on 1st October 1988 discussed the flawed drafts of European regulation and came to the unanimous opinion:

"...that any legislation should focus not on the technique but on the safety or otherwise of the products generated with it. ...Over the last 15 years, experience has shown that recombinant DNA methods, far from being inherently dangerous, are an important tool both for understanding properties of life and for developing applications valuable to humankind and the environment. EMBO strongly believes that there is no scientific justification for additional specific legislation regulating recombinant research per se. Any rules or legislation should only apply to the safety of products according to their properties, rather than according to the methods used to generate them."

This statement was presented to the European Parliament on 16 May 1989 by Max Birnstiel, then the head of EMBO Council, and by Lennart Philipson, the Director General – again to no avail.

Another scientific and well documented attempt to change the course towards product oriented regulation was undertaken by Austrian Scientists (Torgersen, H, et al., 1998), one of the co-authors Helmut Gaugitsch acts today as the manager of the National Focal Point of the Cartagena Protocol, supporting the protocol with all consequences and details). The paper is based on well-selected field analysis data and comes to the following conclusion:

"In practice, the effects of Agricultural measures are more important than the effects of gene transfer and invasiveness, although the latter currently play a major role in risk assessment. In the light of these deliberations, a modification of Annex IIB of EU Directive 94/15/EC is suggested."

However, science lost the battle with the European regulators and the "method is risky and transgenesis is the only one of this sort" was accepted, cementing the Genomic Misconception (Sehnal, F & Drobnik, J, 2009).

It is likewise inexcusable, that joint statements of scientific authorities such as the one published in (Mooney, HA & Bernardi, G, 1990) under the leadership of Werner Arber were completely ignored (Arber W., BG, Brom S., Campbell A., Caplan A., Cherif-Zahar B. Christiansen, F.B., Crawley, M.J., Davila, G., Drake, J.A., Dwyer, D.F., Faust, R.M., Fenner, F., Flores, M., Goursot, R., Jayaraman, K., Kingsbury, D.T., Levin, D.T., Martinez, E., Melis, R., Mooney, H.A., Palacios, R., Pinero, D., Rayko, E., Romero, E., Skalka, A. M., Timmis, K.N., Van Montagu, M., 1990).

"In view of the great potential of new technologies for addressing environmental and other problems, and because most introductions of modified organisms are likely to represent low or negligible ecological risk, generic arguments against the use of new genetic methodologies must be rejected. Indeed, the spectrum of available tools represents an evolving and expanding continuum, which includes conventional methods, rDNA techniques, and others. While much attention has been focused on the methods used to modify organisms, it is the products of these technologies and the uses to which they will be put that should be the objects of attention, rather than the particular techniques employed to achieve those ends." (Arber W., BG, Brom S., Campbell A., Caplan A., Cherif-Zahar B. Christiansen, F.B., Crawley, M.J., Davila, G., Drake, J.A., Dwyer, D.F., Faust, R.M., Fenner, F., Flores, M., Goursot, R., Jayaraman, K., Kingsbury, D.T., Levin, D.T., Martinez, E., Melis, R., Mooney, H.A., Palacios, R., Pinero, D., Rayko, E., Romero, E., Skalka, A. M., Timmis, K.N., Van Montagu, M., 1990)

The list of co-authors in the above declaration is impressive – it is all the more baffling to see this important statement completely ignored in the Cartagena negotiations – the most plausible combination of reasons is the lack of scientific expertise and the political agenda influenced by green activists.

On the framework of the transatlantic divide there are several comprehensive publications available: (Bardy, R & Rubens, A, 2010, Bendiek, J & Buhk, H-J, 2010, Cohen, BJ, 2007, Conko, G, 2005, Conko, G & Miller, H, 2012, Cronin, B, 1987, Kochetkova, T, 2006, Miller, HI, 2003, PRRI, 20090914, Ramjoue, C, 2006, Ramjoue, C, 2007, Seifert, F, 2010, Tenea, GN, et al., 2012, Thro, AM, 2004, Torgersen, H, 2002). By summing up the papers, they show the multifaceted scientific, cultural, historical and socio-political reasons for such a divide, in contrast to the "engineered" and successful political alliance efforts of recent decades.

B) LEGISLATIVE HISTORY OF THE CARTAGENA PROTOCOL AND ITS GENOMIC MISINTERPRETATION OF TRANSGENESIS

The author communicated with many of the first hour participants in the negotiations of the Cartagena Protocol on Biosafety (Cartagena Protocol on Biosafety, 2000). The most notable details come from Prof. Alexander Golikov, member of the Russian Academy of Sciences and executive secretary of the Black Sea Biotechnology Association (BSBA) (http://www.bsbanet.org/) .

During the first session of the biosafety working group creating the Cartagena Protocol on Biosafety (22nd – 26th June 1996 in Aarhus, DK), Prof. Golikov was the rapporteur of the inaugural expert group *(Biosafety Working Group - BSWG-6).* He explicitly warned the working group (oral communication) not to follow the strict process- oriented regulation of GMOs, which was clearly ignored – and also not mentioned in the summary comments looking back to the decision making process (Koester, V, 2001):

"It is possible only to guess the reasons why the negotiations failed in 1999, but succeeded one year later. A group of countries, the so-called 'Miami Group', consisting of Argentina, Australia, Canada, Chile, the US and Uruguay, blocked the finalization of the negotiations in 1999. At the WTO meeting in Seattle at the end of 1999, Canada and the US tried to further a decision on the creation of a working group on biotechnology. This attempt, which was regarded by a number of other countries as an attempt to 'kill' the suspended negotiation on the Biosafety Protocol, failed because of resistance from

EU countries. Over 1999, growing skepticism towards products derived from gene technology and biotechnology had also been seen in countries such as Australia, Canada and the US."(Koester, V, 2001)

This is all-the-more astonishing, when you read about the more open-minded approach of the same chairperson Koester as described by Cantley at another occasion later: (Cantley, M, 1999):

"Following the Rio Summit of June 1992, the executive director of UNEP (UN Environment Program) charged four expert groups with reporting on how to implement the convention—one group being specifically charged to report on Article 19.3. As per the official text, we "considered the need for" a protocol, and opinion was divided; also as to appropriate modality (binding or advisory) if protocol there had to be. I was among those unconvinced of the need, and our chair, Veit Koester (subsequently chair of the Biosafety Working Group drafting a protocol), with the fair-mindedness for which he is renowned, agreed to our publishing (in 1993) a split report, recording both the case for a binding protocol, and the counter-arguments of those who saw neither scientific nor political need, and many practical reasons against."

Unfortunately, this initial view on the exclusive process focus has been cemented later, and only now there is a rising debate about its justification, see the final comments below.

In addition, the conflicts were substantiated in a detailed way by (Hagen, PE & Weiner, JB, 2001), where trade political reasons are enumerated - without mentioning the genomic misconception – and throughout the text it was taken for granted by the authors, that the focus of the biosafety protocol concentrates on LMOs (Living Modified Organisms, thus excluding all products 'Thereof').

"Throughout the negotiations, the Miami Group opposed provisions that would allow governments to subject commodities to advanced informed agreement procedures or documentation requirements (both of which are discussed more fully below) as these obligations would require segregation of LMOs from traditional agriculture products." (Hagen, PE & Weiner, JB, 2001).

About the negotiations, Hagen and Weiner published some details:

"The BSWG (Biosafety Working Group) met a total of six times, beginning in July 1996, and concluded its work in February 1999 at its sixth meeting (BSWG-6). Over one hundred governments, including the United States, participated in the negotiation of the Draft Protocol. In accordance with Decision IV/3 of the COP, the BSWG completed a controversial draft text (the Draft Protocol) in Cartagena and referred it to an extraordinary meeting of the COP (Ex-COP) for possible adoption. The Ex-COP opened February 22, 1999 in Cartagena, Colombia. However, disagreements concerning central features of the Draft Protocol, particularly concerning its scope and impact upon trade in GMOs, proved insurmountable. Unable to arrive at a text acceptable to all 134 CBD Parties in attendance, the COP decided to suspend the extraordinary meeting and reconvene no later than COP-5, scheduled to occur in May 2000." (Hagen, PE & Weiner, JB, 2001).

The 'Genomic Misconception' was discussed in transatlantic debates as an important issue *long before* the Cartagena Protocol negotiations started, and it was clearly one of the major transatlantic disputes, as documented (Miller, HI, et al., 1994) by the dispute on European biosafety research activities, below a proof of the political debate atmosphere in the early biosafety debates:

Crawley decries "arm chair assessment which formerly passed for ecological analysis" by non-ecologist 'pundits' who believed that 'a small transgenic change to genotype would have no impact on phenotype'. However, the 'arm-chair assessors and pundits' were, in this case, an impressive lot, and they included the U.S. National Academy of Sciences (NRC (National-Research-Council), 1989), the British House of Lords Select Committee on Science and Technology as well as a number of other international panels and professional groups. The broad scientific consensus was clear and compelling: 'no conceptual distinction exists between genetic modification of plants and microorganisms by classical methods or by molecular methods that modify DNA and transfer genes.' This broadly accepted opinion was based on the ability to extrapolate from general scientific principles (especially those derived from the knowledge of the biological world and from the understanding of evolutionary biology). These concepts served to remind everyone that they were derived from scientific experiments built upon one another and that real progress is not achieved by trivial confirmations. Let us note what a leading ecologist had to say in these early debates on regulation of GM crops. Crawley for instance agreed with this opinion above, citing among others the statement of the Ecological Society of America (Tiedje, JM, et al., 1989):

"Genetically engineered organisms should be evaluated and regulated according to their biological properties (phenotypes), rather than according to the genetic techniques used to produce them."

And some paragraphs later Tiedje states:

"Transgenic organisms can be designed to minimize the chance of environmental perturbations. The choice of the trait and parent organism used, the form of the genetic alteration, and the control of its expression all affect the likelihood that the genetically engineered organism will have undesirable effects. In addition, the conditions of the organism's introduction can be planned to minimize potential problems. Thus, we believe that with careful design of transgenic organisms and proper planning and regulatory oversight of environmental releases, the introduction of many transgenic organisms can be carried out with minimal ecological risk."(Tiedje, JM, et al., 1989)

But this should according to the authors not be understood as a call for complete deregulation, as they also emphasize:

"Although we support the timely development of environmentally sound products through the use of advanced biotechnology, we believe that these developments should occur within the context of a scientifically based regulatory policy that encourages innovation without compromising sound environmental management."(Tiedje, JM, et al., 1989)

In his own words, Crawley published in the SCOPE/COGEN volume: (Crawley, MJ, 1990)

"There seems to be a view that the ecology of genetically engineered organisms is somehow different - more inscrutable perhaps, but certainly more dangerous - and that the intentional release of genetically engineered organisms poses more of a threat to the balance of nature than other kinds of organisms bred by man. This view is mistaken. While there are risks associated with the introduction of any novel organisms into a habitat, the ecology of genetically engineered organisms is exactly the same as the ecology of any other living thing. The rules are precisely the same, no matter how the genotype is put together. Populations must have an intrinsic rate of increase greater than zero in order to persist (see below). They must be supplied with essential resources at a sufficient rate to allow this multiplication rate to be expressed. Transgenic individuals are exposed to predators, parasites, diseases, and competitors, and suffer the same kinds of losses during dispersal as any other organisms. They may require mutualists for resource gathering, reproduction, defense, or dispersal. They must deal with the vagaries of changing weather and heterogeneous substrate in the same way as any other organisms."

But then Crawley continues in his reply in (Miller, HI, et al., 1994) in a way one would not expect from an independent scientist having written excellent and seminal papers on the ecology of transgenic crops:

"The trouble is, that it doesn't really mean anything. In the real world, GMOs are treated differently from other organisms. The reason they are treated differently is because governments and bureaucrats have decreed that it should be so. And why did they do this? Because of fear and uncertainty." Cited from (Miller, HI, et al., 1994)

The author of this paper's comment is rather simple: the 'real world' should still follow sturdy science, but unfortunately there is a 'false world' clearly following the scientifically wrong path on political and governmental levels and with the help of populist politicians and scientists, not at all justified by peer reviewed science. The last statement of Crawly is all the more astounding, as the same author published a still valid and often cited paper on long term aspects of the environmental impact of GM crops, where he himself cannot find any difference between transgenic and non-transgenic crops related to long term survival, (Crawley, MJ, et al., 2001). His conclusions are interesting:

"These experiments involved GM traits (resistance to herbicides or insects) that were not expected to increase plant fitness in natural habitats. Our results do not mean that other genetic modifications could not increase weediness or invasiveness of crop plants, but they do indicate that arable crops are unlikely to survive for long outside cultivation. The ecological impact of plants with GM traits such as drought tolerance or pest resistance that might be expected to enhance performance under field conditions will need to be assessed experimentally when such plants are developed."

The author agrees that Crawley cannot generalise his conclusions about longevity of transgenic crops towards other, e.g. stress-resistant, transgenic traits, but one cannot ignore the fact that there are non-transgenic traits (bred e.g. with TILLING methods, sometimes enhanced by radiation mutation) with the same characters as transgenic ones (Slade, AJ, et al., 2005). Further, according to Crawley's own logic, transgenic crops with similar characteristics and ecological impact as the conventional ones should be excluded from any concern.

From here the step is a small one to call for a lowering of the obstacles in the regulation of transgenic crops, as the Public Research and Regulation Initiative has called for several times, the last one in May 2012 (PRRI, 20120516); it is a call for the identification of LMOs that are not likely to have adverse effects:

"Consequently, enough knowledge and experience has accumulated to allow countries to formulate simplified procedures or exemptions for various categories. In fact, PRRI believes that the formulation of simplified procedures or exemptions is long overdue in many countries, which not only has seriously hampered the potential of public biotechnology research, but also reconfirms the misperception of many that there is something inherently dangerous about LMOs. PRRI therefore commends the MOP for starting an exchange of views and experiences on identification of LMOs that are not likely to have adverse effects. PRRI envisions that the information and concepts in this present paper facilitates a more in depth consideration by the Parties." (PRRI, 20120516).

Another proof of early disputes on the 'Genomic Misconception' is given in detail in (Huttner, SL, et al., 1995):

"The U.S. Department of Agriculture (USDA) and the Environmental Protection Agency (EPA) took a very different course than FDA, proposing entirely new regulatory schemes specifically targeting the use of the new genetic techniques in research. These regulatory schemes conflict with worldwide scientific consensus that rDNA techniques and rDNA-modified organisms are not inherently dangerous or unpredictable ((Kelman, A, et al., 1987, Mooney, HA & Bernardi, G, 1990) , (NRC (National-Research-Council), 1989) (Fiksel, Ji, et al., 1988), (Sears R., et al., 1998), (UNIDO/WHO/UNEP Working Group, 2001), (APHIS, U, 1987)). There is no valid conceptual distinction regarding safety between modern and older genetic methods. The scientific community has found from millions of laboratory experiments and thousands of field trials that the precision of rDNA techniques actually enhances determinations of safety and risk. This confidence is not, however, reflected in EPA and USDA regulations on field research."

A rich source of the history and dynamics of the transatlantic biosafety dispute can be downloaded at the COGEN site: a selection of the Statement of Werner Arber (Arber W., BG, Brom S., Campbell A., Caplan A., Cherif-Zahar B. Christiansen, F.B., Crawley, M.J., Davila, G., Drake, J.A., Dwyer, D.F., Faust, R.M., Fenner, F., Flores, M., Goursot, R., Jayaraman, K., Kingsbury, D.T., Levin, D.T., Martinez, E., Melis, R., Mooney, H.A., Palacios, R., Pinero, D., Rayko, E., Romero, E., Skalka, A. M., Timmis, K.N., Van Montagu, M., 1990) and 5 publications dealing specifically with the 'Genomic Misconception' are cited here (Campbell, A, 1990a, Campbell, A, 1990b, Crawley, MJ, 1990, Kingsbury, DT, 1990, Skalka, AM, 1990). Interestingly enough, they all are more or less in agreement with the opinion of the Miami Group on the molecular similarity between transgenesis and natural mutation. Mooney & Bernardi (Mooney, HA & Bernardi, G, 1990) edited all the downloadable chapters in a book still available and also downloadable from the SCOPE website http://www.scopenvironment.org/downloadpubs/scope44/contents.htm

There are several more accounts of the history of the Cartagena Protocol dispute, but symptomatically, they are almost completely devoid of the molecular science behind the debate (Giesecke, S, 2000, Munson, A, 1993); nevertheless they give detailed insight into the chronology and the political fights at the surface of the delegate disputes. The same attitude of avoiding the mention of the different genomic views can be detected in the minutes of the first official Negotiations on the Cartagena Protocol on the Bahamas and later, documented in the Earth Negotiation Bulletin (ENB-IISD-Cartagena-Negotiations, 19990214-26).

By contrast, Anatole Krattiger explicitly draws attention to the Genomic Misconception, but still comes to the conclusion in his chapter on biodiversity and biosafety, that although he considers the process focus in regulation not science based, it might still be the best compromise (Krattiger, A & Lesser, W, 1994) to continue this way.

Mark Cantley was mandated to produce a comprehensive report on the regulatory tools developed by governments for the OECD (Cantley, M, 2007), see also (Cantley, M, 2004, Cantley, MF, 2008), and not surprisingly, Cantley sums up the impact of the Cartagena Protocol in a critical way.

The Cartagena Protocol on Biosafety is based on negotiations following on Article 19.3 of the Convention on Biological Diversity:

"The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity."

"The Protocol is thus intended to protect biological diversity and human health from the potential risks arising from GMOs by providing a clear legal framework for their transboundary movement. The Advance Informed Agreement (AIA) procedure established by the Protocol will ensure that countries can make informed decisions on whether to import GMOs intended for introduction into the environment. Shipments of GMO commodities will have to fulfil specific documentation requirements.

The Protocol has enjoyed a high profile, and Environment Ministries see it as a significant instrument, in some degree a riposte to the world trade agreements; although scientifically, it is not clear that GMOs as so far developed and used in fact constitute a threat to biological diversity.

As at October 2006, 134 countries had ratified the Protocol, including the European Union; but with notable absentees, such as the United States, Canada, Argentina, and Australia – all significant agricultural exporters. New Zealand ratified, somewhat hesitantly, in order to exert influence to prevent the requirements imposed becoming more adverse." (Cantley, M, 2007).

Unfortunately, the dynamics of life DNA processes (and so many other facts in molecular sciences as described e.g. by Werner Arber etc.) were not taken properly into account when the Cartagena protocol on biosafety was conceived – no surprise when it is realised how few knowledgeable molecular scientists have actively participated in the legislative process. There was only a minimal overlap of 12 experts between the Cartagena Protocol Roster of Experts and the number of members of the International Society of Biosafety Research in 2004. (PRRI, 2006-2010b) This means, as it has been stated by many molecular scientists that the Cartagena Protocol debates were clearly dominated by politics.

It is unfortunate, that UNIDO as a United Nations Agency for Industrial Development paints, in ignoring the background of the Genomic Misconception, but also points at the political elements in the wrong and calls for revision of regulation (Tzotzos, GT, 2001), but see also the UNIDO presentation at a Kuala Lumpur Cartagena Protocol Meeting in 2007, where Tzotzos explicitly criticises event-based regulation: (Tzotzos George, 2007).

It also has to be stated, that proof is available that the roster of scientific experts remained practically inactive, and it is only known through the initiative of PRRI (Public Research and Regulation Initiative that renewal and activation of this panel would be urgently needed. See the letters of PRRI to officials of the CBD (PRRI, 2006-2010a) , some citations:

" The Public Research and Regulation Initiative (PRRI) believes that the mechanism of the Roster of Experts hasn't worked to date, because there is clearly no common view as to what constitutes an expert and because there is insufficient information on the BCH about the area of expertise of the experts involved. We therefore welcome the decision by the MOP to develop draft criteria, minimum requirements and to explore a quality control mechanism for experts to be included in the Roster of Experts of the BCH."

And:

"The types of expertise that may be needed to assist a country in meeting its obligations under the Protocol are very diverse and include scientific expertise, legal expertise, and administrative expertise. Even within these areas there are many

different specialised fields, such as molecular biology, plant physiology, and population ecology. What is of crucial importance to the functioning of the Roster is that the area of expertise is explained in sufficient detail." (PRRI, 2006-2010a)

Sadly, the PRRI press release 2010 at the occasion of MOP5 at the Nagoya conference of the Cartagena Protocol demonstrates that practically zero progress has been made in this important issue from 2006 to 2011. See also other letters of PRRI (PRRI, 20100923, PRRI, 20101012, PRRI, 20120516) No wonder that the Genomic Misconception has never been debated seriously in these circles. It also provides proof once again that the organisation of the United Nations Biodiversity Convention is not really caring enough about correct science to be implemented in this so crucial biosafety protocol. Citation from the 2010 PRRI letter:

"Tens of thousands of biotechnology researchers in thousands of public research institutes in developing and developed countries strive towards alleviating poverty, sustainable agricultural production, assuring food safety and quality and conservation of the environment. However, these same public sector scientists express concern that these efforts will be futile if regulations such as the Cartagena Protocol are not implemented in a balanced and science-based manner. They call on the negotiating Parties at MOP5 to constantly assess how the implementation of the Protocol will affect crucially important public research, to ensure that the Protocol will indeed contribute to sharing the benefits of this technology."(PRRI, 2006-2010b)

See the Article 19 of the Convention of the Biological Diversity, which is the root of the Cartagena Protocol (Cartagena Protocol on Biosafety, 2000):

Article 19 of the CBD: Handling of Biotechnology and Distribution of its Benefits

1. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties.

2. Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms.

3. The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

4. Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced.(Cartagena Protocol on Biosafety, 2000)

There is also blatant inertia visible in GE crop approval processes, and the CP organisation demonstrates the usual incapability of reacting expediently enough to the growing speed of scientific innovation: a plethora of new genomic manipulations are manifested in hundreds of publications, but the biosafety research community still remains in the realms of Bt crops and herbicide tolerant crops. Correcting the legislation by following insights in the falsehood of the Genetic Misconception would also free the regulatory community from adhering to all

the new kinds of gene splicing (after proper testing and analysis), and could instead concentrate pragmatically and scientifically fully justified on *product oriented regulation*. Just two examples of innovation in transgenesis growing rapidly as a whole:
1. Zinc finger enzyme assisted targeted insertion of transgenes in complex organisms (Shukla, VK, et al., 2009, Shukla, VK & Kumar, S, 2010)
2. The new TALES method is capable of generating site-specific DNS Breaks and has great potential for site-specific genome modification in plants and eukaryotes in general (Li, L, et al., 2012, Mahfouz, MM, et al., 2011, Mahfouz, MM, et al., 2012)

Alone these two gene transfer methods, much more precise and easy to use, call ultimately for a thorough revision of the regulatory process.

Those who want to know more about new technologies can read Lusser et al. for a comprehensive overview: (Lusser, M, et al., 2012). The paper is nolens volens demonstrating the un-surmountable difficulties in regulating with a restrictive focus to transgenesis processes instead of looking at the products.

In a recent publication, Fedoroff and her colleagues (Fedoroff, N, et al., 2011) deplore the US Environmental Protection Agency's (EPAs) departure from the US regulatory system towards an European approach, reacting to new EPA regulatory policies:

"Based on initial reviews of that draft proposal and recent EPA actions associated with biotechnology-derived crops, it is clear that the EPA is departing from a science-based regulatory process, instead walking down a path toward a policy based on the controversial European "precautionary principle" that goes beyond codifying data requirements for substances regulated as PIPs (Plant Incorporated Pesticides) for the past 15 years. While this principle is politically popular in some constituencies, it is not supported by experience gained over the past several decades with transgenic crops."

And:

"Over the last two decades, advances in sequencing and genomic analysis have revealed that biotechnology is more precise and less disruptive to the genome than traditional plant breeding. In fact, recent genomic, proteomic, and metabolomic comparisons of varieties bred (using conventional and transgenic methods) demonstrate that transgenic plants with incorporated novel traits more closely resemble the parental variety than do new varieties of the same crop plant produced by more traditional breeding or mutagenesis techniques. These findings support the crop-level observations that transgene insertion is not inherently disruptive and that transgenic crops present no new or greater hazards than crops produced by breeding techniques now considered conventional. Indeed, they are not only less disruptive, but far more precise because they introduce or modify the sequence or expression of well-characterized genes in predictable ways, objectives which cannot be achieved by any previous method." (Fedoroff, N, et al., 2011)

3. CONCLUSIONS

The conclusions are crystal clear: European regulation and worldwide legislation of GM crop biosafety regulation within the Cartagena Protocol need a thorough overhaul, *a shift from process oriented to product oriented regulation* (Giddings, V, et al., 2012, Kuntz, M & Ricroch, A, 2012, Morris, S & Spillane, C, 2010, Potrykus, I, 2010b).

There can be no doubt that *product-based regulatory approaches* are closest to the scientific principle and that biotechnology is not inherently more risky than other technologies, which have a long and accepted history of application in agriculture and food production, and is also less prescriptive than process-based systems, see (McLean, MA, et al., 2002).

Another valid paper showing constructive conclusions out of the regulatory conflict has been published by Cantley (Cantley, M, 2004). This text calls for action, including a roadmap for solutions; Cantley has searched for proposals with a good mixture of pragmatism and uncompromised application of present day scientific insight:

"The case for benign neglect of biotechnology has been largely lost in Europe at present, but the current Commission strategy may slowly correct this. Europe has supported research, while burdening the technology with disproportionate legislation; preaching the gospel of competitiveness, but forgetting that precautionary regulation should be dynamic and adaptive to scientific evidence and experience. As resources (scientific, administrative and political) are always limited, devoting more to small or non-existent risks subtracts them from more serious needs, thus actually increasing risks." (Cantley, M, 2004)

A summary of the thoughts of Henry Miller and Greg Conko (Miller, HI & Conko, GP, 2004) p.223ff on six strategies for reforming regulatory abuses fits best into what needs to be done:

1. *Scientists must actively protest unscientific policies and regulation*
2. *Scientific institutions must stimulate public discourse*
3. *The media must discount bogus science*
4. *The biotech industry must advocate scientific regulatory policies*
5. *All stakeholders should promote science-based public policy*
6. *Rethink the government's monopoly over regulation (Miller, HI & Conko, GP, 2004)*

As long as the scientific principles of regulations are respected, the rules of internationally agreed risk assessment should be handled flexibly, according to the growing amount of positive experience (Miller, HI, 2010).

1. *"The degree of regulatory scrutiny should be commensurate with the perceived level of risk.*
2. *Similar things should be regulated in a similar way.*
3. *If the scope of regulation – i.e. the regulatory net or the trigger that captures field trials or the finished product for review – is unscientific, then the entire approach is unscientific."*

This paper of Miller (Miller, HI, 2010) has been published in a volume of a study week held at the Vatican in May 2009 on invitation of the Pontifical Academy of Sciences which is also published on the website of the Vatican as an open source conference volume (Potrykus, I & Ammann, K, 2010).

In the same volume, Arber came to the same conclusion for the assessment of long term risks (Arber, W, 2010b):

"Available scientific knowledge and potent investigation methodology represent an efficient and effective basis for a priori responsibly carried out technology assessments before GM organisms, either as produced by genetic engineering or as selected by classical breeding, become released into the environment. Any decision taken on such releases should be based on the specific biological functions involved, not on the ways by which the selected organisms were produced" (Arber, W, 2010b).

It is time to move on and call for a serious amendment of national and international legislation in biosafety assessment of GM crops, as stated with uncompromising demands by (Potrykus, I, 2010a):

"The politicization of the regulatory process is an extremely significant impediment to use of biotechnology by public institutions for public goods. Costs, time and complexity of product introduction are severely and negatively affected (without such political impediment the technology is very appropriate for adoption by developing country scientists and farmers: it does not require intensive capitalization). The regulatory process in place is bureaucratic and unwarranted by the science: despite rigorous investigation over more than a decade of the commercial use of genetically engineered (GE) plants, no substantiated environmental or health risks have been noted. Opposition to biotechnology in agriculture is usually ideological. The huge potential of plant biotechnology to produce more and more nutritive food for the poor will be lost, if GE-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." (Potrykus, I, 2010a)

And a closing word by Miller on the squandered opportunity of the Golden Rice (Miller, HI, 2009) and a last chance to fulfil its great promise:

"In spite of its vast potential to benefit humanity—and negligible likelihood of harm to human health or the environment—Golden Rice remains hung up in regulatory red tape with no end in sight. In a July commentary in Nature, Potrykus pointed out that Golden Rice has been "stalled at the development stages for more than ten years by the working conditions and requirements demanded by regulations."

Recently, this view is supported by more publications. Ingo Potrykus is calling for a revolutionised regulation of GM crops – he has waited for more than a decade for his Golden Rice to come into agricultural use, but in vain. The table on the retarded history of its introduction in Nature (Potrykus, I, 2010b) (p. 561) speaks for itself. This is particularly tragic in view of a well-structured introductory organisation, see www.goldenrice.org . Today, hundreds of thousands of children are still suffering severely under Vitamin A deficiency and connected blindness and death (Berger, SG, et al., 2007, Mayo-Wilson, E, et al., 2011, Tang, G, et al., 2009).

An additional recent comment comes from Patrick Moore, former Greenpeace founder, now active for www.greenspirit.org: (Moore, P & Batra, K, 20120216):

"It is a crime against humanity because some NGOs are preventing the curing of people who are dying by the hundreds of thousands a year due to vitamin A deficiency."

In Ingo Potrykus' own words: Unjustified and impractical legal requirements are stopping genetically engineered crops from saving millions from starvation and malnutrition.

Giddings et al. call for galvanising plant science in Europe will depend on an overhaul of GM crop regulation. They call for a revision of GM crop regulation, in particular in Europe and also in the United Nation Cartagena Protocol on Biosafety (Giddings, V, et al., 2012). Galvanising plant science in Europe will depend on an overhaul of the tangle of indefensible regulations themselves, not on the advent of new plant breeding technologies that may escape existing rules. The world has seldom seen a greater discrepancy between the inherent hazard of a product and the level of regulatory burden imposed on it than exists today for crops improved through biotech. It is important, here, to be very clear: **There is no basis in science for regulation specific to crops and foods improved through biotech or 'GMOs**'.

This view is supported by an editorial of Marshall in the same volume of Nature Biotechnology (Marshall, A, 2012) with the telling headline: 'Agnostic in Agriculture'. He also calls directly for averting a global food crisis which will require the *deconstruction of several hurdles* to the deployment of new strategies in plant breeding.

There should be no illusion: the numerous risk assessment researchers and regulators at national and international levels will need to reverse some dogmatic views about biosafety of GM crops and try to learn that transgenic and conventional crops do not basically differ in food and environmental safety – this is a process which will take years, but needs to be started without further delay.

I want to close with an optimistic outlook. Ronald explains the efficiency and precision of genetic engineering in plant breeding (Ronald, P, 2011): she leaves no doubt that this technology will be an important part of sustainable agriculture:

"Despite the demonstrated importance of genetically improved seed, there are still agricultural problems that cannot be solved by improved seed alone, even in combination with innovative farming practices. A premise basic to almost every agricultural system (conventional, organic, and everything in between) is that seed can take us only so far. Ecologically based farming practices used to cultivate the seed, as well as other technological changes and modified government policies, clearly are also required."(Ronald, P, 2011).

Another optimistic outlook shall close the text, it comes from Swedish colleagues led by Fagerstrom (Fagerstrom, T, et al., 2012), with more details in the long Swedish text (Fagerstrom, T & Wibe, S, 2011):

"Risk research on GM crops in Europe has to come to an end, as do futile battles about disasters that will not happen. A dead parrot is a dead parrot, both in Monty Python sketches and in science. The way to sustainable and productive agriculture is not by maintaining expensive, parallel production systems, using different sets of crop varieties, and relying on expensive regulations for their coexistence. Instead, agricultural systems should use the best available technology at all stages, including plant breeding. It is clear that the approval and decision process within the EU for GM crops is not science-based. The risk assessment and approval process, where the outcome is dominated by the opinions of a few self-interested

stakeholder organizations with special interests is unique. It is alarming that decision-making bodies kow-tow to this non-science-based paradigm." (Fagerstrom, T, et al., 2012)

The title of the last piece above is excellent: ***Stop worrying; start growing***. Risk research on GM crops is a dead parrot: it is time to start reaping the benefits of GM.

Another important aspect is the regulatory comparison of unexpected events – both in GMOs and non-GMOs, a review has been published by Alexander Haslberger: (Haslberger, AG, 2003):

Haslberger, A. G. (2003), Codex guidelines for GM foods include the analysis of unintended effects, Nature Biotechnology, 21, 7, pp. 739-741, <Go to ISI>://WOS:000183886000018 AND http://www.ask-force.org/web/Regulation/Haslberger-Codex-Guidelines-Unintended-2003.pdf

From the introductory comments:

"…the Ad Hoc Intergovernmental Task Force on Food Derived from Biotechnology of the CodexAlimentarius Commission (Rome) agreedin March on principles for the human health risk analysis of GM foods (Codex alimentarius, 20030311-14)

Unintended effects of the product The Codex's aim is to anticipate not only the direct risks, but also the indirect/unanticipated risks that the products of modern agriculture might pose for human health. All of the methods used for breeding or manipulating plant traits, including self- and cross-pollination, the generation of hybrids or haploid breeding, mutational breeding (including X-rays or chemicals) and advanced biotechnologies (including protoplast fusion and/or recombinant DNA technology), have the potential to generate unanticipated effects in plants.

In conventional breeding programs of spring barley, for example, different degrees of a temporary breakdown of the resistance to powdery mildew by a sudden relief of soil water-stress have been attributed to the genetic background rather than the specific allele (Baker, SJ, et al., 1998). There have also been reports that a traditionally bred squash caused food poisoning (Kirschman, JC & Suber, RL, 1989) , a pest-resistant celery variety produced rashes in agricultural workers (which was subsequently found to contain sevenfold more carcinogenic psoralens than control celery (Ames, BN & Gold, LS, 1990, Ames, BN & Gold, LS, 1997)) and a potato variety Lenape contained very high levels of toxic solanine (which was subsequently withdrawn from cultivation).

The use of tissue culture in plant breeding has also often resulted in somaclonal variation of plant lines and irregular phenotypes or field performance. Somaclonal variations are mutational and chromosomal instabilities of embryonic plants regenerated from tissue cultures. These instabilities may result from activation of dormant transposons in the chromosome6 .The consequent genetic variability is known to persist for many generations and is difficult to eliminate by backcrossing.

For plants generated by recombinant technology, unanticipated effects may additionally arise from the process of introducing foreign genes or as a result of the effects of environmental factors/genetic background on the expression of the transgene(s)7

Complex multicopy patterns of transgene integration at the same locus, as well as position effects caused by random integration, are often associated with instability in transgene expression8 .Random insertion of DNA sequences can cause modification, interruption or silencing of existing genes as well as activation of silent genes9,10 .

Safety aspects have been discussed for a transgenic maize line following the observation of integration of recombinant DNA into a retrotransposon11,12

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 could well 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 (Smyth, S & McHughen, A, 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, S & McHughen, A, 2008)

The authors describe in detail how Canadian regulators deal with an assessment system fully taking care of the hurdles, when one leaves the simplistic path of focusing on the process of transgenesis. The fully science based and still pragmatic regulatory system has been in place for over a decade with uncontested success (this has not been the case in the mid and late nineties in Canada; see the regulatory difficulties described by (Belem, MrAF, 1999, Smith Barry, et al., 19960331) in detail!).

Clearly, product oriented regulation brings along a major change, including the difficulty that 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 on “Plants with Novel Traits” (PNTs), the heart of a process – an agnostic decision making system which is now in place successfully for a decade. The process is transparent and deliberately sought the input of those involved in crop development from non-governmental organisations, industry, academia and federal research laboratories. Those plants selected for closer regulation are classified as PNTs: they are modified either via genetic engineering or mutagenesis, in addition these PNTs as well as those that do *not* have a history of production and safe consumption in Canada (hard to understand this sentence). The procedure is described in detail in the Directive Dir2000-07published 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, for details see (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.

- *“The potential of the plant to become a weed or to be*
- *invasive of natural habitats.*

- *The potential for gene flow to wild relatives.*
- *The potential for a plant to become a plant pest.*
- *The potential impact of a plant or its gene products on*
- *non-target species.*
- *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 herbicide-tolerant 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.

- *Directive 94-08: (CFIA, 2004b) Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits.*
- *Directive 95-03: (CFIA, 2009) Guidelines for the Assessment of Novel Feeds: Plant Sources.*
- *Directive D-96-13: (CFIA, 2010) Import Permit Requirements for Plants with Novel Traits, and their Products.*
- *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, S & McHughen, A, 2008)

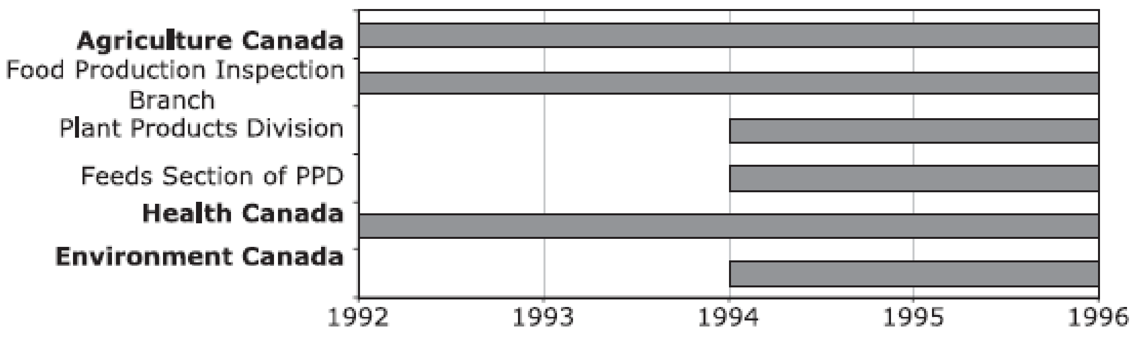

Figure 1 summarizes the involvement of the various regulatory actors over the process. The 7-year process of developing the regulations for PNT crops was time consuming; however, the process was scientifically justified and successful, as there have been no documented problems resulting from 12 years of commercial PNT crop production in Canada. The scientific risks and the governance aspect of risk management were captured within the PNT regulatory framework. However, the process was not without challenges, as was identified by the lack of any defining characteristics regarding substantial equivalence. The regulatory mandate was, to a certain degree, unfocused, as was evidenced by the late involvement of the Feed Section. Regulatory integration of the Feed Section needed to occur in harmony with the larger actions of the PPD. The result of this scattered approach to developing PNT regulations was that the commercial release of PNTs in Canada was delayed by one year. Source: (Smyth, S & McHughen, A, 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 through rDNA, have occasionally triggered regulatory review for expressing novel traits, as in a recent case a bred barley trait with low phytate levels. (Edney, MJ, et al., 2007, Edney, MJ, et al., 2011). 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, A, 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, IR, et al., 1992).

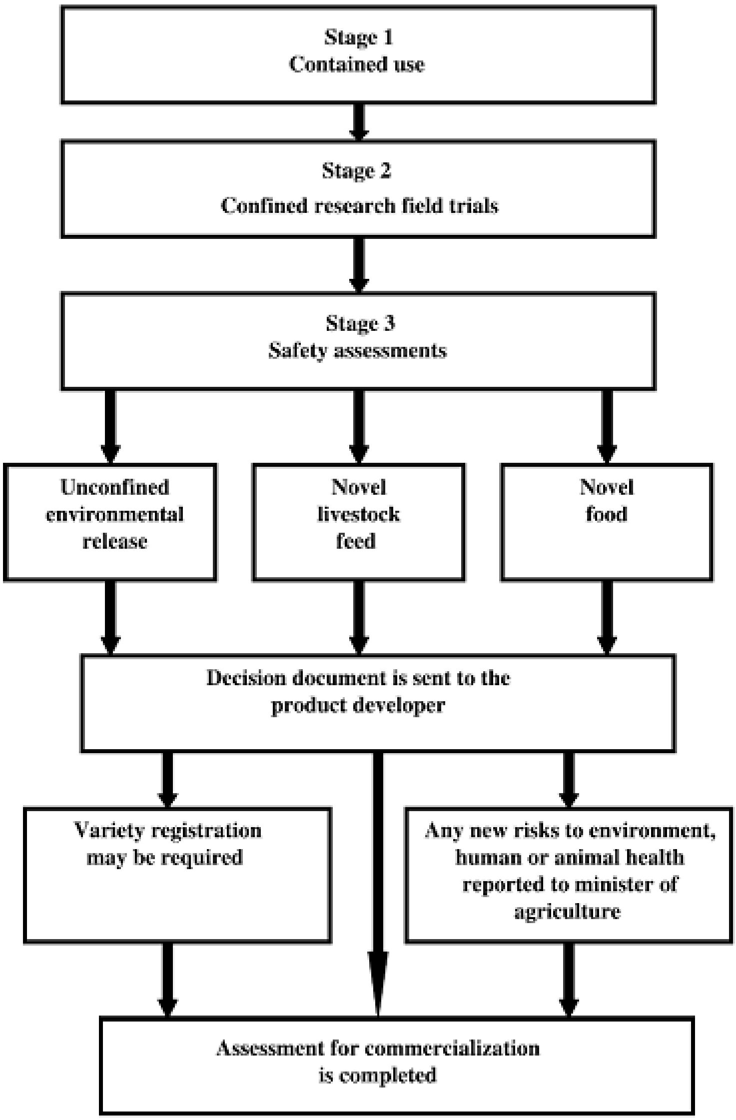

Figure 2 explains the first procedures in detail, the product oriented regulation is functioning well in Canada. (Smyth, S & McHughen, A, 2008) In Stage 1 of the development of a new PNT variety that is intended for unconfined environmental

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). In Stage 2, the PNT variety developer must submit an application to the CFIA and receive authorization to conduct confined field trials in Canada. Directive 2000-07 is used to establish how many trials are allowed in Canada, the size of the plot and the isolation distances that are required. The safety assessment for the new variety is conducted in Stage 3. This stage is designed to address the five priority categories listed above. To provide the necessary information to satisfy these questions, the product developer is required to submit scientific data that have been gathered from the field trials.
For more information about the Canadian regulatory process see
http://www.ask-force.org/web/NewBiotech/Smyth-McHughes-Excerpt-Details-Regulatory-Process-Canada-2008.pdf

Unlike the Canadian Food Inspection Agency (CFIA) the Canadian Health agency tests all transgenic products with a focus on processes (Health Canada, 2006)

- *"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."*

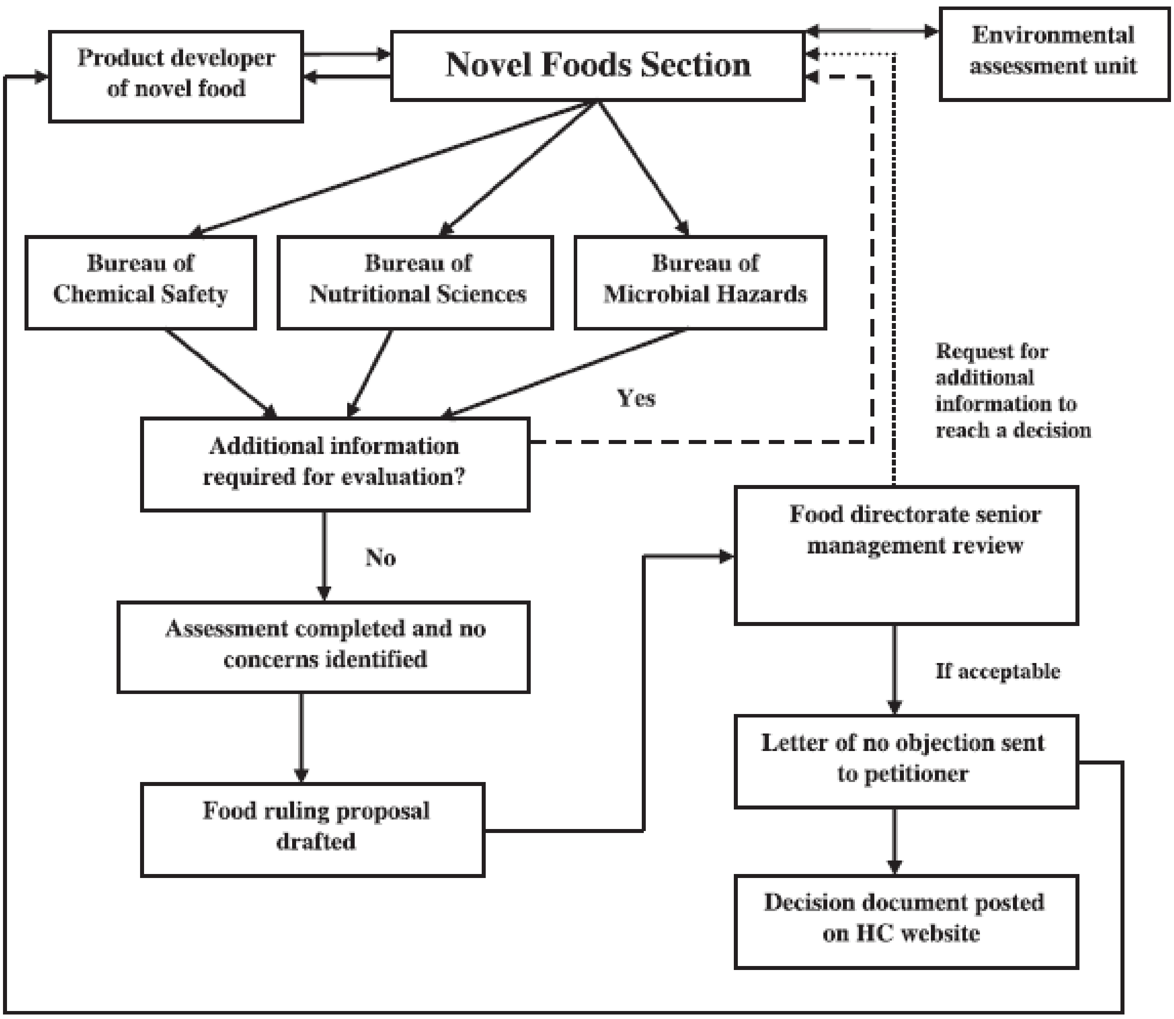

Figure 3: Novel food notification/submission. Regulators at Health Canada take the data from the field trials conducted by the product developer that relate to the category for novel foods in Figure 1. This is when the nutritional, toxicity and allergenicity data are reviewed and assessed. Additional data are needed to satisfy risk assessments regarding dietary

exposure, metabolization and microbiological safety. One salient feature of the Health Canada regulatory process is its use of experience from other jurisdictions. If a PNT product has a history of safe production and consumption in another country, this is admissible as data for regulatory approval in Canada. Health Canada is unique amongst the PNT regulatory bodies in this context, as the CFIA and Environment Canada will not allow a history of safe production and consumption elsewhere as admissible data. Figure 3 provides the Health Canada regulatory process. **Source: (Health Canada, 2006) and (Smyth, S & McHughen, A, 2008).**

A clear downside of the Canadian regulatory system is a lack of harmonization between the three agencies involved in the decision making process: The Canadian Food Inspection Agency, Canady 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. The websites from 2007 are no longer active links as cited in (Smyth, S & McHughen, A, 2008), there are more detailed comments 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 and McHughen would certainly support the petition letters of PRRI to the Cartagena Protocol organisation for a limited exemption of well-known and well regulated GM crops (PRRI, 20090914, PRRI, 20120516) and address this request also to the Canadian regulatory organisations.

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, S & McHughen, A, 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, S & McHughen, A, 2008).

For more details and insight it is recommended to visit the websites of the Canadian Food Inspection Agency CFIA http://www.inspection.gc.ca, Health Canada www.hc-sc.gc.ca and Environment Canada www.ec.gc.ca and some additional selected references: (CFIA, 2010, CFIA, 2012a, CFIA, 2012b, CFIA, 2012c, CFIA, 20120206, Environment Canada, 1999a, Environment Canada, 1999b, Environment Canada, 1999c, Environment Canada, 1999d, Environment Canada, 1999e).

One also has to realise that the Canadian regulatory system has worked 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, MJ, 2000) it may be 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, MJ, 2000).

This pragmatic diagnosis is logically not welcome to an author like (Andree, P, 2002), who argues in a more negative way, citing activists like Jeremy Rifkin, who seem clearly more concerned 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, K & Salamini, F, 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, and cannot be done without an international perspective in times of growing globalization; it may even take years to come about and can only be solved with modern discursive methods of the second generation (Ammann, K & Papazova Ammann, B, 2004, Ammann, K, 2007b). It is also necessary to make use of proposals of regulatory innovation from people experienced in regulatory science, (Sanvido, O, et al., 2008, Sanvido, O, et al., 2009, Sanvido, O, et al., 2011a, Sanvido, O, et al., 2011b, Sanvido, O, et al., 2012) and (Durham Tim, et al., 2011) to give a few examples. 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, C, 2011a, Juma, C, 2011b, Juma, C, 2011c).

5. MORE RECENT SUPPORT FOR ABOLISHING THE 'GENOMIC MISCONCEPTION'

(This chapter has been added after printing processes began, it will be, with additions and updates, be published elsewhere.)

In the last two years several supporting publications appeared independently (some already cited in the text, they all have been published in peer reviewed journals as comprehensive reviews (some are already incorporated in previous comments of this paper:

(Herman, RA & Price, WD, 2013) summarize with precision the present day insights in the genomics of modern crops and call for a thorough overhaul of the regulation of GM crops:

The compositional equivalency between genetically modified (GM) crops and nontransgenic comparators has been a fundamental component of human health safety assessment for 20 years. During this time, a large amount of information has been amassed on the compositional changes that accompany both the transgenesis process and traditional breeding methods; additionally, the genetic mechanisms behind these changes have been elucidated. After two decades, scientists are encouraged to objectively assess this body of literature and determine if sufficient scientific uncertainty still exists to continue the general requirement for these studies to support the safety assessment of transgenic crops. It is concluded that suspect unintended compositional effects that could be caused by genetic modification have not materialized on the basis of this substantial literature. ***Hence, compositional equivalence studies uniquely required for GM crops may no longer be justified on the basis of scientific uncertainty (Herman, RA & Price, WD, 2013).***

Another important support for a thorough revision of GM crop regulation on the genomic level comes from Podevin et al. (Podevin, N, et al., 2012), they call again for a product oriented regulation, since the focus on processes will cause in this static international regulatory framework a lot of confusion due to the accelerating speed of new transfer methods being developed, the high research dynamics shortly described in section 2: History of Regulation.

"The first challenge is to make sure that regulatory frameworks remain fit for purpose. However, frameworks that use process-based definitions as a trigger for regulatory oversight might not be functional over time (Sidebar B). Several authors have argued that new biotechnology-based plant breeding techniques might not fit into, or might rapidly outgrow, the established definitions for GMPs [9,10] or other narrowly defined product definitions ,(Kuzma, J & Kokotovich, A, 2011) and (Waltz, E, 2012) (COGEM, 2008),12]. NPPs blur the sharp distinction between GMP and non-GMP, and introduce a new continuum between genetic engineering and conventional breeding. Process-based and narrowly defined product-based legislation therefore run the risk of quickly becoming obsolete given the rate of innovation in the field. Process-based legislation will require not only updates to the lists of new biotechnological plant breeding techniques but also debate on their classification as GMP or non-GMP. However, such flexibility is rarely evident in regulatory frameworks."

Whereas the COGEM report (COGEM, 2008) only timidly asks for a new look at GM crop regulation, fearing the public non-scientific opinions (including the dogmas against transgenesis of organic farmers (Van Bueren, ETL, et al., 2003, Van Bueren, ETL, et al., 2007) which are interestingly enough not supported by many of the organic farming community), thus not asking straightforward for product-oriented regulation, Kuzma et al. (Kuzma, J & Kokotovich, A, 2011) claim clearly a reshuffling of international regulation towards product-oriented rules. The science journalist E.Waltz (Waltz, E, 2012) collects in the usual uncritical way the opinions and cannot clearly support product-oriented regulation, depending too much on political opinions (Gurian-Sherman) rather than on hard molecular science.

Another a rather indirect way to move regulatory rules is coming from Syngenta's Alan Raybould (Raybould, A, 2012) who warns about decisions of comparative studies positive for GM crops against non-GM crops to rely too much on science, since it is foremost a matter of changing regulation:

"Results of scientific studies are sometimes claimed to provide scientific justification for regulatory decisions about the cultivation of certain transgenic crops. A decision may be scientifically justified if objective analysis shows that the decision is more likely than alternatives to lead to the achievement of specific policy objectives. If policy objectives are not defined operationally, as is often the case, scientific justification for decisions is not possible. ***The search for scientific justification for decisions leads to concentration on reducing scientific uncertainty about the behaviour of transgenic crops instead of reducing uncertainty about the objectives of policies that regulate their use. Focusing on reducing scientific uncertainty at the expense of clarifying policy objectives may have detrimental effects on scientists, science and society."*** *(Raybould, A, 2012).*

It is certainly also important to distinguish between Regulatory and Research Science strategies and conclusions (Raybould, A, et al., 2012), otherwise, lots of misunderstandings will lead to costly and unnecessary extra-research, but again, the authors avoid the deep sitting misunderstandings on the Genomic Misconception.

The same syndrome of calling for regulatory innovation by abstaining to mention the Genomic Misconception can be seen with many biosafety specialists on Bt crops to non-target insects, instead of easing regulation with strictly scientific views, they rather seek solutions in better systems of risk assessment alone: (Romeis, J, et al., 2009, Sanvido, O, et al., 2011a). Some are calling for an encyclopaedic survey of non-target insects resulting in gigantic lists and tedious screening (Meissle M, et al., 2012) for the purpose of reducing biosafety research efforts. or indulging into possible new problems with meticulously measured and calibrated variation in Cry1Ab (Szekacs, A, et al., 2012), a paper with an evident vested interest to blow up regulatory efforts in GM crops without a valid comparison with non-GMO crops based on the often underestimated natural genomic variation of the compared crops.

On another thread, high discovery speed can be seen in the complex interrelationships between natural hybridization (including heterosis) and transgenesis which are much more transparent than ever before: (Flavell, R, 2010, Hakeem, KR, et al., 2012, Jiang, YH, et al., 2012, Kumar, GR, et al., 2010, Moe, KT, et al., 2012, Snowdon, RJ & Luy, FLI, 2012, Soren, KR, et al., 2010, Varshney, RK, et al., 2010, Vega-Sanchez, ME & Ronald, PC, 2010, Zhang, C, et al., 2012, Zhang Ti-fu, et al., 2012).

A final remark: The paper of the CRIIGEN group of France (Seralini Gilles-Eric, et al., 20120918), still lives in the old process focus of regulation, a view which allows a reductionist and entirely negative assessment on GM crops by ignoring a majority of professional regulatory literature. The paper has also received (apart from numerous other critical statements) rebuttals demonstrating dramatic methodological flaws of the paper with a convincing request of retraction (Arjó, G, et al., 2013, EFSA Statement, 20121123, Jany Klaus, 2013).

Apart from the difficult process of writing science bases rebuttals on such papers, in a time when they are absorbed by the opponents already on thousands of websites and abused for their negative arguments, there is hope that finally, science based discourse will win. Years of lobbying of the author, starting with early publications in 2008 e.g. (Ammann, K, 2007a, Ammann, K, 2008) and in a special chapter 5 (Ammann Klaus, 20121228), seems now in Europe to show results, the most recent example is an opinion piece of Brian Heap in Nature: (Heap Brian, 20130626), the text announces the very important report of EASAC (European Academies Science Advisory Council), launched on June 27: (EASAC, 20130627). The report also supports explicitly the product-oriented regulation and announces steps to convince the EU authorities to change their regulatory system.

6. CITED LITERATURE

Ames, B. N. and L. S. Gold (1990), Chemical carcinogenesis: too many rodent carcinogens, Proceedings of the National Academy of Sciences, 87, 19, pp. 7772-7776, http://www.pnas.org/content/87/19/7772.abstract AND http://www.ask-force.org/web/Food/Ames-Chemical-Carcinogenesis-Too-Many-1990.pdf

Ames, B. N. and L. S. Gold (1997), Environmental pollution, pesticides, and the prevention of cancer: misconceptions, The FASEB Journal, 11, 13, pp. 1041-52, http://www.fasebj.org/content/11/13/1041.abstract AND http://www.ask-force.org/web/Food/Ames-Environmental-Pollution-Misconceptions-1997.pdf

Ammann, K. and B. Papazova Ammann (2004), Factors Influencing Public Policy Development in Agricultural Biotechnology *in RISK ASSESSMENT OF TRANSGENIC CROPS., ed. S. Shantaram, P. Christou and H. Klee,* Vol. 9, pp. 1552 Wiley and Sons, Hoboken, NJ, USA, http://eu.wiley.com/WileyCDA/WileyTitle/productCd-047185199X,descCd-tableOfContents.html AND http://www.ask-force.org/web/Wiley/Factors-Discourse-Wiley.pdf and Spanish translation by Maria Wright http://www.ask-force.org/web/Wiley/Ammann-Factores-Influenc-2004.PDF

Ammann, K. and F. Salamini (2004), European Biotech Manifesto, ABIC Newsletter, 4, pp. 1-4, http://www.abic2004.org/download/ABIC2004_newsletter_no4.pdf AND http://www.ask-force.org/web/ABIC/ABIC-Manifesto-2004.pdf AND http://www.ask-force.org/web/ABIC/ABIC2004-Manifesto-deutsch-def.pdf

Ammann, K. (2007a), Reconciling Traditional Knowledge with Modern Agriculture: A Guide for Building Bridges. *in Intellectual Property Management in Health and Agricultural Innovation a handbook of best practices, Chapter 16.7, ed. A. Krattiger, Mahoney, R.T.L., Nelsen, L., Thompson, G. A., Bennett, A.B., Satyanarayana, K., Graff, G.D., Fernandez, C., Kowalsky, S.P.,* Vol., pp. 1539-1559 MIHR, PIPRA, Oxford, U.K. and Davis, USA, The general link to the www.ipHandbook.org. (as of September 2007) AND http://www.ask-force.org/web/IP/Press-Release-ipHandbook-Online-20071101.pdf, AND the Flyer: http://www.ask-force.org/web/Patents/ipHandbook-Flyer1.pdf AND chapter 16.7 http://www.ask-force.org/web/TraditionalKnowledge/Ammann-Traditional-Biotech-2007.pdf free of copyrights AND the exported bibliography with the links: http://www.ask-force.org/web/TraditionalKnowledge/Exported-Bibliography-links-Ammann-2007.pdf

Ammann, K., (2007b) How to deal with traditional knowledge in modern agriculture A User's Guide for Building Bridges, delivered to GTZ March 2007, Klaus Ammann, Manuscript, pp. 32, Manuscript Delft, Netherlands, http://www.ask-force.org/web/GTZ/ORGANOTRANSGEN-20070321.pdf

Ammann, K. (2008), Transgenic Organic Agriculture - Back to the Future, Chapter 2.12 *in Genetic Glass Ceilings, Transgenics for Crop Biodiversity*, *ed. J. Gressel,* Vol., pp. 37-47 The Johns Hopkins University Press, Baltimore, Maryland, http://www.ask-force.org/web/Feral-def/Ammann-Transg-Org-Agriculture-Ch-2-12-2008.pdf IN http://jhupbooks.press.jhu.edu/ecom/MasterServlet/GetItemDetailsHandler?iN=9780801887192&qty=1&viewMode=3&loggedIN=false&JavaScript=y

Ammann Klaus (20121228), The GM crop risk-benefit debate: science and socio-economics, enhanced edition *in In Springer Encyclopedia of Sustainability Science and Technology, enhanced internet version from 28.12. 2013*, *ed. E. M. Paul Christou Volume Editor, Robert A. (Ed.),* Vol. 2012, MMCLXXVIII, 12586 p. 5790 illus., 3613 illus. in color. In 18 volumes, not available separately., pp. 1-195p, Encyclopedia 12586p. Springer, http://www.springer.com/environment/sustainable+development/book/978-0-387-89469-0 AND free preview http://link.springer.com/referencework/10.1007/978-1-4419-0851-3/page/1 AND http://www.ask-force.org/web/Sustain-Journal-Print/Ammann-Strategy-GMO-Debate-enh-20131228-opensource.pdf

Andree, P. (2002), The biopolitics of genetically modified organisms in Canada, Journal of Canadian Studies-Revue D Etudes Canadiennes, 37, 3, pp. 162-191, <Go to ISI>://WOS:000236751100009 AND http://www.ask-force.org/web/Regulation/Andree-Biopolitics--GMO-Canada.pdf

Ansorge, W. J. (2009), Next-generation DNA sequencing techniques, New Biotechnology, 25, 4, pp. 195-203, http://www.sciencedirect.com/science/article/pii/S1871678409000089 AND http://www.ask-force.org/web/Genomics/Ansorge-Next-Generation-DNA-Sequencing-2009.pdf

APHIS, U. (1987), CFR Parts 330 and 340, Plant Pests; Introduction of Genetically Engineered Organisms or Products; Final Rule,, Federal Register, 52, 115, pp. 22892-22815,

Arber, W. (1990), 3 Impact of Human Civilization on Biological Evolution *in SCOPE 44 - Introduction of Genetically Modified Organisms into the Environment*, *ed. H. A. B. Mooney, G.,,* Vol., pp. COGEN, http://www.scopenvironment.org/downloadpubs/scope44/chapter12.html AND http://www.ask-force.org/web/Regulation/Arber-Impact-Human-Civilization-1990.pdf

Arber, W. (2001), MOLECULAR EVOLUTION: COMPARISON OF NATURAL AND ENGINEERED GENETIC VARIATIONS, Pontifical Academy of Sciences Scripta Varia, 103, pp. 90-101, http://www.casinapioiv.va/content/dam/accademia/pdf/sv103.pdf AND http://www.botanischergarten.ch/Genomics/Arber-Molecular-Evolution-Comparison-PAS-1994.pdf

Arber, W. (2002), Roots, strategies and prospects of functional genomics, Current Science, 83, 7, pp. 826-828, <Go to ISI>://000178662800019 and http://www.botanischergarten.ch/Mutations/Arber-Comparison-2002.pdf

Arber, W. (2010a), Genetic engineering compared to natural genetic variations *in Transgenic Plants for Food Security in the Context of Development*, *ed. I. a. A. Potrykus, K.,* Vol. 27, pp. 517-521 Elsevier and Pontifical Academy of Sciences, Amsterdam, http://www.sciencedirect.com/science/article/B8JG4-504JYNT-2/2/a7e6edd02959e1b3167158dd264f24a2 AND http://www.ask-force.org/web/Vatican-PAS-Studyweek-Elsevier-publ-20101130/Arber-Werner-PAS-Genetic-Engineering-Compared-20101130-publ.pdf AND link to Vatican Website http://www.casinapioiv.va/content/accademia/en/publications/scriptavaria/transgenic.html

Arber, W. (2010b), Genetic engineering compared to natural genetic variations, New Biotechnology, In Press, Corrected Proof, pp. http://www.sciencedirect.com/science/article/B8JG4-504JYNT-2/2/a7e6edd02959e1b3167158dd264f24a2 AND http://www.ask-force.org/web/Vatican-PAS-NBT-publ/Arber-Genetic-Engineering-PAS-2010.pdf

Arber, W. (2011a), Genetic Variation and Molecular Darwinism *in Encyclopedia of Molecular Cell Biology and Molecular Medicine*, *ed.,* Vol., pp. 1-24 Wiley-VCH Verlag GmbH & Co. KGaA, http://dx.doi.org/10.1002/3527600906.mcb.200300093.pub2 AND http://www.ask-force.org/web/Genomics/Arber-Genetic-Variation-Molecular-Evolution-2011.pdf

Arber, W. (2011b), Molecular Darwinism: The Contingency of Spontaneous Genetic Variation, Genome Biology and Evolution, 3, pp. 1090-1092, <Go to ISI>://WOS:000295693200056 AND http://WWW.ask-force.org/web/Genomics/Arber-Molecular-Darwinism-Contingency-2011.pdf

Arber W., B. G., Brom S., Campbell A., Caplan A., Cherif-Zahar B. Christiansen, F.B., Crawley, M.J., Davila, G., Drake, J.A., Dwyer, D.F., Faust, R.M., Fenner, F., Flores, M., Goursot, R., Jayaraman, K., Kingsbury, D.T., Levin, D.T., Martinez, E., Melis, R., Mooney, H.A., Palacios, R., Pinero, D., Rayko, E., Romero, E., Skalka, A. M., Timmis, K.N., Van Montagu, M. (1990), Joint SCOPE/COGENE Statement *in SCOPE 44 - Introduction of Genetically Modified Organisms into the Environment*, *ed. H. A. B. Mooney, G.,,* Vol., pp., http://www.scopenvironment.org/downloadpubs/scope44/contents.html AND http://www.scopenvironment.org/downloadpubs/scope44/statement.html AND http://www.ask-force.org/web/Regulation/SCOPE-44-SCOPE-COGENE-Statement-1990.pdf

Arjó, G., M. Portero, C. Piñol, J. Viñas, X. Matias-Guiu, T. Capell, A. Bartholomaeus, W. Parrott and P. Christou (2013), Plurality of opinion, scientific discourse and pseudoscience: an in depth analysis of the Séralini et al. study claiming that Roundup™ Ready corn or the herbicide Roundup™ cause cancer in rats, Transgenic Research, pp. 1-13, http://dx.doi.org/10.1007/s11248-013-9692-9 AND http://www.ask-force.org/web/Seralini/Arjo-Plurality-Opinion-Scientific-Discourse-Seralini-2013.pdf AND http://www.ask-force.org/web/Facultyof1000/Arjo-Plurality-Opinion-Seralini-F1000-Ammann-20130311.pdf

Avery, O. T., C. M. MacLeod and M. McCarty (1944), STUDIES ON THE CHEMICAL NATURE OF THE SUBSTANCE INDUCING TRANSFORMATION OF PNEUMOCOCCAL TYPES, The Journal of Experimental Medicine, 79, 2, pp. 137-158, http://jem.rupress.org/content/79/2/137.abstract AND http://www.ask-force.org/web/Genomics/Avery-O-Studies-Chemical-Nature-1944.pdf

Baker, S. J., A. C. Newton, D. Crabb, D. C. Guy, R. A. Jefferies, D. K. L. Mackerron, W. T. B. Thomas and S. J. Gurr (1998), Temporary partial breakdown of mlo-resistance in spring barley by sudden relief of soil water-stress under field conditions: the effects of genetic background and mlo allele, Plant Pathology, 47, 4, pp. 401-410, <Go to ISI>://WOS:000075458700003 AND http://www.ask-force.org/web/Regulation/Baker-Temporary-partial-breakdown-Barley-1998.pdf

Bardy, R. and A. Rubens (2010), Is there a transatlantic divide? Reviewing Peter F. Drucker's thoughts on ethics and leadership of US and European managers, Management Decision, 48, 4, pp. 528-540, <Go to ISI>://WOS:000278760600006 AND AUTHOR REQUEST 20130301

Batista, R., N. Saibo, T. Lourenco and M. M. Oliveira (2008), Microarray analyses reveal that plant mutagenesis may induce more transcriptomic changes than transgene insertion, Proceedings of the National Academy of Sciences of the United States of America, 105, 9, pp. 3640-3645, <Go to ISI>://000253846500082

Batista, R. and M. M. Oliveira (2009), Facts and fiction of genetically engineered food, Trends in Biotechnology, 27, 5, pp. 277-286, <Go to ISI>://000266018100003 AND http://www.ask-force.org/web/Food/Batista-Facts-Fiction-GM-Food-2009.pdf

Batista, R. and M. Oliveira (2010), Plant natural variability may affect safety assessment data, Regulatory Toxicology and Pharmacology, 58, 3, pp. S8-S12, <Go to ISI>://WOS:000285213900003 AND http://www.ask-force.org/web/Genomics/Batista-Plant-Natural-Variability-2010.pdf

Baudo, M. M., R. Lyons, S. Powers, G. M. Pastori, K. J. Edwards, M. J. Holdsworth and P. R. Shewry (2006), Transgenesis has less impact on the transcriptome of wheat grain than conventional breeding, Plant Biotechnology Journal, 4, 4, pp. 369-380, <Go to ISI>://000238256500001 AND http://www.botanischergarten.ch/Organic/Baudo-Impact-2006.pdf AND http://www.botanischergarten.ch/Genomics/Transgenesis-Comparison-Slides.pdf AND http://www.botanischergarten.ch/Genomics/Transgenesis-Comparison-Slides.ppt

Baudo, M. M., S. J. Powers, R. A. C. Mitchell and P. R. Shewry (2009), Establishing Substantial Equivalence: Transcriptomics *in Methods in Molecular Biology, Transgenic Wheat, Barley and Oats,*, *ed. H. D. Jones and P. R. Shewry,* Vol. 478, pp. 247-272 Humana Press, a part of

Springer Science + Business Media, LLC 2009, <Go to ISI>://BIOSIS:PREV200900189501 AND :10.1007/978-1-59745-379-0_15 AND http://www.botanischergarten.ch/Genomics/Baudo-Establishing-Substantial-Equivalendce-2009.pdf

Belem, M. r. A. F. (1999), Application of biotechnology in the product development of nutraceuticals in Canada, Trends in Food Science & Technology, 10, 3, pp. 101-106, http://www.sciencedirect.com/science/article/pii/S0924224499000291 AND http://www.ask-force.org/web/Regulation/Belem-Application-Biotechnology-Canada-1999.pdf

Bendiek, J. and H.-J. Buhk (2010), Risk Assessment and Economic Applications - the Cartagena Protocol on Biosafety: GMO Approval and Import on a World-Wide Scale, Genetic Modification of Plants: Agriculture, Horticulture and Forestry, pp. 631-648, <Go to ISI>://BIOSIS:PREV201000182534 AND http://www.ask-force.org/web/Economics/Bendiek-Risk-Assessment-Economic-Applications-Cartagena-2010.pdf

Berg, P., Baltimor.D, H. W. Boyer, S. N. Cohen, R. W. Davis, D. S. Hogness, D. Nathans, R. Roblin, J. D. Watson, S. Weissman and N. D. Zinder (1974), POTENTIAL BIOHAZARDS OF RECOMBINANT DNA-MOLECULES, Science, 185, 4148, pp. 303-303, <Go to ISI>://WOS:A1974T535600001 AND http://www.ask-force.org/web/Regulation/Berg-Potential-Biohazards-1974.pdf

Berg, P., D. Baltimore, S. Brenner, R. O. Roblin and M. F. Singer (1975), SUMMARY STATEMENT OF ASILOMAR CONFERENCE ON RECOMBINANT DNA-MOLECULES, Proceedings of the National Academy of Sciences of the United States of America, 72, 6, pp. 1981-1984, <Go to ISI>://WOS:A1975AG70300001 AND http://www.botanischergarten.ch/History/Berg-Summary-Statement-Asilomar-1975.pdf

Berg, P. and M. Singer (1995), THE RECOMBINANT-DNA CONTROVERSY - 20 YEARS LATER, Bio-Technology, 13, 10, pp. 1132-1134, <Go to ISI>://WOS:A1995RY31800031 AND http://www.botanischergarten.ch/History/Berg-Recombinant-DNA-Twenty-years-later-1995.pdf

Berger, S. G., S. de Pee, M. W. Bloem, S. Halati and R. D. Semba (2007), Malnutrition and morbidity are higher in children who are missed by periodic vitamin A capsule distribution for child survival in rural Indonesia, Journal of Nutrition, 137, 5, pp. 1328-1333, <Go to ISI>://WOS:000245882600032 AND http://www.ask-force.org/web/Golden-Rice/Berger-Malnutriition-Morbidity-2008.pdf

Campbell, A. (1990a), 4 Epistatic and Pleiotrophic Effects on Genetic Manipulation *in SCOPE 44 - Introduction of Genetically Modified Organisms into the Environment*, *ed. H. A. B. Mooney, G.,,* Vol., pp. COGEN, http://www.scopenvironment.org/downloadpubs/scope44/chapter04.html AND http://www.ask-force.org/web/Regulation/Campbell-Epistatic-Pleiotropic-Effects-1990.pdf

Campbell, A. (1990b), 2 Recombinant DNA, Past Lessons and Current Concerns *in SCOPE 44 - Introduction of Genetically Modified Organisms into the Environment*, *ed. H. A. B. Mooney, G.,,* Vol., pp. COGEN, http://www.scopenvironment.org/downloadpubs/scope44/chapter02.html AND http://www.ask-force.org/web/Regulation/Campbell-Recombinant-DNA-Past-1990.pdf

Cantley, M. (1995), The Regulation of Modern Biotechnology: A Historical and European Perspective, Chapter 18, A Case Study in How Societies Cope with New Knowledge in the Last Quarter of the Twentieth Century, *in Biotechnology, second completely revised ed. 1996*, *ed. H. J. Rehm, G. Reed, in cooperation with, A. Puhler and P. Stadler,* Vol., pp. 177, 505-631 VCH Verlagsgesellschaft mbH,1995, Weinheim, Germany, http://www.ask-force.org/web/Regulation/Cantley-18-Regulation-Modern-Biotechnology-1995.pdf AND http://www.amazon.com/Biotechnology-2E-12-Vol-Set/dp/3527283102/ref=sr_1_fkmr2_1?s=books&ie=UTF8&qid=1333226144&sr=1-1-fkmr2

Cantley, M. (1999), More views of Cartagena, Nature Biotechnology, 17, 8, pp. 733-733, <Go to ISI>://WOS:000081751400007 AND http://www.ask-force.org/web/Genomics/Cantley-Cartagena-More-Views-NB-1999.pdf

Cantley, M. (2004), How should public policy respond to the challenges of modern biotechnology?, Current Opinion in Biotechnology, 15, 3, pp. 258-263, http://www.sciencedirect.com/science/article/B6VRV-4CB69PT-1/2/48a784f1fbdd848150a50b33ab138a0d AND http://www.ask-force.org/web/Regulation/Cantley-How-Should-Public-Policy-2004.pdf

Cantley, M. (2007), An Overview of Regulatory Tools and Frameworks for Modern Biotechnology: A Focus on Agro-Food edn. OECD, IS: pp. 123, http://www.oecd.org/dataoecd/11/15/40926623.pdf AND http://www.ask-force.org/web/Food/Cantley-Overview-Regulatory-Tools-Agro-Food-2007.pdf

Cantley, M. F. (2008), The Regulation of Modern Biotechnology: A Historical and European Perspective: A Case Study in How Societies Cope with New Knowledge in the Last Quarter of the Twentieth Century. Chapter 18 *in Biotechnology Set, Second Edition*, *ed. H. J. Rehm, G. Reed, In cooperation with, A. Puhler and P. Stadler,* Vol., pp. 177p. 505-681 Wiley-VCH Verlag GmbH, London, http://dx.doi.org/10.1002/9783527620999.ch18o AND http://www.ask-force.org/web/Regulation/Cantley-18-Regulation-Modern-Biotechnology-2008.pdf

Cartagena Protocol on Biosafety (2000), Cartagena Protocol On Biosafety To The Convention On Biological Diversity, Text and Annexes edn. Copyright © 2000, Secretariat of the Convention on Biological Diversity, IS: ISBN: 92-807-1924-6. pp. 30, http://www.cbd.int/doc/legal/cartagena-protocol-en.pdf AND http://www.ask-force.org/web/Regulation/Cartagena-Protocol-2000.pdf

CFIA (2004a), Directive Dir2000-07: Conducting Confined Research Field Trials of Plant with Novel Traits in Canada, publ: http://www.inspection.gc.ca/plants/plants-with-novel-traits/applicants/directive-dir2000-07/eng/1304474667559/1304474738697

CFIA (2004b), Directive 94-08 (Dir 94-08) Assessment Criteria for Determining Environmental Safety of Plants With Novel Traits, publ: http://www.inspection.gc.ca/plants/plants-with-novel-traits/applicants/directive-94-08/eng/1304475469806/1304475550733

CFIA (2009), Directive 95-03, Guidelines for the Assessment of Novel Feeds: Plant Sources; Health, publ: http://www.biosafety.gov.cn/image20010518/5036.pdf AND http://www.ask-force.org/web/Genomics/Directive-95-03-Novel-Feed-Canadian-Food-Inspection-2009.pdf

CFIA (2010), Directive - 96-13: Import Requirements for Plants with Novel Traits, including Transgenic Plants and their Viable Plant Parts, publ: http://www.inspection.gc.ca/plants/plant-protection/directives/date/d-96-13/eng/1323855470406/1323855595412

CFIA (2012a), Regulating Agricultural Biotechnology in Canada: An Overview, publ: http://www.inspection.gc.ca/plants/plants-with-novel-traits/general-public/fact-sheets/overview/eng/1338187581090/1338188593891 AND http://www.ask-force.org/web/Regulation/Regulating-Agricultural-Biotechnology-Canada-Overview-2012.pdf

CFIA (2012b), An Overview of the Canadian Agriculture and Agri‑Food System 2012, publ: http://www4.agr.gc.ca/AAFC-AAC/display-afficher.do?id=1331319696826&lang=eng&src=hp AND http://www.ask-force.org/web/Regulation/Overview-Canadian-Agriculture-Agrifood-System-2013.pdf

CFIA (2012c), Safety Assessment Process for Novel Foods and Agricultural Products of Biotechnology, publ: http://www.inspection.gc.ca/plants/plants-with-novel-traits/general-public/fact-sheets/assessment-process/eng/1338189630096/1338189929476 AND http://www.ask-force.org/web/Regulation/Safety-Assessment-Process-Novel-Foods-Ag-Products-2012.pdf

CFIA (20120206), Procedures for the Registration of Crop Varieties in Canada, THIS DOCUMENT REPLACES THE ONE PUBLISHED ON JULY 8, 2009, publ: http://www.inspection.gc.ca/english/plaveg/variet/proced/regproe.shtml AND http://www.ask-force.org/web/Regulation/Procedures-Registration-Crop-Varieties-Canada-2012.pdf

Codex alimentarius (20030311-14), Report Of The Fourth Session Of The Codex Ad Hoc Intergovernmental Task Force On Foods Derived From Biotechnology in: W. FaO. ALINORM 03/34A, pp. FAO, Rome, http://www.ask-force.org/web/Codex-Alimentarius/Codex-Alimentarius-Report-4th-Session-Japan-March-11-14-2003.pdf

COGEM (2008), New techniques in plant biotechnology, COGEM, Commission on Genetic Modification, No. pp. 40, Netherlands, http://www.ask-force.org/web/Regulation/COGEM-New-Techniques-Plant-Biotech-2008.pdf

Cohen, B. J. (2007), The transatlantic divide: Why are American and British IPE so different?, Review of International Political Economy, 14, 2, pp. 197-219, <Go to ISI>://WOS:000246155100001 AND http://www.ask-force.org/web/Regulation/Cohen-Transatlantic-Divide-IPE-2007.pdf

Cohen, S. N., A. C. Y. Chang and L. Hsu (1972), NONCHROMOSOMAL ANTIBIOTIC RESISTANCE IN BACTERIA - GENETIC TRANSFORMATION OF ESCHERICHIA-COLI BY R-FACTOR DNA, Proceedings of the National Academy of Sciences of the United States of America, 69, 8, pp. 2110-&, <Go to ISI>://WOS:A1972N243300027 AND http://www.ask-force.org/web/Genomics/Cohen-Nonchromosomal-Antibiotic-Resistance-1972.pdf

Cohen, S. N., A. C. Y. Chang, H. W. Boyer and R. B. Helling (1973), CONSTRUCTION OF BIOLOGICALLY FUNCTIONAL BACTERIAL PLASMIDS IN-VITRO, Proceedings of the National Academy of Sciences of the United States of America, 70, 11, pp. 3240-3244, <Go to ISI>://WOS:A1973R376400045 AND http://www.ask-force.org/web/Genomics/Cohen-Construction-Plasmids-in-Vitro-1973.pdf

Conko, G. (2005), Modified crops - Regulate the product, not the process, Chemical Engineering Progress, 101, 9, pp. 4-5, <Go to ISI>://WOS:000231894900001 AND NEBIS 20130114

Conko, G. and H. Miller (2012), The The Ripple Effects of Flawed Agbiotech Regulation, Regulation, Winter 2012-2013, pp. 7-9, http://www.ask-force.org/web/Regulation/Conko-Miller-Ripple-Effects-Flawed-Regulation-2012.pdf

Conner, A. J. and J. M. E. Jacobs (1999), Genetic engineering of crops as potential source of genetic hazard in the human diet, Mutation Research-Genetic Toxicology and Environmental Mutagenesis, 443, 1-2, pp. 223-234, <Go to ISI>://WOS:000081753100014 AND http://www.ask-force.org/web/Genomics/Conner-GE-Crops-Potential-Source-1999.pdf

Crawley, M. J. (1990), 12 The Ecology of Genetically Engineered Organisms: Assessing the Environmental Risks *in SCOPE 44 - Introduction of Genetically Modified Organisms into the Environment*, *ed. H. A. B. Mooney, G.,,* Vol., pp. COGEN, http://www.scopenvironment.org/downloadpubs/scope44/chapter12.html AND http://www.ask-force.org/web/Regulation/Crawley-Ecology-Genetically-Engineered-Organisms-Environment-1990.pdf

Crawley, M. J., S. L. Brown, R. S. Hails, D. D. Kohn and M. Rees (2001), Biotechnology - Transgenic crops in natural habitats, Nature, 409, 6821, pp. 682-683, <Go to ISI>://WOS:000166816400031 AND http://www.ask-force.org/web/Regulation/Crawley-Transgenic-Crops-Natural-2001.pdf

Cronin, B. (1987), TRANSATLANTIC PERSPECTIVES ON INFORMATION POLICY - THE SEARCH FOR REGULATORY REALISM, Journal of Information Science, 13, 3, pp. 129-138, <Go to ISI>://WOS:A1987H950000001 AND http://www.ask-force.org/web/Regulation/Cronin-Transatlantic-Perspectives-Regulation-Information-1987.pdf

Delseny, M., B. Han and Y. I. Hsing (2010), High throughput DNA sequencing: The new sequencing revolution, Plant Science, 179, 5, pp. 407-422, <Go to ISI>://WOS:000282997300001 AND http://www.ask-force.org/web/Genomics/Delseny-High-Throughput-DNA-Sequencing-Revolution-2010.pdf

Durham Tim, Doucet John and Unruh Snyder Lory (2011), Risk of Regulation or Regulation of Risk? A De Minimus Framework for Genetically Modified Crops, AgBioForum, 14, 2, pp. 61-70, http://www.agbioforum.org/v14n2/v14n2a03-durham.pdf AND http://www.ask-force.org/web/Regulation/Durham-Risk-Regulation-Regulation-Risk-2011.pdf

EASAC (20130627), Planting the future: opportunities and challenges for using crop genetic improvement technologies for sustainable agriculture edn. EASAC European Academies Science Advisory Council, 21, EASAC, IS: 978-3-8047-3181-3. pp. 78, http://www.easac.eu/home/reports-and-statements/detail-view/article/planting-the.html AND http://www.ask-force.org/web/EASAC/EASAC-Planting-the-Future-FULL-REPORT-20130627.pdf

Edney, M. J., B. G. Rossnagel and V. Raboy (2007), Effect of low-phytate barley on malt quality, including mineral loss, during fermentation, Journal of the American Society of Brewing Chemists, 65, 2, pp. 81-85, <Go to ISI>://WOS:000246420400004 AND http://cat.inist.fr/?aModele=afficheN&cpsidt=18782592

Edney, M. J., B. G. Rossnagel, R. McCaig, P. E. Juskiw and W. G. Legge (2011), Reduced Phytate Barley Malt to Improve Fermentation Efficiency, Journal of the Institute of Brewing, 117, 3, pp. 401-410, <Go to ISI>://WOS:000298267200016

EFSA Statement (20121123), Final review of the Séralini et al. (2012a) publication on a 2-year rodent feeding study with glyphosate formulations and GM maize NK603 as published online on 19 September 2012 in Food and Chemical Toxicology, EFSA Journal, 10, 11, 2986, pp. 1-10, http://www.efsa.europa.eu/en/efsajournal/doc/2986.pdf AND http://www.ask-force.org/web/HerbizideTol/Seralini-EFSA_2986-annex-1-2012.pdf AND http://www.ask-force.org/web/HerbizideTol/EFSA-final-Review-Seralini--2986-20121123.pdf AND http://www.ask-force.org/web/HerbizideTol/EFSA-Seralini-Final-Press-Release-20121128.pdf

EMBO, C. Weissmann, E. S. Anderson, K. Murray, L. Philipson, J. Tooze, H. Zachau, ICSU and W. J. Whelan (1976), Report on the Fist Meeting ot the EMBO Standing Advisory Committee on Recombinant DNA held at London on 14.-15. Februry 1976, Excerpt, EMBO, No. pp. 3,1, London, http://www.ask-force.org/web/Regulation/EMBO-Report-Feb.1976.PDF AND letter http://www.ask-force.org/web/Regulation/EMBO-Report-letter.1976.PDF

ENB-IISD-Cartagena-Negotiations (19990214-26), BSWG-6, Sixth Meeting of the Open-ended Ad Hoc Working Group on Biosafety Cartagena, Colombia; 15 - 19 February, 1999, ExCOP-1, First Extraordinary Meeting of the Conference of the Parties to the CBD Cartagena, Colombia; 22 - 23 February, 1999 IISD-Linkages, publ: Convention on Biodiversity, Earth Negotiation Bulletin ENB, http://www.iisd.ca/biodiv/bswg6/ AND http://www.iisd.ca/biodiv/bswg6/ AND http://www.ask-force.org/web/Cartagena/ENB-IISD-BSWG-6-Cartagena-P-Negotiations-Montreal-19990817-28.pdf

Environment Canada (1999a), A Guide to Understanding the Canadian Environmental Protection Act, 1999 edn. Environment Canada www.ec.gc.ca, IS: pp., http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=E00B5BD8-1&offset=5&toc=show

Environment Canada (1999b), Canadian Environmental Protection Act, 1999 (CEPA 1999), publ: http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=26A03BFA-1

Environment Canada (1999c), Overview of CEPA 1999, publ: http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=126220C5-1

Environment Canada (1999d), CEPA Environmental Registry, publ: http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=D44ED61E-1

Environment Canada (1999e), A Guide to Understanding the Canadian Environmental Protection Act, 1999, publ: http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=E00B5BD8-1&offset=5&toc=show

EPEC-SANCO (2011), Evaluation of the EU legislative framework in the field of cultivation of GMOs under Directive 2001/18/EC and Regulation (EC) No 1829/2003, and the placing on the market of GMOs as or in products under Directive 2001/18/EC Final Report, in: pp. 137, European Commission DG Sanco, http://ec.europa.eu/food/food/biotechnology/evaluation/docs/gmo_cultivation_report_en.pdf

EuropaBio (2013ff), Undue Delays in the EU Approval of Safe GM Products Status Update of 1 June 2012, EuropaBio, No. pp. 1, Brussels, http://www.europabio.org/filter/agricultural/type/position

Fagerstrom, T. and S. Wibe (2011), Genvägar eller senvägar – vad kostar det oss att avstå ifrån gentekniskt förädlade grödor i jordbruket?, No. pp. 100, Stockholm, http://www.ask-force.org/web/Regulation/Fagerstroem-Loud-Voices-Sweden-2011.pdf

Fagerstrom, T., C. Dixelius, U. Magnusson and J. F. Sundstrom (2012), Stop worrying; start growing, EMBO Rep, advance online publication, pp. http://dx.doi.org/10.1038/embor.2012.59 AND http://www.ask-force.org/web/Regulation/Fagerstroem-Stop-Worrying-Start-Growing-2012.pdf

Fedoroff, N., R. Haselkorn and B. M. Chassy (2011), EPA's Proposed Biotech Policy Turns a Deaf Ear to Science, The FASEB Journal, 25, 9, pp. 2855-2857, http://www.fasebj.org/content/25/9/2855.short AND http://www.ask-force.org/web/Regulation/Fedoroff-Deaf-Ear-2011.pdf

Fiksel, J. i., V. T. Covello, J. R. Fiksel and North Atlantic Treaty Organization. Scientific Affairs Division (1988), NATO advanced research workshop on safety assurance for environmental introductions of genetically-engineered organisms (1987) NATO ASI series. Series G : ecological sciences 18, pp. 35-54, 282pp, http://trove.nla.gov.au/version/22351272

Flavell, R. (2010), Knowledge and technologies for sustainable intensification of food production, New Biotechnology, 27, 5, pp. 505-516, <Go to ISI>://WOS:000285863300011 AND http://www.ask-force.org/web/Genomics/Flavell-Knowledge-Technologies-Sustainable-2010.pdf

Fraley, R. T., S. G. Rogers, R. B. Horsch, P. R. Sanders, J. S. Flick, S. P. Adams, M. L. Bittner, L. A. Brand, C. L. Fink, J. S. Fry, G. R. Galluppi, S. B. Goldberg, N. L. Hoffmann and S. C. Woo (1983), EXPRESSION OF BACTERIAL GENES IN PLANT-CELLS, Proceedings of the National Academy of Sciences of the United States of America-Biological Sciences, 80, 15, pp. 4803-4807, <Go to ISI>://WOS:A1983RB47600043 AND http://www.ask-force.org/web/Genomics/Fraley-Expression-Bacterial-Genes-Plant-Cells-1983.pdf

Fredrickson, D. (2001), The Recombinant DNA Controversy, a Memoir: Science, Politics, and the Public Interest 1974-1981 edn. ASM Press American Society for Microbiology, IS: ISBN-10: 1555812228 ISBN-13: 978-1555812225. pp. 406, http://www.amazon.de/Recombinant-DNA-Controversy-Memoir-1974-1981/dp/1555812228/ref=sr_1_1?ie=UTF8&s=books-intl-de&qid=1295837902&sr=8-1-catcorr, AMAZON ORDER

Giddings, V., I. Potrykus, Ammann K. and N. Fedoroff (2012), Confronting the Gordian knot, Opinion, Nature Biotechnology, 30, 3, pp. 208-209, http://www.nature.com/nbt/journal/v30/n3/abs/nbt.2145.html AMD http://www.ask-force.org/web/Regulation/Giddings-Confronting-Gordian-Knot-2012.pdf AND Editorial A. Marshall http://www.ask-force.org/web/Genomics/Marshall-Agnostic-About-Agriculture-2012.pdf

Giesecke, S. (2000), The contrasting roles of government in the development of biotechnology industry in the US and Germany, Research Policy, 29, 2, pp. 205-223, <Go to ISI>://WOS:000085125700008

Glickstein, N. M. (1995), "The Double Helix" Revisited, The American Biology Teacher, 57, 3, pp. 146-149, http://www.jstor.org/stable/4449951 AND http://www.ask-force.org/web/Genomics/Quiet-Debut-Double-Helix-2003.pdf

Hagen, P. E. and J. B. Weiner (2001), The Cartagena Protocol on Biosafety: New Rules for International Trade in Living Modified Organisms, Georgetown international Environmental Law Review, 12, pp. 697ff, 23 ppp, http://www.ask-force.org/web/Regulation/Hagen-Cartagena-Protocol-Biosafety-1999.pdf AND http://heinonline.org/HOL/LandingPage?collection=journals&handle=hein.journals/gintenlr12&div=31&id=&page=

Hakeem, K. R., R. Chandna, P. Ahmad, M. Iqbal and M. Ozturk (2012), Relevance of Proteomic Investigations in Plant Abiotic Stress Physiology, Omics-a Journal of Integrative Biology, 16, 11, pp. 621-635, <Go to ISI>://WOS:000310648600006 AND http:ask-force.org/web/Genomics/Hakeem-Relevance-Proteomic-Relevance-2012.pdf

Halvorson, H. O. (1977a), RECOMBINANT DNA LEGISLATION - WHAT NEXT, Science, 198, 4315, pp. 357-357, <Go to ISI>://WOS:A1977DX79500005 AND 10.1126/science.11643404 AND http://www.ask-force.org/web/Regulation/Halvorson-Recombinant-DNA-Legislation-1977.pdf

Halvorson, H. O. (1977b), ASM ON RECOMBINANT DNA, Science, 196, 4295, pp. 1154-1154, <Go to ISI>://WOS:A1977DH35400002 AND 10.1126/science.196.4295.1154 and http://www.ask-force.org/web/Regulation/Halvorson-ASM-Recombinant-DNA-1977.pdf

Haslberger, A. G. (2003), Codex guidelines for GM foods include the analysis of unintended effects, Nature Biotechnology, 21, 7, pp. 739-741, <Go to ISI>://WOS:000183886000018 AND http://www.ask-force.org/web/Regulation/Haslberger-Codex-Guidelines-Unintended-2003.pdf

Health Canada (2006), Genetically Modified (GM) Foods and Other Novel Foods, publ: http://www.hc-sc.gc.ca/fn-an/gmf-agm/index-eng.php AND http://www.ask-force.org/web/Regulation/Health-Canada-Genetically-Modified-(GM)-Foods-Novel-Foods-2006.pdf

Heap Brian (20130626), Europe should rethink its stance on GM crops. Second-generation crop genetic-modification techniques avoid some of the issues that previously provoked hostility, argues Brian Heap., Nature, 498, 7455, pp. 1, doi:10.1038/498409a AND http://www.nature.com/news/europe-should-rethink-its-stance-on-gm-crops-1.13265 AND http://www.ask-force.org/web/Genomics/Heap-Europe-Should-Rethink-Stance-20130626.pdf

Herman, R. A. and W. D. Price (2013), Unintended Compositional Changes in Genetically Modified (GM) Crops: 20 Years of Research, Journal of Agricultural and Food Chemistry, pp. http://dx.doi.org/10.1021/jf400135r AND http://www.ask-force.org/web/Genomics/Herman-Unintended-Compositional-Changes-20years-F1000-Evaluation-Ammann-20130307.pdf AND http://www.ask-force.org/web/Genomics/Herman-Unintended-Compositional-Changes-20-Years-2013.pdf

Huttner, S. L., H. I. Miller and P. G. Lemaux (1995), US AGRICULTURAL BIOTECHNOLOGY - STATUS AND PROSPECTS, Technological Forecasting and Social Change, 50, 1, pp. 25-39, <Go to ISI>://WOS:A1995RT49000003 AND http://www.ask-force.org/web/Regulation/Huttner-US-Ag-Biotech-Status-Prospects-1995.pdf

Inglis, I. R., J. T. Wadsworth, A. N. Meyer and C. J. Feare (1992), VERTEBRATE DAMAGE TO 00-VARIETY AND 0-VARIETY OF OILSEED RAPE IN RELATION TO SMCO AND GLUCOSINOLATE CONCENTRATIONS IN THE LEAVES, Crop Protection, 11, 1, pp. 64-68, <Go to ISI>://WOS:A1992HA94000011

Jany Klaus (2013), Critical remarks on the long-term feeding study by Séralini et al. (2012). Does the study provide proof of health threats posed by genetically modified foods?, EFFL - European Food and Feed Law Review, 3, pp. 176-187, http://www.ask-force.org/web/Seralini/Jany-Critical-Remarks-Seralini-Study-EFFL-201303.pdf

Jiang, Y. H., Z. X. Cai, W. B. Xie, T. Long, H. H. Yu and Q. F. Zhang (2012), Rice functional genomics research: Progress and implications for crop genetic improvement, Biotechnology Advances, 30, 5, pp. 1059-1070, <Go to ISI>://WOS:000308773300012 AND http://www.ask-force.org/web/Genomics/Jiang-Rice-Funcional-Genomics-Progress-2011.pdf

Jiao, Z., J. C. Deng, G. K. Li, Z. M. Zhang and Z. W. Cai (2010), Study on the compositional differences between transgenic and non-transgenic papaya (Carica papaya L.), Journal of Food Composition and Analysis, 23, 6, pp. 640-647, <Go to ISI>://WOS:000284394800023 AND http://www.ask-force.org/web/Genomics/Jiao-Compositional-Differences-Papaya-2010.pdf

Juma, C. (2011a), The New Harvest: Agricultural Innovation in Africa Preprint 3 Chapters edn. Oxford University Press (14. Januar 2011) IS: ISBN-10: 0199783195 ISBN-13: 978-0199783199. pp. 296, http://www.ask-force.org/web/Developing/Juma-Governing-Innovation-2011.pdf and http://www.ask-force.org/web/Developing/Juma-Growing-Economy-Ch-1-2011.pdf and http://www.ask-force.org/web/Developing/Juma-Introduction-2011.pdf AND https://www.amazon.de/New-Harvest-Agricultural-Innovation-Africa/dp/0199783195/ref=sr_1_1?ie=UTF8&qid=1320909861&sr=8-1

Juma, C. (2011b), Science Meets Farming in Africa, Science, 334, 6061, pp. 1323, http://www.sciencemag.org/content/334/6061/1323.short AND http://www.ask-force.org/web/Developing/Juma-Science-Meets-Africa-20111209.pdf

Juma, C. (2011c), Preventing hunger: Biotechnology is key, Nature, 479, 7374, pp. 471-472, http://dx.doi.org/10.1038/479471a AND http://www.ask-force.org/web/Developing/Juma-Preventing-Hunger-Nature-2011.pdf

Kelman, A., W. Anderson, S. Falkov, N. Fedoroff and S. Leven (1987), Introduction of Recombinant DNA-Engineered Organisms into the Environment: Key Issues, National Academic Press, No. pp. 24, Washington DC, http://books.google.ch/books/about/Introduction_of_recombinant_DNA_engineer.html?id=IUErAAAAYAAJ&redir_esc=y

Keurentjes, J. J. B., J. Y. Fu, C. H. R. de Vos, A. Lommen, R. D. Hall, R. J. Bino, L. H. W. van der Plas, R. C. Jansen, D. Vreugdenhil and M. Koornneef (2006), The genetics of plant metabolism, Nature Genetics, 38, 7, pp. 842-849, <Go to ISI>://WOS:000238669300023 AND http://www.ask-force.org/web/Genomics/Keurentjes-Genetics-Plant-Metabolism-2006.pdf

Kingsbury, D. T. (1990), 14 Regulation of Biotechnology: A. Perspective on the US 'Coordinated Framework' *in SCOPE 44 - Introduction of Genetically Modified Organisms into the Environment*, *ed. H. A. B. Mooney, G.,,* Vol., pp. COGEN, http://www.scopenvironment.org/downloadpubs/scope44/chapter14.html AND http://www.ask-force.org/web/Regulation/Kingsbury-Regulation-Biotechnology-Perspective-US-1990.pdf

Kirschman, J. C. and R. L. Suber (1989), RECENT FOOD POISONINGS FROM CUCURBITACIN IN TRADITIONALLY BRED SQUASH, Food and Chemical Toxicology, 27, 8, pp. 555-556, <Go to ISI>://WOS:A1989AX36500009 AND NEBIS 20140821

Kochetkova, T. (2006), The transatlantic conflict over GM food: Cultural background, Ethics and the Politics of Food, pp. 325-329, <Go to ISI>://WOS:000240055000053 AND http://www.ask-force.org/web/Regulation/Kochetkova-Transatlantic-Conflict-2006.pdf

Koester, V. (2001), A New Hot Spot in the Trade-Environment Conflict, Environmental Policy and Law, 31, 2, pp. 82-94, http://iospress.metapress.com/content/N3TKKCA1EL731VXD AND http://www.ask-force.org/web/Regulation/Koester-Cartagena-Protocol-Hotspot-2001.pdf

Kogel, K.-H., L. M. Voll, P. Schaefer, C. Jansen, Y. Wu, G. Langen, J. Imani, J. r. Hofmann, A. Schmiedl, S. Sonnewald, D. von Wettstein, R. J. Cook and U. Sonnewald (2010), Transcriptome and metabolome profiling of field-grown transgenic barley lack induced differences but show cultivar-specific variances, Proceedings of the National Academy of Sciences, 107, 14, pp. 6198-6203, <Go to ISI>://WOS:000276374400016 AND http://www.ask-force.org/web/Genomics/Kogel-Transcriptome-Metabolome-2010.pdf AND http://www.ask-force.org/web/Genomics/Kogel-Transcriptome-Metabolome-Supporting-2010.pdf

Krattiger, A. and W. Lesser (1994), Biosafety-An Environmental Impact Assessment Tool - And the Role of the Convention on Biological Diversity *in Widening Perspectives on Biodiversity*, *ed. A. Krattiger, J. A. McNeely, W. Lesser, M. K.G., Y. St. Hill and R. Senanayake,* Vol., pp. 353-366 The Burlington Press, IUCN World Conservation Union, International Academy of the Environment, Cambridge UK, http://www.ask-force.org/web/Cartagena/Krattiger-biodiv-biosafety-1994.PDF

Kumar, G. R., K. Sakthivel, R. M. Sundaram, C. N. Neeraja, S. M. Balachandran, N. S. Rani, B. C. Viraktamath and M. S. Madhav (2010), Allele mining in crops: Prospects and potentials, Biotechnology Advances, 28, 4, pp. 451-461, <Go to ISI>://WOS:000279095800003 AND http://www.ask-force.org/web/Genomics/Kumar-Allele-Mining-Crops-Prospects-2010.pdf

Kuntz, M. and A. Ricroch (2012), Is it Time to Adjust the Current Regulatory Risk Assessment for GM Food and Feed?, ISB News Report, Agricultural and Environment Biotechnology, February 2012, pp. 1-4, http://www.isb.vt.edu/news/2012/Feb12.pdf AND http://www.ask-force.org/web/Regulation/Kuntz-Ricroch-ISB-Time-Adjust-2012.pdf

Kuzma, J. and A. Kokotovich (2011), Renegotiating GM crop regulation, EMBO Rep, 12, 9, pp. 883-888, http://dx.doi.org/10.1038/embor.2011.160 AND http://www.ask-force.org/web/Regulation/Kuzma-Renegotiating-GM-Crop-2011.pdf

Lederberg, J. (2000), The dawning of molecular genetics, Trends in Microbiology, 8, 5, pp. 194-195, <Go to ISI>://WOS:000087036100002 AND http://www.ask-force.org/web/Genomics/Lederberg-Dawing-Molecular-Genetics-2000.pdf

Lee, R.-Y., D. Reiner, G. Dekan, A. E. Moore, T. J. V. Higgins and M. M. Epstein (2012), Genetically Modified alpha-Amylase Inhibitor Peas Are Not Specifically Allergenic in Mice, PLoS ONE, 8, 1, pp. e52972, http://dx.doi.org/10.1371%2Fjournal.pone.0052972 AND http://www.ask-force.org/web/Allergy/Lee-GM-Peas-not-allergenic-2012.pdf

Li, L., M. J. Piatek, A. Atef, A. Piatek, A. Wibowo, X. Fang, J. S. M. Sabir, J.-K. Zhu and M. M. Mahfouz (2012), Rapid and highly efficient construction of TALE-based transcriptional regulators and nucleases for genome modification, Plant Molecular Biology, 78, 4-5, pp. 407-416, <Go to ISI>://WOS:000302252300007 AND http://www.ask-force.org/web/Genomics/Li-Rapid-Highly-Efficient-Construction-2012.pdf

Liu, Z., J. Zhao, Y. Li, W. Zhang, G. Jian, Y. Peng and F. Qi (2012), Non-Uniform Distribution Pattern for Differentially Expressed Genes of Transgenic Rice Huahui 1 at Different Developmental Stages and Environments, PLoS One, 7, 5, pp. e37078, http://dx.doi.org/10.1371%2Fjournal.pone.0037078 AND http://www.ask-force.org/web/Genomics/Liu-Non-Uniform-Distribution-Pattern-2012.pdf

Lusser, M., C. Parisi, D. Plan and E. Rodriguez-Cerezo (2012), Deployment of new biotechnologies in plant breeding, Nature Biotechnology, 30, 3, pp. 231-239, <Go to ISI>://WOS:000301303800015 AND http://www.ask-force.org/web/Regulation/Lusser-Deployment-New-Biotech-Breeding-2012.pdf

Mahfouz, M. M., L. Li, M. Shamimuzzaman, A. Wibowo, X. Fang and J.-K. Zhu (2011), De novo-engineered transcription activator-like effector (TALE) hybrid nuclease with novel DNA binding specificity creates double-strand breaks, Proceedings of the National Academy of Sciences, 108, 6, pp. 2623-2628, http://www.pnas.org/content/108/6/2623.abstract AND http://www.ask-force.org/web/Genomics/Mahfouz-De-Novo-engineered-transcroption-2011.pdf AND http://www.ask-force.org/web/Genomics/CNBC-Kaust-Genomic-Scissors-2011.PDF AND http://www.ask-force.org/web/Genomics/AAAS-News-Fedoroff-Genomics-Kaust-20110303.PDF

Mahfouz, M. M., L. Li, M. Piatek, X. Fang, H. Mansour, D. K. Bangarusamy and J.-K. Zhu (2012), Targeted transcriptional repression using a chimeric TALE-SRDX repressor protein, Plant Molecular Biology, 78, 3, pp. 311-321, <Go to ISI>://WOS:000302251300009 AND http://www.ask-force.org/web/Genomics/Mahfouz-Targeted-Transcriptional-Repression-2012.pdf

Marshall, A. (2012), Editorial: Agnostic about agriculture, Nature Biotechnology, 30, 3, pp. 197, http://doi:10.1038/nbt.2168 AND http://www.nature.com/nbt/journal/v30/n3/abs/nbt.2168.html AND http://www.ask-force.org/web/Genomics/Marshall-Agnostic-About-Agriculture-2012.pdf

Maxam, A. M. and W. Gilbert (1977), A new method for sequencing DNA, Proceedings of the National Academy of Sciences, 74, 2, pp. 560-564, http://www.pnas.org/content/74/2/560.abstract AND http://www.ask-force.org/web/Genomics/Maxam-Gilbert-New-Method-Sequencing-DNA-1977.pdf

Mayo-Wilson, E., A. Imdad, K. Herzer, M. Y. Yakoob and Z. A. Bhutta (2011), Vitamin A supplements for preventing mortality, illness, and blindness in children aged under 5: systematic review and meta-analysis, BMJ, 343, pp. http://www.bmj.com/content/343/bmj.d5094.abstract AND http://www.ask-force.org/web/Golden-Rice/Mayo-Wilson-Vitamin-A-Supplements-2011.pdf

McHughen, A. (2007), Fatal flaws in agbiotech regulatory policies, Nature Biotechnology, 25, 7, pp. 725-727, <Go to ISI>://WOS:000247994000016 AND http://www.ask-force.org/web/Regulation/McHughen-Fatal-Flaws-Agbiotech-Regulatory-2008.pdf

McLean, M. A., R. J. Frederick, P. L. Traynor, J. I. Cohen and J. Komen (2002), A Conceptual Framework for Implementing Biosafety: Linking Policy, Capacity, and Regulation, ISNAR, International Service for National Agricultural Research, No. pp. 1-12, Washington DC., ftp://ftp.cgiar.org/isnar/publicat/bp-47.pdf AND http://www.ask-force.org/web/Regulation/McLean-Conceptual-Framework-ISNAR-47-2002.pdf

Meissle M, Álvarez-Alfageme F, Malone LA and Romeis J. (2012), Establishing a database of bio-ecological information on non-target arthropod species to support the environmental risk assessment of genetically modified crops in the EU EFSA, No. pp. 170, Parma, Italy, http://www.efsa.europa.eu/en/publications.htm AND ftp://server18.hostpoint.ch/www/ask-force.org/web/Bt1/Meissle-Establishing-Database-Nontarget-2012.pdf

Miller, H. I. (1994a), OVERREGULATED BIOTECHNOLOGY, Nature, 371, 6499, pp. 646-646, <Go to ISI>://WOS:A1994PM77300018 AND http://www.ask-force.org/web/Regulation/Miller-Overregulated-Bioitechnology-1994.pdf

Miller, H. I. (1994b), US Must Rationalize Biotech Regulation, Bio-Technology, 12, 5, pp. 441-442, <Go to ISI>://A1994NJ86300010 AND http://www.ask-force.org/web/Regulation/Miller-US-Must-Rationalize-1994.pdf

Miller, H. I., R. Beachy and S. L. Huttner (1994), RISK ASSESSMENT REDUX, Bio-Technology, 12, 3, pp. 216-217, <Go to ISI>://WOS:A1994MZ55000002 AND http://www.ask-force.org/web/Regulation/Miller-Risk-Assessment-Redux-1994.pdf

Miller, H. I. (1995), BIODIVERSITY TREATY MISGUIDED, Nature, 373, 6512, pp. 278-278, <Go to ISI>://WOS:A1995QD40400020 AND http://www.ask-force.org/web/Regulation/Miller-Biotechnology-Treaty-Misguided-1995.pdf

Miller, H. I. (1997), Policy Controversy in Biotechnology: An Insiders View edn. Academic Press, R.G. Landes Company Imprint of Elsevier, IS: ISBN-10: 0124967256 ISBN-13: 978-0124967250 pp. 221, http://www.amazon.de/Policy-Controversy-Biotechnology-Intelligence-Unit/dp/0124967256/ref=sr_1_3?ie=UTF8&qid=1293891836&sr=8-3

Miller, H. I. (1999), Cynicism and politics dominate UN biotechnology deliberations, Nat Biotech, 17, 6, pp. 515-515, http://dx.doi.org/10.1038/9775 AND http://www.ask-force.org/web/Regulation/Miller-Cynicism-Politics-Cartagena-1999.pdf

Miller, H. I. (2002), Agricultural Biotechnology, Law, and Food Biotechnology Regulation edn. John Wiley & Sons, Inc., IS: 9780471250593. pp., http://dx.doi.org/10.1002/0471250597.mur097 AND http://www.ask-force.org/web/Regulation/Miller-Agricultural-Biotechnology-Wiley-2002.PDF AND http://www.ask-force.org/web/Regulation/Miller-Agricultural-Biotechnology-Wiley-Fig-1-2002.PDF

Miller, H. I. (2003), First salvo in transatlantic food fight is far from last word, Nature Biotechnology, 21, 7, pp. 737-738, <Go to ISI>://WOS:000183886000017 AND http://www.ask-force.org/web/Regulation/Miller-First-Salvo-Transatlantic-2003.pdf

Miller, H. I. and G. P. Conko (2004), The Frankenfood Myth, how protest and politics threaten the biotech revolution edn. Greenwood Publishing Group, 2004, IS: 0275978796, 9780275978792. pp. 269, http://books.google.ch/books?id=T1-1RER8tVgC&dq=Henry+Miller+and+Gregory+Conko,+the+Frankenfood+Myth&lr=&source=gbs_navlinks_s AND derived chapter in NAS http://www.ask-force.org/web/Regulation/Miller-Conco-Agriculture-Overregulation-2005.PDF

Miller, H. I. (2009), A golden opportunity, squandered, Trends in Biotechnology, 27, 3, pp. 129-130, http://www.sciencedirect.com/science/article/B6TCW-4VGTGRX-1/2/89948850e8a0e9a03b66f54ad6257a6b AND http://www.botanischergarten.ch/Golden-Rice/Miller-Golden-Opportunity-2009.pdf , AND http://www.genengnews.com/gen-articles/a-golden-opportunity-choked-by-red-tape/3542/?page=2 AND http://www.ask-force.org/web/Golden-Rice/Miller-Golden-Opportunity-Choked-by-Red-Tape-20110201.pdf

Miller, H. I. (2010), The regulation of agricultural biotechnology: science shows a better way *in Transgenic Plants for Food Security in the Context of Development*, *ed. I. Potrykus and K. Ammann,* Vol. 27, pp. 628-634 Pontifical Academy of Sciences, Amsterdam, http://www.sciencedirect.com/science/article/B8JG4-50G06H6-2/2/baec44822399aaf56f2b8fe58d560c28 AND http://www.ask-force.org/web/Vatican-PAS-Studyweek-Elsevier-publ-20101130/Miller-Henry-PAS-Regulation-Agricultural-20101130-publ.pdf AND link to Vatican Website http://www.casinapioiv.va/content/accademia/en/publications/scriptavaria/transgenic.html

Miller, J. K. and K. J. Bradford (2010), The regulatory bottleneck for biotech specialty crops, Nature Biotechnology, 28, 10, pp. 1012-1014, http://dx.doi.org/10.1038/nbt1010-1012 AND http://www.nature.com/nbt/journal/v28/n10/abs/nbt1010-1012.html#supplementary-information AND http://www.ask-force.org/web/Regulation/Miller-Bradford-Bottleneck-2010.pdf

Moe, K. T., S. W. Kwon and Y. J. Park (2012), Trends in genomics and molecular marker systems for the development of some underutilized crops, Genes & Genomics, 34, 5, pp. 451-466, <Go to ISI>://WOS:000310539900001 AND http://www.ask-force.org/web/Genomics/Moe-Trends-Genomics-Underutilized-2012.pdf

Montero, M., A. Coll, A. Nadal, J. Messeguer and M. Pla (2011), Only half the transcriptomic differences between resistant genetically modified and conventional rice are associated with the transgene, Plant Biotechnology Journal, 9, 6, pp. 693-702, <Go to ISI>://WOS:000292337300007

Mooney, H. A. and G. Bernardi (1990), Introduction of Genetically Modified Organisms into the Environment, SCOPE internet edition, pp. 224, John Wiley & Sons; 1 edition (December 7, 1990) Hoboken, ISBN-10: 0471926779 ISBN-13: 978-0471926771 ISBN-10: 0471926779 ISBN-13: 978-0471926771 http://www.scopenvironment.org/downloadpubs/scope44/contents.html AND http://www.amazon.com/Introduction-Genetically-Modified-Organisms-into-Environment/dp/0471926779/ref=sr_1_1?s=books&ie=UTF8&qid=1315502752&sr=1-1

Moore, P. and K. Batra (20120216) Greenpeace Founder: Biotech Opposition is Crime Against Humanity publ: Bio Access Date: http://www.ask-force.org/web/Golden-Rice/Moore-Golden-Rice-Crime-20120216.pdf

Morandini Piero (2012), Academies - Scientific societies - National, international organizations with a positive position on gene technology University of Milano, No. pp. 6, Milano, http://www.ask-force.org/web/Union-Akademien/Morandini-Sources-Academies-societies-2011.pdf

Morris, S. and C. Spillane (2010), EU GM Crop Regulation: A Road to Resolution or a Regulatory Roundabout?, European Journal of Risk Regulation, 4, pp. 359-369, http://www.ask-force.org/web/Regulation/Morris-Spillane-EU-GM-Crop-Regulation-final-2010..pdf

Morris, S. H. and C. Spillane (2008), GM directive deficiencies in the European Union. The current framework for regulating GM crops in the EU weakens the precautionary principle as a policy tool Embo Reports, 9, 6, pp. 500-504, doi:10.1038/embor.2008.94 AND http://www.botanischergarten.ch/Precautionary/Morris-Spillane-EMBO-PA-2008.pdf

Munson, A. (1993), Genetically Manipulated Organisms: International Policy-Making and Implications, International Affairs (Royal Institute of International Affairs 1944-), 69, 3, pp. 497-517, http://www.jstor.org/stable/2622312 AND http://www.ask-force.org/web/Regulation/Munson-Genetically-Manipulated-Organisms-1993.pdf see also New Scientist Forum http://www.newscientist.com/article/mg14219314.900-forum-better-biosafe-than-sorry--abby-munson-says-that-we-need-a-strong-protocol-on-the-release-of-engineered-organisms.html

NAS National Academy of Sciences, A. Kelman, W. Anderson, S. Falkov, N. Fedoroff and S. Levin (1987), Introduction of Recombinant DNA-Engineered Organisms into the Environment: Key Issues. edn. National Academy Press, IS: pp. 24, http://www.ask-force.org/web/NAS/NAS-Introduction-Recombinant-DNA-Engineered-Environment-1987.pdf

NAS National Academy of Sciences, Committee on Genetically Modified Pest-Protected Plants, Board on Agriculture and Natural Resources and National Research Council (2000), Genetically Modified Pest-Protected Plants: Science and Regulation, Prepublication and edn. IS: ISBN: 0-309-06930-0, def: 0-309-50467-8 pp. 290, http://www.nap.edu/catalog/9795.html AND prepublication: http://www.ask-force.org/web/NAS/National-Research-Council-GM-Pest-Protected-prepublication-2000.pdf

http://www.ask-force.org/web/NAS/NAS-Introduction-Recombinant-DNA-Engineered-Environment-1987.pdf AND final copy: http://www.ask-force.org/web/NAS/National-Research-Council-GM-Pest-Protected-def-2000.pdf

NAS National Academy of Sciences (2004), Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects edn. National Research Council IS: ISBN: 0-309-53194-2, . pp. 257, http://www.nap.edu/catalog/10977.html AND http://www.ask-force.org/web/Genomics/NAS-Safety-GE-Unintended-Health-2004.pdf

Norman, C. (1976), GENETIC MANIPULATION - GUIDELINES ISSUED, Nature, 262, 5563, pp. 2-4, <Go to ISI>://WOS:A1976BV88200002 AND http://www.ask-force.org/web/Regulation/Norman-Genetic-Manipulation-Guidelines-1976.pdf

NRC (National-Research-Council) (1989), Field Testing Genetically Modified Organism. Framework for Decisions Committee on Scientific Evaluation of the Introduction of Genetically Modified Microorganisms and Plants into the Environment, National Research Council edn. N. A. o. Sciences, The National Academy Press, IS: ISBN-10: 0-309-04076-0, ISBN-13: 978-0-309-04076-1 pp. 184, free online reading http://www.nap.edu/catalog/1431.html AND http://books.nap.edu/openbook/0309040760/html/3.html AND http://books.nap.edu/openbook/0309040760/html/13.html AND http://books.nap.edu/openbook/0309040760/html/14.html

Ofori, A., H. C. Becker and F. J. Kopisch-Obuch (2008), Effect of crop improvement on genetic diversity in oilseed Brassica rapa (turnip-rape) cultivars, detected by SSR markers, Journal of Applied Genetics, 49, 3, pp. 207-212, <Go to ISI>://WOS:000258459600001 AND http://www.ask-force.org/web/Brassica/Ofori-Effect-Crop-Improvement-Brassica-2008.pdf

Olby, R. (2003), Quiet debut for the double helix, Nature, 421, 6921, pp. 402-405, <Go to ISI>://WOS:000180533000048 AND http://www.ask-force.org/web/Genomics/Olby-Quiet-Debut-Double-Helix-2003.pdf

Podevin, N., Y. Devos, H. V. Davies and K. M. Nielsen (2012), Transgenic or not? No simple answer! New biotechnology-based plant breeding techniques and the regulatory landscape, Embo Reports, 13, 12, pp. 1057-1061, <Go to ISI>://WOS:000311971700012 AND http://www.ask-force.org/web/Genomics/Podevin-Transgenic-or-Not-2012.pdf

Potrykus, I. (1991), Gene Transfer to Plants: Assessment of Published Approaches and Results, Annual Review of Plant Physiology and Plant Molecular Biology, 42, 1, pp. 205-225, http://www.annualreviews.org/doi/abs/10.1146/annurev.pp.42.060191.001225 AND http://www.ask-force.org/web/Genomics/Potrykus-Gene-Tranfer-Plants-1991.pdf

Potrykus, I. (2010a), Constraints to biotechnology introduction for poverty alleviation *in Transgenic Plants for Food Security in the Context of Development,, ed. I. a. A. Potrykus, K.,* Vol. 27, pp. 447-448 Pontifical Academy of Sciences, Amsterdam, http://www.sciencedirect.com/science/article/B8JG4-50J4MRM-3/2/bedd78fb4e30dd32c48c99d0c31f504a AND http://www.ask-force.org/web/Vatican-PAS-Studyweek-Elsevier-publ-20101130/Potrykus-Ingo-PAS-Constraints-20101130-publ.pdf AND Link to Vatican Website: AND link to Vatican Website http://www.casinapioiv.va/content/accademia/en/publications/scriptavaria/transgenic.html

Potrykus, I. (2010b), Regulation must be revolutionized, Nature, 466, 7306, pp. 561-561, http://dx.doi.org/10.1038/466561a AND http://www.ask-force.org/web/Regulation/Potrykus-Regulation-Revolutionized-2010.pdf

Potrykus, I. and K. Ammann (2010), Transgenic Plants For Food Security In The Context Of Development, Proceedings Of A Study Week Of The Pontifical Academy Of Sciences, 27, pp. 445-718, Elsevier, Amsterdam, ISSN 1871-6784: ISSN 1871-6784, http://www.ask-force.org/web/Vatican-PAS-NBT-publ/PAS-NBT-Volume-27-20101130.pdf AND http://www.casinapioiv.va/content/accademia/en/events/2009/transgenicplants.html

Prescott, V. E., P. M. Campbell, A. Moore, J. Mattes, M. E. Rothenberg, P. S. Foster, T. J. V. Higgins and S. P. Hogan (2005), Transgenic Expression of Bean Î±-Amylase Inhibitor in Peas Results in Altered Structure and Immunogenicity, Journal of Agricultural and Food Chemistry, 53, 23, pp. 9023-9030, http://dx.doi.org/10.1021/jf050594v AND http://www.ask-force.org/web/Genomics/Prescott-Transgenic-Expression-Bean-Immunogenicity-2005.pdf

Prince, M. J. (2000), Banishing bureaucracy or hatching a hybrid? The Canadian Food Inspection Agency and the politics of reinventing government, Governance-an International Journal of Policy and Administration, 13, 2, pp. 215-232, <Go to ISI>://WOS:000170048800004 AND http://www.ask-force.org/web/Regulation/Prince-Banishing-Bureaucracy-Canadian-CFIA-2000.pdf

PRRI (2006-2010a), PRRI submission Roster Experts and MOP4, MOP5 Statements on the Roster of Experts, www.pubresreg.org No. pp. CBD and Nagoya Japan, http://www.ask-force.org/web/PRRI-Experts/PRRI-submission-CP-Roster-Experts-20101013.pdf AND http://www.ask-force.org/web/PRRI-Experts/PRRI-submisison-CP-Roster-Experts-20061121.pdf AND http://www.ask-force.org/web/PublicSector-Danforth-20050304/CP-Experts-Overlap-to-ISBR-2004.pdf

PRRI (2006-2010b), PRRI submission Roster Experts and MOP5 Statement on the Roster of Experts, www.pubresreg.org No. pp. CBD and Nagoya Japan, http://www.ask-force.org/web/PRRI-Experts/PRRI-submission-CP-Roster-Experts-20101013.pdf AND http://www.ask-force.org/web/PRRI-Experts/PRRI-submisison-CP-Roster-Experts-20061121.pdf

PRRI (20090914) LMOs or traits of which risks assessments suggest that they are unlikely to cause adverse effects - Letter to Dr. Ahmed Djoglaf, Executive Secretary of the Convention on Biological Diversity publ: Public Research and Regulation Initiative Access Date: September 14, 2009 Brussels http://www.ask-force.org/web/PRRI-MOP5/PRRI-LMOs-unlikely-Adverse-Effects-Notification-2009-103-20090914.pdf

PRRI (20100923), PRRI Letter to EU commission: The impact of proposed changes in the EU rules for GMOs on public research, www.pubresreg.org No. pp. Brussels, http://www.ask-force.org/web/PRRI-Eu-Commission/PRRI-letter-proposals-amendment-GMO-Directive-final-1-2010.pdf

PRRI (20101012), PRRI COP-MOP5 Statement on the Strategic Plan, Exemptions, www.pubresreg.org No. pp. Nagoya, Japan, http://www.ask-force.org/web/PRRI-Exemption/PRRI-MOP5-statement-Strategic-Plan-20101012.pdf

PRRI (20120516), PRRI submission - information on identification of LMOs that are not likely to have adverse effects, publ: PRRI Public Research and Regulation Initiative, http://www.ask-force.org/web/Regulation/PRRI-submission-LMOs-Unlikely-20120516.pdf

Ramjoue, C. (2006), The transatlantic rift in genetically modified food policy, Ethics and the Politics of Food, pp. 334-338, <Go to ISI>://WOS:000240055000055

Ramjoue, C. (2007), The transatlantic rift in genetically modified food policy, Journal of Agricultural & Environmental Ethics, 20, 5, pp. 419-436, <Go to ISI>://WOS:000248855000003 AND http://www.ask-force.org/web/Regulation/Ramjoue-Transatlantic-Rift-2007.pdf

Raybould, A. (2012), Can science justify regulatory decisions about the cultivation of transgenic crops?, Transgenic Research, pp. 1-8, http://dx.doi.org/10.1007/s11248-012-9613-3 AND http://www.ask-force.org/web/Regulation/Raybould-Can-Science-Justify-Decisions-2012.pdf

Raybould, A., R. Kurtz, L. Zeph, C. A. Wozniak and A. McHughen (2012), Regulatory Science, Research Science and Innovation in Agricultural Biotechnology *in Regulation of Agricultural Biotechnology: The United States and Canada*, *ed. C. A. W. a. A. McHughen,* Vol., pp. 317-333 Springer Netherlands, http://dx.doi.org/10.1007/978-94-007-2156-2_15 AND http://www.ask-force.org/web/Regulation/Raybould-Regulatory-Research-Science-2012.pdf

Ricroch, A. E., J. B. Berge and M. Kuntz (2011a), Evaluation of genetically engineered crops using transcriptomic, proteomic and metabolomic profiling techniques, Plant Physiology, preview February 24, printed 2011 Vol. 155, , 4, pp. 26, 1752-1761, http://www.plantphysiol.org/cgi/content/abstract/pp.111.173609v1 AND http://www.plantphysiol.org/content/155/4/1752.full.pdf+html?sid=a29b6f3c-fea8-427d-9f27-cead7551a85f AND http://www.ask-force.org/web/Food/Ricroch-Evaluation-GE-crops-omics-2011.pdf AND http://www.ask-force.org/web/Food/Ricroch-Evaluation-GE-crops-omics-Suppl-T-II-2011.pdf AND http://www.ask-force.org/web/Food/Ricroch-Evaluation-GE-crops-omics-Suppl-TI-2011.pdf AND http://www.ask-force.org/web/Food/Ricroch-Evaluation-GE-crops-omics-Suppl.-References-S2-2011.pdf AND http://www.ask-force.org/web/Food/Ricroch-Evaluation-GE-crops-omics-Suppl.-References-S4-2011.pdf

Ricroch, A. E., J. B. Berge and M. Kuntz (2011b), Evaluation of genetically engineered crops using transcriptomic, proteomic and metabolomic profiling techniques, Plant Physiology, 155, 4, pp. 1752-1761, http://www.plantphysiol.org/cgi/content/abstract/pp.111.173609v1 AND http://www.ask-force.org/web/Genomics/Ricroch-Evaluation-GE-Crops-Omics-def-2011.pdf AND supplements http://www.plantphysiol.org/content/155/4/1752/suppl/DC1

Ricroch, A. E. (2012), Assessment of GE food safety using omics techniques and long-term animal feeding studies, New Biotechnology, 0, pp. http://www.sciencedirect.com/science/article/pii/S1871678412008801 AND http://dx.doi.org/10.1016/j.nbt.2012.12.001 AND http://www.ask-force.org/web/Genomics/Ricroch-Assessment-GE-Food-Savety-Omics-2012.pdf AND http://www.ask-force.org/web/Genomics/Ricroch-Assessment-GE-Food-Savety-Omics-edited-2012.pdf

Rogers, M. (1975), The Pandora's box congress, Asilomar Conference diary, Conference Program, Rolling Stone, 189, 36, pp. http://www.ask-force.org/web/Genomics/Rogers-Pandoras-Box-Conf-1975.PDF

Romeis, J., N. C. Lawo and A. Raybould (2009), Making effective use of existing data for case-by-case risk assessments of genetically engineered crops, Journal of Applied Entomology, 133, 8, pp. 571-583, <Go to ISI>://WOS:000268985800001 AND http://www.ask-force.org/web/Regulation/Romeis-Making-Effective-Use-Data-2009.pdf

Ronald, P. (2011), Plant Genetics, Sustainable Agriculture and Global Food Security, Genetics, 188, 1, pp. 11-20, http://www.genetics.org/content/188/1/11.abstract AND http://www.ask-force.org/web/Genomics/Ronald-Plant-Genetics-Sustainable-Agriculture-2011.pdf

Sanger, F., J. E. Donelson, A. R. Coulson, H. Kossel and D. Fischer (1973), USE OF DNA POLYMERASE I PRIMED BY A SYNTHETIC OLIGONUCLEOTIDE TO DETERMINE A NUCLEOTIDE SEQUENCE IN PHAGE FL DNA, Proceedings of the National Academy of Sciences of the United States of America, 70, 4, pp. 1209-1213, <Go to ISI>://WOS:A1973P380700057 AND 10.1073/pnas.70.4.1209 (not working), http://www.jstor.org/discover/10.2307/62457?uid=3737760&uid=2134&uid=2&uid=70&uid=4&sid=21102315397567 AND with VPN

University of Bern: http://www.jstor.org/stable/pdfplus/62457.pdf?acceptTC=true AND http://www.ask-force.org/web/Genomics/Sanger-Use-DNA-Polymerase-1973.pdf

Sanvido, O., J. Romeis and F. Bigler (2008), Monitoring or Surveillance? Balancing between theoretical frameworks and practical experiences, Journal Fur Verbraucherschutz Und Lebensmittelsicherheit-Journal of Consumer Protection and Food Safety, 3, pp. 4-7, <Go to ISI>://WOS:000264403300001

Sanvido, O., J. Romeis and F. Bigler (2009), An approach for post-market monitoring of potential environmental effects of Bt-maize expressing Cry1Ab on natural enemies, Journal of Applied Entomology, 133, 4, pp. 236-248, <Go to ISI>://WOS:000265035600002

Sanvido, O., J. Romeis and F. Bigler (2011a), Facilitating the evaluation of possible environmental harm from genetic engineering, Agrarforschung Schweiz, 2, 9, pp. 382-387, <Go to ISI>://WOS:000295705000003 AND http://ww.ask-force.org/web/Regulation/Romeis-Making-Effective-Use-Data-2009.pdf

Sanvido, O., J. Romeis, A. Gathmann, M. Gielkens, A. Raybould and F. Bigler (2011b), Evaluating environmental risks of genetically modified crops: ecological harm criteria for regulatory decision-making, Environmental Science & Policy, 15, 1, pp. 82-91, http://www.sciencedirect.com/science/article/pii/S1462901111001390 AND http://www.ask-force.org/web/Regulation/Sanvido-Evaluating-Environmental-Risks-2011.pdf

Sanvido, O., J. Romeis, A. Gathmann, M. Gielkens, A. Raybould and F. Bigler (2012), Evaluating environmental risks of genetically modified crops: ecological harm criteria for regulatory decision-making, Environmental Science & Policy, 15, 1, pp. 82-91, http://www.sciencedirect.com/science/article/pii/S1462901111001390 AND http://www.ask-force.org/web/Regulation/Sanvido-Evaluating-Environmental-Risks-2012.pdf AND http://www.ask-force.org/web/Regulation/Sanvido-Evaluating-Supplement-2012.pdf

Sears R., Siebert J.B. and a. Societies (1998), Letter on Behalf of the American Society of Horticultural Sciences, American Phytopathology Society, and Crop Science Society of America to the Environmental Protection Agency EPA

Testimony of a Consortium of 11 Scientific Societies before the House Committee on Appropriations Subcommittee on VA-HUD and Independent Agencies, No. docket control number [OPP-300370],, pp. http://jpkc.jluhp.edu.cn/zwkx/zwbl/Improve/Graduate/APSNET/testimony.asp.htm AND http://www.ask-force.org/web/Regulation/Siebert-Sears-Testimony-Consortium-11-Societies-EPA-19980421.pdf

Sehnal, F. and J. Drobnik (2009), Genetically Modified Crops, Eu Regulations and Research Experience from the Czech Republic edn. © Biology Centre of the Academy of Sciences of the Czech Republic, v. v. i., 2009, IS: ISBN 978-80-86668-05-3. pp. 98, http://www.ask-force.org/web/Regulation/Sehnal-Drobnik-White-Book-2009.pdf

Seifert, F. (2010), Back to Politics at Last - Orthodox Inertia in the Transatlantic Conflict over Agro-Biotechnology *in Science, Technology & Innovation Studies ed. P. W. Boeschen Stefan,* Vol. 6, 2, pp. 101-127 Science, Technology & Innovation Studies, Available at: <<http://www.sti-studies.de/ojs/index.php/sti/article/view/41> AND www.sti-studies.de AND http://www.ask-force.org/web/Regulation/Seifert-Back-to-Politics-at-Last-2010.pdf

Seralini Gilles-Eric, Emilie Clair, Robin Mesnage, Steeve Gress, Nicolas Defarge, Manuela Malatesta, Didier Hennequin and Joel Spiroux de Vendomois (20120918), Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize preprint, Food and Chemical Toxicology, 50, 11, pp. 4221–4231, www.elsevier.com/locate/foodchemtox AND http://dx.doi.org/10.1016/j.fct.2012.08.005 AND http://www.ask-force.org/web/Seralini/Seralini-Long-Term-Toxicity-RR-2012.pdf AND http://www.ask-force.org/web/Seralini/Seralini-Press-Sustainable-Trust-20120919.pdf AND http://www.ask-force.org/web/Seralini/Seralini-Long-Term-Toxicity-RR-Bt-def-2012.pdf

Shewry, P. R. and H. D. Jones (2005), Transgenic wheat: where do we stand after the first 12 years?, Annals of Applied Biology, 147, 1, pp. 1-14, <Go to ISI>://WOS:000233648200001

Shewry, P. R., S. Powers, J. M. Field, R. J. Fido, H. D. Jones, G. M. Arnold, J. West, P. A. Lazzeri, P. Barcelo, F. Barro, A. S. Tatham, F. Bekes, B. Butow and H. Darlington (2006), Comparative field performance over 3 years and two sites of transgenic wheat lines expressing HMW subunit transgenes, Theoretical and Applied Genetics, 113, 1, pp. 128-136, <Go to ISI>://000238345000016 AND http://www.botanischergarten.ch/Organic/Shewry-Performance-2006.pdf

Shewry, P. R., M. Baudo, A. Lovegrove and S. Powers (2007), Are GM and conventionally bred cereals really different?, Trends in Food Science & Technology, 18, 4, pp. 201-209, <Go to ISI>://WOS:000245784600003 AND http://www.botanischergarten.ch/Wheat/Shewry-Are-GM-Convent-Cereals-different-2007.pdf

Shukla, V. K., Y. Doyon, J. C. Miller, R. C. DeKelver, E. A. Moehle, S. E. Worden, J. C. Mitchell, N. L. Arnold, S. Gopalan, X. Meng, V. M. Choi, J. M. Rock, Y.-Y. Wu, G. E. Katibah, G. Zhifang, D. McCaskill, M. A. Simpson, B. Blakeslee, S. A. Greenwalt, H. J. Butler, S. J. Hinkley, L. Zhang, E. J. Rebar, P. D. Gregory and F. D. Urnov (2009), Precise genome modification in the crop species Zea mays using zinc-finger nucleases, Nature, 459, 7245, pp. 437-441, http://dx.doi.org/10.1038/nature07992 AND AND http://www.ask-force.org/web/Genomics/Shukla-Precise-Genome-Mod-Zink-Finger-publ-2009.pdf
http://www.nature.com/nature/journal/vaop/ncurrent/suppinfo/nature07992_S1.html

Shukla, V. K. and S. Kumar (2010), Conversion of a green light emitting zinc-quinolate complex thin film to a stable and highly packed blue emitter film, Synthetic Metals, 160, 5-6, pp. 450-454, <Go to ISI>://WOS:000276119800024 AND http://www.ask-force.org/web/Genomics/Shukla-Conversion-Green-Light-2010.pdf

Singer, M. and D. Soll (1973), Guidelines for DNA Hybrid Molecules, Science, 181, 4105, pp. 1114, http://www.jstor.org/stable/1736531 AND http://www.ask-force.org/web/Genomics/Singer-Guidelines-DNA-Hybrid-Molecules-Letter-1973.pdf

Skalka, A. M. (1990), Risk Assessment for Genetic Experimentation and Application *in SCOPE 44 - Introduction of Genetically Modified Organisms into the Environment*, *ed. H. A. B. Mooney, G.,,* Vol., pp. COGEN, http://www.scopenvironment.org/downloadpubs/scope44/chapter01.html AND ftp://ask-force.org/www/ask-force.org/web/Regulation/Skalka-Risk-Assessment-SCOPE-44-1990.pdf

Slade, A. J., S. I. Fuerstenberg, D. Loeffler, M. N. Steine and D. Facciotti (2005), A reverse genetic, nontransgenic approach to wheat crop improvement by TILLING, Nat Biotech, 23, 1, pp. 75-81, http://dx.doi.org/10.1038/nbt1043 AND http://www.nature.com/nbt/journal/v23/n1/suppinfo/nbt1043_S1.html AND http://www.ask-force.org/web/Genomics/Slade-Reverse-Genetic-TILLING-2005.pdf

Smith Barry, Marcotte Michelle and Harrison Gordon (19960331), A Comparative Analysis of the Regulatory Framework Affecting Functional Food Development and Commercialization in Canada, Japan, the European Union and the United States of America, Inter/Sect Alliance Inc., No. pp. 102, Ottawa, Canada, http://www.ask-force.org/web/Regulation/Smith-Comparative-Analysis-Canada-Japan-EU-1996.pdf AND http://publications.gc.ca/collections/Collection/WWW96-19E.pdf

Smith, H. O. and M. L. Birnstiel (1976), A simple method for DNA restriction site mapping, Nucleic Acids Research, 3, 9, pp. 2387-2398, http://nar.oxfordjournals.org/content/3/9/2387.abstract AND 10.1093/nar/3.9.2387 AND http://www.ask-force.org/web/Genomics/Birnstiel-Simple-Method-DNA-mapping-1976.pdf

Smyth, S. and A. McHughen (2008), Regulating innovative crop technologies in Canada: the case of regulating genetically modified crops, Plant Biotechnology Journal, 6, 3, pp. 213-225, http://dx.doi.org/10.1111/j.1467-7652.2007.00309.x AND http://www.ask-force.org/web/Regulation/Smyth-McHughen-Regulating-Innovative-Crop-Technologies-Canada-2008.pdf

Snowdon, R. J. and F. L. I. Luy (2012), Potential to improve oilseed rape and canola breeding in the genomics era, Plant Breeding, 131, 3, pp. 351-360, <Go to ISI>://WOS:000304904600001 AND http://www.ask-force.org/web/Genomics/Snowdon-Potential-Improve-Oilseed-Rape-Genomics-2012.pdf

Soren, K. R., K. Ali, V. Tyagi and A. Tyagi (2010), Recent advances in molecular breeding of drought tolerance in rice (Oryza sativa L.), Indian Journal of Biotechnology, 9, 3, pp. 233-251, <Go to ISI>://WOS:000280966900001 AND http://www.ask-force.org/web/Genomics/Soren-Recent-Advances-Drought-Tolerance-2010.pdf

Sunstein, C. R. and R. Zeckhauser (2011), Overreaction to Fearsome Risks, Environmental & Resource Economics, 48, 3, pp. 435-449, <Go to ISI>://WOS:000288390100005 AND http://www.ask-force.org/web/Regulation/Sunstein-Overreaction-Fearsome-Risks-2011.pdf

Szekacs, A., G. Weiss, D. Quist, E. Takacs, B. Darvas, M. Meier, T. Swain and A. Hilbeck (2012), Inter-laboratory comparison of Cry1Ab toxin quantification in MON 810 maize by enzyme-immunoassay, Food and Agricultural Immunology, 23, 2, pp. 99-121, <Go to ISI>://WOS:000304170200002 AND http://www.ask-force.org/web/Bt1/Szekacs-Inter-Laboratory-Comparison-2013.pdf

Tang, G., J. Qin, G. G. Dolnikowski, R. M. Russell and M. A. Grusak (2009), Golden Rice is an effective source of vitamin A, Am J Clin Nutr, 89, 6, pp. 1776-1783, http://www.ajcn.org/cgi/content/abstract/89/6/1776 AND http://www.ask-force.org/web/Golden-Rice/Tang-Golden-Rice-Effective-Source-2009.pdf

Taverne, D. (2011), Don't go all European about modified food, New Scientist, online 24. January 2011, pp. http://www.newscientist.com/article/dn20020-dont-go-all-european-about-modified-food.html AND http://www.ask-force.org/web/Regulation/Taverne-Dont-go-all-European-20110124.PDF

Tenea, G. N., F. Cordeiro Raposo and A. Maquet (2012), Comparative Transcriptome Profiling in Winter Wheat Grown under Different Agricultural Practices, Journal of Agricultural and Food Chemistry, 60, 44, pp. 10970-10978, http://dx.doi.org/10.1021/jf302705p AND http://www.ask-force.org/web/Genomics/Tenea-Comparative-Transcriptome-Profiling-Practices-2012.pdf

Thro, A. M. (2004) Europe on transgenic crops: How public plant breeding and eco-transgenics can help in the transatlantic debate. Commentary. publ: Access Date: http://www.agbioforum.org/v7n3/v7n3a06-thro.htm AND http://www.ask-force.org/web/Regulation/Thro-Europe-Transgenic-Crops-2004.pdf

Tiedje, J. M., R. K. Colwell, Y. L. Grossman, R. E. Hodson, R. E. Lenski, R. N. Mack and P. J. Regal (1989), The Planned Introduction of Genetically Engineered Organisms: Ecological Considerations and Recommendations, Ecology, 70, 2, pp. 298-315, http://www.jstor.org/stable/1937535 AND http://www.ask-force.org/web/Regulation/Tiedje-Planned-Introduction-GM-organisms-1989.pdf

Tooze, J. (1978), Harmonizing Guidelines: Theory and Practice *in Genetic Engineering: International Symposium Proceedings (Symposia of the Giovanni Lorenzini Foundation)*, *ed. H. W. Boyer and S. Nicosia,* Vol., pp. 310 Elsevier Science Ldt., http://www.ask-force.org/web/Genomics/Tooze-Harmonizing-Guidelines-1978.PDF

Torgersen, H., G. Soja, I. Janssen and H. Gaugitsch (1998), Risk assessment of conventional crop plants in analogy to transgenic plants, Environmental Science and Pollution Research, 5, 2, pp. 89-93, <Go to ISI>://000074257100009 AND http://www.ask-force.org/web/Regulation/Torgersen-Risk-Assessment-Conventional-Transgenic-1998.pdf and final print http://www.ask-force.org/web/Regulation/Torgersen-Risk-Assessment-Conventional-Transgenic-final-1998.pdf

Torgersen, H. (2002), Austria and the Transatlantic Agricultural Biotechnology Divide, Science Communication, 24, 2, pp. 173-183, http://scx.sagepub.com/content/24/2/173.abstract AND http://www.ask-force.org/web/Regulation/Torgersen-Austria-Transatlantic-Divide-2002.pdf

Tzotzos George (2007), Adoption of industrial biotechnology:The impact of regulation, in: publ: UNIDO, Uninted Nations Industrial Develpment Organisation, Kualalumpur, http://www.ask-force.org/web/Genomics/Tzotzos-Adoption-Biotech-Regulation-2007.ppt AND http://www.ask-force.org/web/Genomics/Tzotzos-Adoption-Biotech-Regulation-2007.pdf

Tzotzos, G. T. (2001), Prospects of international initiatives in agri-food biotechnology, Journal of the Science of Food and Agriculture, 81, 9, pp. 810-812, <Go to ISI>://WOS:000169828700003 AND http://www.ask-force.org/web/Regulation/Tzotzos-Prospects-International-Initiatives-Agrifood-Biotech-2001.pdf

UNIDO/WHO/UNEP Working Group (2001), Release of Organisms into the Environment: Voluntary Code of Conduct,, Biotech Forum Europe, 9, 4, pp. 218-222, http://www.ask-force.org/web/Regulation/UNIDO-WHO-UNEP-Release-Organisms-Environment-Volutary-20010518.pdf

Van Bueren, E. T. L., P. C. Struik, M. Tiemens-Hulscher and E. Jacobsen (2003), Concepts of intrinsic value and integrity of plants in organic plant breeding and propagation, Crop Science, 43, 6, pp. 1922-1929, <Go to ISI>://000186477700003 AND http://www.botanischergarten.ch/Organic/Van-Bueren-Intrinsic-2003.pdf

Van Bueren, E. T. L., H. Verhoog, M. Tiemens-Huscher, P. C. Struik and M. A. Haring (2007), Organic agriculture requires process rather than product evaluation of novel breeding techniques, Njas-Wageningen Journal of Life Sciences, 54, 4, pp. 401-412, <Go to ISI>://000246556800007 AND http://www.ask-force.org/web/Organic/van-Bueren-Organic-prosess-2007.pdf

Varshney, R. K., J. C. Glaszmann, H. Leung and J. M. Ribaut (2010), More genomic resources for less-studied crops, Trends in Biotechnology, 28, 9, pp. 452-460, <Go to ISI>://WOS:000281944700003 AND http://www.ask-force.org/web/Genomics/Varshney-More-Genomic-Resources-Less-Studied-Crops-2010.pdf

Vasil, I. (2008), A history of plant biotechnology: from the Cell Theory of Schleiden and Schwann to biotech crops, Plant Cell Reports, 27, 9, pp. 1423-1440, http://dx.doi.org/10.1007/s00299-008-0571-4 AND http://www.ask-force.org/web/Genomics/Vasil-History-Plant-Biotechnology-2008.pdf

Vega-Sanchez, M. E. and P. C. Ronald (2010), Genetic and biotechnological approaches for biofuel crop improvement, Curr Opin Biotechnol, 21, 2, pp. 218-24, http://www.ncbi.nlm.nih.gov/pubmed/20181473

Waltz, E. (2012), Tiptoeing around transgenics, Nat Biotech, 30, 3, pp. 215-217, http://dx.doi.org/10.1038/nbt.2143 AND http://www.ask-force.org/web/Regulation/Waltz-tip-toeing-around-transgenics-2012.pdf

Watson, J. C. and J. Tooze (1981), The DNA Story, A Documentary History of Gene Cloning edn. W.H. Freeman and Company, IS: ISBN-10: 0716715902 ISBN-13: 978-0716715900 pp. 605, http://www.amazon.com/DNA-Story-Documentary-History-Cloning/dp/0716715902/ref=sr_1_4?ie=UTF8&qid=1296205252&sr=8-4

Watson, J. D. and F. H. C. Crick (1953a), GENETICAL IMPLICATIONS OF THE STRUCTURE OF DEOXYRIBONUCLEIC ACID, Nature, 171, 4361, pp. 964-967, <Go to ISI>://WOS:A1953UA43900005 AND http://www.ask-force.org/web/Genomics/Watson-Crick-Genetical-Implications-DNA-1953.pdf

Watson, J. D. and F. H. C. Crick (1953b), MOLECULAR STRUCTURE OF NUCLEIC ACIDS - A STRUCTURE FOR DEOXYRIBOSE NUCLEIC ACID, Nature, 171, 4356, pp. 737-738, <Go to ISI>://WOS:A1953UA43400007 AND http://www.ask-force.org/web/Genomics/Watson-Crick-Molecular-Structure-Nucleic-Acids-1953.pdf

Watson, J. D. and F. H. C. Crick (1953c), THE STRUCTURE OF DNA, Cold Spring Harbor Symposia on Quantitative Biology, 18, pp. 123-131, <Go to ISI>://WOS:A1953UC66300019 AND http://www.ask-force.org/web/Genomics/Watson-Crick-The-Structure-of-DNA-Cold-Spring-1953.pdf

Wilkins, M. H. F., A. R. Stokes and H. R. Wilson (1953), MOLECULAR STRUCTURE OF DEOXYPENTOSE NUCLEIC ACIDS, Nature, 171, 4356, pp. 738-740, <Go to ISI>://WOS:A1953UA43400008 AND http://www.ask-force.org/web/Genomics/Wilkins-Helical-Structure-Desoxypentose-1953.pdf

Witkowski, J. (1988), 50 YEARS ON - MOLECULAR BIOLOGYS HALL OF FAME, Trends in Biotechnology, 6, 10, pp. 234-243, <Go to ISI>://WOS:A1988Q244800004 AND http://www.ask-force.org/web/Regulation/Wikowski-Fifty-Years-Molecular-Hall-Fame-1988.pdf

Young, F. E. and H. I. Miller (1987a), HAZARDS OF GENETIC-ENGINEERING, Nature, 326, 6111, pp. 326-326, <Go to ISI>://WOS:A1987G578100017AND http://www.ask-force.org/web/Regulation/Young-Miller-Hazards-Nature-1987.pdf

Young, F. E. and H. I. Miller (1987b), THE NAS REPORT ON DELIBERATE RELEASE - TOPPLING THE TOWER OF BIO-BABBLE, Bio-Technology, 5, 10, pp. 1010-1010, <Go to ISI>://WOS:A1987K239100004 AND http://www.ask-force.org/web/Regulation/Young-Miller-NAS-Report-Toppling-1987.pdf

Young, F. E. and H. I. Miller (1987c), RECOMBINANT-DNA RELEASE - EUROPEAN REGULATION, Science, 238, 4830, pp. 1025-1025, <Go to ISI>://WOS:A1987K886900002 AND http://www.ask-force.org/web/Regulation/Young-Miller-Dickson-Recombinant-DNA-1987.pdf

Young, F. E. and H. I. Miller (1989), DELIBERATE RELEASES IN EUROPE - OVER-REGULATION MAY BE THE BIGGEST THREAT OF ALL, Gene, 75, 1, pp. 1-2, <Go to ISI>://WOS:A1989T678300001 AND http://www.ask-force.org/web/Regulation/Young-Editorial-Gene-Release-Europe-1989.pdf

Zhang, C., Y. Yin, A. Zhang, Q. Lu, X. Wen, Z. Zhu, L. Zhang and C. Lu (2012), Comparative proteomic study reveals dynamic proteome changes between superhybrid rice LYP9 and its parents at different developmental stages, Journal of Plant Physiology, 169, 4, pp. 387-398, <Go to ISI>://WOS:000302207400008 AND http://www.ask-force.org/web/Genomics/Zhang-Comparative-Proteomic-Study-Reveals-2012.pdf

Zhang Ti-fu, Li Bo, Zhang Deng-feng, Jia Guan-qing, Li Zhi-yong and Wang Shou-cai (2012), Genome-Wide Transcriptional Analysis of Yield and Heterosis-Associated Genes in Maize (Zea mays L.), Journal of Integrative Agriculture, 11, 8, pp. 1245-1256, <Go to ISI>://WOS:000307988300004 AND http://www.ask-force.org/web/Genomics/Zhang-Genom-Wide-Transcriptional-Heterosis-2012.pdf

Zilinskas, R. A. and B. K. Zimmerman (1986), The gene-splicing wars: Reflections on the recombinant DNA controversy edn. American Association for Advancement of Science,Washington, DC, IS: pp. Medium: X; Size: Pages: 288, http://www.amazon.com/gp/product/0070728755/ref=oh_o00_s00_i00_details

Zinder, N. (1986), A personal view of the media's role in the recombinant DNA war *in The gene-splicing wars: Reflections on the recombinant DNA controversy*, *ed. R. A. Zilinskas and B. K. Zimmerman,* Vol., pp. 109-118 American Association for Advancement of Science,Washington, DC, Washington DC, http://www.amazon.com/gp/product/0070728755/ref=oh_o00_s00_i00_details ORDERED FROM AMAZON 20120402