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LEAVING GENOMIC MISCONCEPTION, TOWARDS A PRODUCT-BASED REGULATION

A FOLLOW-UP FOR 2015. FIRST DRAFT

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This is a follow-up publication of an extensive literature review on the Genomic Misconception (Ammann, Klaus, 2014)

It includes more arguments, statements, texts and support from new publications, from the, the UK regulatory agencies (DEFRA, ACRE), the British parliaments, the European Academy EASAC, and the regulatory agency EFBS of Switzerland, and EFSA. It deals with new publications from Canada and its very successful regulatory system. It reviews new and old pertinent literature on the subject of product oriented regulation.

Obviously there is a necessity of changing regulatory rules in the face of the numerous emerging new gene transfer technologies. The use of the term product-oriented regulation implies always also a good portion of process oriented clarifications, as the Canadians do it for years. This also means that we will have to adapt the Cartagena Protocol on Biosafety, the EU regulatory laws and most of the national legislation of GM crops. This will be easier than imagined, since it will smooth regulatory processes and will include in a justified way a small part of conventional crops as well.

CONTENTS

0. PREFACE AND EXECUTIVE SUMMARY FOR THE MEETING ON MARCH 11 IN BRUSSELS

No doubt there will be a debate on regulation in the next months to come. The question will be on how to proceed and change the regulatory rules. The arguments and proponents for a product oriented regulation are rapidly growing, up to now we have some of the most respected science bodies worldwide dealing with GMO regulation on the side of the product oriented regulation:

1. UK regulatory agencies ACRE, DEFRA and the House of Lords, the House of Commons with a full support of the leading UK scientists for product oriented regulation.

2. EASAC, the European Academy of Sciences fully supporting product oriented regulation, including its science board.

3. Full support from a new textbook on GM crops from the UK written by Evans et al.

4. Indirect support of the EFSA, comment to intervention of observer Klaus Ammann

5. Continuous support from Canada, the leading agency for product oriented regulation, with new publications demonstrating measurable regulatory success.

6. Full support in the final report of the Swiss National Foundation research project No. 59, including a very clear opinion chapter of Werner Arber, who publishes since years about the scientific foundation of product oriented regulation, see my original paper 2014 on the Genomic Misconception

7. Many earlier pre-2014-publications of the author on the product oriented regulation, bibliography in peer reviewed journals and book chapters, not a single one contradicted.

8. A review of numerous important papers published in peer reviewed journals supporting product oriented regulation

9. The rapid development of new gene transfer methods (at present time ca. 15 new ones) forces regulators to get away from the process oriented regulation towards a product view in regulation.

10. Comparing the real and documented risks, clearly higher in conventional and organic than in transgenic crops demands the inclusion of conventional crops of all kinds for at least a pre-scrutiny in regulatory processes.

11. The indirect consequences of product-oriented regulation offers new opportunities of collaboration and common use of conventional and biotech crops in new organo-transgenic agricultural strategies.

General remarks:
An intense global debate on a new regulatory system is now launched, mainly caused by the avalanche of new transfer methods coming up, some already in concrete application, others published and shortly to be used in modern breeding. They are all hindered dramatically in their approval, mainly due to an insufficient regulatory system, still based on the process and in the EU hampered by a clumsy decision making structure. Clearly the Cartagena Protocol on Biosafety, also the EU regulations and many of the national regulations worldwide have to be changed in a few paragraphs. It would be overstressing the interpretation of the biosafety laws, including the Cartagena Protocol to say that those present regulations include product-oriented rules, this according to the great majority of scientist involved in regulatory matters of GMOs. The critique of the Cartagena Protocol and the EU regulatory system and its creation process has been extensively criticized in the original publication on the Genomic Misconception (Ammann, Klaus, 2014). So far the author has not seen a publication contradicting directly this publication in a peer reviewed journal, on the contrary, as you will see below, there is a lot of support, *in most cased published independently*.

1. UK REGULATORY AGENCIES AND POLITICS: SUPPORT FOR PRODUCT ORIENTED REGULATION

The ACRE-DEFRA-documentation on the subject: (ACRE, 2013a, 2013b, 2013c) and ACRE Advice of new transfer techniques: (ACRE Advice, 2014)

ACRE publishes three reports on the EU regulatory system for GMOs, investigating the framework in which ACRE operates. The first report TOWARDS AN EVIDENCE-BASED REGULATORY SYSTEM FOR GMOS considers the likely future limitations of the current regulatory framework and whether these can be addressed piecemeal or only via an entirely new framework. Report 2 WHY A MODERN UNDERSTANDING OF GENOMES DEMONSTRATES THE NEED FOR A NEW REGULATORY SYSTEM FOR GMOS discusses the scientific validity of employing a regulatory system that captures organisms based on how they were produced rather than on their novel characteristics. Report 3 TOWARDS A MORE EFFECTIVE APPROACH TO ENVIRONMENTAL RISK ASSESSMENT UNDER CURRENT GMO LEGISLATION summarizes shortcomings of the current system for risk assessment and proposes a way forward to avoid future stalemate.

"Executive Summary from report 2:
Our understanding of genomes does not support a process-based approach to regulation. The continuing adoption of this approach has led to, and will increasingly lead to, problems. This includes problems with consistency, i.e. regulating organisms produced by some techniques and not others irrespective of their capacity to cause environmental harm. Classifying the regulatory status of organisms produced by new techniques is becoming increasingly difficult, because the definition of a GMO in the Directive was drafted at a time when many of these techniques had not been conceived. Technology in molecular genetics is developing rapidly, to the extent that plants and other organisms can be modified in ways whereby the use of recombinant technologies leaves no detectable footprint. In some cases, this is because the organisms have not themselves been engineered using recombinant technology.
Our conclusion, that the EU's regulatory approach is not fit for purpose for organisms generated by new techniques, also applies to transgenic organisms produced by 'traditional' GM technology. Whilst it is clear that these will be captured by the GMO legislation, the potential for inconsistency is inherent because they may be phenotypically identical to organisms that are not regulated.
We have highlighted the problems associated with a process-based regulatory system, and suggest there are benefits of a different system that can take account of the novelty of the final product. Such a system is independent of newly arising and currently unforeseen technological developments, and focuses on potential risks associated with phenotype. This approach has many advantages over the existing regulations and should be considered as part of any proposal to improve or replace them." *From the ACRE-report 2: (ACRE, 2013b)*

ACRE-DEFRA considers a more effective approach to environmental risk assessment within the constraints of the principles set out in the current legislation.

It is also good to see the most recent report of the British Parliament from the House of Commons, which means that now the product oriented biosafety assessment has entered relevant political processes in Britain: (House-of-Commons, 2015). (see also the previous report of the House of Lords (House of Lords, 2011))

From 1. Regulatory trigger
"61. The current EU regulatory system for novel crop plants is technology-specific; genetically modified crops are regulated because of the method by which they were created rather than because of the traits that they display. Several influential UK and European bodies—including the European Academies Science Advisory Council (EASAC) (EASAC, 20130627) p.37 the Prime Minister's Council for Science and Technology, (Walport Mark & Rothwell Nancy, 20131121) the Biotechnology and Biological Sciences Research Council (BBSRC) (BBRSC, 20150123) and the Advisory Committee on Releases to the Environment (ACRE) (ACRE, 2013b) — ***have advocated a move to a trait-based regulatory system, as is currently operated in Canada (see box 4 below). They have made this recommendation on the basis of two professed flaws of the current process-based system: i) lack of evidence to support the underlying premise that genetically modified crops present***

higher risk than their conventionally bred counterparts; and ii) the failure of process-based regulation to cope with advances in technology."

"Box 4, *The Canadian regulatory system for plants with novel traits*
In Canada, genetically modified and conventionally bred plants are all regulated under the same 'trait-based' system. Under this system, crops are subject to full risk assessment and regulation only if they are defined as being a 'plant with a novel trait' (a 'PNT'). In order to be classified as a PNT, a plant must display a characteristic not seen in any previously approved product. However, the system does not distinguish between technologies: a PNT may be produced by conventional breeding, mutagenesis, genetic modification or any other technique, and not all genetically modified plants will necessarily be defined as PNTs. (EASAC, 20130627) p.17.

According to the European Academies Science Advisory Council, "this approach acknowledges the fact that it is the product, and not the process, that warrants regulation because it is the presence of novel traits in a plant that potentially pose an environmental or health risk, and not how the traits were specifically introduced". (EASAC, 20130627) p.17.

It added that "a key strength of the Canadian regulatory system is that while the techniques used by plant breeders continue to evolve, the regulatory trigger for PNTs will remain current and consistent". (EASAC, 20130627) p.17.

Canada is the fourth-largest global producer of genetically modified crops and has so far approved over 120 GM crop/trait combinations through this system. (EASAC, 20130627) p.50." from (House-of-Commons, 2015)

Already in an earlier report of the 'European Union Committee of the British House of Lords' (House of Lords, 2010) published the following summary already at that time fully supportive of product-oriented regulation:

"Agriculture faces a global challenge. The world's population, now around 7 billion, is expected to grow to 9 billion by 2050. Many food prices have increased and are likely to go on doing so.
In response, agricultural production must increase—to feed these extra mouths, to keep prices down, and to respond to a world-wide demand for better nutrition. Higher output has to be achieved using finite resources. The world cannot afford to release new land for farming. We need our forests and wilderness to absorb the carbon dioxide we create.
Supplies of fresh water are everywhere under pressure. Projections of climate change show that many areas used for agriculture are under threat, from drought or flooding.
Mitigating climate change also means that farmers must reduce their use of fossil fuels, and change practices that contribute to the emission of greenhouse gases. The response to this challenge has to start now. Decisions have to be taken, and actions implemented, with urgency.
The UK and the EU are not sheltered from the challenge. Europe must act quickly and coherently to transform EU agriculture, and make it ready for this new era. Far from limiting production, the trend of the last decade, European Governments must see as the prime focus of agricultural policy the need to raise productivity, while supporting environmental sustainability. Innovation must be at the heart of this effort. Science is key. In the UK, the Government must maintain the quality of fundamental research but also do more to plug the gaps in applied agricultural research. Between 2007 and 2013 the Common Agricultural Policy budget is around €400 bn;
EU funding for agricultural research is under €2 bn. The European Commission must make a coordinated drive to lift agricultural research to a new level, not least through the European Innovation Partnership on sustainable and productive agriculture. Innovative knowledge must be put into practice. This is not happening systematically across the EU. Member States should improve advice to agriculture; the CAP Farm Advisory System should be extended to stimulate innovative practice. ***Regulation should help, not hinder. Politicians and society must not be afraid of new properly tested technologies. These may include the genetic modification of crops, but GM is only one example of a range of possible technologies. Benefits and risks must be clearly articulated, recognizing that too precautionary an approach may pose risks to global food security.***
This is a challenge that must be addressed across the Government, across the European Commission and across

society. Only collaborative working, bringing together scientists, farmers, retailers, and consumers, will enable agriculture to meet the tests of the future." From (House of Lords, 2011).

Comment

Lots of references to continental-Europe-publications are lacking in the UK-reports – after all, the British Isles have their own rules based on excellent science. I am happy to see an independent view of regulation professionals attacking the artificial and non-scientific barrier erected by international regulation between transgenic and conventional crops: The UK-studies contain some interesting arguments for the same issue. DEFRA's and ACRE'S work demonstrates a pioneer role of the UK in Europe, including the activities of the former Environmental Minister Owen Paterson and Anne Glover as an advisor to the EU commission, both unfortunately dismissed from their posts under strange circumstances. The new regulatory spirit has now resulted into a House of Commons report clearly supporting product-oriented regulation, it should be a strong signal to Continental Europe including the EU, and likewise to the global regulatory community including the Cartagena Protocol.

(A side remark about the British influence on international regulation of GMOs: Clearly, the British Scientists and Regulators have a pioneer role in Europe, at present times very positive, but we should not forget their unfortunate 'pioneer' role with the Pusztai affaire causing a major shift to the negative in GMO regulation, it actually initiated in the UK decades ago by the paper of Arpad Pusztai, finally also published in Lancet: (Ewen & Pusztai, 1999a, 1999b, 1999c).

The rebuttal of Harry Kuiper (Kuiper et al., 1999) was, typically enough, rarely cited in the first hysteria period around 2000, but never really contradicted. The full story on how the Arpad Pusztai opinions and publications were finally fully debunked: See the literature review: (Ammann Klaus, 20121127) – it took years of hard work of regulators committed to arrive to more experimental precision and reproducibility.)

2. SUPPORT FROM EASAC, THE EUROPEAN ACADEMIES SCIENCE, THE ADVISORY COUNCIL

A Nature piece by Brian Heap clearly advocated product oriented regulation (Heap Brian, 20130626)

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

A headline as an insert in the text: THE OBJECTIVE MUST BE TO REGULATE THE PRODUCT AND NOT THE TECHNOLOGY THAT PRODUCES IT.

"Researchers and plant breeders across Europe urgently need to know the legal status of these novel breeding techniques. Recent safety assessments by expert advisory groups of the European Food Safety Authority in Parma, Italy, have already judged that hazards are similar for conventionally bred plants and those produced by cisgenesis (in which only genes from the same species or a normally interbreeding relative are introduced), and that targeted mutagenesis (in which only specific nucleotides in a gene are changed) is also likely to minimize unintended effects associated with the disruption of genes or regulatory elements in the modified genome." from (Heap Brian, 20130626).

The Nature opinion piece of Brian Heap is based on the report of the European Academy of Science:

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

Under 2. Regulation: "The trait and product not the technology in agriculture should be regulated, and the regulatory framework should be evidence-based.
Regulations should help not hinder' (House of Lords European Union Committee, 2010) and taking too precautionary an approach to new technologies poses risks to global food security. There is a need to unify and harmonize the regulatory and innovation-enabling roles of the EU policy-making institutions. The specific physiological changes to plant function introduced by genetic modification are easier to characterize and assess than the less specific changes produced in other ways. When used appropriately and properly integrated within well-managed agronomic systems, GM crops can be economically, environmentally and socially beneficial. There is no validated evidence that GM has greater adverse impact on health and the environment than any other technology used in plant breeding. EU GM legislation was formulated when there was not yet sufficient data to substantiate these conclusions, but now there is. ***Given the experience gained, the legislation, data requirements and level of scrutiny need to be revisited and recalibrated. As emphasized by EASAC in other areas of bioscience (EASAC, 2010; EASAC–JRC, 2011), all risk assessment must be evidence-based and should focus on the product not the technology. In the interim, a move to a trait-based regulatory system would facilitate simpler regulation for crop traits closely related to those already approved.*** *Decisions on regulatory oversight have to be based on scientific principles and accumulated experience, and it is highly desirable to have consistent, proportionate regulatory regimes worldwide to facilitate both scientific exchange and trade. It is understandable why the present stringent GM regulatory framework was introduced originally into the EU even though, conceptually, it may not be defensible to suppose that one technology is intrinsically more in need of regulation than any other. As a general principle, it must be a science-based decision as to whether surveillance and regulation are necessary and, if so, to what degree.*

If the EU is to be competitive, it is also essential that regulation of the outputs of the New Breeding Techniques and molecular farming must have a firm foundation in sound science. Any risk of adopting a new technology must be compared with the risk of not adopting it and all innovation should be evaluated according to the same standards and principles. P. 37". from (EASAC, 20130627).

In the EASAC report, the author's Springer Handbook piece on Regulation is cited in the print version from 2012, now in the internet in a steadily enhanced version: (Ammann, Klaus, 2014), including a chapter on the Genomic Misconception.

3. SUPPORT IN A NEW BOOK "FEEDING 9 BILLION", NEW GENETIC TECHNOLOGIES

A new review book of Evans, Bennett and Jennings (Evans Peter et al., 2014) on genetically engineered crops comments on the Genomic Misconception in Chapter 15, p.121

Evans Peter, David Bennett and Richard Jennings (2014), Feeding 9 billion. The contribution of new genetic technologies to global food production, pp. 216, Banson,27, Devonshire Road, Cambridge CB1 2BH, UK, Cambridge, UK, 978-0-9563387-8-5: 978-0-9563387-8-5, http://www.ask-force.org/web/Developing/Evans-Feeding-9-billion-Intro-Ch15-16-2014.pdf

"The genomic misconception
at the heart of opposition to GM, in the words of the Swiss botanist Klaus Ammann, lies the "genomic misconception". (Ammann, Klaus, 2014). Many people believe that GM technologies create new, unique and unprecedented risks to human and animal health, the environment, farming practices and agricultural development. And this view manifests itself in the regulatory structures that governments around the world have adopted.
The genomic misconception stems from an emphasis not on the product of GM technology but on the process by which it was produced*.*
When the USA set up the machinery to regulate agricultural biotechnology, it adopted a policy of using existing legal and administrative agencies and an approach focusing on the end product rather than the means of production. In practice, however, things worked out differently.
The US Department of Agriculture, Animal and Plant Health Inspection Service created a new category of "regulated article" for field trials and the commercial release of GM crops. The Environmental Protection Agency also created a new category for genetically engineered insect-resistant crops called plant-incorporated protectants. And the Food and Drug Administration also modified its demands for foods containing ingredients from GM crops. Thus, the USA's regulatory agencies all subject them to extra, intensive oversight.

The European Union (EU) from the outset has had totally new laws and regulatory procedures for predominantly agricultural GM products. These new laws and procedures are focused solely on the process by which such products are produced and emphazise both risks and speculative hazards. They demand close to zero risk before granting approval, and tend to downplay, if not ignore, the benefits of agricultural technology.
At a broader level, the genomic misconception is represented in international law through the Convention on Biological Diversity's clause calling for a binding agreement on trade that deals solely with GM products. Likewise, the Cartagena Protocol on Biosafety singled out agricultural GM products as special cases of risk and liability indeed, the Protocol uses the term "benefit" only three times and "risk" 67 times.

Predictable and unfavorable consequences
Not surprisingly, these regulatory structures have had adverse effects on agricultural GM. In 2011, the US regulatory agencies approved a nutritionally enhanced soybean and a drought-tolerant maize for commercial release. By 2013, the country had approved 165 applications for commercial release of GM traits in eight different major crops — maize, soy beans, cotton, rapeseed, sugar beet, alfalfa, papaya and squash — and 70.1 million hectares were planted with GM seeds that same year. So on the face of it, the US regulatory structure seems very accepting of GM innovation.

In practice, however, the approval process has become increasingly time-consuming, costly and effort-intensive. The approval of GM products costs ten times as much as for conventionally bred products — multi-millions of dollars —and takes afar longer time, usually five to seven years. The necessary documentation also far exceeds that needed for conventionally bred non-GM products.

Even more discouraging is the fact that some GM products languish in a regulatory limbo for a very long time without getting a decision: GM salmon has been more than 10 years in the regulatory waiting room. Another promising when the EU's regulatory system threatens their exports to Europe. Zambia, Kenya and Zimbabwe have even gone so far as to ban imports of GM grain that would feed populations facing famine, denying hungry people access to agricultural commodities." Chapter 15 from (Evans Peter et al., 2014)

4. INDIRECT SUPPORT OF THE EUROPEAN FOOD SAFETY AUTHORITY EFSA

With the status of an observer, the author deposited at the GMO panel 81st meeting of EFSA in 17.-18. April 2013 a request on regulatory matters, here the comments of EFSA, the minutes (excerpt):

Professor Niklaus Ammann (CH), PRRI, ASK-FORCE, Switzerland
1. "My question which I already asked at the plenary 10years meeting „What progress can be expected for a general shift in the biosafety research strategy from process-oriented to product-oriented regulation in the future? I would also be ready to serve as an external expert on those matters."
The answer of EFSA:

"The Chair of the GMO Panel answered that the EFSA GMO Panel issues its Scientific Opinions and Guidance in line with Directive EC 2001/18 and Regulation 1829 EC. In the European legislation, the requirement for a safety assessment is based on the technology used to produce a GMO, rather than the trait expressed by that GMO. The GMO Panel is aware that traits such as herbicide tolerance may be generated either by genetic modification or by conventional breeding (as in the „Clearfield‟ system). The GMO Panel is also aware that in different world regions different regulatory systems exist; for example, Canada assesses the safety of „plants with a novel trait‟ using identical regulations, whether these traits are introduced using biotechnology, mutagenesis or conventional breeding techniques.

However, although the GMO Panel advises, elected representatives decide. Hence, this question is better directed to bodies with more influence on these matters than the Panel. Only through a change in legislation, voted on by Member States, could a change from process-oriented regulation to product-oriented GMO regulation come about within the EU".

The full EFSA meeting minutes: http://www.ask-force.org/web/EFSA/EFSA-GMO-Panel-81st-Parma-Minutes-adopted20130529.pdf

5. NEW PUBLICATIONS FROM CANADA, LEADING IN PRODUCT ORIENTED REGULATION

New publications from Canada give more insight in the detailed regulatory processes and results under the Canada regulatory law and confirm that the product oriented risk assessment method is successful.

Price, W. D. and L. Underhill (2013), Application of Laws, Policies, and Guidance from the United States and Canada to the Regulation of Food and Feed Derived from Genetically Modified Crops: Interpretation of Composition Data, Journal of Agricultural and Food Chemistry, 61, 35, pp. 8349-8355, http://dx.doi.org/10.1021/jf401178d AND http://www.ask-force.org/web/Genomics/Price-Underhill-Application-Laws-Canada-Regulation-2013.pdf

"ABSTRACT: With the development of recombinant DNA techniques for genetically modifying plants to exhibit beneficial traits, laws and regulations were adopted to ensure the safety of food and feed derived from such plants. This paper focuses on the regulation of genetically modified (GM) plants in Canada and the United States, with emphasis on the results of the compositional analysis routinely utilized as an indicator of possible unintended effects resulting from genetic modification.. This work discusses the mandate of Health Canada and the Canadian Food Inspection Agency as well as the U.S. Food and Drug Administration's approach to regulating food and feed derived from GM plants. This work also addresses how publications by the Organization for Economic Co-operation and Development and Codex Alimentarius fit, particularly with defining the importance and purpose of compositional analysis. The importance of study design, selection of comparators, use of literature, and commercial variety reference values is also discussed."

Related to product oriented regulation:
On the basis of an overview of the country/union laws, the food and feed regulatory processes for GM crops can be viewed as two types of regulatory procedures. (Nap et al., 2003): ***The first type is the specific product-based procedure (characteristics of the GM product), as is evident in the United States and Canada. The second type is the process-based procedure (process of making the GM crop) that is evident in the European Union and Australia****. (Nap et al., 2003) However, the common regulatory mandate of all countries is to ensure the safety of all domestic and imported foods intended for human or animal consumption. Compositional analysis of key components is a part of all safety assessments (FAO-WHO & Codex alimentarius, 2009)*

Smyth, S. J. (2014), The state of genetically modified crop regulation in Canada, GM Crops & Food, Vol.5, /3, pp. 195-203, http://dx.doi.org/10.4161/21645698.2014.947843 AND http://www.ask-force.org/web/Regulation/Smyth-State-GM-Crop-Regulation-Canada-2014.pdf

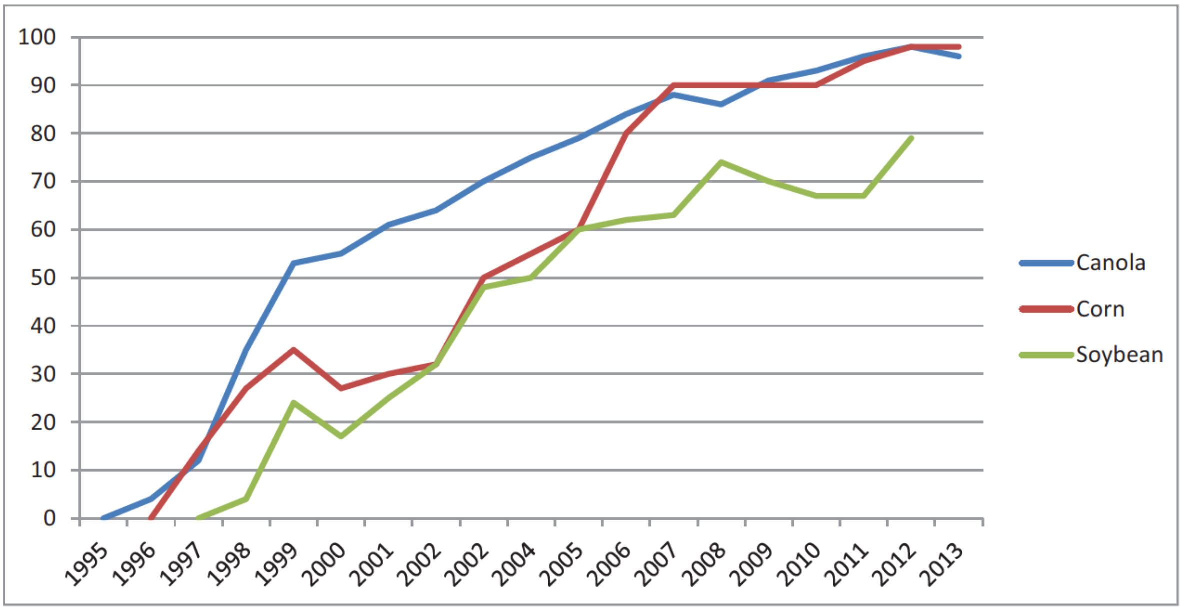

Figure 1. Adoption percentage of GM crops in Canada.[7-10]

"The key observation to take away from a review of the Canadian regulatory situation following 20 y of commercial GM crop production is that the market is capable of managing issues without government regulation and is able to inform

government as to when legislation is required. This situation is the polar opposite of the situation in the EU, where govern-ments are attempting to regulate the most insignificant aspects of the technology and have created a situation of complete paralysis, where no new GM crop varieties are able to proceed through the regulatory system. *The Canadian government revised patent legislation in the 1980s, which were upheld by the Supreme Court, the government facilitated the development of voluntary labeling standards when asked by the food industry and the government has been cautiously proceeding with LLP policy to reassure international trade partners.* ***The role of government in the regulation as demonstrated by the actions of the Canadian government highlight the actions of a responsible approach to the regulation of GM crops, unlike the efforts of the EU, which is (unsuccessfully) attempting to micro-manage the technology****." From (Smyth, 2014)*

Compare this to the sad figures from Europe, here just the latest bad news from Europe, based on constantly renewed statistics:
http://www.ask-force.org/web/EU-Sanco/EU-Undue-Delays-GMO-Approvals-20140103.pdf

How the Canadians solve the problems with product-oriented regulation (the system counts, not who is working with it)
(from **Price, W. D. and L. Underhill (2013),** Application of Laws, Policies, and Guidance from the United States and Canada to the Regulation of Food and Feed Derived from Genetically Modified Crops: Interpretation of Composition Data, Journal of Agricultural and Food Chemistry, 61, 35, pp. 8349-8355, http://dx.doi.org/10.1021/jf401178d AND http://www.ask-force.org/web/Genomics/Price-Underhill-Application-Laws-Canada-Regulation-2013.pdf

"Results of Novel Foods Reviews in Canada. In Canada, as of February 2013, over 100 novel foods and feeds have also been assessed, and the developers of these foods and feeds have been issued letters of no objection/approval, in accordance with the Novel Food Regulations and the Novel Feed Regulations. These foods and feeds are listed on the Health Canada and the CFIA Web sites, respectively (http://www. novelfoods.gc.ca; http://www.inspection.gc.ca). Many crops from which food and feed are derived have been genetically modified using genetic engineering and are legally marketed in Canada and the United States. The scientific regulatory authorities in both countries have done thorough scientific reviews of the GM crops before they were marketed. Detailed analytical compositional analyses of these GM crops, designed to detect unintentional adverse effects, have been completed by sellers or petitioners prior to release for food and feed use. No such adverse effects have been discovered. (FDA, 20141128), (Ridley et al., 2011) (Ricroch, 2013). (Herman, R. A. et al., 2009)", lit refs in Price et al. [But see also (Herman, R. A. et al., 2004; Herman, Rod A. & Price, 2013)]

6. SUPPORT FROM THE REPORT ON THE SWISS NATIONAL RESEARCH PROJECT NFP 59

The Swiss Research group of the **National Research Program No. 59** has also explicitly approved the similarities of transgenic and non-transgenic crops related to risk analysis and they call for a product-oriented risk analysis:

NFP-59 Synthese (2012), Nutzen und Risiken der Freisetzung gentechnisch veränderter Pflanzen Programmsynthese des Nationalen Forschungsprogramms 59, CHANCEN NUTZEN, RISIKEN VERMEIDEN, KOMPETENZEN ERHALTEN edn. Leitungsgruppe NFP59, Autoren:, Detlef Bartsch, Herbert Burkert, T. Bernauer, Dirk Dobbelaere, Karoline Dorsch-Häsler, Christoph Errass, Robert Finger, Joachim Frey, Urs Gasser, Karin Hoffmann-Sommergruber, Beat Keller, Stefan Kohler, Michael Siegrist, Joachim Scholderer, Daniel Schümperli, Rainer J. Schweizer, Jeremy B. Sweet, Wim Verbeke, Wilfried Wackernagel, Michael Weber and Josef Zeyer, copyright 2012, vdf Hochschulverlag AG an der ETH Zürich, IS: ISBN 978-3-7281-3483-7 (Printausgabe)

ISBN 978-3-7281-3484-4/DOI 10.3218/3484-4 (open access). pp., http://www.vdf.ethz.ch/service/3483/3484_Nutzen-und-Risiken-der-Freisetzung-gentechnisch-veraenderter-Pflanzen_OA.pdf AND http://www.ask-force.org/web/NFP-59/NFP-59-Synthese-Nutzen-Risiken-Freisetzung-GVOs-2012.pdf

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"1. Es gibt keine wissenschaftliche Begründung, um klassische und gentechnisch hergestellte Nutzpflanzen mit unterschiedlichen Massstäben zu bewerten. Bei der Risikobewertung soll das Produkt (also die Pflanze) und nicht die Technologie, mit der sie hergestellt worden ist, im Vordergrund stehen.
Gentechnisch veränderte Sortenlinien müssen - genau wie neue Sortenlinien, die mit klassischen Methoden gezüchtet werden, als biologische Produkte auf ihre Verträglichkeit für Mensch, Tier und Umwelt getestet und auf die jeweiligen agronomischen Konzepte abgestimmt werden.
2. Neue Techniken der Pflanzenzucht nutzen Gentechnik in der Art, dass in dem für den Anbau vorgesehenen Produkt keinerlei gentechnische Veränderung mehr zu erkennen ist. Gemäss den EU-Richtlinien sind Produkte aus diesen neuen Techniken keine GVO. Dies ist künftig bei der Beurteilung von Freisetzungsgesuchen durch die Behörden und bei der Warendeklaration zu berücksichtigen."
English:
*„**1.** There is no scientific reasoning, to evaluate conventional and genetically engineered with different scales. Risk evaluation should be based on the product (i.e. the plant) and not the production technology. **Traits altered through genetic engineering, as well as conventionally bred crops, be tested as biological products on their compatibility with humans, animals and the environment by governmental agencies and must be declared as products.***
2. New plant breeding technologies apply genetic engineering in such a way that as a result in the product for agricultural use there is no genetic alteration any more recognizable. According to the EU regulation such products from those new technologies are no GMOs. This should be recognized in future in the evaluation of field releases and product declaration by the governmental agencies."

See Werner Arber's summary in the same NFP 59 report: (Arber Werner, 2012):
Many of the earlier publications of Werner Arber, the discoverer of the restriction enzymes, an important basic technology making genetic engineering of organisms possible have already been cited in my 2014 publication (Ammann, Klaus, 2014), here a new one, again emphasizing product oriented regulation, printed in the context of the report to the NFP-59:

Arber Werner (2012), Gentechnik: Ursprung, Konzept, Risikoevaluation und Zukunftspotenzial *in Nutzen und Risiken der Freisetzung gentechnisch veränderter Pflanzen, ed. Leitungsgruppe des Nationalen Forschungsprogrammes NFP 59,* Vol., pp. 118-121, total 308 pp vdf Hochschulverlag ETHZ, Zurich und Bern, http://www.vdf.ethz.ch/service/3483/3484_Nutzen-und-Risiken-der-Freisetzung-gentechnisch-veraenderter-Pflanzen_OA.pdf AND Arber http://www.ask-force.org/web/NFP-59/Arber-Gentechnik-Ursprung-Konzept-NFP-59-Synthese-2012.pdf

The full Report http://www.ask-force.org/web/NFP-59/NFP-59-Synthese-Nutzen-Risiken-Freisetzung-GVOs-2012.pdf

After detailed description of the similarities between natural and artificial processes in the change of the genomes of organisms, his conclusion is again the same as in his earlier publications:

„Abschliessend können wir feststellen, dass kein wissenschaftlich fundierter Grund besteht, den Verfahren der Gentechnik besondere, methodisch begründete Risiken zuzuordnen. Aus Erfahrung weiss man, dass weder die natürlich verankerte biologische Evolution noch die klassischen Züchtungsverfahren drastische Risiken beinhalten.
Im Hinblick auf die grosse Ähnlichkeit zwischen gentechnischen Verfahren und natürlicher genetischer Variation können wir annehmen, dass sich allfällige Risiken der Gentechnik im gleichen Rahmen wie die der natürlichen biologischen Evolution bewegen, also weitgehend unbedeutend sind."
English:
„Finally we can conclude that there is no science based reason to address special risk assessment methods to the process of genetic engineering. From experience one knows, that neither naturally based evolution nor conventional breeding comprises drastic risks.
With regard to the high similarity between genetic engineering and natural genetic variation we can assume, that the possible risks of genetic engineering follows the same framework as natural evolution, thus largely negligible."

7. EARLIER PUBLICATIONS OF KLAUS AMMANN REFERRING TO THE SAME TOPIC:

The author already earlier (since about 2002) made several direct or indirect pleas for product oriented regulation (in most cases only with a few words): the full bibliography:

Ammann K. (2015, March 4, 2015). *Publications of Klaus Ammann, Relating to GMO Regulation and a Plea for Changing the Rules Towards Product Oriented Biosafety Assessment*. Neuchâtel. http://www.ask-force.org/web/Genomic-Misconception/Ammann-Publications-Genomic-Misconception-20150304.pdf

Some of the more important publications:

Ammann, K. (2004). The impact of agricultural biotechnology on biodiversity: Myths and facts, in: Agricultural Biotechnology: Finding Common International Goals 16. NABC Meeting University of Guelph), A. Eaglesham, Wildeman A., Hardy R. W. F.,. 16, 111-117, National Agricultural Biotechnology Council (2004) University of Guelph, Canada, ASIN: B007HFH9V4 http://www.ask-force.org/web/Canada-Guelph/Ammann-Guelph-Talk-Myths-Ammann-2004.pdf

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

The author's overview (Ammann Klaus, 2012) with a broad spectrum on sustainable measures in agriculture is reaching out from the narrow scope of transgenic seeds to agro-ecology and sustainability, respecting the farmer's life. It contains a special summary chapter No.5 on the Genomic Misconception, it has appeared in an electronic version with lots of updates (Ammann Klaus, 2014a).

With special emphasis to the history of international regulation of transgenic crops, the main publication on the Genomic Misconception remains the print in the New Biotechnology Journal, here with some earlier manuscripts included:

Ammann Klaus (20130415), Genomic Misconception. A fresh look at the biosafety regulation of transgenic and conventional crops: a plea for a process of agnostic regulation, open source, final version, in: New Biotechnology, 30, 50 and typeset 17, Ammann K., Neuchatel, http://www.sciencedirect.com/science/article/pii/S1871678413000605 AND http://www.ask-force.org/web/NewBiotech/Genomic-Misconception-20130415-names-links.pdf AND typeset corrected: http://www.ask-force.org/web/NewBiotech/Ammann-Genomic-Misconception-corrected-final-20130514.pdf AND German Abstract http://www.ask-force.org/web/NewBiotech/Ammann-German-Abstract-Highlights-20130415.pdf

The author has given numerous keynotes at international conferences on the same topic of the Genomic Misconception, here an example with streamer and slides from Ottawa, Canada, November 2012:

Ammann K. (20121128), Against the Genomic Misconception - a plea for the Canadian product - oriented regulation of novel crops and youtube closing presentation 1-3, in: Genomic Canada / Gairdner Foundation, publ: K. Ammnnn, Ottawa, Canada, http://genomicspowerandpromise.cvent.com AND http://www.ask-force.org/web/Ottawa-Nov-2012/Ammann-Ottawa-def-20121128.ppt AND http://www.ask-force.org/web/Ottawa-Nov-2012/Ammann-Ottawa-def-20121128.pdf AND http://www.ask-force.org/web/Ottawa-Nov-2012/Ammann-Ottawa-def-20121128-SUPPL.ppt AND http://www.ask-force.org/web/Ottawa-Nov-2012/Ammann-Ottawa-def-20121128-SUPPL.pdf AND
closing presentation part 1 http://www.youtube.com/watch?v=FUWrx9iapX4
closing presentation part 2 http://www.youtube.com/watch?v=zoG4t751k9o
closing presentation part 3 http://www.youtube.com/watch?v=uftt4scJ72Q

8. PAPERS NOT MENTIONED IN THE PUBLICATION FROM 2014, RELATED DIRECTLY OR INDIRECTLY TO THE GENOMIC MISCONCEPTION

A lot of papers published before 2014 have been already commented and referenced with full text links in my 2014 publication (citation with full text links: (Ammann, Klaus, 2014). Here some additional findings before and after the print:

A broader view about mutant breeding implicates indirectly a product oriented regulation:

Suneson, C. A., R. T. Ramage and B. J. Hoyle (1963), Compatibility of Evolutionary and Mutation Breeding Methods, Euphytica, 12, 1, pp. 90-&, <Go to ISI>://A19631404B00012 AND http://www.ask-force.org/web/Organic/Suneson-Compatibility-1963.pdf

„X-ray induced barley mutants and their prototype Hannchen were tested for their behavior in evolutionary breeding (the term is used to indicate the application of population genetics to plant breeding). It was shown that only the "better" mutants survive. Eventually only the fittest mutants and recombinants will comprise the population.
This competitive as well as conventional evaluation of 16 barley mutants suggests that in populations only the "better" mutants survive. Furthermore, the mutant associated sterilities foster natural crosses. While these are heterozygous they may have an advantage. Eventually only the fittest mutants and recombinants will comprise the population."

Proof that transgenic and non-transgenic maize have similar variation patterns in field experiments:

Coll, A., A. Nadal, R. Collado, G. Capellades, J. Messeguer, E. Melé, M. Palaudelmàs and M. Pla (2009), Gene expression profiles of MON810 and comparable non-GM maize varieties cultured in the field are more similar than are those of conventional lines, Transgenic Research, Vol. 18, /5, pp. 801-808, http://dx.doi.org/10.1007/s11248-009-9266-z AND http://www.ask-force.org/web/Genomics/Coll-Gene-Expressioin-Profiles-Comparable-2009.pdf

*"**Our results show that most sequences selected as differentially expressed in plants grown in vitro were similarly expressed in MON810 and near-isogenic varieties cultured in the field. This suggests that unintended variation between MON810 and comparable varieties has little impact apart from the introduced character**. In vitro methods have clear advantages with respect to sample uniformity, while field cultivation of GM plants is not only more difficult but is also subject to strict controls and prohibitions. But environmental conditions have an important effect on the plant growth and thus in its transcriptome at a given developmental stage. **Expression patterns of 38 selected genes in V2 plants grown in vitro and V2 and VT plants cultivated in the field were highly conserved between MON810 and non-GM comparable varieties; and less conserved between conventional (or between GM) varieties: this is in agreement with recent literature reporting that differences between cultivars result in more variation than the comparison of GM versus non-GM.** Our results highlight the importance of not only accurately assessing possible unexpected effects of GMO under highly controlled conditions, but also the need to study plants grown in a real agricultural environment. The two approaches should be considered as complementary to gain additional insights into potential unexpected effects of transgenes." From (Coll et al., 2009)*

See also (Coll et al., 2010)

Coll, A., A. Nadal, R. Collado, G. Capellades, M. Kubista, J. Messeguer and M. Pla (2010), Natural variation explains most transcriptomic changes among maize plants of MON810 and comparable non-GM varieties subjected to two N-fertilization farming practices, Plant Molecular Biology, Vol. 73, /3, pp. 349-362, <Go to ISI>://BIOSIS:PREV201000284454 AND http://www.ask-force.org/web/Genomics/Coll-Natural-Variation-Explains-2010.pdf

Quijano, C. D., Brunner, S., Keller, B., Gruissem, W., & Sautter, C. (2015). The environment exerts a greater influence than the transgene on the transcriptome of field-grown wheat expressing the Pm3b allele. *Transgenic Research, 24*(1), pp. 87-97. <Go to ISI>://WOS:000346784000007 AND http://www.ask-force.org/web/Golden-Rice/Quijano-Environment-exerts-greater-influence-2015.pdf

*"Wheat provides 20 % of the calories consumed worldwide. Powdery mildew infections of wheat can result in more than 30 % yield loss but it has been demonstrated that wheat overexpressing Pm3b, an allele of the R gene Pm3, has enhanced resistance against powdery mildew under field conditions. A gene expression profile study using GeneChip Wheat Genome Array and Fluidigm 96.96 Dynamic Arrays was performed to obtain insights into the mode of action of Pm3b and to elucidate the molecular basis of pleiotropic effects observed in three out of four independent transgenic events under field conditions. A cluster analysis of the microarray data and a principal component analysis of the Fluidigm 96.96 Dynamic Arrays data showed that transgenic lines and null segregants grouped together. **The microarray analysis of samples from fungicide-treated plants revealed that significantly fewer genes were differentially expressed in Pm3b#1 than in Pm3b#2, which had a pleiotropic phenotype in the field, compared to their null segregants. Together, our data provide evidence that the environment influenced gene expression in the Pm3b lines more than the transgene itself".** from (Quijano et al., 2015)*

This is a new publication clearly supportive in its content for the product oriented regulation:

(The above publications fit well with the many publications on genomic similarities across breeding methods, they are all cited in the author's paper of 2014: (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))

A real pearl among publications which had escaped the author – an excellent summary of the issue of the Genomic Misconception resulting into product oriented regulation – actually nothing to add:

Conko, G. (2005), Modified crops - Regulate the product, not the process, Chemical Engineering Progress, Vol. 101, /9, pp. 4-5, <Go to ISI>://WOS:000231894900001 AND http://www.ask-force.org/web/Genomics/Conko-Modified-Crops-Regulate-Product-not-Process-2005.pdf

The concluding sentences:

"The disproportionate attention to recombinant DNA technology suggests that the critics are less concerned about the real risks of plant breeding than they are with condemning one technique. But this narrow focus ignores the lessons of both biology and the history of agriculture. For thousands of years, human hands have used both crude and sophisticated techniques to generate both subtle and gross genetic changes in the food crops upon which we rely. Yet, with very few exceptions, standard assessments conducted by plant breeders have produced safe and nutritious foods. Tragically, overregulation of one process needlessly raises the cost of research and development while failing to advance consumer or environmental safety.

The question we must ask is not whether regulation generally is or is not justified, but rather what should be regulated and how? Focusing only on rDNA techniques, and treating all engineered products as though they are uniquely risky, is counterproductive. Instead, regulatory efforts should be redirected to focus oversight on new organisms that express characteristics likely to pose significant risk, regardless of the methods used in their development, while leaving relatively low-risk traits of both classical and rDNA modification unburdened by costly regulation." *From (Conko, 2005).*

Another basic paper on the different frameworks of national regulations provides reliable information – not easy to find as chapter 6 in a book publication, with lots of good information:

Tzotzos George T., Head Graham P., & Hull Roger. (2009). Chapter 6 - Regulatory Frameworks. In Tzotzos George T., Head Graham P., & Hull Roger (Eds.), *Genetically Modified Plants* (pp.147-172, tot. 256). San Diego: Elsevier, Academic Press http://www.sciencedirect.com/science/article/pii/B9780123741066000060 AND http://www.ask-force.org/web/Genomics/Tzotzos-Regulatory-Frameworks-2009.pdf

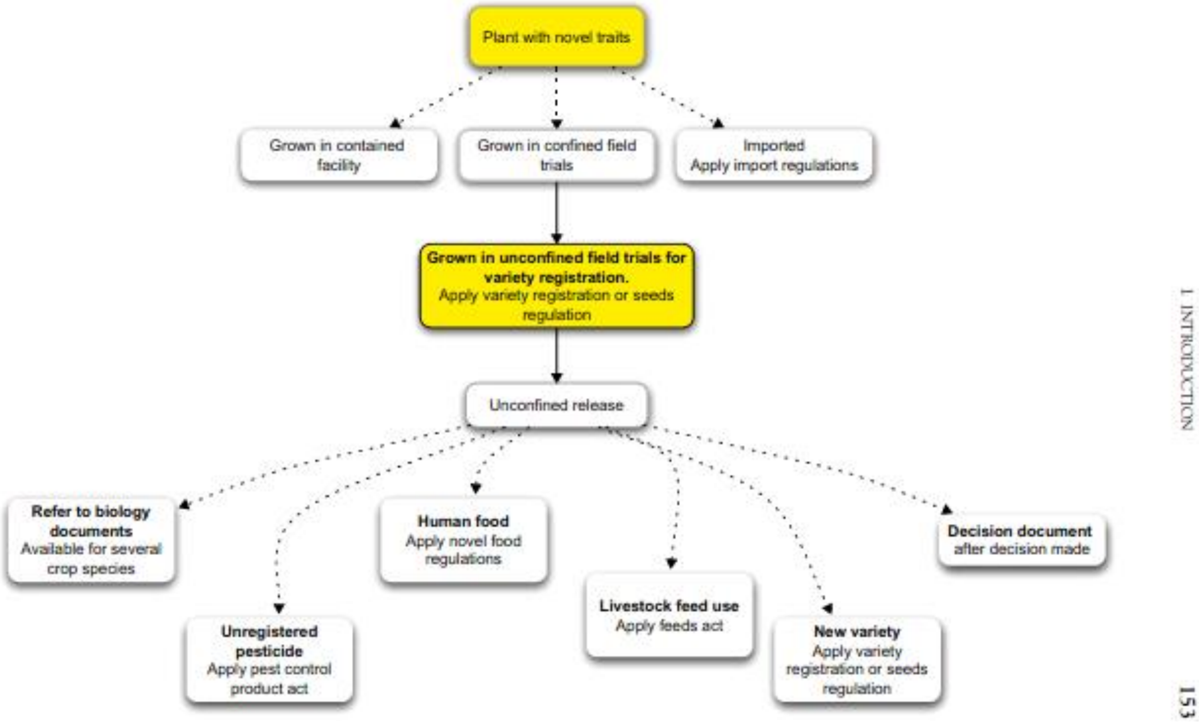

Figure 1 Diagram showing the interlinking of considerations in the Canadian Novel Foods Regulations (see color section) Figure 6.1 from (Tzotzos et al., 2009)

A table from the same report is very useful, Table 6.2 summarizes the rather complex structure of US GMO regulation, which is – taken as a whole, also product-oriented (with the exception of the often discussed inclusion of (Bt)-Endotoxins in the list of pesticides)

TABLE 6.2 Overview of responsible agencies under the coordinated framework.

Responsible agency	Jurisdiction	Regulatory trigger
Food and Drug Administration (FDA)	Food and food additives; feed and veterinary drugs	• Intentional and unintentional adulteration of food and food components with substances considered poisonous or hazardous to human health. A food or food component is considered adulterated if reasonable certainty exists that its consumption may have deleterious effects on human health. • Substances intentionally added to foods that are not generally recognized as safe (GRAS) based on prior scientific testing or historical use, or that are not otherwise exempt (e.g., pesticides, etc.). A substance may be considered as a food additive if determined to be significantly different in structure, function or amount from a substance already consumed as part of the diet or lacks a sufficient history of safe use.
US Department of Agriculture. Animal and Plant Health Inspection Agency (USDA/APHIS)	Plant pests, plants, veterinary products	• For a transgenic plant to be considered as a regulated article, any of the donor or recipient organism, vector or vector components must be in the list of plant pests or noxious weeds regulated under the Federal Noxious Weeds Act.
US Environmental Protection Agency (US EPA)	Planting and food/feed uses of pesticidal plants; new uses of existing pesticides, novel micro-organisms	• Pesticidal substances intended to be produced and used in living plants, or in plant-derived products, and the genetic material necessary for the production of such a pesticidal substance. • Genetically modified microbial pesticides, i.e. bacteria, fungi, viruses, protozoa, or algae, whose DNA has been modified to express pesticidal properties. The modified micro-organism generally performs as a pesticide's active ingredient.

Figure 2 the jurisdiction of the different agencies is shown in Table 6.2. The jurisdiction of the regulatory agencies is determined by the regulatory mandate of the respective agencies, as well as the intended use of the GMO. Consequently, the safety review process may or may not involve all three agencies. Finally, it should be noted that the distinction between product- and process-based regulation is blurred in the case of transgenic plants developed through transformation technologies using Agrobacterium as the transformation vector. The latter is included in the list of plant pests and, therefore, any such product is regulated by USDA/APHIS. Fig. 6.2. from (Tzotzos et al., 2009)

A comparison of process- and product oriented regulation in Table 6.3:

TABLE 6.3 Comparison of process-based and product-based regulations.

Regulatory trigger	Assumptions	Advantages	Disadvantages
Process based	GM technology represents new sets of risks	Single authority offers a better coordination mechanism	Conventional products that are potentially risky can escape the net of regulation; regulation lags scientific progress leading, potentially, to overregulation.
Product based	"there is no scientific basis for specific legislation to regulate the use of recombinant DNA organisms"	Focus on phenotypic characteristics	Choice of comparator difficult and as such establishing familiarity and/or substantial equivalence difficult (see Chapter 2).

Figure 3 A comparison of process-based and product-based regulations. Under Disadvantages: comparator choice difficult, but this has been overcome by the Canadian regulatory scientists with a feasible and successful scrutiny of Novel Crops.

In the publication of the chapter 6 of the biotechnology handbook (Tzotzos George T. et al., 2009) the authors just compare process- and product oriented regulation without making up their own mind and draw conclusions.

In a presentation at a Cartagena meeting in Kualalumpur in 1997 (already cited in the authors 2014 publication) George Tzotzos himself expressed his opinion clearly in favor of product oriented regulation, see his slide no. 12, Rationalizing biotech regulation from (Tzotzos George, 2007):
1. Move focus away from the transgenic process. 2. Rationalize the basis of transgenic regulation. 3. Exempt selected transgenes from regulation. 4. Create regulatory classes in proportion to potential risk. 4. Revisit 'event' based regulation

The author was present at the meeting cited in Kualalumpur and witnessed that George Tzotzos clearly made up his mind in favor of product oriented regulation.

A paper from (Nap et al., 2003) describes in detail the regulatory systems from a global perspective with a view up to 2002, but warns strongly against a shift to product oriented regulation:

Nap, J. P., Metz, P. L. J., Escaler, M., & Conner, A. J. (2003). The release of genetically modified crops into the environment Part I. Overview of current status and regulations. *Plant Journal, 33*(1), pp. 1-18. <Go to ISI>://WOS:000180276400001 AND http://www.ask-force.org/web/Regulation/Nap-Release-GM-crops-Environment-2003.pdf

"In the past 6 years, the global area of commercially grown, genetically modified (GM) crops has increased more than 30-fold to over 52 million hectares. The number of countries involved has more than doubled. Especially in developing countries, the GM crop area is anticipated to increase rapidly in the coming years. Despite this high adoption rate and future promises, there is a multitude of concerns about the impact of GM crops on the environment. Regulatory approaches in Europe and North America are essentially different. In the EU, it is based on the process of making GM crops; in the US, on the characteristics of the GM product. Many other countries are in the process of establishing regulation based on either

system or a mixture. Despite these differences, the information required for risk assessment tends to be similar. Each risk assessment considers the possibility, probability and consequence of harm on a case-by-case basis. For GM crops, the impact of non-use should be added to this evaluation. ***It is important that the regulation of risk should not turn into the risk of regulation. The best and most appropriate baseline for comparison when performing risk assessment on GM crops is the impact of plants developed by traditional breeding. The latter is an integral and accepted part of agriculture****."*
From (Nap et al., 2003)

The paper includes lots of valuable details for the regulation in the USA, Canada, the EU and the Cartagena Protocol, Argentina, Australia, Asia etc., demonstrating that most countries rely on process based regulation, only for the USA and Canada the author confirms the product oriented regulation (which he considers to be successful systems). The above sentence in bold leaves you with the impression that Nap is in favor of product oriented regulation. Not so: Paradoxically enough in his final comments he makes a strong negative point that countries should not adopt product oriented regulation with the following words:

"In this context, the impact of regulation is going to be a crucial issue that must not be forgotten. It is important to emphazise that the regulation of risk is currently turning into a risk of regulation. The regulatory process itself may already cause one of the greatest risks (Brown, 2001). The level of scrutiny imposed is unprecedented for the products of plant breeding. As regulations become impractical, compliance with them becomes less controllable and they are likely to become considerably more costly than anticipated. The plant breeding industry, in general, does not have the resources for GM crop material to be assessed in the same detail as a pharmaceutical. The cost of meeting regulatory requirements is currently a significant negative impact on the release of GM crops compared to the release of cultivars from traditional breeding. Excessive regulatory reviews will frustrate and curtail research and application to such an extent that only a few large multinational companies can afford to make progress. In this manner, over-regulation will help to promote a situation that is a concern of many: corporate control of agriculture (Dawkins et al., 2002) = [review of (Vogler & Russell, 2000)]. This trend is already clearly apparent and may result in the creation of a single (or a few) companies dominating world food production and increasing world dependence (Dawkins et al., 2002); (Josling & Nelson, 2001)).

A potentially even larger danger of the trend toward zero-risk in current regulation is that a similar risk scrutiny will be imposed on the activity of traditional, non-GM plant breeding. The results of a recent National Academy of Sciences study (NAS & National Research Council, 2002) already suggests that conventional crops may pose undesired environmental risks and should be monitored (Gewin, 2002). This would basically be the end of plant breeding as we know it, and dramatically affect the future of plant science. Such ends do not seem to justify the means. Plants, crops and innovation in crops and crop growing will remain essential for global well-being in the future.

It is correct that an extension of regulation from GMOs to conventional crops without the accompanying Canadian system of Novel Crops pre-assessment would simply complicate the situation unnecessarily, but including the pre-evaluation system of the Canadians it is the best solution, as shown since 12 years of its implementation in Canada with considerable success. Also from the point of view of real risks the situation is clear: 0 incidences for GM crops, dozens of incidences causing retraction with conventional and organic crops, see chapter 12.

Also a paper from 2010 stresses the difficulties of process-oriented regulation with an international perspective, but does not propose product-oriented solutions: On the contrary, it advocates a harmonization of the US and the EU system: (Davison, 2010)

"For many years the USA has been an ardent critic of EU GMO regulations, claiming that they are not science-based and represent a concealed trade barrier enabling the EC moratorium on GMO authorizations (1998–2004). This prompted the WTO dispute between the EU and the USA, Argentina and Canada. Given this previous logic, it is curious that two new US reports, (GAO, 2008) 16], now indicate that admixing of unauthorized and foreign GM-crops in US supply chains, now need to be taken into consideration for GMO regulations in the USA. US GMO regulations may thus converge with the EU regulations in areas of authorizations, coexistence of supply chains, detection and traceability."

The main difference between the Canadian (and the US) regulatory system, namely the product oriented regulation in contrast to the focus on processes in the EU, is not mentioned in this paper. On the other hand, Davison et al. cite the GAO report, where we find some interesting statements about product oriented regulation:

„FDA is responsible for ensuring the safety of most of the food supply, with the exception of meat, poultry, and egg products, which are under USDA's authority. FDA established its basic policy regarding the review of GE foods in its 1992 Statement of Policy: Foods Derived from New Plant Varieties, which explained that substances introduced into food or feed by way of breeding were potential food additives if they were not generally recognized as safe or if they were pesticides, and described the kinds of assessments FDA expected companies to perform to assure themselves that foods and feeds from new plant varieties were as safe as comparable foods and feeds already on the market, and otherwise did not raise regulatory concerns. In 1995, FDA established its voluntary consultation process, through which companies developing foods and feeds from GE plants voluntarily notify the agency and submit a safety assessment report containing a summary of test data and other information on the foods before they are marketed. ***The company evaluates, for example, whether the level of allergens, toxins, nutrients, and antinutrients— compounds that inhibit the absorption of nutrients—in the GE food is comparable to the level of these substances in the food's conventional counterpart, and whether the GE food contains any new allergens or toxins****. FDA assists the company with questions related to the regulatory status of the food. If FDA has no further questions about the safety of the food or feed, it provides the company with a letter to that effect. Although the consultation process is voluntary, it is FDA's experience that companies do not commercially market their GE crops until they have received this letter. As of July 2008, FDA had completed 72 voluntary consultations on GE crops intended for use in animal feed, human food, or both. FDA does not track which of these GE crops have been marketed; industry data indicate that many have been, but that some are no longer commercially available.*

9. MULTIPLE NEW GENE TRANSFER BREEDING METHODS CALL FOR PERMANENT RENEWAL OF LEGISLATION, THEREFORE IT IS MORE EFFICIENT TO SHIFT TO PRODUCT ORIENTED REGULATION.

There are new publications emerging with a broad review of new gene transfer technologies, such as the one of Benno Vogel in German, describing in 2012 some twenty transfer methods as a whole –whether transgenesis involved or not: (Vogel Benno, 2012), a broad literature review, but abstaining from all regulatory conclusions. There is a rich literature list provided by Vogel, just several highly interesting additional papers: (Gaj et al., 2013; Guan et al., 2015; Peng et al., 2015; Podevin et al., 2013; Spangenberg German et al., 2003).

Confronted with serious regulatory difficulties, which is evident especially in Europe, it is urgent that we need a thorough renewal of GMO crop regulation worldwide, and we can learn from the Canadian successful example:

Inghelbrecht, L., Dessein, J., & Van Huyienbroeck, G. (2015). Explaining the present GM business strategy on the EU food market: The gatekeepers' perspective. *New Biotechnology, 32*(1), pp. 65-78. <Go to ISI>://WOS:000347507800010 AND http://www.ask-force.org/web/Regulation/Inghelbrecht-Explaining-Present-GM-Business-2015.pdf

"The use of genetically modified (GM) crops and their applications is partially suppressed in European Union (EU) agriculture, even if one would expect otherwise given their complementarity with the neoliberal and industrialized EU agricultural regime in place. By applying a qualitative content analysis, this paper analyses how food manufacturers and retailers (referred to as gatekeepers in the food industry) explain and defend the exclusion of GM-labelled food products on the EU market. The study design places emphasis on the role of perceptions in the strategic behaviour of gatekeepers and on the role of interaction in this regard, as we assume that the way in which gatekeepers perceive the 'rules of the game' for commercializing GM crop applications on the EU food market will be influenced by their interaction with other agribusiness actors.
In a first stage, the analysis determines thematic congruence in the (types of) perceptions that explain an agribusiness actor's overall interpretation of the EU business environment for GM crop applications.
This perceived 'structuring arena' (SA) for GM crop applications – as conceptualized within our framework – contains areas of either internal and external tensions, that have a compelling or noncommittal influence on the agribusiness actor's

interpretation. In a second stage, the analysis particularly defines how gatekeepers in the food industry perceive and experience the SA for GM crop applications on the EU market, and how these perceptual tensions subsequently influence their strategic behavior for GM-labelled products on the EU market. Finally, we highlight how these perceptions and actions (or inaction) suppress the main changes in practice that are necessary to manage this wicked problem." From (Inghelbrecht et al., 2015)

In an earlier paper the authors confront the readers with the wicked problems arising from a GMO free policy in Europe:

Inghelbrecht, L., Dessein, J., & Van Huylenbroeck, G. (2014). The non-GM crop regime in the EU: How do Industries deal with this wicked problem? *Njas-Wageningen Journal of Life Sciences, 70*, pp. 103-112. <Go to ISI>://WOS:000345822100015 AND http://www.ask-force.org/web/Regulation/Inghelbrecht-The-non-GM-crop-regime-EU-2014.pdf

„In the European Union (EU), genetically modified (GM) crops are regarded as a socially-sensitive technology. At present, GM crops are rarely cultivated in the EU and non-genetically modified ingredients dominate the EU market. However, most consumers are unaware of the fact that many genetically modified ingredients (GMI) are present in EU supermarkets in spite of this virtual ban on GM. For example, eggs, meat or milk derived from GM-fed animals are marketed without a GM label. Moreover, the EU political landscape has failed to create a stable and predictable environment in which to either implement or reject GM crops and their applications. As such, the present non-GM crop regime in the EU presents a tricky and challenging environment for agribusiness companies to determine their GM business policy. Few academic studies have analysed this industry perspective on the current EU non-GM crop regime. In this paper, we therefore analyse which discourses influence the GM business policy of agribusiness companies that are active on the EU market and how these discourses influence the decision-making process of several agricultural industry sectors on whether to include or exclude GMIs in products for the EU market.

The paper outlines three discourses that shape the discursive space of GM crop applications in the EU from an industry perspective, (i) GMIs as an agricultural payoff; (ii) GMIs as a marketing threat; and (iii) non-GM crops as a preset end goal. The paper also discusses how these discourses influence the GM business decision-making process for several agricultural industry sectors, these being the agricultural biotech industry, the compound feed industry, the food manufacturing and marketing industries, the potato industry and the organic farming sector. Accordingly, our research classifies the present non-GM crop regime in the EU as a "wicked problem", due to the high level of conflict, discord and complexity involved.

Wicked problems cannot be solved, but only managed. Therefore, this paper proposes a different type of solution to break the impasse, either in favour of or against GM crop applications, by demanding multilevel stakeholder engagement instead of the current supply-chain-focused mode-of-action in industry. Nevertheless, it is necessary to adapt our knowledge about governing the particular dynamics of wicked problems, and this presents a highly complex - albeit interesting - challenge for future research." from (Inghelbrecht et al., 2014)

Both papers demonstrate in detail the policy problems of GMO manufacturers in present day Europe and what strategies could be choosen.

A recent publication from Agnès Ricroch and Marie-Cécile Hénard-Damave provides a thorough insight in multiple new breeding technologies, thus opening a beginning new era of global plant breeding and hopefully also frees breeders from the bottleneck of the few regulated commodity crops: (Ricroch & Hénard-Damave, 2015), the paper also is in favor of product oriented regulation, which would facilitate approvals.

Ricroch, A. E., & Hénard-Damave, M.-C. (2015). Next biotech plants: new traits, crops, developers and technologies for addressing global challenges. *Critical Reviews in Biotechnology, 0*(0), pp. 1-16. http://informahealthcare.com/doi/abs/10.3109/07388551.2015.1004521 AND http://www.ask-force.org/web/Genomics/Ricroch-Henard-Next-Biotech-Plants-2015.pdf

Biotechnology uses are clearly expanding to a wider range of plants to address diverse pressing issues in agriculture for both food and non-food purposes. New crops (outside of commodity crops) and traits (outside of herbicide-tolerance and pest-resistance) are being increasingly developed in developing and emerging countries, often thanks to research consortia with joint public/private research efforts. There are now various breeding techniques that are very effective when used in combination. These are not alternatives to transgenesis, but serve to complement each other. In addition to marker assisted selection, several modern breeding technologies include cisgenesis/intragenesis, RNA interference, novel DNA-editing technologies producing genetically edited organisms (GEOs) which do not have inserted genes from other organisms (site-directed mutagenesis through various techniques, oligonucleotide directed changes and others). To date, new editing tools have not been applied in fruit and vegetable breeding (Nagamangala Kanchiswamy et al., 2015)

Interestingly, the cost and time required to develop new plants considered as genetically modified organisms by regulatory authorities seem to discourage a number of developers, especially in the public sector and small and medium enterprises (Ammann, Klaus, 2014; Chassy, 2010; Kuntz & Ricroch, 2012), from using classic recombinant DNA technologies, and aforementioned breeding techniques are sometimes preferred (Camacho et al., 2014)There is a continuum in science progress and discoveries, and biotechnologies are not static. Whether these editing technologies will develop further depends on several factors: it will not only depend on how efficient and appropriate they will prove to be in the various plants of interest for mankind, ***but also on how stringently they will be regulated. If they are regulated like transgenesis (GMOs), whereby the process is regulated like transgenesis rather than the final product, these technologies may not live up to their full potential.***

A review on new gene transfer methods written by the author for the Swiss Federal office of Agriculture will summarize the character and methodology of the new methods and its regulatory consequences.

Lusser, M., Parisi, C., Plan, D., & Rodriguez-Cerezo, E. (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

"The fact that the field is evolving quickly is supported by the identification in our survey of additional techniques used by breeders and not included in our study. These include new approaches to targeted mutagenesis (e.g., engineered meganucleases). Application of engineered nucleases for targeted mutagenesis is a particularly active research field where systems based on different nucleases are constantly being developed. The new breeding techniques are adopted by the industry because of the potential technical and economic advantages they offer compared with alternative techniques. The extent of the adoption, and the application of the techniques to a wider range of crops, will depend on many factors, including the need to increase the technical efficiency of some processes and the decisions on their regulatory status worldwide. ***In the next few years, many regulatory jurisdictions around the world will make decisions on the governance of new plant breeding techniques, which will have implications for technology adoption, but also for the global agricultural supply chain*****.** ***Decisions on regulatory oversight governed by both scientific principles and political expediency are also complicated by the fact that the products of many of these techniques are not detectable or identifiable with standard methods used for GMO detection.***

The differences worldwide in the regulatory regimes for GM crops have resulted in asynchronicity in approvals of new crops*. Because agriculture is an open process, the presence of unauthorized GM material cannot be excluded in traded commodities. If the importing country operates a 'zero tolerance' policy, imports may be rejected if they contain traces of unauthorized GMOs. A global discussion on the governance of these new techniques seems necessary in the light of previous experiences with current biotech-derived crops and trade disruptions." From (Lusser et al., 2012)*

Comment on the Lusser paper: The authors are describing a future regulatory chaos in a diplomatic way, call for new regulatory debates and decision to clarify the asynchronous and heterogeneous decision making processes. This can, in the opinion of the author, only be solved by a shift to product oriented regulation, and indeed also a close look at the processes with their different kinds of impact and detectability. Non-detectability on the molecular level does not imply automatically that those new traits will be lacking any new impact on health and environment. Additional links to the paper and its background:

http://www.ask-force.org/web/Genomics/IRC-Lusser-Davies-Workshop-New-Breeding-Suppl-1-20130907.pdf
AND http://www.ask-force.org/web/Genomics/Lusser-Davies-Criteria-New-Methods-Suppl-2-20130307.pdf
AND http://www.ask-force.org/web/Genomics/Lusser-Davies-Definitions-GMOs-Suppl-3-20130307.pdf

Palmgren et al. make a plea for quitting with the transgenic crops of the first generation and "go back to nature" – with reverse breeding, gene editing etc., "go back to nature".

Palmgren, M. G., Edenbrandt, A. K., Vedel, S. E., Andersen, M. M., Landes, X., Østerberg, J. T., Falhof, J., Olsen, L. I., Christensen, S. B., Sandøe, P., Gamborg, C., Kappel, K., Thorsen, B. J., & Pagh, P. (2014). Are we ready for back-to-nature crop breeding? *Trends in Plant Science*, pp. http://www.cell.com/trends/plant-science/abstract/S1360-1385(14)00290-8 AND http://www.ask-force.org/web/Regulation/Palmgren-Are-we-ready-back-nature-breeding-2014.pdf

"Sustainable agriculture in response to increasing demands for food depends on development of high-yielding crops with high nutritional value that require minimal intervention during growth. To date, the focus has been on changing plants by introducing genes that impart new properties, which the plants and their ancestors never possessed. By contrast, we suggest another potentially beneficial and perhaps less controversial strategy that modern plant biotechnology may adopt. This approach, which broadens earlier approaches to reverse breeding, aims to furnish crops with lost properties that their ancestors once possessed in order to tolerate adverse environmental conditions. What molecular techniques are available for implementing such rewilding? Are the strategies legally, socially, economically, and ethically feasible? These are the questions addressed in this review." From (Palmgren et al., 2014).

The misunderstanding should be noted: With modern molecular breeding methods compared to the "traditional" transgenesis you are in both cases just as "close to nature". It's the wrong concept of nature: the process of transgenesis is similar to natural mutation, as explained by Werner Arber in many publications, e.g. (Arber, 2010). Despite the wrong nature concept it is nevertheless laudable to aim at incorporating useful ancestral genes from wild relatives, this will be certainly a valid target in modern breeding.

Lynch Diahanna and David Vogel (20010405),The Regulation of GMOs in Europe and the United States: A Case-Study of Contemporary European Regulatory Politics, Council on Foreign Relations Press, pp. 39, http://www.cfr.org/genetically-modified-organisms/regulation-gmos-europe-united-states-case-study-contemporary-european-regulatory-politics/p8688 AND
http://www.ask-force.org/web/Regulation/Lynch-Regulation-GMOs-Europe-USA-2001.pdf

This paper begins by reviewing comparative studies of health, safety and environmental regulation in Europe and the United States in order to place contemporary cross-Atlantic regulatory differences in an historical context. It then summarizes the evolution of American and European policies governing GMOs. The third section of the paper reviews a number of explanations for the differences in European and American regulatory policies toward this new agricultural technology, and the final section advances an explanation rooted in the emergence of a new European approach toward risk regulation in general, and food safety in particular. From (Lynch Diahanna & David Vogel, 20010405)

A complex text with lots of interesting details about the growing differences in GMO regulation between the USA and Europe. Many elements have helped to create the present day transatlantic divide. The different role of NGOs (growing stronger in Europe, becoming less important in the USA), and very important (but neglected in this text: the important political debates in the US Congress, in Europe in contrast somehow persistently weak and politically not important enough. Science was prevailing in the US, in Europe political and cultural elements got growingly important. Lynch and Vogel thus conclude that the product oriented regulation in the USA and Canada became the main focus since there was a political agreement that regulation should be strictly science based, whereas in Europe the process oriented regulation made its way mainly because of political and cultural reasoning and a resulting irrational stigmatization process.

Hopefully we will gradually overcome the opinion- and regulatory divide politics worldwide, we urgently need dialogue and discourse on a professional level (Ammann Klaus, 2014b), the stakes are high and go way beyond our problem of GMO regulation: (Biermann, F. et al., 2012; Biermann, Frank et al., 2012). It should be finally able to look beyond the edge of our nose, it's all about Science and Politics on a big scale.

The big perspective is also given by papers of Lofstedt - provided we can witness important emancipation processes in science, NGOs and Government.(Lofstedt, Ragnar et al., 2011; Lofstedt, R. & Fairman, 2006; Lofstedt, R. & Vogel, 2001)

In a sort of “birds-eye-view” David Vogel provides hope that the transatlantic divide is less prominent today than it was in the seventies:

Vogel, D. (2003). The Hare and the Tortoise Revisited: The New Politics of Consumer and Environmental Regulation in Europe. *British Journal of Political Science, 33*(04), pp. 557-580. http://dx.doi.org/10.1017/S0007123403000255 AND http://www.ask-force.org/web/Regulation/Vogel-Hair-Tortoise-Revisited-2003.pdf

“There has been an important shift in the pattern of divergence between consumer and environmental protection policies in Europe and the United States. From the 1960s through the mid-1980s American regulatory standards tended to be more stringent, comprehensive and innovative than in either individual European countries or in the European Union (EU). However, since around 1990 the obverse has been true; many important EU consumer and environmental regulations are now more precautionary than their American counterparts. The 'new' politics of consumer and environmental regulation in Europe are attributable to three inter-related factors: a series of regulatory failures within Europe, broader and stronger political support for more stringent and comprehensive regulatory standards within Europe and the growth in the regulatory competence of the European Union. In many respects, European regulatory politics and policies since the 1990s resemble those of the United States during the 1970s. Thus health, safety and environmental politics and policies in the United States are no longer as distinctive as many scholars have portrayed them.” (Vogel, 2003)

10. REGARDING THE RISK OF NOVEL CROPS IT IS NECESSARY TO INCLUDE CONVENTIONAL CROPS IN REGULATION - PROVIDED WE ADAPT THE CANADIAN PRE-SCRUTINY FOR NOVEL CROPS

From the presentation of Bojin Bojinov from Bulgaria for the Brussels meeting a really very informative slide, demonstrating clearly that the real risks related to Mycotoxins are connected to conventional and organic crops, not to GMOs:

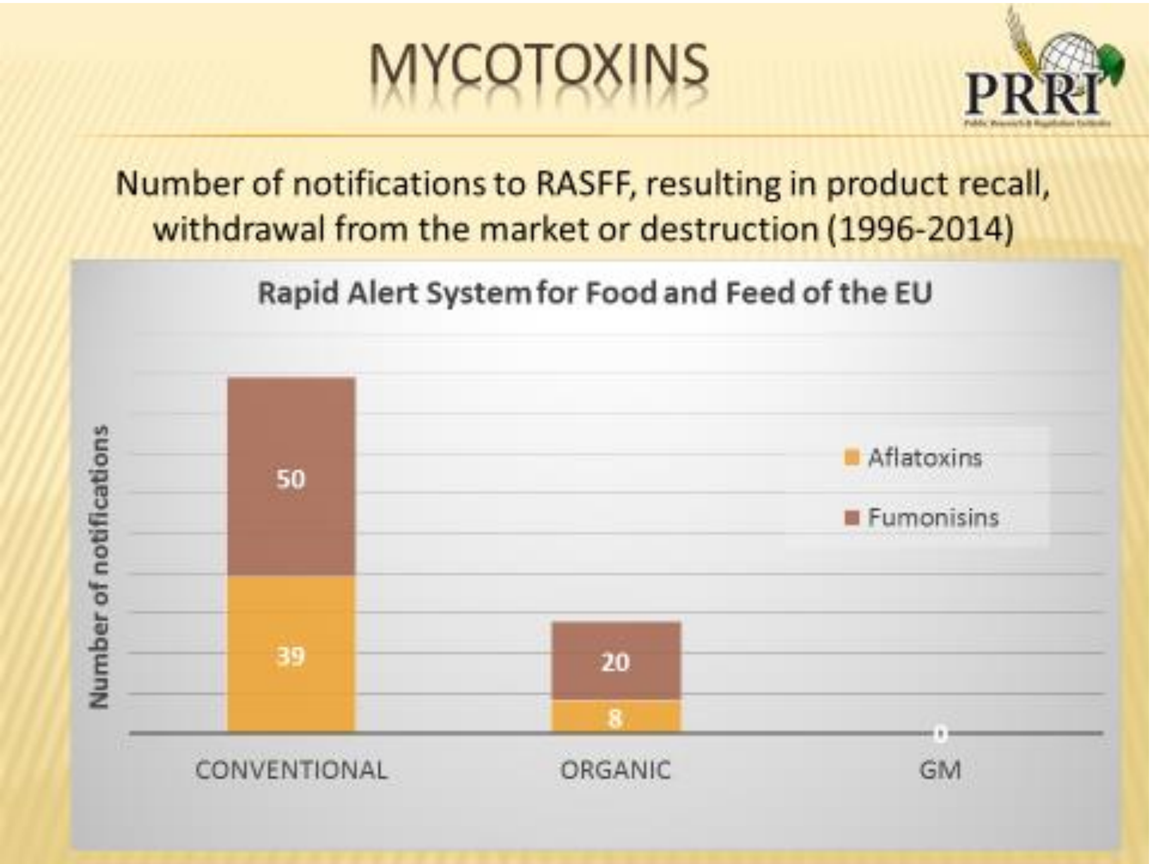

Figure 4 Number of notifications to RASFF related to Mycotoxins, resulting in product recall, withdrawal from the market or destruction (1996-2014) From Bojin Bojinov's presentation in Brussels for the Farmers-Scientist Network meeting on March 11.

Consequently, if regulators around the world would refer to the reality and not anti-GMO – ideology, they would immediately ban certain conventional maize traits for real and proven health reasons (Wu et al., 2014) and deregulate Bt – maize traits with a much lower mycocoxin level on a broad scale.
Nothing has been changed related to the basic statements of Munkvolds classic paper, the dozens of follow-up publications all show a drastically lower mycotoxin content of the Bt crops, simply due to the fact that insect damage is reduced and does not allow for abundant fungal infections.

Munkvold, G.P., Hellmich, R.L., & Showers, W.B. (1997) Reduced Fusarium ear rot and symptomless infection in kernels of maize genetically engineered for European corn borer resistance. Phytopathology, 87, 10, pp 1071-1077://A1997XZ38000013 AND http://www.botanischergarten.ch/Bt/Munksvold-Reduced-Fusarium- 1997.pdf

"Field experiments were conducted in 1994, 1995, and 1996 to evaluate the incidence and severity of Fusarium ear rot and the incidence of symptomless Fusarium infection in kernels of maize hybrids genetically engineered with Bacillus thuringiensis genes encoding for the delta-endotoxin CryIA(b). Treatments included manual infestation with European corn borer (ECB) larvae and insecticide applications to limit ECB activity to specific maize growth stages or mimic standard ECB control practices. Fusarium symptoms and infection were affected by the specific cryIA(b) transformation used in each hybrid that determines tissue-specific expression of CryIA(b). In hybrids expressing CryIA(b) in kernels, incidence and severity of Fusarium ear rot and incidence of symptomless kernel infection were reduced compared with near-isogenic hybrids lacking cryIA(b) genes. In plants that were manually infested with ECB, ear rot incidence was reduced by 87, 58, and 68%; severity was reduced by 96, 54, and 64%; and incidence of kernel infection by Fusarium species was reduced by 17, 38, and 38% in 1994, 1995, and 1996, respectively. Results were similar in treatments that were not manually infested, but differences between transgenic and nontransgenic hybrids were smaller. Most kernel infection was due to F. moniliforme, F. proliferatum, and F. subglutinans (section Liseola) collectively, and it was within this group that transgenic hybrids exhibited reduced infection. Expression of CryI-A(b) in plant tissues other than kernels did not consistently affect Fusarium symptoms or infection. Disease incidence was positively correlated with ECB damage to kernels. Insecticide applications also reduced Fusarium symptoms and infection when applied to nontransgenic plants." From (Munkvold et al., 1997)

An unpublished documentation comprising 56 pages on the comparative Mycotoxin contents of Bt- and non-Bt maize is in preparation: (Ammann, K, 2010).

Another reason for product oriented regulation is the enabling of proper comparison research and safety assessment in order to understand the full range of morphological, physiological and epigenomic differences between transgenic and conventional lines, such as has been revealed in the case of a Bt-cotton compared to his conventional counterparts: (Li et al., 2015)

Li, X., Ding, C., Wang, X., & Liu, B. (2015). Comparison of the physiological characteristics of transgenic insect-resistant cotton and conventional lines. *Scientific reports, 5*, pp. 8739. http://f1000.com/725376097 AND http://www.ask-force.org/web/Bt1/Li-Comparison-Bt-conventional-cotton-2015.pdf

"Conclusions
In conclusion, the results obtained here show that, at least in the material analyzed in this study, the difference in genetic background is the main factor responsible for the effects on the biochemical characteristics of transgenic cotton when incubating with F. oxysporum. This suggests that the unintended variation of biochemical resistance between transgenic and non-transgenic comparable cotton fall into the generally acceptable range, naturally occurring in different cultivars or lines of the species. However, genetic modifications had significantly greater influences on the stomatal structure of transgenic cotton than the effects of cotton genotypes. With regard to this, it is important to note that transgenic cotton could face greater challenges to global climate change, such as elevated O3 and drought. ***However, these pronounced differences between the transgenic and non-transgenic lines of the same genetic background should be verified in further pair-wise studies, as well as in other developmental stages. Our results highlight the differences in the physiological characteristics in transgenic cotton that might depend on genetic background and/or genetic transformation. Both causes should be considered to investigate the potential unexpected effects of transgenic cotton."***
(Li et al., 2015)

11. INDIRECT CONSEQUENCES OF THE REDUCTION OF GMO STIGMATIZATION CAUSED BY THE FOCUS ON PROCESSES IN REGULATION

Critique on the Genomic Misconception opens doors to acceptance of GM bio-fortification and to new, nearly revolutionary views of 'organo-transgenic' breeding. Even among scientists and especially among regulators the political-commercial split between transgenic and conventional crops is very popular and based on fundamentalist propaganda against GM technology in the present day agriculture. A major part of the arguments for such a stigmatization of GMOs against conventional cultivars is lost when you accept the scientific foundations of product-oriented regulation. The acceptance of the Genomic Misconception as a wrong way of looking at the new technologies is of enormous consequences, as demonstrated in an extensive literature review for the example of the Golden Rice and the worldwide debate on GMOs, soon ready for publication including chapters of the following subcategories: Fear, technophobia, social exclusion (stigmatization), moral self-licensing, exclusion of mankind from nature (GMOs not natural). It is not only a battle of facts and their misinterpretations, it is foremost a debate on social, legal, historic and cultural aspects: this will be the way out of the facts-tennis match with its near eternal tiebreaks.

'Organo-Transgenic' (or 'orgenic') concepts: See below: (Ammann, K., 2008; Ammann, Klaus, 2009; Ammann, Klaus & van Montagu, 2009; Ammann Klaus, 20141208; deRenobales-Scheifler, 2009; Ronald & Adamchak, 2008; Ryffel, 2012)

Ammann, K. (2008), Feature: Integrated farming: Why organic farmers should use transgenic crops, open source citations, New Biotechnology, Vol. 25, /2, pp. 101 - 107, http://www.ask-force.org/web/NewBiotech/Ammann-Opinion-Integrated-Farming-20080825-names-links-edited.pdf

Ammann, K. (2009), Feature: Why farming with high tech methods should integrate elements of organic agriculture, New Biotechnology, Vol. 25, /6, pp. 378-388, http://www.sciencedirect.com/science/article/B8JG4-4WKTX50-1/2/1698b7149ed724fd0a49b3ae49f234ab AND http://www.ask-force.org/web/Organic/Ammann-High-Tech-and-Organic-2009.pdf

Ammann, K. and M. van Montagu (2009), Organotransgenesis arrives, New Biotechnology, Vol. 25, /6, pp. 377-377, http://www.sciencedirect.com/science/article/B8JG4-4W7YY1F-1/2/28740dfca05cf12bb3b973b4f4568ccb AND http://www.ask-force.org/web/NewBiotech/Ammann-Montagu-Editorial-Oranotransgenesis-arrives-2009.pdf

"Much has been written about the vast field of biodiversity and agriculture; if you include related social sciences, a few quick search moves easily find well more than 9500 references, most of them published in peer-reviewed journals. In nature conservation circles, it has become clear that optimal plant and animal protection cannot be reached by neglecting the major factor: agricultural production. This is especially important in regions with an important percentage of agricultural production on all inhabited continents. Conservation efforts are paying off particularly in regions with a highly productive industrial agriculture where ecological and also socio-economic insights are often neglected. This is where a trend towards a better integration of biodiversity conservation makes most sense. This cannot be achieved by regressing to old-fashioned production schemes of small-holder agriculture, as some eco-romantics advocate, because it is unethical to stress eco-friendly production in poor countries at the cost of the livelihoods of smallholders, where the ultimate priority would be to come swiftly to better production figures to fight dramatic hunger situations. This does not mean that much higher yields should be reached at the excessive cost of environmental deterioration and in addition it is equally important to focus not only on higher yield but also on the socioeconomic side of enhancements.

This can only be achieved through a serious commitment to deliver innovation in agriculture. Plant biotechnology is widely acknowledged as a key resource for environmentally responsible and sustainable plant productivity practices. International organizations such as the WHO and FAO cite genetically modified crops as an important component of programs for sustainable agricultural development and poverty alleviation. Indeed since the first commercial plantings in 1996, there have been extensive documentations of the impact of GM crops in terms of land use, crop varieties, quality and quantity of food, environmental benefits, socio-economic development in neglected rural areas and health. As the technology matures further, new crop varieties will be developed to conserve more resources, such as water, land and energy. Most notably, crops with improved ability to tolerate periods of drought and other water-related stresses will be invaluable to both food security and the environment in the long term.

Now we need new paradigms of agriculture, which take into account the best from many different production strategies, including some practices in organic farming, which has its advantages, not in the ideologically steered exclusion of *innovative agricultural technologies, but in taking very seriously socio-cultural aspects and integral views, among them landscape quality. In the concept of Organo-transgenesis, there is no place for a sterile ideological warfare between biotechnology and eco-agriculture; rather the reverse, there is a necessity to forget the contrasts and urgently work together for the sake of humanity and nature and create synergies.*

In a first publication in this journal (New Biotechnology 25:101–107, 2009), the analysis of such new paradigms revealed that there are ample reasons, even in accordance with most of the official rules of organic farming, why certain transgenic crops could well fit into new agricultural practices. In the second part of the analysis in this issue, it can be demonstrated that some organic practices could very well be adopted by hi-tech agriculture; indeed, they actually fit well into modern concepts of high yield agriculture, especially when it comes to the adoption of biodiversity-friendly landscapes. Moreover, new insights in resistance management – by introducing a concept of crops with stacked genes or even better by introducing seed mixtures of modern traits, which could be assembled with the help of new knowledge in community ecology and adapted to local needs – might be a way forward. Finally, a future oriented and dynamic concept of sustainability is introduced, taking into account innovative agro-ecological, social and evolutionary management systems."
Klaus Ammann (Guest Professor), Sabanci University, Istanbul, Turkey
Marc van Montagu, European Federation of Biotechnology, Spain" from (Ammann, Klaus & van Montagu, 2009)

deRenobales-Scheifler, M. (2009), More sustainable food: Genetically modified seeds in organic farming edn. Junta General del Principado de Asturias Sociedad Internacional de Bioética (SIBI), IS: pp. 119, http://www.sibi.org/ingles/jgp/p2009.htm English, AND http://www.sibi.org/jgp/p2009.htm Spanish AND http://www.ask-force.org/web/Organic/DeRenobales-Scheifler-GM-Seeds-Organic-2009.pdf AND http://www.araba.ehu.es/p208-content/eu/contenidos/noticia/20100211_mertxe_renobales/eu_np/20100211_mertxe_renobales.html

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