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New GMO regulations for old:

Determining a new future for EU crop biotechnology.

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John Davison (1) and Klaus Ammann (2)

1. John Davison Corresponding Author
Institut National de la Recherche Agronomique (INRA), Route de St Cyr, F-78026 Versailles, France
Phone: +33 1 30 83 30 00
disclaimer:
The personal views expressed in this article do not necessarily represent those of INRA.
E-mail address: jrndavison@gmail.com.
Research Director (retired), John DAVISON,
Conflict of Interest: None. Financial Disclosure: None

2. Klaus Ammann
University of Bern, Prof. hon. emeritus
Former Director of the Botanical Garden of the University
Switzerland, 2000 Neuchâtel, Monruz 20
Phone: +41 79 429 70 62
disclaimer:
The personal views expressed in this article do not necessarily represent those of the University of Bern
E-mail address: klaus.ammann@ips.unibe.ch
Conflict of Interest: None. Financial Disclosure: None

Abstract:
In this review, current EU GMO regulations are subjected to a point-by point analysis to determine their suitability for agriculture in modern Europe. Our analysis concerns present GMO regulations as well as suggestions for possible new regulations for genome editing and New Breeding Techniques (for which no regulations presently exist). Firstly, the present GMO regulations stem from the early days of recombinant DNA and are not adapted to current scientific understanding on this subject. Scientific understanding of GMOs has changed and these regulations are now, not only unfit for their original purpose, but, the purpose itself is now no longer scientifically valid. Indeed, they defy scientific, economic, and even common, sense. A major EU regulatory preconception is that GM crops are basically different from their parent crops. Thus, the EU regulations are "process based" regulations that discriminate against GMOs simply because they are GMOs. However current scientific evidence shows a blending of classical crops and their GMO counterparts with no clear demarcation line between them. Canada has a "product based" approach and determines the safety of each new crop variety independently of the process used to obtain it. We advise that the EC re-writes it outdated regulations and moves towards such a product based approach.

Secondly, over the last few years new genomic editing techniques (sometimes called New Breeding Techniques) have evolved. These techniques are basically mutagenesis techniques that can generate genomic diversity and have vast potential for crop improvement. They are not GMO based techniques (any more than mutagenesis is a GMO technique), since in many cases no new DNA is introduced. Thus they cannot simply be lumped together with GMOs (as many anti-GMO NGOs would prefer). The EU currently has no regulations to cover these new techniques. In this review, we make suggestions as to how these new gene edited crops may be regulated. The EU is at a turning point where the wrong decision could destroy European agricultural competitively for decades to come.

1. Introduction

The EU has the one of the most severe sets GMO regulations in the world and as a consequence of a hostile legal and political climate, almost no significant quantities GM crops are cultivated in Europe. Spain is an exception and cultivates MON810 (the only GM-crop authorized for EU cultivation). Small amounts are also cultivated in Portugal, the Czech Republic, Romania, and Slovakia.

1. On top of these decades-old GMO regulations, three new developments are particularly troubling:
   In previous times, EU Directive 2001/18/EC EU-Directive (20010312), permitted cultivation of authorized GMO crops anywhere in the EU. However, the latest major amendment of the EU regulation EU-Directive 2015-412 (20150311) permits individual member countries to opt-out of GM cultivations for reasons not concerned with food safety. To date, 17 member

states have used the “opt-out” clause as regards cultivation of the GM crops for their whole territory. These are Austria, Bulgaria, Croatia, Cyprus, Denmark, France, Greece, Germany, Hungary, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland and Slovenia. In addition, two member states have used the “opt-out” clause for part of their territory: Belgium – for the Region of Wallonia – and the UK, for Scotland, Wales and Northern Ireland but not England. The case of the UK is curious since the climate is not propitious for the cultivation of GM crops with the exception of potatoes, wheat and beets; none of which are authorized for cultivation in the EU. The case of Ireland and Scotland is even more curious since one proposed GM-potato that they refuse to cultivate is resistant to *Phytophthora infestans* - the cause of the Irish and Scottish potato famines (1845 and 1852) that killed millions and caused mass migrations Fraser E.D.G. Fraser (2003). In the course of the GMO battles these important facts are often forgotten.

2. Even more recently EC President Juncker, who is renowned for his anti-GMO convictions, attempted (2016) to introduce legislation that would allow any member state to restrict prohibit the import, sale or use of approved GM food or feed within its borders. This initiative was rejected by the European Parliament (EP) (by 577 votes to 75, with 38 abstentions) Chatain Baptiste (20151025), a clear indication of the level of stupidity of the proposed law. The EC- proposal was criticized by the EP as being detrimental to the single market and the customs union, as well as being impossible to control without re-introducing border controls between Schengen countries. It was further criticized for its complete lack of any impact assessment. In particular, all member states of the EU are completely dependent on imported high protein GM feed (for example the EU imports 34 million tonnes of GM soya beans per year). The authors of this article would further criticize both these recent EC proposals on another issue not considered by the EP, namely their lack a scientific basis. In fact, President Junker’s EC GMO policy has simply turned its back on science. The EC has also continuously neglected the recommendations of the European Food Safety Authority (EFSA), delayed approvals of GM food and feed, and ignored the results of its own many years of EC Framework funded biosafety projects, which were completed at vast cost and effort, by multi-national partnerships of EC scientists. It is to be noted that the opt-out clause was initiated by the then EU-Commissioner for Health and Food Safety John Dalli (2010), who was later requested to resign. Mr. Dalli, was an accountant, turned politician, and became Minister for Social Policy in Malta. Dalli had no qualifications enabling him to have opinions on genetically modified (GM) crops, nor for being EU-Commissioner for Health and Food Safety. Ellul-Grech Joseph (20100902), Sansone Kurt (20110305), Galizia Daphne Caruana (20110305), Welt-on-line (20110508) After Dalli’s sudden departure, the idea of an opt-out clause was then continued; first by the then European Commissioner José Manuel Barroso and then completed by his successor Jean-Claude Juncker. It is thus clear that there is continuity in the anti-science attitude of the European Commission (despite the paradoxical high esteem of scientists in the polls) and this will continue during Juncker’s presidency. Indeed, this growing disdain for science among polititians and the population which was well demonstrated by Juncker: as one of his first acts as EC President, he abolished the position of Chief Scientific Officer and fired the current holder of the position Professor Anne Glover, Waterfield B. et al. Waterfield Bruno and Gosten Emily (20141113). There is irony here, since had Glover still been Chief Scientific Officer, she would have certainly advised against the proposal on national GMO bans for which President Juncker suffered first a humiliating

defeat at the hands of the EP. While still in her position, she tried hard to get science back to its deserved and essential position in biosafety decisions: van der Meer J., Glover A. Glover Anne, Dekant Wolfgang, et al. (20130713, van-der-Meer Jos WM (201407).

3. A collection of new techniques has evolved over the few years and are known in Agriculture as New Plant Breeding Techniques (NBT) and permit precise editing of plant genomes, often without the addition of new or foreign DNA. A more general description of the new, rapidly developing methods are summarized under Gene Editing (GE). These techniques are currently being reviewed by an EC committee of Competent Authorities from Member States. These people are not scientists, but take their orders from their national political masters and have been 'studying' NBTs and GE for the past 7 years without reaching any conclusion. The present authors feel scientific input into this debate is necessary and we actually attempt here to make such an innovative input. It is worrying that this political committee may classify the NBTs and GE as being recombinant DNA without any differentiation and thus set back European biotechnology for the years to come.

In this review article, the authors discuss the present EC regulations on GM-crop including their fallacies, weaknesses and political implications. Comparisons with regulations in other countries have been made previously Davison J., Lynch D. et al., Smyth S.J. et al., Giddings V. et al. Davison (2010B) Lynch Diahanna and David Vogel (20010405) Smyth and Phillips (2014) Giddings, Potrykus, et al. (2012) and will not be treated extensively here. In this review the authors propose ways in which EC regulations could be improved to correspond to science-based reality. We will firstly consider the decades-old GMO regulations and how they might be modified, or, even better, discarded, in favor of newer science-based alternatives. Importantly, the authors also propose possible new approaches to science-based regulations for the so-called New Breeding Techniques for which the regulatory future in the EU is presently uncertain. The NBT are so new that they are not presently subject to regulations in most countries, including the EU (though a gene-edited mushroom was recently approved by the USDA as not being a GMO). (see the recently launched regulation proposal by APHIS 2017 ref. 138.

It is our hope to introduce scientific logic into EC regulations and reduce political interference, so that these new non-GMO techniques do not follow the fate of GM crops over the last 30 years. In this way, the EU may benefit scientifically and economically from NBT whereas it previously failed with GMOs.

2. Present EC GMO Regulations

The biggest fallacy with EU regulations is that they begin with the assumption that GM crops are intrinsically different (i.e. more dangerous) from their non-GM equivalent. When GM regulations were formulated in the late 1980s, GM crops were not well known and plant genomics was in its infancy. From the beginning the USA and Canada avoided this error, NAS NAS National Academy of Sciences, Kelman, et al. (1987). However, the EU, and the creators of the Cartagena Protocol, did not, despite early and explicit interventions, Ammann K. Ammann Klaus (2014). Today however, we know, even in Europe, that GM crops are not very different from the parent crop, and with the emergence of NBTs, it has become clear that there is a continuous spectrum of minor differences between them, such that it is impossible to draw a differentiating line. This concept has been well explained by one of the present authors, as well as many

others, as ACRE, NAS, Morris S. et al. Tagilabue G., ACRE (2013A, ACRE (2013B, ACRE (2013C) Morris and Spillane (2010) NAS, Gould Fred, et al. (20160517) NAS (2016) Tagliabue (2015A, Tagliabue (2015B) Van Eenennaam and Young (2014) Masip, Sabalza, et al. (2013) and their arguments will not be repeated here.

It should be noted that (like those of the EU), most, but not all, national GMO regulations are also triggered by the GMO definition. However, the Canadian (and partly the US) system is different in that it considers the food safety of all new plant varieties, GM or traditional. Thus, in contrast to the EU (and the Cartagena) system, which is triggered by the process by which food and feed is derived, the Canadian system is triggered by the safety of product. Such a system makes more scientific sense for improved food safety and consumer confidence. This point will be more extensively in the discussion Smyth (2014).

In the first section we dissect present EC regulations to show their inadequacies being based on decades-old preconceptions.

3. Definition of a GMO in the EU-Legislation

According to Directive 2001/18/EEC: EU-Directive (20010312) "genetically modified organism (GMO) means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination"**.** (Nota bene: It is difficult to interpret the phrase **"**with the exception of human beings" since no further explanation is given. Does this mean that GMO-human beings are not to be considered GMOs? This would be curious; what then are they? The EFSA definition does not include this phrase.)

It should be noted however that in view of the development of New Breeding Techniques (NTBs), discussed below, some anti-GMO NGOs would like to change the definition of GMOs so that plants made by the NTBs are fully included in the GMO definition. As discussed below, we resist to this suggestion in the hope that European NTB crops can get a new and fruitful start in the regulatory debate - different from that of GM crops.

Directive 2001/18/EEC covers the deliberate release of GMOs in the environment (field trials and cultivation), in the absence of specific containment measures. It also regulates commercialization (importation, processing and transformation) of GMOs into industrial products. As stated above, Directive 2001/18/EEC previously permitted the cultivation of approved GMO crops anywhere in the EU. However, in view of persistent refusal by several member-states this Directive has been modified (2015) so that individual member states can ban GM crops for a variety of reasons unrelated to biosafety. GM crops cannot be banned by member-states for reasons of food or feed safety, since evaluation of safety is the brief of EFSA (see below). Possible (non-food safety) reasons for refusing to grow GM crops include: environmental or agricultural policy objectives, town and country-planning, land use, coexistence, socio-economic impacts, or public policy. The authors of this review regret this denial of science for political reasons.

Given that only one GM-crop, insect resistant MON810 maize, is grown in the EU, and that the vast majority of EU Member States have opted-out of growing even MON810, and that field trails in the EU have largely been prevented by their destruction by anti-GMO NGOs, Directive 2001/18/EEC is now largely dysfunctional Kuntz M. Kuntz (2012A). Its only remaining function is in the regulation of GM products invented and imported into the EU from elsewhere; since the EU is no longer involved in front-line crop biotechnology research Kuntz M. Kuntz Marcel (20140715)

GMO cultivation in the EU

As correctly stated above, the only GM-crop cultivated in the EU is the Monsanto maize MON810. However, for a very short period another GM-crop, the Amflora potato, was cultivated in 2010 -2011 in Czech Republic, in Germany and Sweden. In 1996, the company BASF requested permission to cultivate the Amflora potato, which is rich in amylopectin and poor in amylose and thus more useful to the starch industry. The Commission gave its approval (13 years after the BASF application) after consideration of the positive EFSA opinion EFSA Scientific Opinion (2012) that Amflora posed no threat to human health or the environment. However, the EC decision was challenged by Hungary, France, Austria, Poland and Luxembourg and was overturned in the EU General Court (2013) on the technicality that the EC had Commission failed to fulfill its procedural obligations EU documents EU-documents-Amflora (2013), Amflora documents: Bachtle, Stellbrink, et al. (2011, San-Juan-Hernandez Isabel (2014, Wandelt (2007), Ryffel (2010). In response, BASF immediately announced that it was withdrawing all of its research activities to North Carolina and was halting its plans for developing GM crops for Europe. Syngenta had made a similar decision several years previously and Monsanto no longer has EU-based research facilities. Thus, the only remaining major plant biotechnology company in Europe is Bayer Crop Science (who have also intimated the possibility of leaving Europe).

The extent to which EU governments will go to illegally prohibit the cultivations of GMO was revealed by Kuntz M. Kuntz, Davison, et al. (2013). Regulation 1829/2003 contains an Emergency Measures clause permitting GMOs to be prohibited for valid scientific reasons. Such an Emergency Measure was made by the Ministry of Ecology (then headed by Nathalie Kosciusko-Morizet) and the Ministry of Agriculture (then headed by Bruno le Maire) on behalf of the French Government (then headed by Nicolas Sarkozy) to the EC to prohibit cultivation of Monsanto maize MON810. This document was originally published on the site of the Ministry of Agriculture but has since mysteriously disappeared (is this strange behaviour by the French government an attempt to rewrite history?) Fortunately, we have retained a copy, which we can distribute to interested parties, and an English translation was posted for posterity on the Nature Biotechnology website. In their publication Ricroch E. et al. Kuntz, Davison, et al. (2013) demonstrated that the French Government deliberately distorted scientific publications, including even those of ESFA to whom the EC transmitted the Emergency Measures. Affidavits were obtained from the authors of misrepresented publications. Ricroch A. et al. stated *"What we find most heinous about the French and other European bans on MON810 maize is the clear evidence of government interference with science to justify political handling of risk management and bypass European and national agencies in charge of biotech risk assessment under European directives. This behavior appears to be increasingly the norm*".

Naturally, the French Emergency Measures document was rejected by EFSA - but even after this rejection, the Italian and German Governments submitted similar documents. In fact, the Italian Emergency Measures document was a simple word-for-word translation of the French document Kuntz M. et al. Kuntz Marcel, Agnès Ricroch, et al. (20131205). EFSA also rejected the Italian and German documents. Indeed, science has lost against politics in this case – and there is no general outcry about such preposterous procedures on the highest political level.

It is troubling and a reflection of the anti-GMO attitude of the European press, that, while the French Emergency Measures document received considerable publicity, the rebuttal by Ricroch et al. Kuntz, Davison, et al. (2013) despite being published in the prestigious journal *Nature Biotechnology,* received virtually none. Having failed to make public this blatant falsehood by presenting pseudoscientific arguments to the EC for the promotion of banning of MON810, the French government then went relentlessly ahead and banned it unilaterally at national level, just a few months later. This decision was

later reversed by the French State Counsel Court Byrne Jane Byrne Jane (20161014) on the grounds that France's agriculture ministry "has not provided the proof (that the corn) presents a major risk to human or animal health, or to the environment.", but too late to allow planting. (The EU court also overruled earlier another French ban on Bt-Maize, see Louet S. Louet (2000). Kuntz et al (2014) concluded "France fails the science test: how politics beat reason". Kershen Drew L. (2014)

Regulation (EC) 178/2002 resulted in the creation of EFSA and in a general obligation for traceability of at least one step forwards and one step backwards in the food chain. EFSA is meant to be a scientifically independent advisory organization free from political interference. The members of EFSA are chosen from imminent independent scientist from all 27 member states (and associate states) and EFSA is "committed to safeguarding the independence of its experts, methods and data from any undue external influence and to ensuring that it has the necessary mechanisms in place to achieve this", the following EFSA documents are proof of one of the strictest possible selection modes. EFSA Independence (20121028B)

The panel on genetically modified organisms evaluates the safety of GM food and feed and makes safety assessment recommendations on new GM crops. The same section evaluates GM-micro-organisms and animals. In reality, the functioning of ESFA is frequently, and unjustly, criticized by the governments of Member States who wish to bend EFSA to their respective wills. It is clear that the independent scientific opinions of EFSA are only appreciated when they agree with the political opinions of the Member States, though this is usually not the case. EFSA has been the target related to their scientific independency by NGOs, see some few of the many examples of the controversy: Devos, Aguilera, et al. (2014, Perry, Arpaia, et al. (2012) Wynne and Wickson (2012) EFSA Guidelines and Renn Ortwin (20120402) Violent demonstrations including smoke bombs etc. continue over the years regularly. The latest examples are letter-bombs targeted at EFSA in Parma Kelly-E- (20160623). This prompted an open letter from 56 science organizations to the President of the European Parliament to encourage society to respect independent science advice and to condemn physical attacks on scientists epso and Beltran José Pio (20160701). It is a sad reflection on the anti-science mood of European society and politics that such a letter needs to be written. The incident is by no means isolated; attacks happen several times an year on various institutions and conference events, the latest example: an ugly attack of activists "fertilizing" the EUCARPIA conference audience in Zurich with urine and feces, EUCARPIA EUCARPIA, Boller Beat, et al. (20160830).

EFSA does not approve GM crops; it simply makes strictly science-based recommendations which it then submits to the EC who then passes them to the Standing Committee on the Food Chain and Animal Health (SCFCAH) and from this point the approval process becomes very complicated since political considerations predominate with the weighting system favoring the opinions of the heavyweights Germany, France and Italy. The Member State's identity is the chief factor in voting behavior and indeed, the characteristics of the GMO are largely irrelevant since all GMO's are seen in the same light. As a result of this, SCFCAH has never been able to reach a qualified majority and, in such circumstance, the decision becomes the responsibility of the EC which then has the duty to authorize the OGM. This ability of the EC to approve GM crops when SCFCAH was unable to reach a qualified decision has been a source of serious discontent among Member States. Naturally this complicated approval process is a serious source of loss of time and potential revenues for the applicant companies as well as for EU agriculture. In terms of enhanced efficiency, one could ask whether SCFCAH serves any real purpose (other than to slow down GM-authorization requests) and whether it should be disbanded, Smart R.D.et al. and EFSA: Smart, Blum, et al. (2015) EFSA and EuropaBio (20150706)

For several years now, Europe is suffering a crisis of anti-science that has diminished the credibility of science, reduced recruitment of young researchers and caused a brain-drain to more scientific countries, we agree with Kuntz (2012B) that especially in Europe we are confronted with a postmodern assault on science. This anti-science sentiment is also directed towards EFSA. Criticism of EFSA, by NGOs EFSA Independence (20121028A) and the notorious disregard for its opinions by the EP, has seriously weakened its authority to a point where it may not completely recover. Indeed, while EFSA is good at defending scientific truth, its opinion is often ignored. This is illustrated by two recent examples:

1. The International Agency for Research on Cancer (IARC), a unit of the United Nations' World Health Organization, reported glyphosate as a probable carcinogen IARC (201507). EFSA disagreed with this evaluation EFSA update (20160526) and with a thorough peer reviewed study of 107pp. EFSA Conclusion (2015), and the IARC report was later shown to be unfounded by other units *within* the WHO-FAO: WHO-FAO (20160509) . Nonetheless, the EP ignored the ESFA and WHO-FAO-recommendations and extended permission for glyphosate utilisation in a very limited way.
2. A publication by the Seralini laboratory Seralini G.E. et al. Séralini, Clair, et al. (2012, 2014) (subsequently retracted by the journal) claiming that glyphosate-tolerant Maize NK603 induced tumors was widely discredited by many international organizations including EFSA: EFSA Statement (20121123), Academies Francaises (20121018-19), Council-Biotechnology (20120920, EUSJA Board (20121005, Riviere-Wekstein (20100119, VIB-Report (20121008) and researchers like Jany K. 2012 JANY KLAUS (2013), ARIO G. ARJÓ, PORTERO, ET AL. (2013), Snell et al. Snell Chelsea, Aude Bernheim, et al. (2011), and three important papers analyzing rat experiments from the GRACE framework program Schmidt, Dohring, et al. (2016, Zeljenkova, Alacova, et al. (2016, Zeljenkova, Ambrusova, et al. (2014) came to conclusions which exclude the Séralini experiments from serious evaluation: Herbicide tolerant crops analysed are nutritionally equivalent to the conventional crops nad 90-day rat experiments, they are scientifically sound and sufficient, an extention to 2-3 years is scientifically not justified. Also the statistics of the cited Séralini paper is deeply flawed according to Panchin A: Panchin (2013, Panchin (20121107). A recent German paper presents results of a thorough analysis of human impact of Glyphosate and concludes clearly that no harm must be expected: Conrad A. et al. Conrad, Schröter-Kermani, et al. (2017) Yet, nonetheless the EP considered, evidently under heavy political influence, that EFSA should implement expensive protocols for 2-year food testing in compliance with suggestions from the Séralini paper.

Regulation (EC) 1946/2003 is concerned with the trans-boundary movement for living modified organisms (LMO) destined for deliberate release, or for food and feed or for immediate processing, under the terms of the Cartagena Protocol on Biosafety. It relies heavily on what is known as the "Precautionary Principle" which is defined as:

"The precautionary principle to risk-management (or legally correct precautionary approach with a clearly different meaning) states that if an action or policy has a suspected risk of causing harm to the public , or to the environment, in the absence of scientific consensus (that the action or policy is not harmful), the burden of proof that it is not harmful falls on those taking an action that may or may not be a risk".

While scientists, being scientists, can rarely find complete unanimity on anything, the majority of scientific reports from international scientific organisations find no evidence that GM crops are more hazardous than their non-GMO counterparts. The National Academy of Sciences declared no consistent biosafety related differences between GMOs and Non-GMOs NAS National Academy of Sciences, Kelman, et al. (1987). Hundreds of studies supported by the European Community revealed no biosafety problems European Commission (2001, European Commission (2010). The Royal Society of the UK Royal Society (2016) stated

"Since the first widespread commercialization of GM produce 18 years ago there has been no evidence of ill effects linked to the consumption of any approved GM crop."

A list of the over 600 opinions in the form of reports from intellectual academies and peer-reviewed publications may be found on the GMO Pundit web site of David Tribe http://gmopundit.blogspot.ch/#! , among many other references also the extensive bibliographies of Weaver et al. Weaver and Morris (2005) and Nicolia A. et al. Nicolia, Manzo, et al. (2014)

As far as GMOs and LMOs are concerned the precautionary principle is simply an excuse by politicians to do nothing and to justify this due to lack of scientific certainty. It provides a justification for halting all progress, while gaining political votes for the protection of the population from all evil (real or imagined). The UK House of Commons gave its recommendations: House of Commons (20160607).
"Too often, the precautionary principle has been willfully misused in the formulation of EU life science policy-making, including and notably for Genetically Modified Organisms. There remains a fundamental need for what the minister called "an enlightened regulatory system on the side of innovation". A change to a 'product-based approach' from the existing unhelpful 'process-based approach' would make sense. The Government should renew its earlier efforts to engender in the EU and other states a far more robust scientific application of the precautionary principle, informed by existing good science evidence".

Another overview on the misunderstandings and misuses of the precautionary principle (actually legally defined as "precautionary *approach"*) is given with good details by Tagliabue (2016B).

Regulation (EC) 1829/2003 covers mainly the commercialization of food and feed. It facilitates GMO detection by obliging the providers of GM plants to disclose methods for their detection. These methods are then verified and validated by the Joint Research Center Central Reference Laboratory (JRC/CRL), with the support of the European Network of GMO Laboratories, (ENGL), before being made public. This regulation imposes labeling for authorized GMOs above a threshold of 0.9%. Labeling is not required for conventional or organic food and feed containing the adventitious, or technically unavoidable, presence of authorized GMOs at levels less than 0.9%. Unauthorized GMO are not permitted entry in the EU, even at levels less than 0.9%. Only Switzerland approved a lower level of 0.5% for unauthorized GMO imports, provided those are approved elsewhere. Stein (2010) and Federal Authorities of the Swiss Confederation (2008).

It should be noted that the 0.9% threshold is simply a number devised for political reasons and has no scientific basis. It was originally intended to be 1% but a change to 0.9% seemed more acceptable to consumers. In other countries with a GMO threshold the number is different (though equally without any scientific basis); 5% in Japan, 3% in Korea. Such a threshold in the EU would make a dramatic difference to the cost of GMO detection and its implementation. Davison John and Bertheau Yves (2007)

Regulations 1829/2003 and 1830/2003 (below) pose a number of problems which are only outlined in the present review. (for details see Davison John and Bertheau Yves (2007) Davison and Bertheau (2008))

The only method used for the determination of the completely arbitrarily threshold of 0.9% is achieved by quantitative real time PCR which has large error measurement at this level of detection. Gupta A. Porcar and Juárez-Pérez (2003). Still worse is the problem of the sampling procedure which is particularly difficult and costly when dealing with very large cargoes where the potential GMO presence is neither

homogeneous, nor restricted to a single type. In addition, the quantification of unauthorized GMOs which are not permitted at any level is clearly impossible; zero % cannot be scientifically measured.

In addition, there is the problem of mixtures of GMOs which can easily occur during harvest, road transport or shipping. Imagine a cargo containing 99.2 % non-GM maize and also 0.8% of a technically unavoidable adventitious presence in the form of an authorized GM-maize. Such a cargo would obviously not need to be labeled since it is less than 0.9% GMO. Now imagine that the same cargo also contains a tiny fortuitous amount of an authorized GM-soybean. This cargo must then be labeled “contains GMOs” since the soybean is 100% GMO. If the soybean is non-authorized, then the cargo must be destroyed or returned to its country of origin.

Problems of this type are compounded by problems of asynchronous authorization (where a GMO is authorized in one country but not in another). This situation results in a ridiculous tug-of-war between the EC and international companies such as Bunge and Carghill who may refuse to transport certain cargoes to the EU since they may contain unauthorized GM crops and yet the EC refuses, for reasons of “precautionary principle” to authorize these for import unto the EU. The situation is ridiculous since EU animal feed industry is almost completely dependent on GM crops from North and South America and thus the EC *must* authorize these GM crops or face an animal feed supply crisis PRRI Public Research and Regulation Initiative Palmer Roxanne (20130425). This was made clear in a letter to the EC signed by the heads of COCERAL, a European group representing grain traders; FEDIOL, representing European vegetable oil producers, and FEFAC, a federation of European animal-feed makers. According to the USDA, GM-soybean accounts for 94% of the US soybean production and 92% of maize production. No alternative sources exist in sufficient quantities to satisfy Europe’s need. Very recently the EC finally did come to its senses and authorized the import of the soybeans in question; Monsanto’s soybean MON 87708 x MON 89788, soybean MON 87705 x MON 89788 and Bayer CropScience’s soybean FG 72, see PRRI documents World Grain Staff (20160722) and Bunge Jacob (20160609).

In conclusion, the EC system for GM labeling is both very expensive and very unreliable and encourages regulatory decisions not based on science. It also poses great economic risks for the farmers (usually in North or South America), for the transporters and for the continued availability of animal feed in the EU (without which the EU supply of poultry, pork and beef will dry-up). It must be changed into scientific, logical, realistic, and economic wording. The easiest way to do this would be a form of international GMO authorization procedures. It should be noted that this situation of asynchronous approval is not unique to the EU but exists also between the exporters in North and South America and importers in China, Japan and Korea and other countries. At this moment there are no international discussions on this subject of global regulation despite years-long pressing Masip G. et al. Van Eenennaam and Young (2014), PRRI Gupta (2000). On the level of the global Cartagena Protocol, there were numerous interventions made by PRRI, which remained unanswered in substance. The interventions to create a scientific committee specifically on biosafety of GMOs within CBD are, although PRRI (Public Research and Regulatory Initiative) was active over many years, not successful until now. PRRI (2006-2010, PRRI (20090914, PRRI (20100923, PRRI (20101012, PRRI (20120516, PRRI (20131016).

Another situation that periodically arises is the thornier problem of USA unapproved GM crops Ledford (2013) which are thus automatically also not approved in the EU, China, Japan and Korea. Such a situation arose (again) very recently with the discovery of unauthorized GM-wheat in Washington state. There was a previous escape of unauthorized GM-wheat in Oregon in 2013. Such unauthorized GM crops cannot legally be grown in the USA or be imported into any country. The EC issued a report on unapproved GM

crops almost 10 years ago Davison (2010A) EU-Regulation (20031018) and nothing has been done since to resolve the problem which has since increased in magnitude.

Regulation (EC) No 1830/2003 concerns the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms, in accordance with Regulation (EC) No 1829/2003. Its objective is:

"It is necessary to ensure that consumers are fully and reliably informed about GMOs and the products, foods and feed produced there from, so as to allow them to make an informed choice of product." EU-Regulation (20031018).

As has been discussed in previous publications this regulation is not about food safety: which is the brief of EFSA Davison and Bertheau (2008, Davison John and Bertheau Yves (2007)

Few people would disagree with the intention to allow the consumer to make an informed choice. The difficulty with this regulation is that these "intentions" (if they truly were the real intentions) do not correspond to the observed result. The result of labeling "contains GMOs" is that EU supermarkets refuse to stock the product (in some cases they first had to be blackmailed by activists at the front entrance). There is thus no freedom of choice since products containing GMOs are unavailable. In this way, GM products are deliberately excluded from the marketplace (which was probably the real political intention). And then the major problem: what does it mean to be "informed"? The reality is that the European population is alarmed with the label because they believe the false negative propaganda of activists. Actually, if science would prevail, labelling should and could convince the consumers that labelled GMO containing food is safer than conventional food, which is proven by several incidences (the potato with toxic amounts of solanine Lenape USDA-Canada (1970), EHEC (Enterohaemorhagic E.coli) King, Nogareda, et al. (2012), the still well remembered and by opponents also recently cited Starlink case should be a warning: Based on shaky analysis a big scandal of 'contaminated' food was constructed, and fear was raised about possible allergies, which were later all dismissed by scientific assessments, see some selected publications related to the Starlink case: Carter and Smith (2007, Chowdhury, Mikami, et al. (2003, SAP-Report 2000-06 (2000, Siruguri, Sesikeran, et al. (2004, Sutton, Assaad, et al. (2004, Windels, Bertrand, et al. (2003, Yonemochi, Ikeda, et al. (2003)

Labeling is triggered because the product contains 0.9% material consisting, containing or produced from GMOs. Labeling is not triggered when the product contains less than 0.9% of technically unavoidable adventitious presence of GMOs. It must be shown on every occasion that the material is technically unavoidable and adventitious. This phrase "*material consisting, containing or produced from GMOs*" is interesting and it is defined in the text:

"Produced from GMOs' means derived, in whole or in part, from GMOs, but not containing or consisting of GMOs".

Thus, if the product is a highly-refined substance (such as oil, lecithin, flour, starch, or sugar) and it is 'derived in whole or in part from GMOs' then it must be labeled. There are two problems: 1) these products contain virtually undetectable traces of GMO DNA or protein. 2) Since the DNA is not present the labeling relies entirely on traceability (also covered by Regulation (EC) 1830/2003). However, traceability records are much more easily falsified than DNA analyses. In conclusion, the Regulation (EC) No 1830/2003 labeling process is triggered simply because a product was derived from a genetically engineered organism. Imagine the identical situation with GM insulin or growth hormone, where the GM product is safer than the product from human cadavers which they replace; yet these latter products could be legitimately referred to as the "natural" product. To further the comparison GM-feed is eaten by

animals and any DNA protein is destroyed in the gut; while GM-insulin and growth hormone are injected directly into the blood stream. See good articles on the questionable distinction between red and green GM, including some insights coming from social sciences Bonfadelli (1999, Bonfadelli (2002, Gaskell, Allum, et al. (2000).

It is perhaps time for politicians to admit that Regulation (EC) No 1830/2003 was simply a gigantic and expensive hoax. Its purpose was never to '*inform the customers and enable an informed choice*'; its purpose was to keep GM-food out of the EU supermarkets for mainly political and protectionist reasons. Regulation (EC) No 1830/2003 should be recognized for what it is and be abandoned.

4. Towards a Dynamically Scalable Regulation

Clearly, it is time to renew the whole regulatory system on breeding technologies. This has been also generally described in a previous text published in the EMBO journal Ricroch, Ammann, et al. (2016) : Public pressure, numerous lobby groups against modern agriculture has seemingly taken over, also for the reason that they are extremely well financed: Bouillon Hardy (201405). But it seems, that the whole anti-GMO climate is slowly weakening and the regulatory debate, with the boost of Gene Editing, turns to a more positive and realistic mood: Prakash C. S. (20151214). We hope that in the new constructive area there is more room for basic regulatory revisions, departing from the timid strategies of just changing a few details in the EU paragraphs for the reason of imaginary time saving. It is for sure time for new ideas which could also have global impact. And hopefully a first important step will be taken by the European Union Jones (2015B). But it should leave the door open for a well negotiated international harmonization for the coming years.

a) Ideas on how to introduce a dynamically scalable regulation

This section will recommend a "**dynamically scalable regulation"** which can be applied to all regulatory systems worldwide. Two research teams of Podevin and Wolt published seminal papers for those new ideas of regulation, basically both are proposing *"dynamically scalable systems",* including all NBTs, Podevin, Davies, et al. (2013), Podevin, Devos, et al. (2012), Wolt, Keese, et al. (2010), and Wolt Jeffrey D., Wang Kan, et al. (2015). Including all NBTs means in other words: product-oriented regulation is realized in a scheme which also takes into account the present-day knowledge of breeding processes on a molecular level. In the previous chapters, it has become clear that today we are drifting away from the clear divide of GMOs and non-GMOs, which has never existed in proper terms: stated with convincing arguments by Tagilabue. Tagliabue (2015B) We have, seeing the plethora of new gene editing methods, a **continuum from strictly conventional to the most advanced biotech-based crops**, a future scheme must be probably multi-dimensional The most recent proposal comes from Wolt et al. Wolt Jeffrey D., Wang Kan, et al. (2015)

Wolt et al. make a plea for a radical change of the regulatory strategy. It is time to quit the regulatory focus on the process, the authors make a convincing argument for a new focus on the novel phenotype developed, thus leaving behind the uncertainties involved in old regulatory systems. In contrast to many other recently developed regulatory systems, also the OMMs (based on Oligo-Mediated-Mutagenesis) not involving transferred DNA in the end-product, should undergo biosafety scrutiny, although on the lowest

level for a maximum of a few years. Wolt et al. denominate the new regulatory strategy a DYNAMICALLY SCALABLE REGULATORY SYSTEM.

From Wolt et al: Wolt Jeffrey D., Wang Kan, et al. (2015): The acronyms used by the authors in this **dynamically scalable scheme** considers the approach to DSB (**D**ouble **S**trand **B**reak) repairs that are achieved by NHEJ (**N**on **H**omologous **E**nd **J**oining) **S**ite **D**irected **N**ucleases 1-3 (SDN1), homologous recombination (SDN2) or the classic transgene insertion (SDN3) and whether the technique for introduction of the **G**enome **E**diting with **E**ngineered **N**ucleases are fully transient **(Category 1),** and in addition the OMM (**O**ligonucleotide **M**ediated **M**utagenesis, also named ODMs = OligoDirected Mutations) approach produces Double Strand Breaks (DSBs) repaired by Non homologous End Joining (NHEJ) and therefore is analogous to SDN1 in terms of its regulatory characterization to the extent the changes are viewed as 'point mutations' and not template insertions after Hartung and Schiemann (2014), Lusser and Davies (2013) or introduces rDNA within the plant genome with sub-sequent removal **(Category 2)** or entails stable plant genome integration of rDNA **(Category 3)** (the actual 'classic' transgenics which fall under the present EU-CBD paragraphs and in the case of long-years use on millions of hectares should be exempt according to the CBD under Art. 7.4)**.**

Summarizing the three categories (SDN1, SDN2 and SDN3) and taking into account all explanations from Wolt and Podevin: Wolt Jeffrey D., Wang Kan, et al. (2015) and Podevin, Davies, et al. (2013, Podevin, Devos, et al. (2012) , those details clarify lots of questions which might arise related to the creation of new laws in biosafety assessment, and they also make clear, that it is unwise (for political reasons or an illusory shortening of the creation process of new laws) to call for partial revisions of the present day totally outdated paragraphs. For excellent comments see Tagliabue Tagliabue (2015A, Tagliabue (2016A)

Two tables (sidebars A and B) in Podevin, Devos, et al. (2012) on p. 3-4 are giving all the knowledge and suggestions, Podevin and her research group want to suggest 3 main categories distinguished: **Category 1**, where recombinant DNA is introduced (Zink Finger, with and without repair of the template ZFN1 and ZFN2). Included is also the oligonucleotide-directed mutagenesis (ODM) and Agro-Infiltration, resembling transgenesis, but the end-product does not contain foreign DNA, actually, they will (also in field trials) be indistinguishable from conventionally bred plants (unless they get a marker gene, e.g. for field and food-feed trials). The **Category 2** only contains in an intermediate stage some foreign DNA, but the end products are in most cases undetectable Lusser M. et al: Lusser, Parisi, et al. (2011)

It is evident, (and somehow logical from a strictly process-oriented view) that modern agricultural production is highly interested in a deregulation of the CRISPR-technology, a review illustrates this in a balanced way – no final regulatory decisions are proposed: R. Arnaud et al. Arnason Robert and Western Producer (20151120). This is an important message to all those molecular biologists who have ready made decisions of exclusion at hand.

Two examples of publications demonstrate the view that DNA-free Oligo-Mediated Mutagenesis should finally be excluded from biosafety regulation: Their argument is that those OMMs lack "foreign" DNA, whatever this may mean…Hartung and Schiemann (2014) :These authors deplore the regulatory vagueness of legal definitions, they vary from continent to continent strongly, see below the comments of Ledford H. Ledford Heidi (20160414). We agree: If scientists and polititians do not achieve a globally well defined regulatory system, modern plant breeding (and its economy) would be seriously hampered – a system, which simplifies modern breeds to GMOs and non-GMOs the old way, would stall the development of modern agriculture seriously. Despite biotech-opponent simplifiers, the rapid

development of a stunningly broad variety of Gene Editing methods (which will develop into new unchartered realms) calls for a less stringent process-oriented definition of the various categories of modern breeds. We agree that the focus on strict process views, though presently legally valid, has to be dismissed in considering the future new regulatory definitions. It does not help much to interpret product-orientation into some regulatory wording of the EU paragraphs in a view that actually product-oriented regulation is included in the EU regulatory system of today, it is an interpretation on shaky grounds and falsified at the latest since 2008: Miller H. Miller (2008) The political reality in the present day regulatory decisions in Europe are all still taken with a focus on the process level. Clearly, there is broad consensus about this situation, since today that most scientific institutions call for a product-oriented regulatory view, see Box 3 in Ricroch, Ammann, et al. (2016) .

The latest publication of the same group with Sprink et al. Sprink, Eriksson, et al. (2016) gives a very detailed analysis of the present day research on Gene Editing and confirms the conclusion, that progress in breeding technologies call urgently for an updated legislation. The authors describe the regulatory situation and the planning for new regulatory elements as highly complex, they need to be decided by the EU - their view: rather than a) presenting a full concept for how regulation of plant-breeding techniques should be conceived, they focus on b) arguing in a flexible way why genome editing techniques should not automatically be defined as GMO according to the EU definition.

"Despite the fact that the Directive 2001/18/EC contains both process- and product related terms, it is commonly interpreted as a strictly process-based legislation. In view of several new emerging techniques which are closer to the conventional breeding than common genetic engineering, we argue that it should be actually interpreted more in relation to the resulting product."

Thus, we agree that, according to Sprink et al we should focus on the interpretation of the current Directive 2001/18. We agree with Sprink et al. that we certainly do not propose that EU should adopt a new model where all GE techniques are excluded from regulation. Rather to the contrary, we do speak favorably, in the conclusion following the Stanford model Conko, Kershen, et al. (2016) , which seems to us to have at least some similarities to the proposed model for dynamically scalable regulation according to Wolt et al.

Our view of modern and conventional breeding methods cannot fix on processes or products alone, and after all, it is a commonly accepted truism, that all products are made by processes, and all processes end somehow into products.

We agree with the authors in Sprink et al., that despite the fact that the Directive 2001/18/EC contains both process- and product-related terms (using a somehow stressed “flexible” view), it is commonly (and worldwide) interpreted as a strictly process-based legislation. The public *and* the regulators and most polititians maintain the process view, including many researchers and agronomists, not to speak about biotech-opponents, all they are still united in this view. We agree, that it is now time to implement new regulatory decisions, since the present day situation is untenable. It is important to see that the regulation should be defined in a way, which does not hamper scientific, agricultural and economic progress, and this alone makes it impossible, to stick to the old view of process-orientation alone. Those new gene-editing techniques will change the entirety of plant breeding at an accelerated speed in the future. One of the biggest hurdles will be to internationally harmonize the biosafety laws, which still incorporate many basic differences. We agree with the view of a rapidly growing complexity of molecular insight, this alone

demands for a differenciated and thorough debate, taking into account the regulatory systems worldwide.

We should include all the highly complex molecular insight, also with the balanced discussions taking into account many regulatory systems worldwide. But this kind of open-minded analysis also makes it clear that we are very far away from any proper solution of global regulatory solutions. Sprink et al. nevertheless try to come to a rather short cutting regulatory conclusion: It is not convincing to exclude straightforward some brand-new methods of genomic alteration from all regulation just for strict process-oriented views (no “foreign DNA involved). We cite from the text an example showing the full intricacy of the problematics (as also well illustrated by Abbott Alison (20151215).

No doubt, there will be more such complex cases of method comparison and mixtures, and again the conclusion is not to fix the view too much on the details of the process (especially in the very tempting case of oligo mediated mutations OMMs which cannot be distinguished from naturally mutated organisms). It will be wise to focus on the NOVELTY of the resulting crop, and not to get involved in the question of natural or unnatural breeding processes. The Canadian way of selecting novel crops for biosafety assessment, combined with the approach of a dynamically scalable view will lead to solutions – after a few years of negotiations, testing and reflection by the leading regulators and scientists.

Related to OMMs a study, from Woo J.W. Woo, Kim, et al. (2015), demonstrates again that the end-products of OMM activity can be indistinguishable from naturally mutated traits, and they conclude for an exemption of such traits from the present day regulation. But we emphasize here nevertheless, that the technique is still novel, not all details are really known within the process, and a first few years of risk assessment should be carried out before exemption from regulation is considered, in the strategy of the above mentioned dynamically scalable regulation.

Woo J.W. and other colleagues such as Kanchiswamy, Malnoy, et al. (2015) and most recently Kanchiswamy (2016), have developed further on the precision of CRISPR to a degree of highest precision, which should convince the most ardent opponents of biotechnology that the new breeding technologies are coming closer and closer to natural mutations. Yet, in our opinion, even the high-precision gene editing methods are too novel to be dismissed altogether from any biosafety assessment. Indeed, the RGEN RNP method is a new, much more precise tool, it will pave the way for efficient use of available genome sequences of many crop plants to modulate economically important traits and bring these genetically edited crop plants to the field without going through laborious, expensive, and time-consuming high regulatory hurdles. So far, the RGEN RNP technology has been successfully adopted in Arabidopsis, tobacco, lettuce, and rice through protoplast transformation and regeneration. It would, according to Woo and Kanchiswamy, enable breeders to modulate economically important crop species and prepare for a later regulatory exemption after a few years of testing. Note that Woo and Kanchiswamy do not consider that such RGEN RNP organisms could undergo low level biosafety assessment as proposed by Podevin et al. and Wolt et al.

The example of the present day work on regulatory renewal in the United States shows the same highly complex picture: Ledford Ledford Heidi (20160414). Interestingly enough, she does not forget the international perspective:

An overview of the present-day decisions shows that the countries are still divided on whether Genomic Editing on the lowest level of micromutations should be regulated or not.

Ledford considers that USA regulations are ripe for change:

"Many feel that regulations in the United States, which grows more GM crops than any other country, are particularly ripe for change. The USDA itself has acknowledged that it might be over-regulating some crops if they have traits that have already been scrutinized. Also, it uses its authority to restrict the release of 'plant pests' as a way to regulate GM crops — an approach that applied widely in the 1980s, when crops were often created using genetic elements from plant viruses or bacteria.

But researchers have since developed tools that do not rely on these components. Over the past five years, the USDA has determined that about 30 types of GM plant — from soya beans whose oil has a longer shelf life, to pineapples with rose-colored flesh — do not fall under its regulatory rubric. Some were made using gene-editing techniques" Comments Ledford Heidi (20160414).

Ledford H. Ledford (2013) produced a list of GMOs not being regulated by the US system, but actually released: among those Switchgrass (biofuels), Grapes (color), Turf grasses (herbicide tolerant), Maize (improved nutrition), faster breeding tobacco, higher yields in Sorghum.

Indeed, since 2010, the US Department of Agriculture has told at least 10 groups that their genetically modified (GM) crops would not be regulated because a plant pest was not used to do the engineering. It demonstrates indeed, that despite some rules (and hearsay) of product-orientation, many US decisions are still taken on the process level: With the example of Cisgenesis Schouten, Krens, et al. (2006) see the APHIS letter to Schouten, when his request to free Cisgenesis from regulation was rejected Gregoire M.C. (20120402), Schoutens arguments sound reasonable: Cisgenesis is indeed operating with transgenes from the same species (or group of species), see details about the controversy in Ledford H. Ledford (2013). The rejection by the US regulatory body was underpinned with the argument that the Cisgenes *have been transferred* with Agrobacterium. Indeed, there is proof showing that *Agrobacterium* causes indirectly in the neighborhood of the insertion of the transgene some genomic changes Gelvin, S.B Gelvin (2010) and Pitschke A. et al. Pitzschke and Hirt (2010). This kind of uncertainty will be clarified (maybe corrected or made obsolete with more precise transfer methods) and needs limited regulation. The table of Ledford cited above is the result of a certain helplessness and euphoria of new discoveries in breeding technologies. With the new call for regulatory revision the US government should put things on a solid new platform. In the mean-while APHIS has now launched a proposal in the internet, it does not seem to create consensus among leading researchers. APHIS and USDA (20170119) Promptly, this release with feedback possibility until May 19, 2017, is criticized in a Nature news. Maxmen Amy (20170119)

b) Coming to regulatory decisions about gene editing (Conclusions)

We lean towards the Canadian proposals: *"Decisions are made on the basis on whether the crops have new traits, irrespective of how the traits are produced".* The essence of those proposals, presently also in development again, can be found in McHughen and Smyth (2012, Smyth (2014)

Again: the time should be over when one considers GMO-GE regulation as strictly process-oriented; this was a political situation of the early pioneer times and the decision was based on early enthusiasm of discovering the new breeding world and also a risk-oriented and wrong focus on GMOs alone. Yet it is still a fact today: all decisions to exclude GE methods (strictly based on micro-mutations Type 0 in the Figure 2 from

Jones (2016) are based on a strictly process-oriented view. It is the *results* of these fantastically efficient and cheap GE methods which still need to be tested on food and environmental safety, just as the Canadians have decided – by including also novel crops done with *conventional methods* which might have some unknown impact.

A very thoughtful and new approach in regulation has been proposed by H. Jones cuts through in a rather simple way the impressively broad variety of new gene editing methods and could actually lead to agreements. Jones proposes a possibility of getting out of the trap of an integral revision of the EU regulation: leave the "traditional" GMOs out of new considerations and concentrate on the 3 categories of Gene Editing, in the case below categorized according to processes: See fig. 2 in Jones (2016)

Jones 2016 proposes to exempt Type 0 from regulation with the argument, that DNA is not involved in the final product, a position which is to be taken serious, it is also supported by APHIS, USDA: USDA and Firko M. Aphis (20160413) However, in this letter to Yinong Yang it is made clear that EPA and FDA may come to another decision by including type 0 in the forthcoming new regulatory rules. See also Barrangou in GENeS GENeS (20160414) with a different message. The first CRISPR crop (a mushroom) should not be regulated.

H. Jones made some more published pragmatic proposals which one should give a chance of realization in the difficult battlefield of Gene Editing Regulation: Jones (2015A): Jones suggests a *scalable solution*: he wants to move away from the process defined regulation and he wants to apply a proportionate, transparent risk/benefit analysis to novel crop types on a case-by-case basis using conventional varieties and farming practices as a baseline comparator *and also taking into account the risks of not adopting change*.

With the same intentions (also with similar regulatory remarks as in our first sectionJones (2015C) It is again a plea not to follow the erroneous and illogical process-oriented approach in regulation. We propose a case-by-case risk assessment as above, it should focus on the novelty of the product in the regulatory process.

Actually, we follow in the present review a pragmatic regulatory solution to Gene Editing, similar to suggestions of Jones (2016) Fig. 2, however, we would still keep Type 0 *within* a regulation (at least for a few years of low level biosafety assessment, and adapt the depth of regulatory scrutiny according to a *dynamically scalable strategy:*

We agree in this review with the arguments for a regulation on the lowest level according to Wolt et. al. 2016 (see Fig.1) and Type 1-3 should also be correlated to Wolt's regulatory levels. The arguments are simple: All Gene Editing methods (from Type 0 to 3) are, according to all authors and inventors, an *efficient way* to alter the genomes, and this is why it is not only the process on a low molecular level, but also the *result* – the product that is relevant, when it comes to regulatory level decisions. Admittedly, Type 0 does not raise serious concerns as a genomic process – it is close to nature (whatever this means). The Genomic Misconception Ammann Klaus (2014), explains that the processes of natural mutation and biotech transgenesis are identical, a position first expressed in many publications by Arber W. Arber (2010). But results of *any* altered crop genome (from Type 0 to 3) should be tested for food safety and environmental impact: Specifically Type 0 should also undergo a short period of 1-3 years of field and food testing, despite the fact that it corresponds to our lowest level of genomic alteration and can be interpreted as identical to conventional mutations (but indeed still produced with an artificial process).

A suggested parallelization of the regulatory levels with the scheme of Wolt needs to be debated and decided by a group of experts, details must be carefully analyzed. These experts should only have in mind

the possible and realistic risks from a product perspective. And basically different from the Biosafety Convention, they should also take into account the *benefits* (a term, which is completely lacking in the Biosafety Protocol. Indeed, they can proclaim a new age in crop breeding based on a few innovative researchers see the concise summary of Church G. Church (2015). But, despite this justified enthusiasm, we should not forget all of the principles of biosafety assessment. Despite the fact, that some of those OMM methods do not involve "foreign" DNA (i.e. DNA introduced from a different species), we do not really know all details in the artificial process of making OMM plants. To be explicit: The new regulatory rules must be achieved without molecular prejudice. Still, also this paper can only be *a discussion basis* which still needs to be detailed and realized in its regulatory goals.. We have to realize, that more sophisticated edits of crop genomes, such as rewriting genes it-selves or inserting new ones – are just around the corner. Ledford Heidi (20160414)

The US regulators are preparing their future decisions by also including public comments (FDA dockets), two of the many hundred comments are cited here: Fedoroff Nina (20151106) and Ammann Klaus (20151112).
Finally, the debate will be decided on a *political level*, by including important elements of public acceptance, as a whole still a mixed bag: a valid summary given in the Genetic Literacy Project by Smieszek. Smieszek Sandra (20160413) It is realistic to point by the authors to the hostility of the European public, and also worldwide the resistance is growing steadily, not least also by the generous and permanent financial support of GM-opposition organizations: Bouillon Hardy (201405), Genetic Literacy Project Gallery (20151105) and Miller Michelle (20160915) In the present day fight on regulation, approvals and rejection of modern crops, administration and science need to reassemble forces in order to achieve progress in faster approval of new breeds, a complex structure, well addressed by Parrott and Giddings. Parrott and Giddings (20170125)

Indeed, opponents easily find populist views in the strive for stronger regulation, which are not built on science, and unfortunately, the complexity of the multiple GE methods blur the picture for lay people. In the "old times" GM-opponents found many ways of creating fear to lay people for one single method of genetic engineering (the "simple" transfer of foreign genes). These processes happen in the hidden world of molecular biology and are very difficult to grasp for lay people and politicians. This opens the way for any kind of molecular and corporate conspiracy theories and fear-creating stigmatization, this is why some GM opponents fervently fight for the uncompromising inclusion of Gene Editing into a future strict regulation: Steinbrecher C. Steinbrecher (201512)

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