Innovative Solutions for the Regulation of GM crops in times of Gene Editing.

For a science based new regulation of modern agriculture.

Dedicated to Werner Arber, his innovative research remains an important basis for modern agriculture.

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Plant Biotechnology: Progress in Genomic Era,
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Contents

1. Introduction:

If we want to escape years-long fruitless debates on plant biotechnology and biodiversity, we have to do more than just to deplore the debate full of artificial (or imagined) contrasts, fake news and cheap

propaganda, the main arguments on a strict science basis are summarized below. The debate needs a professional *discursive structure* and we must embrace different kinds of knowledge, and new solutions should not be excluded by principle, on the contrary: in new regulatory structures surprising new discoveries of better crops and in the science of GM safety also must be anticipated. Basically, a mutual understanding of the different views on agricultural strategies (from organic farming to the application of new breeds may stimulate the debate and lead to innovative solutions. Thanks go to Giovanni Tagliabue and Klaus Jany for helpful remarks.

In their publication of **Zetterberg and Edvardsson Björnberg (2017)**, the authors come up with a programmatic summary, which can well serve here as a motivation to go ahead with a courageous proposal for a regulatory change of GM crops: The main argument goes that the European regulatory framework does not satisfy the criteria of legal certainty, non-discrimination and scientific level and adaptability.

With the necessary courage and organized workforce those plans can be realized in a few months of intensive redaction - it should also be possible to achieve solutions in a reasonable time for the complex system of European and international regulation.

Thanks go to Prof. Klaus Jany for valuable corrections.

2. The structure of a regulatory discourse:

2.1. First: Look behind the curtain

We need to see behind the curtain and focus on the main driver elements behind the debate. The industry, together with important farmer organizations, wants to see better results of the new breeds in the field for commercial marketing. The scientists focus on facts, strive for innovation and progress in agricultural breeding, and they believe in new solutions to fight the hunger in the world still existing **Council for Agricultural Science and Technology (CAST), Baenziger P.Stephen, et al. (2017)**. Decisive opposition comes from professional NGOs like Greenpeace and Friends of the Earth, most often with arguments which are not supported by science. Both opponent sides build on heavy financial support and are reluctant to lose their expensive structural organization. Scientists often do not understand that a discourse on modern breeding including the public institutions is an absolute necessity. NGOs also fear that public support will faint, a support which is still of very important dimensions going into billions every year: **Bouillon (201405)**. Recently, part of the GM opposition deplores to lose the debate related to the more precise methods of Gene Editing which might be more acceptable to the public and politics. GM-Opponents still consider the modern breeds full of risks but are unable to present convincing facts **Steinbrecher and Paul (2017)**). A veritable fear industry has grown: see Gardner's comprehensive book review: **Gardner (2008, 2009)**. And see more specifically to the abuse of fear **Kahan D. M. and Slovic P. (2005)**. Indeed, the debate is often carried in a merciless way, apart from the usual righteousness, major discourse participants actually risk a major loss of income by losing the debate. **Miller, Morandini, et al. (2008)**. The main driver behind opponent campaigns is often *diffuse fear*, built on questionable interpretations of substantial equivalence and sustainability and thus often full of additional false arguments constructing negative but unsubstantiated effects of modern breeding. But such negative contributions counting on a successful fear mongering for the public, are contradicted heavily by breeding optimism, here one example dealing only with the great genomic potential of wild relatives: **Wettberg, Chang, et al. (2018)**: The conclusions are important: Breeders should take professional care of

the genomic treasures of the wild relatives of our main cultivars related to favourable morphological characteristics, phenology, nutritional density, resistance to parasites, heat tolerance and cold stress.

It will be important to abstain from unilateral thoughts and try to integrate various methods and approaches for a healthy and future-minded breeding in agriculture: **Ammann (2012), Dollacker (2018)** and **Ricroch, Harwood, et al. (2016)**. The latest regulatory decision of the USA on "bioengineered" food got indeed devastating remarks, a proof for the urgent necessity of a more insightful and innovative crop breeding: **Miller and Kershen (2015)**. (The full integrative regulatory debate in chapter 3 below).

2.2. Second: The 'Genomic Misconception' of existing GM regulations

Not surprisingly, molecular science and unbiased views on agricultural history should be able to ease down the contrasts in this debate, here two of many arguments:

a) The process of gene transfer is identical, whether done in natural mutation or modern biotechnology, a view supported in the past many times by Nobel Prize Winner Werner Arber **Arber (2010)**, summarized with details of the regulatory history in the *Genomic Misconception*, a review published 2014 by **Ammann (2014)**.

According to latest papers of Werner Arber, Genetic Engineering represents a safe approach for innovations improving nutritional contents of major food crops **Arber (2017A), Arber (2017B)**

b) It is on the other side clear that the *application* of the huge potential of the new methods including *Gene-Editing*, will have important consequences in the future of agriculture. There is a plethora of new crop trait possibilities which are already tested or need to be tested, whether involving "foreign DNA" or not, since all new traits done with molecular methods *embrace a certain procedural novelty*. The present-day politics of many scientists aims a special treatment of those very precise Oligo-Mutations which end up without "foreign" DNA in the product: they should be fully excluded from regulation **Breyer, Herman, et al. (2009B)**. This sounds convincing, but a closer look at the methods of Gene Editing will lead to more precautionary conclusions, as shown below. Some insight in the present day debate on regulation of GM crops can be read in a selection of publications – it is nearly impossible to distill out of the considerable variety of regulatory thoughts into a clear, simple concept (see chapter 3) : **Zetterberg and Edvardsson Björnberg (2017), Eriksson (2018A), Eriksson (2018B)** and **Davison and Ammann (2017), Eriksson and Ammann (2017), Ricroch, Ammann, et al. (2016), Tagliabue, Ammann, et al. (2016), Tagliabue, Kuntz, et al. (2017)**.

2.3. Third: Organo-transgenic thoughts

The consequences from the Genomic Misconception analysis are the following:

It is fact, after Wood et al. **Wood and Lenne (2001)**, that our main world crops (Rice, Wheat and Sorghum) have been chosen by our ancestors because they already lived naturally in *large monodominant stands*, an important precondition of efficient early food production. The often-heard argument that huge monocultures are directly and negatively related to modern breeding has no logic or historic background. On the contrary, modern breeding can be key to conceive a more ecological methodology in agriculture **Ammann (2007B), Ammann (2012)**. In consequence, we need proposals to merge organic farming with its good sides in biodiversity management. Unfortunately, most eco-minded breeders have unfortunately a strict focus on anti-biotechnology and hostility towards industrial farming with its uncritical perspective on production alone – a critical view which in the latest years received a lot

of correction also in conventional agriculture: Consequently, it is better to think the unthinkable such as *Organo-Transgenics*: Indeed, organic farming and biotech farming could actually go together under well-defined circumstances - across ideological and commercial barriers. **Ammann (2008), Ammann (2009), Ammann and van Montagu (2009)**, about cis-genic potatoes see **Gheysen and Custers (2017)**. There are notable recent exceptions of such unilateral thinking also coming from organic farming: **Niggli and Maurin (20160406)**, resulting in bitter and purely ideological reactions from the "church of organic farming"…

2.4. Complex debate needs a professional discourse procedure covering 2.1 to 2.3:

Clearly, in a pluralistic society an objective definition of equity does not exist, and basically, policies that respond to social problems cannot be meaningfully correct or false, definite and objective answers to wicked problems do not exist in this complex situation of a multifaceted dispute, it is important to conduct future discourses under the auspices of a *modern discourse strategy*, as already promoted by **Churchman (1979, 1984), Rittel and Webber (1973, 2005)**, a bibliography of Rittel see **Rith and Dubberly (2007)**. Such modern discourse builds on different kinds of knowledge, active listening and an open-ended spirit for new solutions. It is simple fact, that such discourse attempts need professional preparation and are not done in a happy weekend, it needs hard work over months.

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3. Innovative regulatory proposals:

3.1. Dynamically Scalable Regulation

The regulatory views should in consequence not be black and white for part or the whole modern and traditional breeding: A *dynamically scalable regulatory modus* should be more realistic and more acceptable to friends and foes, see **Wolt J. D., Keese, et al. (2010), Wolt J. D., Wang Kan, et al. (2015)** and **Podevin, Devos, et al. (2012A)** and **Wolt (2017)**. The Gene Editing methods which finally do not contain any foreign DNA should still be regulated in a modest way for a few years, then released swiftly after and almost certain positive outcome to the world agriculture applications. More details about the Dynamically Scalable Regulation can be checked out in the citations above. One illustration from Jeffrey Wolt explains concisely the strategy:

The anticipated scrutiny of the various regulatory methods is well summarized in **Wolt J. D., Wang Kan, et al. (2015)**, specifically in its figure 1 below:

The full text of interpretation in Wolt is given here with some editing of the author for the reason of a precise argumentation for his dynamically scalable regulation scheme in figure 1, including the citations with some added items:

Regulatory discussion of a wide range of new breeding techniques applied to crop development was initiated in 2011 with an EU-convened international workshop that considered the techniques then available for site-directed genome editing **Lusser and Davies (20130307), Lusser, Parisi, et al. (2012), Lusser, Parisi, et al. (2011)**. Based on the categorizations identified by this group, its elaboration by **Podevin, Devos, et al. (2012B)** see also **Devos, Aguilera, et al. (2014)**—and accounting for the emergence of new techniques in the interim—a schema for regulatory characterization specific to genome editing techniques can be described (Figure 1). This schema considers the approach to DSB repairs that are achieved by NHEJ (SDN1), homologous recombination (SDN2) or transgene insertion

(SDN3) and whether the technique for introduction of the GEEN is transient *(Category 1),* introduces rDNA within the plant genome with subsequent removal *(Category 2)* or entails stable plant genome integration of rDNA *(Category 3).* The OMM approach produces DSB repaired by 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: **Hartung and Schiemann (2014)**; **Lusser and Davies (20130307)**. It is somehow plausible to exclude Oligo-Mutations from the usual regulatory scheme, as many US and EU authors conclude. But apart from this solution, indeed rather simple and tempting from the regulatory point of view, this exclusion will meet decisive opposition from many GM critiques such as **Steinbrecher and Paul (2017)**, we propose a differentiated solution, by taking up the views of Jeffrey Wolt et al. within the following three categories:

3.1.1. Category 1 of a new dynamic regulation (SDN1 or SONI)

Techniques involve transient introduction of recombinant DNA using in vitro synthesized nucleic acids and DNA delivery methods that *do not integrate* into the host genome **Pauwels, Podevin, et al. (2014)**. These techniques, therefore, resemble transgenic processes but produce phenotypes that are indistinguishable from plants obtained through conventional plant breeding. The techniques would include site-specific point mutations with oligonucleotides (OMM), site-specific random mutations by NHEJ (SDN1) and site-specific mutations with DNA repair via homologous recombination (SDN2). Novel techniques avoiding the use of rDNA through direct introduction of the nuclease or mRNA encoding the nuclease **Baltes, Gil-Humanes, et al. (2014), Baltes and Voytas (2015)**; **Martin-Ortigosa, Peterson, et al. (2014)** to catalyze similar mutation events would also fall into this category.

3.1.2. Category 2 of a new dynamic regulation (SDN1 or SDN2)

Consists of stable introduction of rDNA into the host genome and an intermediate step involving expression of SDN1 or SDN2 to effect DSBs and repairs. Subsequent breeding selection for null segregants results in phenotypes that are indistinguishable from phenotypes obtained through conventional plant breeding. Therefore, evidence will generally be lacking in the product to indicate a transgenic process was involved in the intermediate step. Plant phenotypes developed by SDN1 methods as described in either of the forgoing categories represent simple point mutations and with few exceptions (Canada) regulators do not consider crops developed by mutagenesis in the same context as GM crops. The regulatory opinions regarding plant phenotypes developed by SDN2 methods are not as clear, as the nature and extent of the edits used to effect the desired change in the phenotype obtained by the technique would influence opinions as to whether the phenotype represented a GM product. For instance, deletions are viewed as less consequential than are additions. And in the case of additions, the greater the number of bases added, the greater the level of regulatory concern. Important in this context is the determination as to whether the NHEJ accomplished by the technique is viewed as a template insertion into the genome **Lusser and Davies (2013)**.

3.1.3. Category 3 of a new dynamic regulation (SDN3)

Category 3 finally involves techniques which result in stable integration of rDNA where '**G**enome **E**diting with **E**ngineered **N**ucleases' (GEEN) is used to specifically target delivery of a transgene or multiple transgenes through insertion by homologous recombination (SDN3).
Current examples of this technique involve the site-directed stacking of transgenes **D'Halluin and Ruiter**

(2013). Thus, they simply represent a refined technique to accomplish *Transgenesis* and would be considered no differently than GM products by regulators. The European Food Safety Authority (EFSA) Panel on Genetically Modified Organisms—an expert panel providing independent scientific advice to EFSA on GMOs—has developed the regulatory opinion that existing EFSA guidance documents apply to the SDN3 technique **EFSA GMO Panel (2012)**, see also other important EFSA-publications: **EFSA Gmo Panel Working Group on Animal Feeding Trials (2008), EFSA Guidance (2011), EFSA Guidelines and Renn Ortwin (20120402), EFSA Independence (20121028), EFSA letter and Paoletti Claudine (20151015), EFSA Opinion (2015)**. But because the technique can specifically target transgene delivery into the genome, it has the potential to minimize potential hazards associated with gene disruption or regulatory elements in the recipient genome. It is important to mention, that the most commonly distributed transgenic maize, soya and wheat crops are marketed and in good use on millions of hectares and should be exempted from regulation (this also according to article 7.4 of the old, still valid regulatory system)

*Thus, plants developed using SDN1 (SONI) methods may require less data for risk characterization than more conventional approaches to transgenesis: see the s*ummary with edits of the author from **Wolt J. D., Wang Kan, et al. (2015)**

See the new table of regulatory categories 1-3 from **Wolt (2017)**

	Category 1	**Category 2**	**Category 3**
SONI	NHEJ or nucleotide replacement with transient introduction of reagent	NHEJ with stable integration of nuclease-encoding rONA and subsequent NS selection	NHEJ with stable integration of nuclease-encoding rONA
SDN2	HDR with transient introduction of reagent	HOR with stable integration of nuclease-encoding rDNA and subsequent NS selection	HOR with stable integration of nuclease-encoding rONA
SDN3	Transient introduction of reagent with site-directed transgene insertion	Site-directed transgene insertion with stable integration of nuclease-encoding rONA and NS selection	Sit e-directed transgene **insertion with stable** integration of nuclease-encoding **rDNA**

*Fig. 1 See the explanation from the first paper of Wolt et al. 2016, above table from **Wolt (2017)***

Again, in this latest publication **Wolt (2017)** Jeffrey Wolt insists (as does the author) on a ***Dynamically Scalable Regulatory Modus,*** and the author emphasizes that regulatory decision making involves robust standards, anticipate significant engagement and investment to answer questions of regulators and the civil society. For details see also Box 2 in Wolt (2017). The fig. 1 in **Duensing, Sprink, et al. (2018)** summarizes the complex regulatory situation well: The point of debate: the “incuced mutations”, all man-made transgenics, but in the old regulatory system those are pro parte excluded.

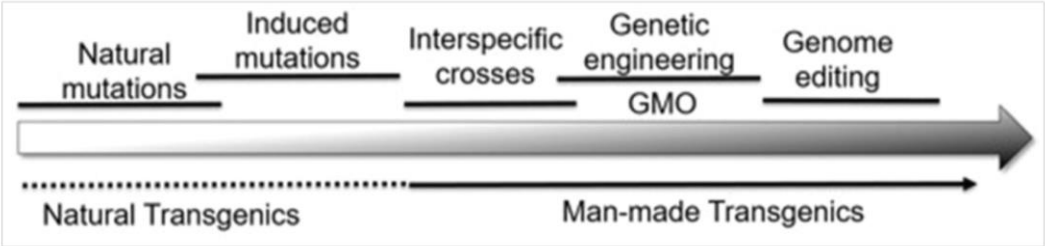

Fig. 2 A wide range of natural and artificial processes serves to alter the plant genome in many ways. From a biological perspective, it becomes difficult, if not impossible, to draw vertical lines separating one category of modification from the other. From Fig. 1 in ***Duensing, Sprink, et al. (2018)***

3.2. Important alternative regulatory strategy developed mainly by the United States regulatory system and many European scientists:

Clearly, there is still an ongoing regulatory dispute coming up with innovative solutions among scientists:

As co-author, the author published together with colleagues the opinion in **Tagliabue, Kuntz, et al. (2017)** (co-signed by 19 researchers): "The pseudo-controversy over pseudo-categories has been rejuvenated by the attention paid to the relatively new techniques of 'gene editing', including transcription activator-like effector nucleases (TALENs), zinc finger nucleases, and clustered regularly interspaced short palindromic repeats-CRISPR-associated protein 9 (CRISPR-Cas9). We oppose simplistic solutions that would
(1) include all gene editing in old or new regulatory law or
(2) exclude all exogenous DNA-free new varieties from regulation. Rather, we promote a stratified approach (such as described in detail in **Conko, Kershen, et al. (2016)**. We emphasize, however, that the objective of formulating more scientifically defensible and risk-based regulatory approaches cannot be merely redefining 'GMO' to be more widely acceptable. Rather, regulations must be genuinely risk based."

However, most scientists in the USA, USDA: and an important number of European scientists insist today in a non-regulatory status of Oligo-Mutations not containing "foreign DNA", a position which can be seen with some scientific merits **GENeS (20160414)**: It sounds somehow logic that final products of mutational breeding not containing foreign DNA should not fall under the present day tedious and cumbersome regulation.

The argument that the new Oligo-mutation breeds are made with an *over-all new methodology*, but still, the minimum of regulatory proofing from the developers is considered sufficient, this although papers like **Schaefer, Wu, et al. (2017** claimed mismatched edits with a higher count of off-target mutations. This paper is clearly contradicted and finally retracted for good reasons, follow the debate in the full text (open source) links of Kellie Schaefer, Wu et al. 2017. See as a summary of all the critique and the retraction in **Han (20170626)**. Actually, against the authors objections, Nature Methods published an expression of concern, followed by 2 more notes and finally retracted the paper, details in Han above. Considerable amount of mismatched edits have been reported formerly by **Fu, Foden, et al. (2013), Sander and Joung (2014)**, **Schaefer, Wu, et al. (2017), Zischewski, Fischer, et al. (2017)**, but other authors claim low incidence of such edits: **Veres, Gosis, et al. (2014)**: unanticipated downstream effects of off-target mutations are not important and this comes with the assurance that genome reagents do not occur in final products. Indeed, the often-heard argument by GM opponents that the new CRISPR methods produce uncontrollable amounts of mutations, has been dismissed by including new methodological CRISPR approaches: **USDA, APHIS, et al. (20160413)**, more recently and with detailed arguments supporting this opinion: **Cohen (20170413), Giles (20180320 AND 20180402), Haydon (20170602)**. The debate on mismatched edits has been closed finally, the review of **Duensing, Sprink, et al. (2018)** is convincing: In this paper, some supporting publications are cited again, confirming that with

the latest CRISPR-Methods unexpected mutations can be neglected in the Fig. 2 and Fig. 4 are giving an excellent overview of the regulatory situation, including a vast amount of literature as presented up to now:

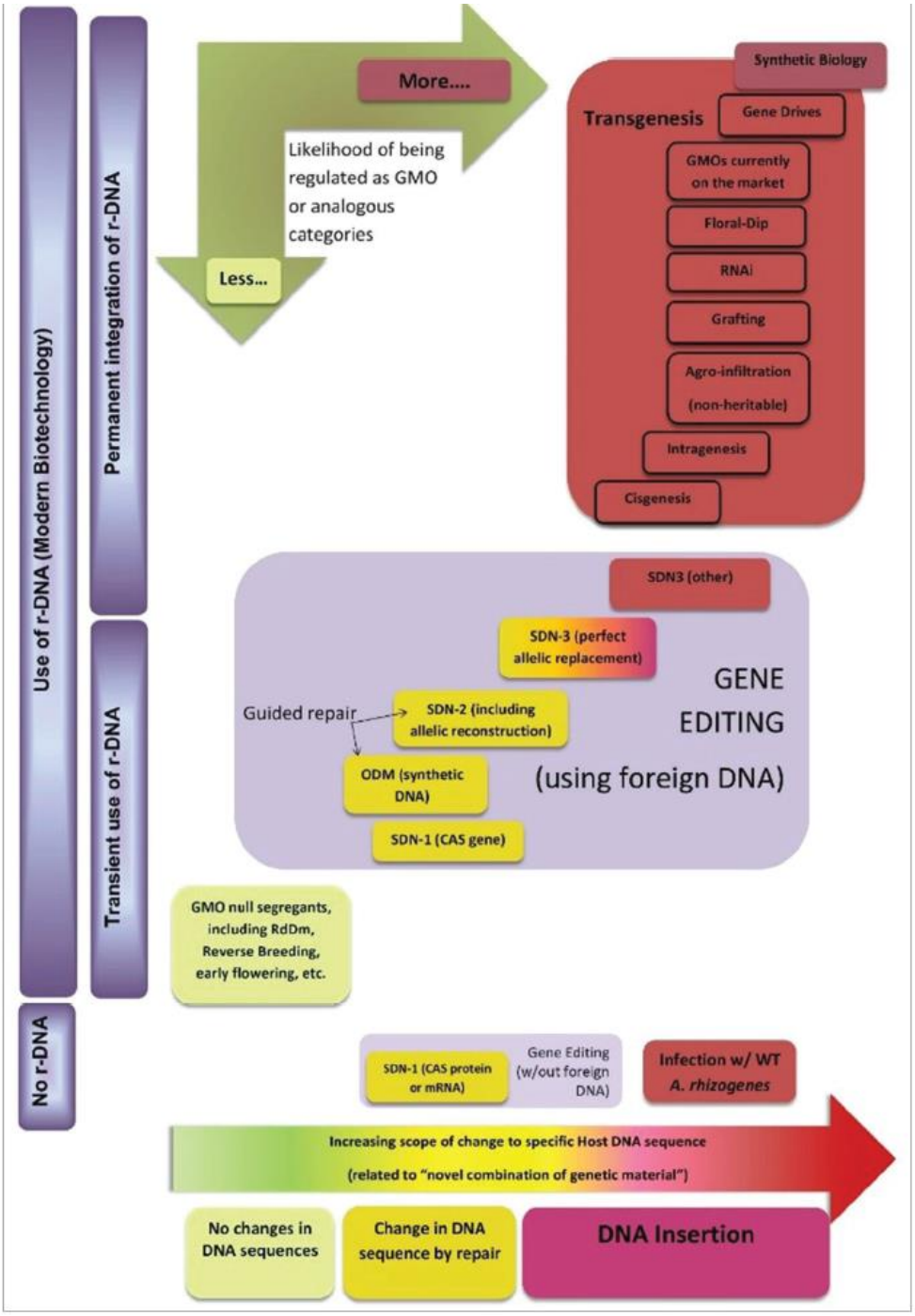

Fig. 3 Classification map of new breeding techniques for regulatory purposes. The authors would like to thank Dr. Huw Dylan Jones from Aberystwyth University for fruitful discussion during the elaboration of this diagram. See text for details. From Fig. 4 in ***Duensing, Sprink, et al. (2018)***

4. Outlook, insight in the complex regulatory debate on modern breeding

Recent papers demonstrate with detailed conclusions and comments about the Regulation of GM crops within Europe, that the scene of new ideas remains volatile: **Ammann (2017), Conko, Kershen, et al. (2016), Davison and Ammann (2017), Eriksson and Ammann (2017), Ricroch, Ammann, et al. (2016), Tagliabue, Ammann, et al. (2016)**, **Tagliabue and Ammann (2018), Tagliabue, Kuntz, et al. (2017)**. More interesting ideas and concepts on modern regulation have been published mainly by German and US authors: **Hokanson, Ellstrand, et al. (2018), Raybould, Kurtz, et al. (2012), Roberts, Devos, et al. (2014)**. And clearly, the European Union needs a national GMO opt-in mechanism: **Eriksson (2018B)**. In Europe, it is still the question, whether regulatory hurdles for genome editing should be process- or product-based approaches in different regulatory contexts: **Sprink, Eriksson, et al. (2016)**, although most authors lean towards a product-view. In the eyes of the author this question depends on the perspective of the treated crop regulation. The divide (dissent) among scientists often focuses to the regulation of Oligo-Mutations which lack in the final product "foreign" DNA, many follow the US decisions of not regulating those breeds, some, like the author, would like to see instead of such a rather theoretical molecular regulatory divide a *dynamically scalable regulation* as defined above, which includes also the Oligo-Mutations without foreign DNA, but with a minimum stretch of only 2-3 years of regulatory scrutiny – as described above. See also **Urnov, Ronald, et al. (2018)**, where all Gene Editing methods are excluded from regulation. A very detailed and important debate about the regulation of Gene Editing is given by Jeffrey Wolt 2017: **Wolt (2017)**, see above and remarks below:

Deciding on regulatory needs for 'Genome editing with engineered nucleases' (GEEN) it is not done with the simplistic distinction between products with or without foreign DNA, the questions on safety situation are more complex, the author agrees with Jeffrey Wolt, here his more detailed comments from 2017 (p.220ff). See figure 2 and 3 above.

One concern are the off-target effects claimed by opponents, they claim those effects are still not studied enough: **Jacobs, LaFayette, et al. (2015)**, Jeffrey Wolt's comments **Wolt (2017)**: Clearly, increased editing efficiency may still increase off-target mutations, further research will be needed. Specifically, Wolt cites the **National Academies of Sciences (2016)** emphasizing properly, that there is only limited opportunity of uncontrolled gene drive escape since domesticated crops and food animals are not competitive anymore with (the sexually incompatible) wild species, the probability of environmental establishment is low.

Recent papers, summarized in **Duensing, Sprink, et al. (2018)** confirm with scientifically established field data that the recently designed CRISPR organisms are safe.

A recent literature research on Gene Drive debates reveals that the previous concerns are overcome and the future of CRISPR is bright (or should be…): **Makarova, Wolf, et al. (2018), Schug, Urnauer, et al. (2019), Shin, Behura, et al. (2019), Smolenski (2019), Smyth (2018), Smyth, Kerr, et al. (2017), Strassheim and Schenkel (2018), Turgeman-Grott, Joseph, et al. (2019), Vieira (2018), Ward, Hemp, et al. (2018), Wilkins, Prowse, et al. (2018), Zannoni (2019)**

6. The unfortunate decision of the European Curia

The unfortunate decision of the Curia Europaea surprised many:

Hopes were real that the European Court would take a decision along those lines of analysis, as one of the closest experts like *Advocate General Michal Bobek* still in January 2018: (cited in the GAIN Report) **GAIN Report, Smith, et al. (20180116)**. Therein the Advocate General's legal opinion, considered as non-binding and advisory for the panel of judges who decide the case; but Bobek's opinion was nonetheless viewed as important in shaping the final determination.

The non-binding opinions of Advocate General Michal Bobek were published months before the Curia decision on January 18: **Bobek and Advocate General CURIA (20180118A), Bobek and Advocate General CURIA (20180118B)**

Abstract and conclusions from January 18 by Michal Bobek are crystal clear, unfortunately the expectations of Advocate General Michal Bobek's from January 2018 were nearly fully neglected by the Curia: Many scientists, breeders, and agri-food industry stakeholders had anticipated with him that Curia would categorize organisms derived from these newer mutagenic techniques as GMOs, but exempt them from the regulatory obligations in the Directive, as also their closest scientific Bubak expert (see above) anticipated.

Unfortunately, the European Court has decided otherwise – despite of having heard and read (but obviously not understood) many scientifically sound arguments of Bobek, the Court determined in **InfoCuria (20180725), InfoCuria (20180727)** that Gene Editing should be included without exception and differentiation into the existing EU regulatory law: On July 25, 2018, the Court of Justice of the European Union issued its judgment that organisms created through many newer genome editing techniques are to be regulated as genetically modified organisms (GMOs) in the EU. This decision subjects such organisms, and consequently also food and feed products containing these organisms, to an expensive and lengthy approval processes as well as traceability, labelling, and monitoring obligations. In addition to affecting global agricultural trade, this judgment has significant negative consequences for the EU breeding innovation and innovation in agricultural approaches.

Indeed, the Court (Curia Europaea) **InfoCuria (20180727)** issued in Luxembourg a judgment for the Case C-528/16 taking a very restrictive view of how the EU's main GMO legislation from 2001, **EU-Directive (20010312)** applies to organisms created by new plant breeding techniques such as CRISPR/Cas or Talen. The full preliminary text published from the Curia website in English, (see citation above with the link for the French version, which is the legally binding original text).
The main Curia statements from 1-4 you can read in **InfoCuria (20180727)** paragraph 25, points 1-4. The full text of the decision does not offer more relevant details: **InfoCuria (20180725)**

When you go to the original opinion paragraph 161 of the full paper of Bobek **Bobek and Advocate General CURIA (20180118B)**, such interpretation as above should be further-on discussed, see point 161, 162 and 163, evidently not cited or regarded as to be included in the final text by the InfoCuria full version **InfoCuria (20180725)**
Unfortunately, many scientists, breeders, and agri-food industry stakeholders (including the author) had wrongly anticipated that the Court would categorize organisms derived from these newer mutagenic techniques as GMO's, but exempt them from the strict, expensive and time-consuming regulatory obligations in the existing Directive.
Nevertheless: hope is still alive, that the EU commission will overturn or heavily revise this judgement, which is built on a restricted set of arguments of law and that the commission comes to a more tenable and scientifically solid solution.
Indeed, after a first shock we can view the court's decision more rational and hope that a detailed analysis will also lead the way out of the debacle. The search for new regulatory solutions should be influenced by the early critique of regulatory decisions taken within the Cartagena Protocol. **Ammann (2014) Chassy,**

Hlywka, et al. (2004), De Greef (2004), ENB-IISD-Cartagena-Negotiations (19990214-26), Gupta and Falkner (2006), McHughen (2006), Miller (20171012), Morris (2008), Nobs, Lamb, et al. (2003), Pythoud (2004), **Tagliabue (2018)**.

Already in an early statement of **Breyer, Herman, et al. (2009A)**, the authors make clear, that Oligo-Mutations (OMMs) not containing foreign DNA should be excluded from GM regulation, since the technique does not involve the introduction or integration of new genetic material, instead it alters chromosomal or episomal sequences in situ in their natural genetic background.

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The overwhelmingly negative reactions about the European court's decision were loud and clear, here only a small selection of letters, publications and official statements, most of them criticizing heavily the Court's decision, including some strong statements to keep certain CRISPR methods out of regulation even before the Curia decision was taken: **Bawden and Raines (20170102), BVL (20170228), Callaway (2016), Hackenbroch and Schmiedel (20171223), House of Commons (20170208), Miller (20171012), Scheufele and Peter (20170518), ScienceMediaCentre (20180725), transGEN and Fladung (20180530), White (20170831), Whitechurch (20171120)**

8 devastating opinions of major English scientific experts (from the John Innes Centre, the Earlham Institute, the University of Exeter, South Wales, the Sainsbury Laboratory and the British Society of Plant Breeders on the EU court's decision are published in the **ScienceMediaCentre (20180725)**. All experts deplore the negative impact of the decision on future plant breeding research and they leave no doubt that they hope for corrections in the final regulatory decisions.
Two of those experts have published also separately a clearly negative review of the Curia decision: **Hundleby and Harwood (2018)**, in the eyes of the author the best resumé on the problematics of an unfortunately persisting negative attitude towards modern breeding within Europe: They emphasize that it is time to acknowledge how the EU can better contribute to the long- term goal of global food security, by implementing fit- for- purpose regulation of improved crops.

Excellent comments and concrete proposals come also from **Purnhagen, Kok, et al. (2018)** in Nature Biotechnology: After heavily criticizing the Curia decision, the group of leading experts produces some important proposals for a sturdy correction of the present day regulatory system and proposals.

Depending on a host of societal and economic factors, meeting the interests of proper science AND of the public, without stifling innovations in the crop breeding sector: See also the publications of **Eriksson (2018A), Eriksson (2018B), Eriksson and Ammann (2017), Eriksson, de Andrade, et al. (2018)**.

Also **Urnov, Ronald, et al. (2018)** come to conclusions, that despite the Curia decision regulatory corrections are still possible, they say: "The CJEU ruling does not explicitly ban gene-edited crops. Instead, it categorizes them with transgenic plants and subjects them to such extensive risk evaluation that the cost of gaining approval could be borne by only the largest corporations. From a scientific perspective, this is, in plain terms, nonsensical: as explained above, thousands of crops produced with radiation carry a wealth of small genetic changes and are deemed safe. Why would a crop in which just one such change has been introduced by genome editing be regulated differently?". The author could not agree more…

7. Conclusions, possible solutions

The follow-up of many comments is summarized by Tagliabue and Ammann **Tagliabue and Ammann (2018)**, the abstract if giving the major thoughts, here summarized:

For the coming years it is suggested by Tagliabue and Ammann to follow along two work-avenues of regulatory development along the targets of a radical regulatory reform: Unfortunately, faulty concepts are frequent while debating crop regulation, "NBTs" as a term will hopefully lead to the disappearance of the term GMOs, heavily criticized in **Tagliabue (2015)**, beyond health and safety issues we should consider seriously socio-economic aspects, sustainability must be included in the regulation, but not as a killing, rather as a helpful argument of genetic engineering and finally, theoretical and legal EU texts must be included in the new legislative debates.

The author is not fully decided on whether Oligo-Mutations lacking in their final stage foreign DNA should be excluded from regulation, however, he rather leans towards a short-time (2-3 years) inclusion for regulation, since after all, this is still a product still based on a new, basically untested method, see the detailed debate under chapter 5.

The proposals of a regulatory follow-up of the author:

A: Quick mending of the most important legal text parts hindering a reasonable progress in modern agricultural breeding. If you read the full text of the new InfoCuria decision, you will discover that there is considerable space of interpretation and good reasoning for swift and small regulatory changes, but also it offers ample reasoning for a full revision of European (and worldwide) regulation of modern breeding.

B: Full revision of the GM crop regulation of Europe, this means a complete overhaul of the existing paragraphs, and also make some decisions to exempt selected GM crops already existing which are used without any problems since decades (this may be done already under A).
It should be adapted to international developments and come to a more pragmatic solution under full respect of safety issues. This will take more time, but not years as some suggest, a new European working group with an efficient timetable and some finances for the practicalities of the work (not for writing fees) will solve the problems less than 1 year to come.

Within both amendment pathways, it is of crucial importance that some text adaptations will allow also for *future, unexpected breeding developments*. As history of (Plant Breeding) Science has always told us, *we must reserve ample room for unexpected surprises in scientific progress*, **Brown (2019)** and **Norero (20180228)**. It is also important to build bridges between traditional and modern agriculture on all levels, **Ammann (2008), Ammann (2009)**. Equally of great importance is to decide on exclusion of certain well known and worldwide successfully spread classic transgenic crops from regulation, due to the ca. 20-years of positive experience of some traits spread on millions of hectares and cultivated over decades, this exclusion is already foreseen in the old regulatory system, but unfortunately it has never been applied.

8. Science as a cultural responsibility

It is high time to come from the usual factual dispute wars to a cultural perception of science on a higher level. We too often reduce the debate on modern Science on factual arguments, and we forget in a tragic way that true Science can only be founded in a broad and deep perception of culture. Lots of

reasons for the importance of social elements in the discourse on modern breeding are given in **Ammann, Papazova Ammann, et al. (2004 AND REV. 2017)**

I comprehensive summary of the present-day difficult situation comes from Philipp Aerni: **Aerni Philipp (2018)**. His introduction to the chapter 3 of the book edited by James HR. Jr. "Ethical Tensions from New Technology", the case of Agricultural Biotechnology comes in a deep-going analysis right to the point of all the falsehood of the present-day GMO debate, especially in Europe. Typically, concerns related to GMOs are often framed as an ethical rather than a scientific issue.

Another one of the profound texts analyzing the situation about Cultural Materialism in the Science debate comes from **Harris (2001)**: In his own words: "Cultural materialism is a non-Hegelian strategy whose epistemological assumptions are rooted in the philosophical traditions of David Hume and the British empiricists - assumptions that led to Darwin, Spencer, Tylor, Morgan, Frazer, Boas, and the birth of anthropology as an academic discipline." And: "Cultural materialists have idealistic motives just like everyone else. And as for sure, unselfish devotion to humankind, rightly or wrongly, a large segment of world opinion today ranks Marx as the equal or superior of Jesus Christ. Needless to say: the technical distinction between cultural materialism and idealism has nothing to do with such invidious comparisons. It refers exclusively to the problem of how one proposes to account for sociocultural differences and similarities. Despite the negative images the word "materialism" evokes, I would be intellectually dishonest not to use it."

And from another side, but the same view of an enlarged cultural dimension of the debate on GM crops comes from *Bruno Latour*, who until lately, was a strong defender that scientific facts should be seen as a mere product of scientific enquiry, and that facts are networked, they stood or fell not on the strength of their inherent veracity but on the strength of the institutions and practices that produced them and made them intelligible. If this network broke down, the facts would go with them. But in a notable interview with the New York Times, he made a major shift in his view of Science: **Kofman and Latour (20181025)**. It must have taken courage for Latour to meet with one who threatened his view, and to come to a more flexible concept, directly including social elements in the discourse.

It is promising to see the change of the basic Science debate, it is not anymore on facts alone, but involves all the important other fields of science, including social sciences and philosophy. This is where the ardent and seemingly ever-lasting GM crop debate must adopt a different basic view and attitude. The author of this text has long since advocated this kind of broader debate view: **Ammann (2007A), Ammann (2007B), Ammann (2012), Miller, Morandini, et al. (2008)**

There are also leading GM crop scientists who deal seriously with ethical thoughts of modern agricultural breeding: **Ricroch, Guillaume-Hofnung, et al. (2018)**: The decisive sentences: "We have then refocused on moral 'imperatives', such as freedom, justice and truth. Doing so does not resolve all conflicting views - but allows a gain in clarity in the sense that the ethical concerns are shifted from a technology (and its use) to the morality or amorality of various stakeholders of this debate."

And let us consider seriously the definition of Enlightement, as given by **Pinker (2018)**, a reminder which seems to be highly necessary in the times of growing blank materialism: Pinker insists that the *Principle of Enlightement* is not old-fashioned, rather it merits as the ideal of reason, science, humanism and progress a wholehearted defense.

Another aspect is the social discourse dynamics on how valuation can be influenced by ***pride,*** it has been studied by **Sznycer, Al-Shawaf, et al. (2017) .** Clearly, different cultures echo each other both in what are the reasons for pride and in what elicits positive evaluations, suggesting that the underlying valuation systems are universal.

As a caveat, the one-sided view of agricultural intensification can be seen in a critical way, especially when socio-economic aspects are left out or under-estimated, or, as here, not fully included in the statistics: **Rasmussen, Coolsaet, et al. (2018)**: Indeed, agricultural intensification rarely leads automatically to simultaneous positive ecosystem service and wellbeing outcomes.

A final word comes from Biljana Papazov Ammann in one of her contributions for the Bibliotheca Alexandria: **Papazov Ammann (2016)**. Indeed, "Biologists must see through the trick of confusing fear with unrest, and not succumb to it, or let themselves be sucked in. Why does this exchange-mechanism work in the confrontation between Science and Society? Because we can no longer approach scientific problems in a fragmented way." For more details and statements see her link: Call for Hope: https://youtu.be/19s8dEdD1eA with English subtitles.

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