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## *COMMENTARIES*

# Responsible decision-making for plant research and breeding innovations in the European Union

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**ABSTRACT.** Plant research and breeding has made substantial technical progress over the past few decades, indicating a potential for tremendous societal impact. Due to this potential, the development of policies and legislation on plant breeding and the technical progress should preferably involve all relevant stakeholders. However, we argue here that there is a substantial imbalance in the European Union (EU) regarding the influence of the various stakeholder groups on policy makers. We use evidence from three examples in order to show that the role of science is overlooked: 1) important delays in the decision process concerning the authorization of genetically modified (GM) maize events, 2) the significance attributed to non-scientific reasons in new legislation concerning the prohibition of GM events in EU member states, and 3) failure of the European Commission to deliver legal guidance to new plant breeding techniques despite sufficient scientific evidence and advisory reports. We attribute this imbalance to misinformation and misinterpretation of public perceptions and a disproportionate attention to single outlier reports, and we present ideas on how to establish a better stakeholder balance within this field.

**KEYWORDS.** plant research, breeding, innovation, RRI, European Union

Plant research and breeding benefits from substantial technical progress over the past few decades and has great potential for contributing to minimize the severe negative impacts of food insecurity and malnutrition, environmental degradation, climate change, and to reduce

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our dependence on non-renewable industrial raw materials. These technical advances may contribute to the transition towards a more bio-based, sustainable and prosperous society. Science has developed new techniques, which enrich the characteristics of agricultural production such as increased resistance to environmental changes. To fulfil the promises though, it is important that the EU regulatory framework enables plant research and breeding to deliver benefits to society in a safe and predictable manner. Given the potential for societal impact, it is also important that strategies for technology development and application are adequately anchored within all stakeholder groups. This is emphasized in the concept of Responsible Research and Innovation (RRI), which has gained increasing European Union (EU) policy relevance in the last few years, in particular within the European Commissiońs (EC) Science with and for Society (SwafS) funding programme;[1] "*Responsible Research and Innovation (RRI) implies that societal actors (researchers, citizens, policy makers, business, third sector organisations, etc.) work together during the whole research and innovation process in order to better align both the process and its outcomes with the values, needs and expectations of society.*"[2] There are still no standardized guidelines on how to implement RRI, However, it is important to ensure that there is an appropriate balance between diversity and representation in the inputs provided by the various stakeholder groups that may be involved in any particular case and the way these inputs are used in making policy proposals. We argue here that there is a persistent imbalance of stakeholder input that affects national decision makers and by extension the EU decision-making processes for plant research and breeding innovations. As a result, decisions can be driven by political interests and not scientific evidence. This imbalance is counterproductive to the attempts at developing a responsible governance of research and innovation as it allows for significant politicization of the decision-making processes. The imbalance is most notably expressed in the progressively diminished weight of scientific advice regarding modern plant research and breeding innovations over the past two decades,[3] to which we will present three examples.

## FIRST EXAMPLE: REGULATORY DELAYS FOR GM MAIZE

In a meeting on 27 January 2017,[4] the European Commission (EC) Standing Committee on Plants, Animals, Food and Feed – Section on Genetically Modified Food and Feed and Environmental Risk voted on draft regulations for the cultivation in the EU of two genetically modified (GM) insect-resistant maize events (Bt11 and 1507) and the renewal of one further event (MON810). The vote was the first of its kind, since a new legislation on national prohibition of GM crop cultivation came into force in 2015; Directive 2015/412.[5] The application for commercial cultivation of Bt11, developed by Syngenta Seeds, was first submitted in 1996 and the application for 1507, developed by Pioneer Hi-Bred, was first submitted in 2001. The European Food Safety Authority (EFSA) has repeatedly delivered scientific opinions concluding that these two maize cultivars are unlikely to have any adverse effects on human health or the environment. However, this was once again not acknowledged by the EU Member State representatives in the meeting on 27 Jan, when 13 of 28 (representing 33% of the EU-28 population) voted against authorization, 8 (representing 43% of the EU-28 population) voted in favour, and 7 (representing 24% of the EU-28 population) abstained, thus failing to obtain any qualified majority either for or against authorization. This voting pattern was also more or less repeated in the Appeal Committee for Genetically Modified Food and Feed and Environmental Risk on 27 March 2017. It is now up the EC to decide on authorization of these maize events, while being put under a lot of pressure bymany stakeholder groups. This situation has caused many of the seed companies to abandon their efforts to develop GM products for the EU market, as for example BASF announced in 2012.[6]

## SECOND EXAMPLE: THE GMO NATIONAL OPT-OUT DIRECTIVE

Only one GM event is currently authorized for commercial cultivation in the EU, the insect-resistant MON810 developed by Monsanto and approved in 1998. One more GM crop, the Amflora potato with improved industrial starch composition developed by BASF Plant Science, was authorized in 2010, however it has now been removed from the market. There is a persistent regulatory "gridlock" in the EU approval process for cultivation of GM crops, effectively blocking EU farmers´ access to these improved cultivars. Smart et al.[7] analyzed the voting behavior of EU Member States from 2003 to 2015 on the approval of GM crops and came to the conclusion that endogenous factors ("identity", such as political directions, public policies etc.) of the Member States played a larger role than crop characteristics or crop use, indicating that the voting behavior is fixed and not likely to change according to projected benefits of particular cultivars. In response to some EU Member States suggesting that the safeguard clause (Article 23) of Directive 2001/18 was not sufficient, the EC developed Directive 2015/412 (the "national opt-out Directive") amending Directive 2001/18 to allow Member States to restrict or prohibit cultivation of GMOs in their territory,[5] and so far 17 countries and two regions have implemented the opt-out mechanism provided by Directive 2015/412.[8] The votings in the EC Standing Committee on 27 January and in the Appeal Committee on 27 March demonstrated clearly though that many of these Member States keep voting against the authorisation of GM cultivation despite extended possibilities for national prohibitions, which was also foreseen by Smart et al.[7] What is most conspicuous is that Directive 2015/412 provides an official approval to bypass the scientific opinion delivered by the European Food Safety Authority (EFSA) and restrict or prohibit GM crop cultivation "*based on compelling grounds such as those related to: (a) environmental policy objectives; (b) town and country planning; (c) land use; (d) socioeconomic impacts; (e) avoidance of GMO presence in other products without prejudice to Article 26a; (f) agricultural policy objectives; (g) public policy.*"[5] This means that the imbalance in stakeholder input for plant breeding innovations is further exacerbated, to the detriment of science. Worth noting is also that the animal protein feed requirement in the EU depends to more than 70% on import of feed derived from GM crops, mostly soybean from South and North America.[9] There appears to be no compelling grounds against the import of products derived from these GM crops, however denying farmers in the EU access to these improved cultivars further indicates an imbalance in the stakeholder influence on the political decision-making process since the opinions of many important stakeholder groups, including farmers,[10] on these issues are not taken into account.

## THIRD EXAMPLE: LACK OF REGULATORY STATUS FOR EMERGING TECHNOLOGIES

Over the past decade, several so-called New Plant Breeding Techniques (NPBT) have been developed and implemented in research and breeding all over the world. These techniques include genome editing techniques such as site-directed nucleases (SDN) and oligonucleotide-directed mutagenesis (ODM), cisgenesis and intragenesis, RNA-dependent DNA methylation (RdDM), grafting, reverse breeding and agro-infiltration.[11] Despite being successfully applied already in other parts of the world, and despite plenty of advisory reports produced in the past five years by EU institutions, Member State national competent authorities, international scientific expert organisations, the private seed sector, and farming organisations, the regulatory status of these techniques is still uncertain in the EU. It is beyond the scope of this article to summarise all the reports that have been delivered, however the EC is clearly not short of advice on how to handle NPBTs. The regulatory delay for NPBTs that the EC is responsible for is not satisfactory and reinforces the imbalance of stakeholder input in the area of plant breeding innovations.

## REASONS FOR THE STAKEHOLDER IMBALANCE

Public engagement in research and innovation is desirable, though not always straight-forward to implement. Tait highlighted, amongst other issues, the problem that upstream engagement to some extent has provided certain activist groups with the means to further strengthen their influence on EU policy- and decision-making on GMO, while the voices of the general public are still not heard.[12] EC opened up for public consultation on GMO decisions in the early 2000s, which was essentially an appropriate democratic measure but which also opened up for PR-learned interest groups to lobby intensely on the policy makers.[13,14] The problem of recruitment bias[12] is apparent in these public consultations with uncommitted citizens unlikely to participate and those with an alternative agenda most likely overrepresented. One reason why the scientific community is not more visible in this context is the lack of funding for outreach activities towards the public or towards policy makers. Competition for research funding puts a strong pressure on scientists which means that little time is left for information to the public or policy advice.

It is commonly assumed that a majority of the general public in Europe is against GMOs, however there are also studies that indicate a slightly more sophisticated picture. A study with focus groups covering five EU Member States indicated that the public is neither "for" nor "against" GMOs, but instead discriminate between various types of GMOs as well as consider the context in which they have been developed.[15] Another study shows that other factors, such as price, also are important and that a sizeable minority of European consumers would buy GM food if offered.[16] This means that marketing decisions by food retailers, rather than consumer rejection, preserves the preexisting negative attitude to GMOs and that exposure to GM products may change the attitudes.[17] A meta-survey including 214 different studies also indicated both that the public discourse and opinions expressed by EU policy makers against biotechnology has led researchers in Europe to put more emphasis on riskiness and moral or ethical implications in their public surveys, which in turn has an influence on the responses, and also that, after correcting for this bias, no evidence could be found to sustain the claim that EU consumers in general are more reluctant to accept biotechnology in food products than in other regions.[18] The idea that consumers in the EU are strongly negative to GM products is persistent though, and is influencing the policy makers.

The question is then how policy makers and regulators can, within an RRI framework, take into account the large proportion of the public who may in the end be indifferent to which specific techniques have been used to develop a certain product but instead pay attention to other factors such as price, quality, nutrition, taste, environmental impact and other things? To have a truly representative and responsible governance of innovations, this needs to be accounted for as well. Another issue that needs to be properly addressed is whether or not the so-called deficit model (i.e. that people reject modern biotechnology because they do not have sufficient knowledge to understand it) is valid. It is a common assumption among many scientists and policymakers that when controversies over science occur, ignorance is at the root of public opposition.[19] It is beyond the scope of this article to discuss the merits of the deficit model, however the discussion above at least suggests that a "market exposure model" is also necessary to explain the situation in Europe today compared to e.g. USA.

An additional compromising factor for plant biotechnology is that isolated publications implying risks associated with GMOs often receive disproportionate attention and consequently have a large influence on public attitudes and political decision-making.[20] This is normally not how science works. The principle of science is that evidence and knowledge accumulate through a cautious and iterative challenging of consensus, and single, spectacular studies are ideally weighed against the entire body of accumulated research within a specific area.

## *ESTABLISHING A BETTER STAKEHOLDER BALANCE*

Political decision-making in a democratic society ideally takes into account the opinions of all relevant stakeholders including the civil society. It is particularly important that this works in a satisfactory way when it comes to innovations that are potentially disruptive in the sense that they hold potential for significant societal changes as well as challenge existing business models and/or regulatory frameworks.[21,22] We appreciate the importance of aligning political decisions with the needs and expectations of all societal actors, and therefore regret that scientific advice is often overlooked when it comes to plant breeding innovations. This will impede any efforts to develop responsible governance of innovations using these techniques, particularly since many stakeholder groups do support the evidence provided by scientists. It is also a problem that farmers who want access to these improved seeds[10] are denied the possibility.

The question is then how to create a social license to operate within the area of plant breeding innovations? A model has recently been proposed for forward-looking, multi-stakeholder discussions around the adoption of improved plant breeding techniques, including the establishment of a "technological baseline" and developing a quantitative discourse among all stakeholders about technical progress and its regulation.[23] The proposed model fits well into an RRI framework, however it is necessary to further outline the details and discuss how to put it into action. One thing that needs to be specified is where along the research and development chain (e.g. upstream, downstream) the input of a specific stakeholder is most relevant? It may not be taken for granted that an optimal model for responsible and democratic governance automatically means that all stakeholders should have an equally weighted influence at all stages; on the contrary, a dynamic and stakeholder-sensitive model may in some cases be preferred.

Another thing of relevance to responsible governance of plant research and breeding innovations would be to develop complementary legislation that would be the opposite of Directive 2015/412, i.e. to provide the possibility for individual EU Member States to *authorize* the cultivation of GMOs in their territory, rather than restrict or prohibit it. The decision-making process for GMOs was to some extent decentralized starting with the first GMO Directive in 1990,[24] whereas the oversight during the period 1998–2003 established a more centralized process.[20] Directive 2015/412 was a step towards re-nationalization of the decision-making process. Though it regrettably goes against the idea of a common market in the EU, the suggested "opt-in" mechanism would contribute to a better balance accounting for the opinions of all stakeholders at a national level. We believe it would also be compatible with the EU principle of subsidiarity.

Despite the imbalance of stakeholder input depicted here specifically for plant breeding innovations, there are nevertheless indications of a trend towards more formal scientific advice with an increasing number of scientific advisors at a national level as well as the recently established High Level Group of advisors to the EC Scientific Advisory Mechanism (SAM HLG).[25] To assist the EC in the process of developing the legal guidance on breeding techniques, SAM HLG was commissioned with preparing an explanatory note on NPBT.[26] The establishing of SAM HLG has also been followed by the establishment of SAPEA (Science Advice for Policy by European Academies) which is supported by Horizon 2020 and will enable five European Academy Networks to complement the core of SAM HLG which provides independent, scientific advice to the EC.[27] The outcome of these developments is now anticipated with cautious optimism.

## *DISCLOSURE OF INTEREST*

The authors declare no conflict of interest.

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