Elevating the conversation about GE crops

To the Editor:

In your December issue, L. Val Giddings and Henry Miller critiqued[1] the US National Academies report entitled *Genetically Engineered Crops: Experiences and Prospects*[2]. As authors of that report, we welcome further public discussion of its content. Here, we would like to point out to your readers core statements in Giddings and Miller's letter that misrepresent what we wrote, are factually incorrect, or favor an authoritarian role for science that we contend has proven counterproductive. Before we lay out our response, we would like to clarify the process by which we developed the report as we feel this may not be apparent to all your readers.

When we were first planning our study in 2014, it was obvious that we were addressing highly contentious issues. Some individuals and groups have long held the perspective that genetically engineered (GE) crops are safe but over-regulated, whereas others view them as risky and under-regulated. Even before our committee's first meeting, letters were sent to the US National Academies highly critical of our study[3,4]. Some saw no need for yet another study of what they consider a proven, safe technology, whereas others believed that our specific committee members would write a report biased in favor of GE crops and cropping systems. Meanwhile, much of the US public remained uncertain about the health, environmental, and socio-economic effects of GE crops[5]. This contentiousness and uncertainty made it even more critical for our committee to conduct the study in a careful and open manner, analyzing as much of the available information on GE crops and foods as possible.

The main charges to our committee from the US National Academies were to "assess the evidence for purported negative effects of GE crops and their accompanying technologies" and to "assess the evidence for purported benefits of GE crops and their accompanying technologies." We relied on many sources of evidence, especially the peer-reviewed literature from the past 20 years. When specific positive or negative evidence was strong, we pointed that out; when the evidence was weak we pointed that out as well. It should be noted that our 20-person committee, drawn from diverse fields of expertise, examined the evidence from many perspectives before coming to a consensus on the report's findings and recommendations. It is not surprising that our detailed conclusions, which are often crop-, trait-, and context-specific, do not sit well with those who want blanket approval or condemnation of all GE crops.

The US National Academies require that for all reports "efforts are made to solicit input from individuals who have been directly involved in, or who have special knowledge of, the problem under consideration." This mandate was especially important, given our committee's task. We held public meetings and webinars and heard from 80 speakers, ranging from representatives of non-governmental organizations (NGOs) that are critical of GE crops to leaders of multinational and small companies that are producing GE crops. These presentations are archived on our website (http://nas-sites.org/ge-crops/) and were a key source of information for our report. We also invited anyone to provide information to the committee through our website, receiving over 700 responses. All of this input helped our report address the issues of most importance to the public as well as directly involved individuals and groups.

The majority of our work involved carefully combing through the literature, focusing more on primary research studies than on reviews. Just for the three report chapters concerning currently commercialized GE crops, our report includes over 900 references. Once our committee developed a full draft of the report, it was sent to 26 reviewers with diverse expertise and perspectives (these reviewers were anonymous to the committee, until they were acknowledged in the final report). Each of the 918 comments and criticisms in the reviews had to be specifically addressed by the committee to the satisfaction of a US National Academies' independent review board before the report could move forward for the Academies' approval. Clearly, the report represented more than the opinions of the 20 committee members. Giddings and Miller's statement that the report's "unwillingness to overtly back GE crops, and the report's efforts to give credence to alternative viewpoints —rather like the media's obsession with giving two sides of an argument equal play, irrespective of which view is supported by the evidence" is, in effect, an uninformed indictment of the US National Academies' process.

Giddings and Miller also charge that we understate how much GE crops have contributed to yield increases, commenting that the report "muddies the debate about yields of GE crops compared with 'conventionally' bred crops, [and] gives undue credence and prominence to views backed by paltry peer-reviewed evidence." In fact, our report carefully states, based on all evidence available to us, that when there was substantial pest pressure, insect-resistance traits did have higher yields compared with conventionally bred crops. However, we also report that many of the early studies purporting to show yield increases due to GE herbicide-resistance and insect-resistance traits were not designed rigorously. Furthermore, we point out that there is less evidence of herbicide-resistance traits increasing yield. So why were these GE

crops adopted so quickly and widely? There are many reasons other than yield increase for farmer adoption of new agricultural technologies. From the literature and presentations to the committee by farmers and extension agents, it was clear that the rapid adoption of herbicide-resistance traits by US maize, cotton, and soybean farmers was mainly based on ease, flexibility and cost of production. Furthermore, in developing countries, there is some evidence that the use of insect-resistance traits in cotton in lieu of insecticides has improved farmer health.

One purported benefit of GE technology is that it accelerates the rate of yield increases and will enable us to feed a future world with billions more people. Historical data on US yields of maize, soybean, and cotton amassed by the US Department of Agriculture[6] show that yields for these crops have been increasing steadily for more than half a century. However, these same data show that the rate of increase has not changed since adoption of GE varieties in 1996. Giddings and Miller write that "the NAS report obfuscates the issue [of yield increase] in an odd way by focusing instead on the rate of change in the rate of yield increases with GE crops." Rather than being "odd", this trend analysis was included because of the claims of feeding the world, and was just one part of our analyses of yield increases.

The two major, currently commercialized GE crop traits—insect resistance and herbicide resistance—were mainly aimed at protecting crops from pests and making farming more efficient, not increasing potential yield. Importantly, two chapters in our report move beyond these current traits to focus on new GE technologies and new GE traits in the pipeline. In the future, we envisage a greater variety of traits for disease resistance and improved nutrient content being deployed in crops of importance to farmers in developed and developing countries. Longer-term investment in GE and conventional breeding also may produce crops with substantially higher potential yield and lower water and fertilizer requirements, although the report indicates that it is too early to make detailed predictions.

Giddings and Miller mistakenly allege that our report recommends that regulations specifically for GE crops should be more stringent. Our recommendation about future regulation was very clear: "In determining whether a new plant variety should be subject to a premarket government approval for health and environmental safety, regulators should focus on the extent to which the characteristics of the plant variety (both intended and unintended) are likely to pose a risk to health or the environment on the basis of the novelty of traits, the extent of uncertainty regarding the severity of potential harm, and the potential for exposure, *regardless of the process* [emphasis added] by which the novel plant variety was bred." For example, our approach does not differentiate a variety made resistant to a new herbicide through conventional or GE approaches.

To demonstrate the high cost of regulation, Giddings and Miller quote one study that estimated the average regulatory costs for a GE crop being at least $45 million, which they expect to be prohibitive to any group other than the "world's largest seed and agrochemical companies." We note that regulatory costs vary by trait–crop combination and country. Our report and a recent study of regulatory costs in a developing country[7] show that the regulatory costs for specific countries can be more than an order of magnitude less than $45 million. Indeed, some crop varieties developed with new gene editing methods are not regulated at all in the United States. We conclude that "regulation of GE crops inherently involves tradeoffs. It is necessary for biosafety and consumer confidence, but it also has economic and social costs that can slow innovation and deployment of beneficial products."

Giddings and Miller challenge our recommendation that omics methods could be used in the future to detect any intended or unintended changes in a new crop variety's characteristics. Although they state that according to the report omic "patterns in a new GE variety would be compared with a 'comparator', usually the parent of the new plant," our report specifically steers away from this comparison, and instead recommends comparisons "between the variety under consideration and a set of conventionally bred varieties that represent the range of genetic and phenotypic diversity in the species." We use the broad term "range of genetic and phenotypic diversity" for the comparison and make clear that the focus is not GE versus conventional. The report is in agreement with Giddings and Miller that more work needs to be done to develop omics databases and associated knowledge of crop genetics before these can be used as the backbone for a regulatory system. We conclude that investment in these rapidly developing technologies is worthwhile.

The authors also take our report to task for its recommendation that "governance authorities should actively seek public input on decisions, including decisions on how to approach emerging genetic-engineering technologies…and their regulation." The one study they reference to demonstrate that the approach we recommend is misguided is not about "agricultural biotech" and does not come to the conclusions that Giddings and Miller say it does. We refer readers instead to the highly cited 1996 Academies report *Understanding Risk: Informing Decisions in a Democratic Society*[8] that lays out the rationale as well as approaches for including diverse stakeholders.

With regard to our recommendation to seek public input, it is worth recalling a 1999 speech by the then US Secretary of Agriculture, Dan Glickman, who clearly made the point that "with all that biotechnology has to offer, it is nothing if it's not accepted. This boils down to a matter of trust. Trust in the science behind the process, but particularly trust in the regulatory process that ensures thorough review—including complete and open public involvement"[9]. The approach to governance endorsed by Giddings and Miller is unlikely to generate such trust.

The authors of "US National Academies report misses the mark"[1], and others who read our report in search of overt endorsement of one or another perspective on all GE crops, are likely to be disappointed by the report. We made many case-specific findings and recommendations in the report, and we tried to make the evidence and logic behind the specific conclusions accessible to the public by summarizing the comments/questions received by the committee from the public on our website http://nas-sites.org/ge-crops/2016/05/04/appendix-f/. Any reader can click on a specific question/comment and be taken to the place in the report where it is addressed. The reader can then decide if the rationale and data that we use fairly assess the issue. In our report, we used studies sponsored by academic institutions, governments, and companies. A recent Pew Research Center survey of US adults[10] found that 24% do not trust food industry leaders "at all" to give them "full and accurate information about the health risks and benefits of eating genetically modified foods." Therefore, we have a section on our website that, for each of the >900 studies referenced in the chapters on current GE crops, identifies the first author's job affiliation and who sponsored the research http://nas-sites.org/ge-crops/2016/05/02/references/. We think that most of our findings can be supported without reliance on the industry-sponsored research, but readers can decide for themselves. Finally, we knew we were bound to have made some errors and omissions in our 584-page report. In May 2016, we requested that readers of the report send us comments about errors that they found. Our website has a page http://nas-sites.org/ge-crops/2016/05/01/errata/ where we list

errors found in the prepublication version and the corrections.

We realize that only a small fraction of the public will take time to scrutinize our report, but we hope that those who do will use the evidence in the report to elevate the level of public conversation about GE crops, not simplify it.

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The authors declare competing financial interests: details are available in the online version of the paper.

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National Academies report has broad support

To the Editor:

Last December, the US National Academy of Sciences (NAS) Board of Agriculture and Natural Resources convened a Forum of Scientific Society Leaders on Genetically-Engineered Crops: Experiences and Prospects (http://dels.nas.edu/Upcoming-Event/Forum-Scientific-Society-Leaders/AUTO-5-80-52-G?bname=banr). Invited participants were representatives of professional scientific societies or other organizations with an interest in the science behind the agronomic, health, environmental, and socioeconomic implications of genetically engineered (GE) crops. They were asked to comment on the scientific validity of the findings and recommendations of the NAS GE crops report released in May 2016 (ref. 1) and to suggest future directions. The participants represented 17 major scientific societies and independent research organizations and thousands of scholars working on GE-crop-related research. Forum participants expressed general support for the majority of the report findings, offering a nuanced and appreciative view of its contents.

This contrasts markedly with the sharp critique of the same NAS report by L. Val Giddings and Henry Miller[2] published in your December issue. After reading their Correspondence, we wish to share our assessment of the NAS report with your readers. We represent a subset of Forum participants. Although our views have not been formally endorsed by all of our respective scientific societies, we represent a wealth of diverse scientific expertise and experience.

As a whole, our professional assessment is that the NAS report offers an extensive and authoritative review of peer-reviewed scientific literature on a wide range of topics related to the agronomic performance of GE crops, the social, economic, political, health, safety, and regulatory context that guides the trajectory of GE technological innovation, and the costs and benefits of these technologies. We broadly agree with key conclusions of the NAS report that:

- "…no differences have been found that implicate a higher risk to human health safety from these GE foods than from their non-GE counterparts" (p. 19);
- GE crops "have generally had favorable economic outcomes for producers who have adopted these crops, but there is high heterogeneity in outcomes" (p. 20);
- the ability of GE crops "to benefit intended stakeholders will depend on the social and economic contexts in which the technology is developed and diffused" (p. 22); and finally,
- the scientific evidence suggests that "it is the product, not the process, that should be regulated" (p. 26).

The NAS report notes that most of the extant peer-reviewed scientific research is focused on resistance to herbicides (mainly glyphosate) and resistance to insect pests (via *Bacillus-thuringiensis*-derived Cry proteins). We concur with the committee's conclusion that GE crops have been adopted on millions of hectares without the emergence of scientific evidence of serious health and environmental problems that were expected by early critics of the technology. At the same time, we applaud the report for not overstating what is known about potential short- and long-term health, environmental, and socioeconomic implications of emerging GE traits.

Giddings and Miller criticize the qualified language of the report because they were hoping for the NAS to "overtly back GE crops." But in our view, the more nuanced phrasing in the NAS report represents a balanced and objective reading of the peer-reviewed evidence.

The NAS committee reported that, on a national scale, rates of yield increases in maize, cotton, and soybean were the same before the advent of GE crops as afterward, concluding