Global expert survey reveals how regulation can help or hurt crop gene-editing innovation

The adoption of genome editing depends among others, on a clear and navigable regulatory framework that renders consistent decisions. Some countries like the United States decided to deregulate specific transgene-free genome edited products that could be created through traditional breeding and are not considered to be plant pests, while others are still challenged to fit emerging technologies in their regulatory system.

Here we poll international experts in plant biotechnology on what approach should nations agree upon to accommodate current and future new breeding technologies and derived products. A key finding is product-based models or dual-product/process systems are viewed as potential appropriate frameworks to regulate outcomes of genome editing. As regulation of novel products of biotechnology is expected to impact research and trade, we test the impact of experts' worldviews on these issues. Results show that region influences worldviews of trade but not of agricultural innovation. In contrast, there was no effect of experts' worldviews on how products of novel biotechnologies should be regulated.

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The survey was completed by 113 participants, resulting in a response rate of 23.6%. The panel is dominated by males (80%), aged between 45 and 65 years (70%). Forty-one of the participants reside in North America (NA), 34% in Europe, and 25% are from the rest of the world (ROW: 5% in Africa, 5 % in Asia, 6% in Oceania and 9% in Central and South Americas).

The majority of respondents hold a PhD degree (71%) and 20% have a masters' degree. Forty percent work for industry, 26% for a university, and 20% in government. Seventy-one percent identified themselves as scientific experts, and 29% as social experts (lawyers, agribusiness professionals, etc.). When asked about their frequency of engagement in regulatory activities, 44% reported they are often or almost always engaged during the course of their work, 46% are occasionally involved (Sometimes: 28%, Rarely: 18%) and 10% are almost never involved in such tasks. Engaging in regulatory activities include providing input data (24%) and/or input analysis (32%), contributing to decision-making (25%) and rule-making (15%).

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For many participants, the outcome of a technology (either crop type or end-product) matters the most for farmers and consumers as it is the use that determines how risky or valuable a new trait actually is. Experts generally agree that the final product—regardless of how it is developed—can generate potential risks. Experts further agree that each trait should be comprehensively characterized, including its social impact, ethical considerations and sustainability One justification is that the process-based system may be unable to keep pace with emerging technologies. One view is that a product-based safety assessment is the "only scientifically valid approach".

One respondent stated that: “Focusing on the process, in transgenesis, has led to bad decision-making, especially in Europe, and groundless fears in parts of the general public.” Another added: “The process can be performed under controlled settings and thus any risk mitigated at the site of execution of the process. Products are released to the public… it makes most sense to regulate what reaches the public.” According to one expert, a product-based approach would help overcome the problem of defining a GMO, debates around novel crops, and thus consumer acceptance and understanding of the technology.

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Our expert survey reveals that there is an emerging consensus that the regulatory processes need to innovate to address the challenges resulting from new technical opportunities. Our finding that experts operating in their professional capacity in the context of research and innovation can, and do, find middle ground is positive.

The challenge will be to reconcile any resulting consensus with the divergent views held based on where one lives. Experts think the key to realizing genome editing’s potential is in regulatory transparency and open dialogue but the notion that an open dialogue with society on genome editing will lead to greater understanding needs to be validated, as recent structured dialogues have not led to greater acceptance or use.

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