



American Society of Plant Biologists

Cultivating a better future through plant biology research.

Response to FDA-2015-N-3403: Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology and Developing a Long-Term Strategy for the Regulation of the Products of Biotechnology; Request for Information

Response:

Periodic review of the regulatory regime governing the use of biotechnology products is an important aspect of public safety and confidence in the process. The 1992 OSTP update to the 1986 Coordinated Framework established a risk-based, scientifically sound basis for the oversight of introducing biotechnology products into the environment. The update affirmed that Federal oversight should focus on the characteristics of the product, the environment into which it is being introduced, and the intended use of the product, rather than the process by which the product is created. In the absence of any credible evidence to indicate that the process itself introduces risks, the American Society of Plant Biologists (ASPB) continues to fully support the 1992 policy.

It is the view of ASPB that this risk-based assessment focused on the product rather than the process has effectively protected all parties. The nature of this process, however, has had the unintended consequence of greatly reducing public sector participation. Current regulatory practices, while thorough, are costly for developers of products to meet and limit significant participation to large companies. The current regulatory structure has had a chilling effect on innovation from start-up, small and medium-sized companies as well as public and non-profit research institutions. The inadvertent effect of the current regulatory system has been to consolidate biotechnology products within a small number of major companies. High costs have resulted in a focus on a few high-value agronomic traits that do not directly benefit consumers. This focus has in large part alienated consumers who feel that they bear all of the risks with none of the benefits of the technology. Furthermore, consumers observe, and often, dislike, any oligarchical control of technology and products. Any modification in the current system should factor in the costs and the impacts on small business and public sector product development.

It is essential that any future evaluation system be process independent. We are on the verge of a major shift to precision engineering of plant genomes. New genome editing technologies precisely alter the specific sequence of one or a few of the billions of nucleotides making up a plant's DNA. Less precise technologies (mutation breeding) have existed for many decades, are unregulated, and the products of that labor are widely used in modern agriculture. The emerging techniques are more precise methods to change plant traits, and should revolutionize plant breeding. It is critical that genome editing be viewed in this context and not burdened with new regulatory requirements; a process-independent evaluation of new varieties is essential. The focus should be on traits and phenotypes, and not methods to achieve phenotypes.

The current regulatory system relies upon approval from one to three federal agencies, depending on whether the product can be considered to be a “pesticide” (EPA) and/or used for drugs, feed, or food

(FDA). The system relies upon the complementary expertise of the relevant agencies. While inter-agency coordination can be challenging and result in unintended delays, the system is built upon existing strengths and, in theory, is commendable. USDA is responsible for the evaluation of plant management, particularly as related to weediness, ability to outcross with wild species and spread through the environment. FDA is responsible for possible issues related to human health safety. EPA is responsible for assessing impacts of the introduced plant either as a pesticidal agent or with respect to use of pesticides, when appropriate. There is potential overlap in coverage, particularly between USDA and EPA. The current system of independent review is time-consuming and at least partially redundant. Furthermore, developers of products sometimes cannot easily ascertain whether potential products would be subject to regulations. One suggested change to the system is to establish interagency task forces, assembled as needed for the individual product assessment, charged with working as a unit to approve or disapprove a potential product.

Since the first introduction of biotechnology-derived plant products, not a single documented issue with regard to human safety has arisen. From the human health perspective, the current system has proven to be effective. There can be no question that concerning human health, the current system has worked effectively for over two decades. There is a case to be made that regulatory barriers are too high and the current one-size-fits-all model does not serve the public good.

There have been periodic concerns raised about the widespread use of biotechnology-derived products and their impacts on flora and fauna. For example, a scientific report in the early 2000's regarding impacts on monarch butterflies led to a re-evaluation of the use of plants expressing the *Bacillus thuringiensis* insecticidal protein. Extensive work by many independent academic researchers showed that the original concerns were not justified. Currently, there is extensive discussion surrounding the issue of weeds evolving resistance to commonly used herbicides, especially glyphosate. It is our view that a vigorous scientific discourse within and between the public, private and federal sectors on such issues is vital.