

USDA reveals plans to regulate GM plants based on traits, not breeding method



USDA's Sid Abel and Doug McKalip just briefed me on the new regulatory framework that is shaping up for the oversight of plants modified by what they are now calling "plant breeding innovations." These include the much-touted CRISPR/Cas-based [gene editing](#), as well as other new approaches to the modification of plants' genetic material.

I could barely believe what I was hearing. So here goes.....

To begin with, as [announced](#) in late March by USDA Secretary Perdue, the agency does not and will not regulate plants that could have been developed using what are now considered "traditional" methods of genetic modification. I drilled down a bit, since I know what kinds of things happen when plants are subjected to such "traditional" methods of genetic modification as radiation and chemical mutagenesis. These include breaks in the DNA, the repairs of which are often a bit untidy, resulting in small insertions and deletions (elided into "indels"), in addition to single base changes. And yes, they intend to exclude such minor changes from regulation.

It's worth mentioning here that such DNA sequence changes occur all the time in all organisms – they're the stuff of evolution. 20th century scientists figured out how to increase the frequency of such genetic changes using chemical and radiation mutagenesis. This was a very widely used strategy in 20th century plant breeding. So widely used that half or more of the food crops grown today (including organic crops) have such a mutagenesis step in their pedigrees. Mutagenized plants and seeds are grown in untold millions and examined for useful genetic changes, aka mutations. These techniques for genetic modification were not, and are not, regulated.

It is also perhaps worth mentioning that artificially induced mutations are indistinguishable from naturally occurring mutations at the DNA sequence level. They are also indistinguishable from the genetic changes produced by the newer methods, such as CRISPR/Cas-based gene editing. New plant varieties produced using chemical and radiation mutagenesis have never been regulated. Nor have they produced either human and animal health or agricultural disasters. So is quite sensible not to regulate new plant varieties with the same kinds of mutations produced by the newer, more specific techniques.

The indistinguishability of genetic changes made by nature, 20th century mutagenesis and 21st century gene editing highlights the absurdity of regulating genetic modification based on the process used, as the Court of Justice of the European Union (CJEU) [ruled](#) in July of 2018. Specifically, the CJEU ruled that gene-edited organisms must be regulated, assessed for their health and environmental impacts, and labeled because they constitute genetically modified organisms (GMOs) under the original directive.

But I digress. There's more good news....

USDA plans to confine its regulatory oversight to organisms that might actually damage agriculture, as specified under the [Plant Protection Act](#) (PPA). If the organism is neither a weed nor a plant pest, it does not come under the jurisdiction of the PPA. And it won't be subject to regulation. But even if it is a plant pest or weed, the proposal is to issue permits that will allow developers to proceed to commercialization,

even as the USDA regulators determine whether the modification might increase the organism's potential to harm agriculture.

This is a really important change. The decision will be based on the actual properties of the organism and the small number of traits that could be problematic, not on the method by which the trait was introduced. And new instances (previously called "events") of organism/trait combinations that have already passed through the regulatory process will not have to do it again.

Yes, there are some fine points yet to be worked out. When the proposed regulations are published for comment, probably early next year, there will be a good bit of controversy. And of course this puts US policy at odds with the biotechnology regulatory policies of a number of other countries.

But the fact of the matter is that we are now able to modify plants with exquisite precision to make use of the enormous fund of molecular and physiological knowledge about them accumulated over the past century. Taking apart the regulatory thicket will make it possible for scientists in all kinds of institutions and not just big biotech companies to use the most advanced molecular techniques to solve the many local agricultural problems that are becoming ever more acute as the climate warms and agriculture intensifies.

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This article was originally published at AgriPulse as [Opinion: Trait-based regulation of GM plants is on the horizon – at last!](#) and has been republished here with permission.