Will White House review of biotech regulation lead to expanded or streamlined rules?

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The Obama administration recently announced an ambitious White House initiative to update the 30-year-old Coordinated Framework for the regulation of Biotechnology. (Disclosure: the coauthor of this article, John Cohrssen, was legal counsel to the White House working group that developed and implemented the 1986 Coordinated Framework.) The White House has directed the three regulatory agencies with biotechnology oversight — the EPA, FDA, and USDA — to update the Framework and develop a long-term strategy to ensure that the regulatory system is prepared for the future products of biotechnology, using a newly commissioned expert analysis of the biotechnology landscape.

By creating an environment that is friendly to biotechnology and the commercialization of products, the Obama White House has a unique opportunity to reduce the regulatory obstacles to continued U.S. advances in agriculture. . . Clearly, reforms are needed to make regulation scientifically defensible and risk-based, and to ensure that it provides acceptable cost-benefit.

As a practical matter, this means that to the extent appropriate, products of biotechnology should be regulated no more stringently than products developed by older and less precise manufacturing processes.

Twenty years of continuing White House and regulatory agencies' disregard of the Coordinated Framework and "scope" policies have led to the unnecessary, anti-competitive obstacles to U.S. agricultural applications of biotechnology that the Obama White House now supposedly seeks to address. In order to rationalize regulation, we need to return to a scope of regulation that is based on scientific evidence of an unreasonable risk — the overarching principle adopted by the White House to prevent unnecessary regulatory burdens in the first place.

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