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United States Environmental Protection Agency
Via: https://www.regulations.gov/docket?D=EPA-HQ-OPP-2014-0293

This letter provides comments on Docket EPA-HQ-OPP-2014-0293, due on June 2, 2017. The subject matter is the proposed registration of an RNAi-based plant-incorporated protectant aimed at controlling corn rootworm and other lepidopteran pests on corn. ITIF believes that facts laid out by the EPA support a normal product registration, without the proposed five-year limitation.

EPA evaluates an extensive list of potential hazards that public commenters have suggested might be associated with this new product and others similar. But the EPA's analysis overlooks some facts about the fundamental biology involved.

RNAi is a phenomenon that is widespread in nature, if not ubiquitous, and it appears to have ancient evolutionary origins.[1] Its characteristics are documented in an abundant body of scientific knowledge and literature, and it was the subject of the 2006 Nobel Prize in Physiology or Medicine.[2] The value of RNAi technology in solving a variety of problems in agriculture, biomedicine, and other spheres is substantial and growing. Nothing in this broad and deep body of knowledge suggests the existence of hazards unique to products of this technology, as has been exhaustively and repeatedly demonstrated with respect to other biotechnology innovations in recent decades.[3] Special scrutiny or restrictive regulatory constraints are therefore not supported by science, and cannot be justified under existing U.S. policy governing the regulation of biotechnology products, which stipulates that management be aimed at avoiding "unreasonable risks."[4]

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[1] Heriberto Cerutti and J. Armando Casas-Mollano, "On the Origin and Functions of RNA-Mediated Silencing: From Protists to Man," *Current Genetics*, 50 (2) (2006): 81-99. DOI: 10.1007/s00294-006-0078-x.
[2] "All Nobel Prizes," Nobel Prize, accessed May 30, 2017, https://www.nobelprize.org/nobel_prizes/lists/all.
[3] U.S. National Academies of Science, Engineering and Medicine, *Genetically Engineered Crops: Experiences and Prospects* (Washington, DC: 2016), https://www.nap.edu/catalog/23395/genetically-engineered-crops-experiences-and-prospects.
[4] Office of Science and Technology Policy (OSTP), The White House, "National Bioeconomy Blueprint," (Washington, DC: April 2012), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/national_bioeconomy_blueprint_april_2012.pdf; Robbie Barbero et al., "Increasing the Transparency, Coordination, and Predictability of the Biotechnology Regulatory

In a departure from long-established U.S. policy aimed at the prevention of unreasonable risks, EPA nonetheless is proposing a conditional approval to this particular RNAi corn product with no hypothesis of risk. Three "unresolved issues" are cited as justification for these limitations: 1) an assertion that there needs to be further examination of the extent to which dsRNA accumulates in soils; 2) an assertion of need to show how dsRNA in plant tissues degrades in water; and 3) an assertion of need for an easy assay for this dsRNA to help in resistance management.

None of these assertions of need is supported by any explanation of a credible (or other) risk hypothesis (remembering that risk equals exposure to a hazard, and in this case no hazard is identified). In the absence of any identified hazard, real or hypothetical, there is no credible basis for asserting the existence of any risk, much less an unreasonable risk of the sort EPA is bound by longstanding policy to address. EPA's history of ignoring this risk-based objective underlying U.S. policy has impeded or discouraged entire fields of innovation, such as anti-microbial technologies and algal biofuels. Treating virus- and plant-derived genes as pesticides has severely hampered the development of biotech approaches to disease-resistant plants, directly causing prolonged reliance on the use of topical fungicides and pesticides, the environmental impact of which is opposite of what EPA should be trying to achieve.

While regulators apparently believe it would be "nice to know" the answers to the unknowns they have identified, they have not articulated any way in which, in the absence of any plausible risk, that information might be helpful in informing risk-management actions aimed at mitigating unreasonable risk, as U.S. regulatory policy requires. The proposed limitations should therefore be set aside, and unless EPA can articulate a compelling justification for the kind of premarket regulatory clearance such as they are here imposing, RNAi applications not associated with any credible hypothesis of risk should be exempted from any registration requirement.

Thank you for the opportunity to comment.

Sincerely,

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System," *The White House Blog*, January 4, 2017, https://obamawhitehouse.archives.gov/blog/2017/01/04/increasing-transparency-coordination-and-predictability-biotechnology-regulatory.