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Trump USDA and FDA Spar Over Regulation of Genetically Engineered Animals – Does This Sideshow Have Any Actual Implications for Regulatory Policy?

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At the outset of the Biden Administration it is clear that there will be a sharp pivot in the Federal Government's approach to many environmental regulatory policies. One area that will be interesting to keep track of regulation of agricultural biotechnology (ag biotech). As previously discussed, efforts to modernize the U.S. regulatory system applicable to ag biotech was one of the few areas of environmental regulation and policy that saw a consistent approach between the Obama and Trump Administrations. In fact, Executive Order 13874, Modernizing the Regulatory Framework for Agricultural Biotechnology, could be viewed as a direct outgrowth of the Update to the Coordinated Framework that was issued by President Obama's Administration in January 2017.

USDA and EPA both took affirmative actions to implement the mandate of Executive Order 13874. USDA, which overcame a history of incomplete attempts stretching back over a decade, finally in 2020 promulgated amendments to the 7 C.F.R. Part 340 regulations that govern the movement of genetically engineered organisms that are or may be plant pests, and EPA published for comment a proposal to implement an exemption from FIFRA regulation for genetically engineered plant-incorporated protectants that are developed using genetic material from sexually compatible plants. With respect to genetically engineered animals, in 2017 FDA had released Guidance for Industry #236, which had the effect of transferring to EPA

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regulatory jurisdiction over mosquitoes genetically engineered to effectuate mosquito population reductions, and in 2019 FDA lifted the "import alert" on the genetically engineered AquaAdvantage salmon.

With these efforts to update and improve the Federal regulatory approach to ag biotech providing context, in late December 2020, USDA published an Advance Notice of Proposed Rulemaking that sought comments on the concept of transitioning regulatory authority for certain genetically engineered animals from FDA to USDA. As described in the USDA ANPRM, regulatory jurisdiction for certain agricultural animals produced using genetic engineering would be transitioned from FDA, which currently regulates intentional genomic alterations in animals as animal drugs under the Federal Food, Drug, and Cosmetic Act (FFDCA), to USDA, which would regulate these GE animals under the Animal Health Protection Act (AHPA), the Federal Meat Inspection Act (FMIA), and the Poultry Products Inspection Act (PPIA). USDA opened a 60-day comment period for the public to weigh in on the concepts discussed in its ANPRM.

Apparently not content to merely take comments on the concept of transitioning regulatory authority over certain GE agricultural animals from FDA to USDA, on the day before President Biden's inauguration, USDA released a "Memorandum of Understanding" (MOU) in which it was purported that USDA and FDA had agreed to formalize policies wherein the two agencies would take steps to effectuate the transition of regulatory authority over certain GE animals by (1) USDA developing a new regulatory apparatus and (2) FDA ceding "portions" of its current animal biotechnology regulatory oversight to USDA. In what was immediately noted by observers as an odd twist, the MOU was not signed by FDA, but, rather, by Brett Girior, Assistant Secretary for Health in HHS. Then-FDA Commissioner Stephen Hahn, however, immediately made clear that the MOU did not have the backing of FDA.

So, what are the implications of these actions for oversight of ag biotech going forward?

First, completed regulatory actions are final and cannot be overturned by the new Administration absent initiation of a new regulatory process. Thus, the amended Part 340 regulations will continue to be implemented by USDA.

Second, regulatory actions that were not completed at the close of the last administration may be altered or withdrawn by the new Administration. Therefore, EPA's proposed PIPS exemption may be delayed or withdrawn altogether (or, the new Administration could review the comments and decide to go forward with it).

Third, USDA's GE animal ANPRM does not have any procedural weight under the Administrative Procedure Act and may never see the light of day or be heard of again.

Finally, the purported USDA-FDA "MOU" also has no legal significance absent a decision by the Biden Administration to accept its terms. The USDA MOU was an agreement by political appointees in USDA and HHS. New political appointees in USDA and HHS can just as easily disavow that agreement. Moreover, given the strong objections to the MOU that were voiced by then-Commissioner Hahn, which likely reflect the feelings of FDA staff, the MOU may very well not be supported by the Biden Administration – at least not

without further process and buy-in by FDA.

That being said, the issue of how GE animals that are the subject of the MOU should be regulated is a critical issue. USDA has revised and updated its regulatory approach to GE organisms under its authority; EPA has proposed to take a first step in revising and updating its regulatory approach to GE plants under its authority. It is altogether reasonable that FDA and USDA should act together to revise and update the regulatory approach to GE agricultural animals. As FDA and EPA determined in the context of GE mosquitoes intended to suppress pest mosquito populations, regulating the genetic alterations as animal drugs under the FFDCA is not an efficient or effective means of regulating these organisms. Similarly, regulating as animal drugs genetic alterations in agricultural animals that are intended to alter their production value or the composition of food tissue also is not efficient or effective. Hopefully, last week's MOU kerfuffle will not delay or derail necessary updating of the regulatory approach to GE agricultural animals in the United States. (For a discussion of a recently initiated effort by the UK to update its regulatory approach to GE organisms see this blog post.