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ALERT

USDA Announces ANPRM on a Transition of Regulatory Jurisdiction Over Certain Genetically Engineered Animals

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As the U.S. regulatory agencies responsible for oversight of agricultural biotechnology strive to evolve the regulatory framework applicable to such products, the U.S. Department of Agriculture (USDA) continues to lead the way in taking steps to ensure implementation of science-based, evidence-based, risk-based safety reviews of the products of ag biotech. On December 21, 2020, USDA announced that it will publish an advanced notice of proposed rulemaking (ANPRM) that will discuss and seek comment on the notion of transitioning jurisdiction over the safety reviews of certain agricultural animals produced by genetic engineering from FDA to USDA.

With its ANPRM, USDA is seeking public comment on the notion of transitioning regulatory jurisdiction over certain agricultural animals (e.g., catfish, cattle, equines (including horses and mules), goats, hogs and pigs, poultry, and sheep) that are developed using genetic engineering (the ANPRM defines "genetic engineering", consistent with 7 C.F.R. § 340.3, as "techniques that use recombinant, synthesized, or amplified nucleic acids to modify or create a genome"). The ANPRM discusses clarification of regulatory jurisdiction such that USDA would regulate certain agricultural animals produced using genetic engineering through its authorities under the Animal Health Protection Act (AHPA), the Federal Meat Inspection Act (FMIA), and the Poultry Products Inspection Act (PPIA). (As is typical in regulatory matters involving the Coordinated Framework, the sets of animals that are regulated by USDA under the three statutes are not the same; therefore, the ANPRM discusses a Venn diagram approach

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to the subset of genetically engineered agricultural animals that it contemplates would be regulated by USDA under the new regulatory scheme.) Currently, the Food and Drug Administration (FDA) regulates intentional genomic alterations in animals as animal drugs under the Federal Food, Drug, and Cosmetic Act (FFDCA). This is a regulatory accommodation that arose as a result of the haphazard and disjunct manner in which the regulation of agricultural biotechnology initially developed under the Coordinated Framework. Gradually, under the Obama and Trump Administrations modernizing of the Coordinated Framework, FDA is ceding regulatory authority over genetic alterations that are not, in any reasonable understanding of the science, animal drugs. (See, for example, *FDA's Guidance for Industry #236, Clarification of FDA and EPA Jurisdiction Over Mosquito-Related Products*," which ceded to EPA regulatory authority over mosquitoes that are genetically engineered to effectuate suppression of mosquito populations.) While FDA should be commended for originally stepping into these biotechnology regulatory voids using its authority under FFDCA, it clearly would be a more rational approach to regulate certain GE agricultural animals using USDA's authorities to regulate food and animal safety (with coordinate regulation by EPA where genetic alterations are intended to prevent, destroy, repel, or mitigate a pest). The ANPRM discusses a process whereby USDA would promulgate the necessary regulations, and FDA and USDA would clarify their respective regulatory jurisdiction over GE animals via a Memorandum of Understanding.

The ANPRM invites questions on all aspects of the topics discussed, and includes a number of detailed requests for comment on specific issues. Dealing with ANPRMs is tricky. An ANPRM is not subject to the requirements of the APA; therefore, an agency does not have an obligation to respond to comments or, in fact, to do anything at all with the ANPRM. Notwithstanding, if an agency publishes an ANPRM on a matter that it seriously intends to move forward on, that can constitute an excellent opportunity to raise issues and influence the agency's thinking as it develops an actual Notice of Proposed Rulemaking. In the context of this ANPRM, that may be more true than is typically the case. The pre-publication version of the ANPRM states that it will be open for a 60-day comment period from the time that it publishes in the *Federal Register*. Of course, this means that the entirety of the effort to address the proposed jurisdictional transition discussed in the ANPRM will fall to the Biden Administration. That would include evaluating comments submitted on the ANPRM, developing an NPRM that explains and provides justification for the proposed transition of regulatory authority, evaluating comments on the NPRM, and developing a final rule to effectuate the reassignment/clarification of regulatory authority. It, of course, remains to be seen what will be the Biden Administration's approach to ag biotech; however, given the consistency of approach to the evolving ag biotech regulatory structure by both the Obama and Trump Administrations, it would not be surprising if the Biden Administration also continued the evolution of a more science-based, evidence-based, and risk-based approach to regulation of ag biotech – including genetically engineered animals. It would behoove stakeholders that would support such consistency of regulatory approach to submit detailed comments that would assist USDA in developing such an NPRM.

As with all opportunities to provide comments on Federal agency proposals, it is important to submit concise, substantive, and well-supported and well-documented comments to the administrative docket. In this case, given the trans-Administrations nature of the action, it is important that interested stakeholders use this opportunity to best advantage to urge the Biden Administration to continue a 21st Century approach to

regulating ag biotech.

Wiley attorney Keith A. Matthews (former Director of EPA's Biopesticides and Pollution Prevention Division) is particularly well positioned to assist stakeholders in developing comments on USDA's ANPRM regarding GE animal regulatory jurisdiction. Should you have any questions on the history and/or legal bases for USDA's action, or any other issues concerning the regulation of ag biotech, please contact Keith at kmatthews@wiley.law. Keith will discuss USDA's GE animal ANPRM in an upcoming session of Wiley's 2021 Biotech Briefings, a series of webinars, podcasts, and interviews discussing new developments in biotechnology regulation.