

MEMORANDUM

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Re: FDA and USDA Announce Agreement on Cooperation and Coordination

U.S. Food and Drug Administration (FDA) Commissioner Scott Gottlieb, M.D., and U.S. Department of Agriculture (USDA) Secretary Sonny Perdue announced a formal agreement on January 30, 2018, intended to increase coordination and collaboration between the two agencies. ^{1/} The high-level agreement is limited on details, but includes commitments to developing interagency working groups for the following three “issues of shared concern.”

- **Dual-Jurisdiction Food Facilities:** The agreement states that FDA and USDA share the goal of streamlining oversight of dual-jurisdiction facilities by identifying and potentially reducing the number dual-jurisdiction facilities. The agencies also aim to bring greater clarity and consistency to jurisdictional decisions under USDA and FDA’s respective authorities and decrease unnecessary regulatory burdens.
- **Produce Safety:** FDA and USDA express their commitment to enhancing their collaboration and cooperation on produce safety activities, including the implementation of FDA’s Produce Safety regulation under the FDA Food Safety Modernization Act (FSMA).
- **Federal Regulation of Biotechnology Products:** The agreement states that the agencies are committed to modernizing the Coordinated Framework for the Regulation of Biotechnology, as well as the U.S. agricultural biotechnology regulatory system to develop efficient, science-based regulatory practice by working in partnership with other federal agencies. Both agencies have commitments for improving the regulation of biotechnology that are outlined in the September 2016 National Strategy for Modernizing the Regulatory System for Biotechnology Products ^{2/} and a recent Task Force on Agriculture and Rural

^{1/} Formal Agreement between USDA and FDA Relative to Cooperation and Coordination (Jan. 30, 2018), available at <https://www.fda.gov/Food/InternationalInteragencyCoordination/DomesticInteragencyAgreements/ucm594371.htm>.

^{2/} National Strategy For Modernizing the Regulatory System for Biotechnology Products (Sept. 2016), available at <https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GEPlants/UCM537320.pdf>.

Prosperity Report. 3/

The agreement was prompted in part by FSMA, which granted FDA additional authority over farms, an area for which USDA historically has developed considerable expertise. In a statement, Secretary Perdue said USDA has knowledge and expertise to support FDA's work related to farming. 4/

USDA's interest in realigning some aspects of its jurisdiction may bear fruit. USDA's Food Safety and Inspection Service (FSIS) recently proposed (in FSIS's Egg Product HACCP proposed rule) to expand FSIS's definition of "egg products" to include several egg-based products historically regulated by FDA. And in informal statements, FSIS officials have expressed an interest in revisiting earlier divisions of jurisdiction for some products such as pizzas that often have both FSIS- and FDA-regulated versions produced in the same facility. Officials have suggested that efficiency and food manufacturers' perspectives would be important considerations for any such jurisdictional changes.

The question of streamlining regulation of dual jurisdiction facilities – *i.e.*, those that make products subject to both FDA and FSIS authorities, such as soup or pizza facilities – has been a subject of interest for many years. The agencies last issued a possible framework to streamline these oversight activities in November 2005 under the George W. Bush Administration, and companies may look to that document for a potential starting point for future decision-making. 5/

The agreement will remain in effect for 10 years and may be amended at any time.

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We will continue to monitor for further developments concerning collaboration between FDA and USDA on FSMA implementation and other issues. Please contact us if you would like further information on this issue.

3/ Report to the President of the United States from the Task Force on Agriculture and Rural Prosperity (Oct. 21, 2017), available at <https://www.usda.gov/sites/default/files/documents/rural-prosperity-report.pdf>.

4/ FDA, USDA announce formal agreement to bolster coordination and collaboration (Jan. 30, 2018), available at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm594424.htm>.

5/ Meeting to Discuss Possible Changes to the Regulatory Jurisdiction of Certain Food Products Containing Meat and Poultry, 70 Fed. Reg. 67490 (Nov. 7, 2005).