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FDA declares action plan to improve innovation in biotech

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Execute coordinated actions aimed at promoting regulatory alignment and efficiency while enhancing the regulatory science to inform decisions.



The FDA announces its Plant and Animal Biotechnology Innovation Action Plan aimed at supporting advances in the space while ensuring product safety. The plan focuses on three key priorities:

Advancing public health by promoting innovation. The agency intends to update and clarify its policies, when appropriate, to ensure that its regulatory processes are efficient, predictable and risk-proportionate. It plans to refine its comprehensive policy framework to support the development and oversight of animal biotech products, including those derived from genetically altered animals.

It is launching a new pilot program, the Veterinary Innovation Program, aimed at providing technical and programmatic assistance for developers seeking approval for products based on intentionally genetically altered animals, animal cells, tissues, cell-based products or tissue-based products. The new guidance will be issued in 2019 that will clarify the agency's approach.

The draft guidance will also be issued in 2019 clarifying the FDA's approach in plant biotech, building on the knowledge gained in its 25 years' experience overseeing foods from genetically edited crops.

Strengthening public outreach and communication. It intends to actively engage with stakeholders to promote understanding of its regulatory approaches together with making the information more accessible online.

Increasing engagement with domestic and international partners. Execute coordinated actions aimed at promoting regulatory alignment and efficiency while enhancing the regulatory science to inform decisions. For example, it will continue to work with the U.S. EPA and USDA on regulatory approaches to genetically altered products as well as international authorities to share information and achieve more consistency in global regulatory processes.