

Chicken Out - FDA approves Transgenic Chicken



Article By
[Food and Drug Law at Keller and Heckman](#)
[Keller and Heckman LLP](#)
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[**FDA approves transgenic chicken, but not for consumption.**](#)

- FDA has the authority to approve genetically modified (GM) animals as “new animal drugs.” In 2009, FDA approved a GM goat — [the ATryn Goat](#) — that produces a therapeutic biologic in its milk. In November 2015, FDA approved its first-ever GM animal intended for direct human consumption — the [AquAdvantage Salmon](#).
- On December 8, 2015, FDA approved the Kanuma Chicken — a GM chicken designed to produce a therapeutic biologic in its egg whites. As was the case with the ATryn goat, the Kanuma Chicken received approvals from two FDA centers. The Center for Biologics Evaluation and Research (CBER) approved the human biologic based on its safety and efficacy, and the Center for Veterinary Medicine (CVM) approved the rDNA construct in the chickens that produce the biologic. In its review of the GM chicken application, CVM had to assess the safety of the GM technology — including its safety to the animals and a review of the rDNA construct and its stability in the chicken genome over multiple generations. CVM also had to conduct an environmental impact assessment related to the approval of the chickens, in which the Agency determined that the approval does not cause any significant impact on the environment because the

animals are raised in highly secure indoor facilities.

- Regulatory actions of this nature highlight the complexity of the FDA review that may be required for certain innovative products. The chicken approval represents only the third time that FDA has approved a transgenic animal via its new animal drug authority, with two approvals coming in 2015 alone. We have yet to see whether the rate of such approvals will increase in the future. In any event, the existing approvals help to set precedents for future innovators who seek to consider the marketing and regulatory possibilities related to the application of GM technology to animals.

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