FOOD & AGRICULTURE

Allowing Slaughter-Free Meat

Federal regulation is hindering the development of food from cell culture technology.

BY RANDALL LUTTER

Animal cell culture technology—a process to make food from cultured animal cells—has the potential to address some consumers' ethical concerns about eating meat, poultry, and fish by providing slaughter-free alternatives. It might also reduce the environmental footprint of conventional agriculture and fishing by devoting resources to growing only tissues that people value highly and not less useful items like hides, hooves, and horns. But whether these potential benefits are ever realized depends largely on how and whether Congress or the White House prunes back the thicket of regulatory obstacles blocking these products' path to market.

A TALE OF TWO REGULATORY AGENCIES

Last November, the Food and Drug Administration claimed in an official statement that it "spurs innovation" for food using cell culture technology. That assessment seems more than a bit premature. The statement followed a 13-month FDA "consultation" with UPSIDE Foods of Berkeley, CA, about the firm's process to make food from cultured chicken cells. The FDA said it had "no further questions at this time about the firm's safety conclusions," hardly a final green light. Additionally, the FDA noted that UPSIDE still needs to meet U.S. Department of Agriculture requirements for the new technology.

Regulation of new food products is often complicated because federal statutes authorizing the FDA and USDA to regulate food do not directly address the regulation of products made with new technologies. So federal agencies commonly develop and assert their preferred interpretation of preexisting statutes. Policies developed in this way exist for food made from genetically engineered food, gene-edited plants, and now food made through cell culture technology.

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In 2019 the FDA and the USDA's Food Safety and Inspection Service (FSIS) signed an agreement to "jointly oversee" the production of food derived from the cells of livestock and poultry. Such joint oversight is highly unusual if not completely unprecedented and erects costly and unnecessary barriers to cell culture technology's path to market.

The longstanding practice is for the USDA-FSIS to regulate specific food products identified in federal statutes and for the FDA to regulate everything else. For instance, the USDA-FSIS regulates meat products from named livestock (cattle, sheep, swine, and goats), poultry products, and egg *products* because Congress expressly assigned those to it. The FDA, meanwhile, has authority over eggs in shells. The FDA regulates all seafood and fish, except for catfish (Siluriformes), an exception that Congress assigned to the USDA-FSIS in the 2008 Farm Bill. Congress specified conditions for the USDA to regulate pizzas containing USDA-regulated meat or poultry products. Other complications and exceptions exist. For example, for bison and rabbits, the USDA-FSIS has some expertise and offers voluntary inspections but without any supporting statutory authority, while the FDA has authority to conduct inspections.

The 2019 agreement on cell-cultured food products, however, is a completely different soup: an agreement *between regulatory agencies* to "jointly oversee" production of a category of food products.

One federal agency should be enough to regulate the safety of identifiable products. This principle is necessary for effective White House and congressional accountability and oversight because it makes clear which agency should be called to account if food is found to be adulterated or linked to foodborne illness. President Bill Clinton's Executive Order 12866, still in effect, directs each agency to "avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies." In departing from this principle, the 2019 FDA–USDA agreement does not provide reasons why joint oversight is *necessary* to ensure the safety of food produced using cell culture technology. The agreement does not argue that each agency's unique strengths make joint oversight more cost-effective. It also does not assert that joint oversight is required by statute. Rather, it reads as if agreement among regulators is itself sufficient to justify joint oversight.

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The FDA and USDA-FSIS have no other agreement to jointly oversee a category of food, even in cases where the goulash of federal food safety regulation is most confusing. For example, in facilities producing both vegetarian pizza without meat or poultry ingredients and an "everything" pizza with chicken and pork sausage, the FDA regulates the former and the USDA-FSIS regulates the latter. In this instance both agencies have oversight of the "dual jurisdiction" facility, but only one oversees each food item it produces, and an agreement between the two agencies explains how.

The FDA's recent statement shows just how tangled is the path to market for UPSIDE Foods' cell culture chicken product. The FDA explained that its recently concluded pre-market consultation included an evaluation of the firm's production process and its cultured cell material, including the establishment of cell lines and cell banks, manufacturing

controls, and all components and inputs. The FDA concluded "that after our careful evaluation of the data and information shared by the firm, we have no further questions at this time about the firm's safety conclusion."

Importantly, that does *not* mean that UPSIDE Foods' new chicken product can now be marketed. The FDA noted:

> The [food production] facility also needs to meet applicable U.S. Department of Agriculture (USDA) and FDA requirements. In addition to the FDA's requirements, including facility registration for the cell culture portion, the manufacturing establishment needs a grant of inspection from USDA-Food Safety and Inspection Service (FSIS) for the harvest and post-harvest portions and the product itself requires a USDA mark of inspection.

But that is not all.

WHAT'S IN A NAME?

The names for cell-cultured meat and poultry products that the USDA-FSIS would prefer or permit are apparently still pending. The FDA's letter to UPSIDE Foods acknowledges the uncertainty about names, noting, "Our use of the term "cultured chicken cell material" in this letter is not our recommendation of that term as an appropriate common or usual name for declaring the substance in accordance with the Food Safety and Inspection Service's (FSIS) labeling requirements."

Given that having two federal agencies regulating the same foods makes no sense, one might ask which agency should have jurisdiction. A comparison of the approaches of USDA-FSIS and FDA to food labeling offers insights about which agency should step back from oversight of food products made using cell culture technology.

In 2021, the USDA-FSIS took an early step toward issuing a new labeling regulation for products made from livestock and poultry cells, asking for public comment on appropriate names, including whether and how proposed names might distinguish cell-cultured products from conventional ones. While soliciting public comment about regulatory actions is standard practice and generally essential for regulators to acquire private information about the effects of proposed regulations, soliciting public comment about potential names for products that are not yet marketed is likely to reveal strongly held opinions but negligible information about the effects of alternative names.

Indeed, the Farm Bureau in one state asked the USDA-FSIS that food produced using cattle cells based on cell culture technology be labeled "not a meat product." The nonprofit Center for Food Safety suggested that for some foods, an acceptable label might read, "Synthesized or imitation "burgers" made from cell-cultured meat [or poultry] cells from cows [or turkeys]." Neither presented data in support of those recommendations. At this writing, USDA-FSIS's plans are unclear because it has not announced a schedule for issuing a proposed regulation, nor has it said it is *not* pursuing this rulemaking.

The FDA, unlike the USDA-FSIS, has not initiated a rulemaking process for labeling cell culture seafood, although in 2020 it publicly requested information about such labeling. The FDA's existing regulations about packaged food labeling—aimed at avoiding consumer misunderstanding and familiar to food producers—seem already applicable to cell culture food. They state that principal display panels for packaged foods shall state the commodity's identity, and if there is no name specified in any applicable federal law or regulation and no common or usual name of the food, then the stated identity "shall be an appropriately descriptive term." They also explain that a food shall not be labeled an "imitation" if it is not nutritionally inferior and if it bears an appropriately descriptive name that is not false or misleading. Perhaps given this regulation, the FDA is not planning to develop guidance for labeling cell culture seafood products.

The FDA's regulations reflect federal courts' openness to labeling statements that are not false or misleading. Under the FDA approach, cell cultured beef producers might label food "slaughter-free" because it would be "appropriately descriptive." Similarly, firms selling traditional steaks could state, "Made from four-legged cattle without use of bioreactors," provided such statements are factually true. Such labeling, related names, and the resulting marketplace competition are beneficial because they help consumers make informed choices.

The USDA-FSIS oversees labeling more tightly than the FDA. It typically requires premarketing approval of food labeling changes, although such review and approval can be simplified through "generically approved" labeling provisions. Premarketing approval of labels, which can delay timely introduction of new products, is a regulatory procedure absent from FDA regulations.

The FDA's approach to food labeling thus seems preferable to that of the USDA-FSIS. It adequately protects consumer understanding and avoids the uncertainty of new labeling regulation as well as provides premarketing approval for food labeling changes. Additionally, the legal basis for USDA-FSIS oversight in this area is weak at best. The USDA-FSIS has not claimed that its authorizing statutes compel it to oversee labeling of these products, and the statutory definition of "meat food product" is one "made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats." Because a cell taken from a living barnyard animal does not meet dictionary definitions of meat or a portion of a carcass, the USDA-FSIS seems to have no clear statutory authority for regulating food products made using cell culture technology. Given that two agencies shouldn't regulate the same foods and the FDA is better equipped for the task at hand, the USDA-FSIS should concede oversight authority to the FDA.

Unfortunately, further questions about labeling may arise given the FDA's mention of the use of a "genetic engineering process" in its letter to UPSIDE Foods. In 2018, the USDA's Agricultural Marketing Service issued a regulation establishing a new standard for food producers to disclose information about

bioengineered food and food ingredients. That rule was developed without regard to cell culture technology, making its implications for labeling UPSIDE Foods' chicken product unclear, although the rule's list of bioengineered foods is subject to annual update.

TO KILL A BETTER BIRD

The burden of unnecessary regulation has already limited food innovation in the United States relative to other countries. The Good Foods Institute reported that Dutch cultivated pork company Meatable and Singaporean plant-based butcher Love Handle are cooperating to produce "hybrid" products, combining cultured cell technology and plant-based proteins in Singapore, a leader in protecting food safety.

Innovative foods have previously languished and died at least partly because of federal regulatory overreach. In 2015, the FDA approved AquaBounty's AquAdvantage Atlantic salmon, now growing in land-based recirculating systems in Indiana. The fish—genetically modified to grow in cold conditions—should be widely seen as environmentally friendly because it avoids both the carbon-intensive air travel from fish farms in Chile or the Faroe Islands and the contamination from conventional ocean-cage fish farming. Unfortunately, the lesson of AquaBounty—with its first commercial harvest coming in 2021, decades after its first submission to the FDA, and an annual revenue of just over $1 million—is instead that investors should shun innovative food technologies. AquaBounty has not developed products other than its salmon. It remains a niche player and has not inspired imitators, partly because FDA review is burdensome and partly because activists vilified the fish. (See "Regulators Kept a Fish Treading Water for Years," Fall 2021.) The FDA has okayed for human consumption only two genetically altered animals besides the AquaBounty salmon: a hypoallergenic pig developed primarily to address transplant organ shortages and a heat-tolerant bovine that the FDA cleared in March 2022.

Those three cases are dwarfed by a depressing list of dozens of genetically modified animals that have been developed without ever seeing an FDA decision about marketability. One remarkable example is a transgenic chicken, developed in 2011, kept at the Roslin Institute in the United Kingdom, but extinct since 2019. That chicken suppressed transmission of bird flu, a disease that may become transmissible among humans. Such chickens could have promoted animal welfare by greatly reducing the massive culling of poultry flocks during bird flu outbreaks—39 million birds during a 2015 outbreak in the Midwest, and nearly 50 million birds in the United States in 2022—and limiting the associated harm to farmers and consumers in the form of higher prices for poultry. The Roslin Institute is now working on using gene editing techniques to produce chickens that resist bird flu and resist transmitting it. One of the researchers said a chicken resistant to bird flu "has the potential to stop the next flu pandemic at its source." I am unaware of any efforts by the USDA or the federal government generally to help develop comparably innovative animal breeds.

THE GREAT (AND NECESSARY) DIVORCE

Federal oversight of food from cell culture technology should return to basics. Regulators should ensure that foods are safe and that labeling and marketing are truthful and not misleading, while also removing unnecessary barriers to the marketing of safe, innovative products.

The Biden administration should toss the existing agreement between the FDA and the USDA-FSIS and replace it with one that assigns sole oversight authority to the FDA.

Such basics would effectively and appropriately resolve questions regarding whether cell culture technology can be applied at large scale and low cost, as venture capital backers and cell culture technology advocates believe. Some skeptics question the feasibility of low-cost scaling because the "fermentation" must be essentially free of bacterial or viral contaminants. And some economists who have modeled the wholesale cost of meat produced using cell culture technology believe it may occupy only a small market. Resolving such questions, however, is exactly what markets do well, provided that firms can market the products in question.

The Biden administration should toss the existing agreement between the FDA and USDA-FSIS and replace it with one that assigns sole oversight authority to the FDA for all aspects of foods based on cell culture technology. That would include foods from cell lines derived from livestock and poultry that the USDA-FSIS currently regulates. An important but limited exception would be those issues where Congress has expressly granted statutory authority to the USDA, as with the 2018 rule issued by USDA's Agricultural Marketing Service about the labeling of bioengineered foods.

The FDA, for its part, should identify through notice and comment clear criteria for firms to avoid premarket consultations and performance goals for consultations that it conducts. A yearlong FDA consultation, such as the one conducted on UPSIDE Foods, should be rare and seen as a failure as soon as the FDA has done several.

These reforms, if implemented promptly, would allow shoppers to make informed decisions about what foods to buy while ensuring that the foods are safe. *R*