

Two views of the emperor's new clones

To the editor:

Your editorial "The emperor's new clones" (*Nat. Biotechnol.* 25, 1, 2007), which discusses the US Food and Drug Administration's (FDA) preliminary decision that food from cloned animals is safe to eat, notes the uncertainty about whether the agency will follow where the science leads or make "radical changes in the finalized regulation after public consultation." Precedents offer ample reasons for concern.

Both antitechnology, nongovernmental organizations and influential members of the new Democratic-controlled US Congress have already begun to challenge the FDA's decision, and history teaches us that in such circumstances, the FDA has hardly deserved a profile in courage. As head of the agency's Office of Biotechnology from 1989 to 1993, I recall that during the regulatory review in the 1980s of recombinant DNA-derived bovine somatotropin (bST), a drug used to enhance the productivity of dairy cows, the agency was easily intimidated. Largely as a result of the misguided efforts and bullying of Senator Patrick Leahy (D-Vt) and Rep. John Conyers (D-Mich), the FDA's evaluation of the drug took a stunning nine years; in contrast, review of an almost identical product for injection into growth hormone-deficient children had taken a mere 18 months. And these antitechnology demagogues are back in the driver's seat: Leahy is now the chairman of the powerful Senate Judiciary Committee, and Conyers chairs the House Judiciary Committee. *Caveat* cloner.

Although your editorial predicts that European consumers will reject dairy and meat products derived from cloned animals, history suggests a different outcome in the United States, despite fears of such actions expressed by a few sectors of the food industry. Twenty years ago, there were similar concerns when dairy farmers began

using bST, with some analysts predicting that its introduction would so frighten consumers that milk consumption could decline as much as 20%. Although exhaustive tests indicated that the milk is no different or less wholesome than that obtained from untreated cows, activists demanded special regulations, including mandatory

labeling of dairy products from bST-treated animals. The FDA demurred; the product was hugely successful commercially; and a decade after milk from bST-treated cows began to be marketed, an analysis by the US Department of Agriculture's Economic Research Service (Washington, DC) concluded: "scientific evidence about food safety will not prevent controversy. . . . Even intense

controversy may have minimal or no effect on total demand [and] the absence of reports of harm from consumption contributes to continued consumption."

The bST experience serves as a reminder that the mere presence of controversy—or pseudo-controversy generated by antitechnology activists—should not cause industry (or government regulators for that matter) to overreact.

Once again, compelling scientific evidence about food safety hasn't prevented controversy. The FDA risk assessment released in late December reflected a high degree of assurance—"[e]xtensive evaluation of the available data has not identified any food consumption risks or subtle hazards in healthy clones of cattle, swine, or goats"—but that didn't deter the biotech bashers. They got indigestion from the realization that because the meat from cloned animals is indistinguishable from the parent, it is highly unlikely that US regulators will require labeling to identify food derived from cloned animals. (Activists have adopted a two-pronged strategy—trying to coerce food producers and processors into rejecting new food technology and to induce government

agencies to overregulate. An important element of these efforts is mandatory labeling of food made with technologies the activists dislike, because that makes it possible for them to demonize those products; to intimidate their producers, distributors and retailers; and to pounce on any inconsequential mislabeling).

The US Federal Food, Drug and Cosmetics Act requires that food labels be truthful and not misleading, and federal law prohibits label statements that are likely to be misunderstood by consumers, even if they are, strictly speaking, accurate. For example, although a 'cholesterol-free' label on a certain variety or batch of fresh broccoli is accurate, it could run afoul of the FDA's rules because it could be interpreted as implying that broccoli usually does contain cholesterol, even though, in fact, it does not.

Analogously, instead of educating or satisfying the consumers' need for certain information, mandatory labels on food from cloned animals would imply a warning—that is, it would be misconstrued by some consumers as a suggestion that food from cloned animals differs in an important way (such as safety or nutrition) when it does not. The FDA's current approach to labeling, which has been dubbed 'need to know'—as opposed to the European Union's view that consumers have a 'right to know'—has been upheld both directly and indirectly by various federal court decisions.

Cloning technology will offer yet another tool to enable biologists and animal breeders to make foods more consistent, nutritious and tasty. The controversy it has generated is less about the possible risks of a 'cloneburger' than about the bad-faith attempts by activists and members of the US Congress to delay or derail a promising technology.

COMPETING INTERESTS STATEMENT

The author declares that he has no competing financial interests.

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