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The emperor's new clones

If regulators conclude that food from clones poses no more risk than food from other animals, the US and Europe could be on course for another biotech trade war.

The US Food and Drug Administration (FDA) is about to release its Draft Risk Assessment on Animal Cloning. Information from inside the agency (p. 39) indicates that this assessment will find no scientific basis for treating the products of cloned animals any differently from those of other animals. If this turns out to be the case—and the FDA makes no radical changes in the finalized regulation after public consultation—meat and dairy products from adult cell–derived clones could be on US menus in the not-too-distant future. This has implications for US trade relations with Europe, where consumers are likely to be even less enthusiastic about food from clones than they are about genetically engineered products.

People don't like clones. They don't like the idea that cloning could meddle with the health and welfare of animals. And they don't like the idea that cloned products could come anywhere near their dinner plates. Why should they eat them when it is only agricultural producers who benefit from the technology?

A recent poll commissioned by the nonprofit, Washington, DC–based International Food Information Council found that only 9% of US respondents would "very likely" buy products derived from cloned animals, even if deemed safe by the FDA, and ~60% would not touch them at all, compared with 40% when the same question was about genetically engineered animals (p. 7). Given their past aversion to recombinant products, European consumers are unlikely to welcome cloned animal products with open arms.

The irony in all this is that food from clones has been a part of our diet for years. Many common fruits (e.g., pears, apples, oranges and lemons) and several vegetables (e.g., potatoes and truffles) are clones. And most of us have probably ingested meat and dairy products from livestock cloned by natural reproduction (monozygotic siblings), mechanical embryo splitting or even nuclear transfer from an embryonic donor cell into an enucleated oocyte.

Regulators traditionally paid scant attention to clones as a group—and rightly so. Clones are after all (albeit imperfect) copies of animals. But the birth of Dolly the sheep and the advent of technology for cloning animals from adult cells—so-called somatic cell nuclear transfer (SCNT)—has prompted the FDA to take a closer look.

Particular scrutiny has focused on the effects of SCNT on the health of sires and their cloned offspring. Success rates for SCNT remain relatively poor (e.g., only ~2–10% of cloned bovine embryos develop to term). And because reprogramming of the nucleus of the donor cells is incomplete, aberrant chromatin remodeling is sometimes associated with pre-, peri- and postnatal deaths and developmental defects among cloned offspring.

These problems may well be addressed by better animal management and will likely diminish as SCNT technology is refined, donor cell lines optimized, the role of hyperacetylation in reprogramming better defined and the appropriate cell-cycle stages ascertained for nuclear donors and recipient oocytes. But from a practical standpoint, the current inefficiency and expense of SCNT means that for the foreseeable future its use in agriculture will be limited to occasional insurance against the loss of prize animals by disease or injury before they have had a chance to reproduce.

Put all this together with past trade spats between the US and Europe over recombinant products, and a disconcerting scenario emerges.

Sometime in the near future, the FDA will give the all clear for SCNT clones to enter food production. Although breeders occasionally will resort to SCNT to generate elite animals, by far the majority of meat, milk and other products will remain derived from animals produced by other methods. No changes will be implemented to the US food distribution system—segregation and labeling would be after all pointless for products that are indistinguishable from other products (and no wholesale changes were made when recombinant foods were introduced).

The bombshell will hit Europe some time soon after. Activists will claim that the US is dumping cloned meat on European consumers. Voters will cry foul to their politicians. And media outlets will add to the chorus urging legislators to segregate SCNT-derived food from 'natural' food.

European regulators will then face a thorny problem: how to tell which products to regulate when, by definition, SCNT animals are virtually identical to their noncloned progenitors? Unlike recombinant products, where PCR can detect heterologous sequences at vanishingly low levels, there is no obvious, fast and accurate means of detecting SCNT animals.

One solution may lie in implementing from scratch a labeling and traceability program for SCNT products. Any animal, dairy or meat product, sperm or ovum sample from an SCNT animal would be labeled 'clonal'. European producers would provide SCNT animals and products with documentation and 'passports'. Europe's single-market ethos would ensure that all European farmers/food producers assume the same regulatory burden. An unfortunate consequence of the burdensome regulations would be a hefty price rise in European beef and pork.

Not to worry, though. Europe will expect her trading partners also to conform to this 'higher' standard. To preserve European consumers' rights to choose, beef producers in the United States, Argentina, Australia and Africa, for instance, will have to adopt European labeling/traceability rules or risk losing access to European markets. Either route is a recipe for economic contraction and trade disputes.

There is, however, another way. Why not label the cloned products with recombinant DNA? By happy chance, the presence of recombinant DNA already falls within existing European rules on genetically engineered organisms.

Of course, it is absolutely absurd to suggest that European regulators would actually insist on compulsory GM labels for cloned products. We hope it won't happen. But if it does, it wouldn't be the first time that the entire trading bloc has been burdened with erosive, meaningless rules based on nonscientific drivel.