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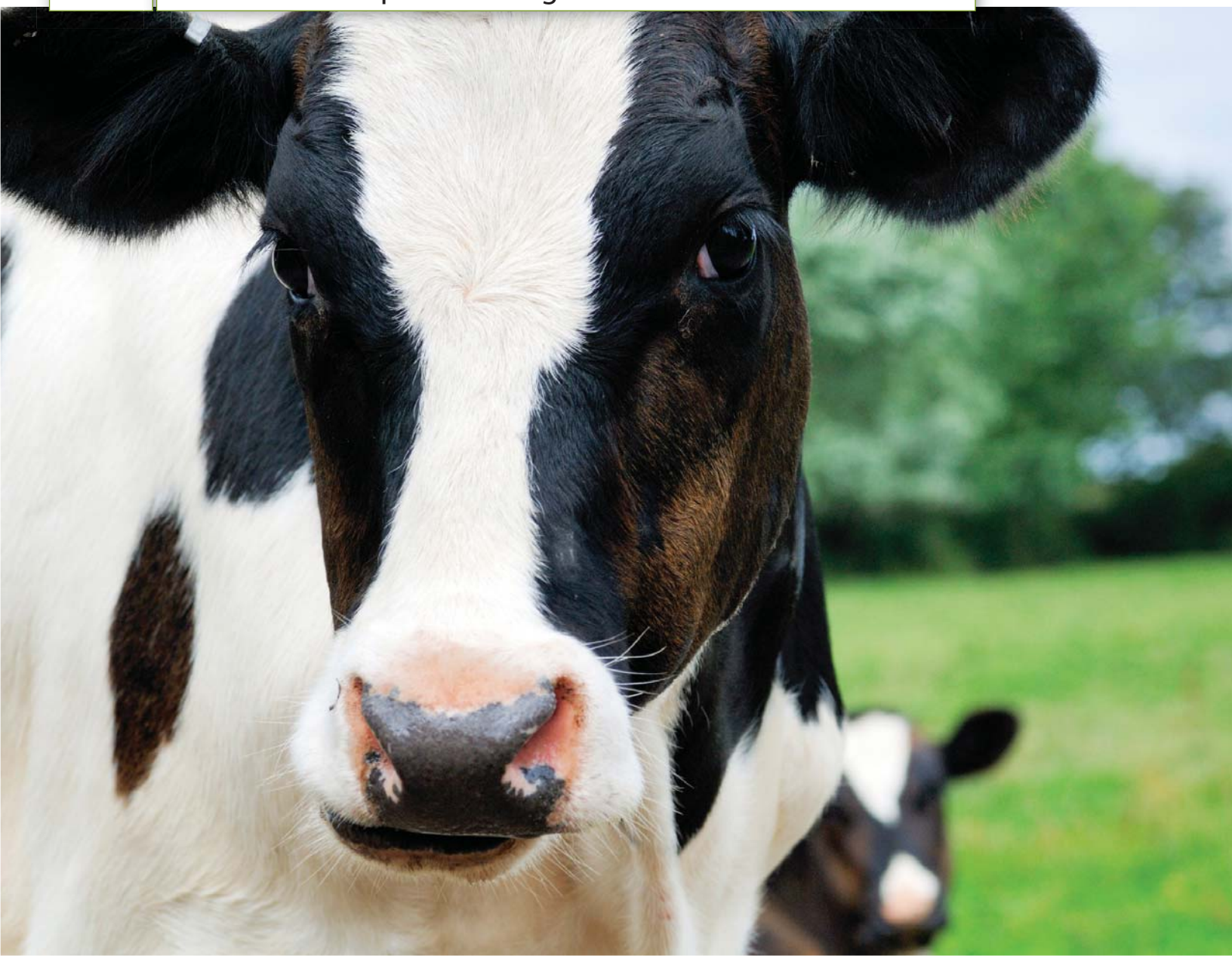
Critical Issue Report: Cloning for Food



Is the FDA's Cloning Proposal Ready for Prime Time?

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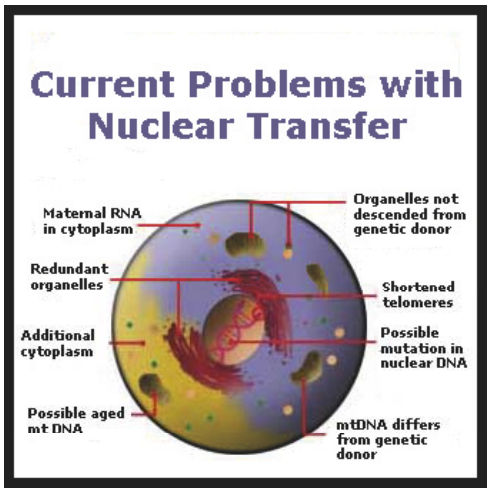
I. Executive Summary

On December 28, 2006, the Center for Veterinary Medicine (CVM) at the U.S. Food and Drug Administration (FDA) issued a draft risk assessment, a risk management plan, and guidance to industry on meat and milk from cloned animals. A Federal Register notice was issued on January 3, 2007, in which the FDA requested comments on all three documents.

The documents address the risks associated with somatic cell nuclear transfer (SCNT), the most common method used to create cloned animals, and do not address other cloning technologies or risks associated with genetically engineered animals. The document acknowledges that there are ethical, cultural, and religious issues raised by animal cloning. The agency offers to participate in discussions of these issues "…in other fora," but makes clear such considerations are not germane to its conclusions regarding the safety and animal health impacts of animal cloning.

Throughout the FDA risk assessments, the health risks to surrogate mothers used in the cloning process are compared to the risks associated with other "Assisted Reproductive Technologies" (ARTs), such as artificial insemination, embryo transfers and splitting, and in vitro fertilization.



The Organic Center has issued this Critical Issue Report to provide background on the FDA's proposal and the cloning process so that readers can better understand:

- What the FDA found in its scientific assessment and is proposing;
- The impacts of cloning on animal health and reproduction;
- Potential impacts of animal cloning on food quality and safety; and
- The status of cloned animals, their progeny and products in organic agriculture.

The FDA Assessment and Proposal

According to the notice, the FDA developed the draft risk assessment to evaluate the health risks to animals involved in the process of cloning and to identify the food consumption risks, if any, that may result from consumption of edible products derived from animal clones or their progeny.

In a nutshell, the FDA identified no new or worsened food safety risks associated with the consumption of cloned animals, or milk from cloned dairy cows. The FDA expressed this finding in the risk assessment's executive summary by saying the risks from juvenile or adult cattle, pig, and goat clones "pose no additional food consumption risk(s) relative to corresponding products from contemporary conventional comparators."

In two cases the FDA was unable to support a finding of no new or worsened food safety risks. The FDA concluded there was insufficient information to draw a final conclusion regarding food safety risks associated with consumption of meat from cloned sheep. And in the case of just-born bovine calves, the agency said that consumption of these young animals by humans, or placing them into the livestock feed or pet food supply through rendering, "may pose some very limited food consumption risk." The FDA concluded, however, that rendering these animals will not pose such risks in animal feed or to humans consuming animals fed material derived from the clones.

This finding extends, apparently, even to deformed animals that can, under FDA's risk management plan and guidance to industry, enter the livestock feed or pet food supply through rendering. The FDA's risk management plan states, "No feed risks unique to clones were identified. Therefore, as stated in our accompanying Draft Guidance for Industry, it is our current thinking that clones of any age or species could be used in the production of feed for animals without additional restriction especially for clones."

For all species of animals, the FDA concluded that the meat and edible products from the progeny of clones "pose no additional food consumption risk(s) relative to corresponding products from other animals."

The risk assessment encompasses both food safety risks to humans and animals consuming food or feed derived from clones, as well as health risks to the surrogate mothers involved in the cloning process. The FDA concludes that surrogate mothers used to grow out clones are "at increased risk of adverse health outcomes relative to conventional animals." The agency goes on to say "None of these adverse outcomes, however, are unique to cloning." The full meaning of this sentence is not made clear, but implies that the FDA differentiates between existing and novel risks. For example, an "adverse outcome" linked to a health complication that is known to sometimes occur with embryo transfer is more acceptable than an "adverse outcome" triggered by some complication unique to cloning.

The risk management plan acknowledges areas of scientific uncertainty and points out that cloning technology is rapidly evolving. The FDA states that emerging cloning technologies might raise risks different from current techniques.

In the notice, the FDA also announced the availability of, and requested comments on, a proposed risk management plan for animal clones and their progeny. The proposed risk management plan takes into account the risks identified in the draft risk assessment and establishes proposed measures that FDA might use to manage those risks. With a few narrow exceptions, the risk management plan simply states, for all intents and purposes, "Enjoy your cloned meat and milk!"

In addition, the FDA announced the availability of draft guidance for industry, open for public comment. This draft guidance describes FDA's recommendations regarding the use of edible products from animal clones and their progeny in human food or in animal feed. The "Guidance to Industry" document is less than two pages, with most of the text describing the overall process used by FDA to evaluate risks from cloned animals. Its substance appears in four paragraphs that begin with the statement – "No unique risks for human consumption were identified in cattle, swine, or goat clones." Because of the lack of applicable science, the FDA recommends that, "edible products from sheep clones not be introduced into the human food supply."

Industry is reminded in the guidance document that edible products from clones must meet all applicable federal and state food safety laws.

In its report, the FDA has acknowledged that, even if two animals have identical genes, the animals can turn out differently if their genes are turned on or off at different times, or are sequenced differently from the original sequence. These unpredictable genetic variations are linked to the high failure rate of cloned animals. (Only about 4 to 7% of cloned animals survive.) Many clones die during gestation or shortly after birth, while some are born with deformed heads or limbs or problems with their hearts, lungs or other organs.

In its report, the FDA admits animal health problems, by stating that "some animals involved in the cloning process (i.e., cattle and sheep surrogate dams, and some clones) are at increased risk of adverse health outcomes relative

to conventional animals." "Cows and ewes used as surrogate dams for SCNT-derived pregnancies appear to be at increased risk of late gestational complications" and "There is an increased risk of mortality and morbidity in perinatal calf and lamb clones."

The most severe errors in reprogramming will result in death, obvious malformations, or metabolic derangements, and are reflected in the low "success rate" of cloning, the perinatal difficulties observed in some newborn clones, and occasional examples of altered metabolic pathways in very young animals.

Can Cloned Meat and Dairy Products Be Sold as Organic?

Animal cloning is not allowed for organic production under the NOP for several reasons. An initial technical step in animal cloning is cell fusion, a process involving the transfer of DNA from one cell to another. Cell fusion is an "excluded method" in organic production under the National Organic Program (NOP) regulation.

Cell fusion, and hence cloning based on it, narrows the gene base, while organic production relies on maintenance of a broad and diverse gene pool. A species with a broad and deep gene pool is better positioned to adapt to new disease threats and environmental changes.

In addition, cloning is dependent on the use of artificial hormones to induce labor of surrogate dams. The use of artificial hormones to induce labor is prohibited in organic agriculture.

In the draft risk assessment, the FDA acknowledges a variety of animal health problems both with clones, especially in the first days and weeks of life, and the surrogate mothers required to bring them to term. For example, FDA concluded that, "Cows and ewes used as surrogate dams for SCNT-derived pregnancies appear to be at increased risk of late gestational complications."

The NOP regulation requires organic livestock producers to establish and maintain animal husbandry systems that allow natural behaviors, including those involved in reproduction, and promote the health and well-being of the animals. Breeding practices like SCNT cloning that result in "adverse health outcomes," "increased risks of late gestation complications," and "increased risks of mortality and morbidity" do not meet the NOP's proactive health care requirements.

Unlabeled Clones and the Organic Market

The FDA has not ruled on whether or not cloned animals and their products will need to be tracked and labeled in the human food supply and for animal feed and pet food uses. Labeling is essential in order to:

- Prevent entry of cloned animals, their progeny, and products into the organic food system;
- Protect organic livestock producers from financial losses associated with the accidental introduction of cloned animals into the organic herd;
- Conduct long-term studies on effects on human and animal health;
- Sustain consumer confidence in the food system;
- Respect consumers' right to know about the foods they consume; and
- Protect conventional livestock producers not using cloning technology from likely negative economic impacts.

A Fundamental Flaw

The FDA report states, "The Center assumes that if clones were to pose food consumption risks, the only mechanism by which those risks could arise would be from inappropriate epigenetic reprogramming…" The draft assessment states that animal clones can develop with apparently normal functions, but with subtle sub-clinical physiological anomalies, which can "…include alterations in key proteins affecting the nutritional content of food and leading to dietary imbalances." It also acknowledges that many cloned animals die during gestation or develop abnormally due to a misarranged genetic code. Despite these potential risks, the FDA assumes that existing federal and state meat inspection laws will prevent abnormal clones from entering the human food supply because they will clearly be sick or different from normal animals.

Clones that are "virtually indistinguishable" from normal progeny may enter the food supply. Sick and malformed clones may be rendered and enter the food supply indirectly via animal feed, or may find their way into pet food.

The concept of cloned animals and their products being “virtually indistinguishable” to animals resulting from natural breeding is similar to the doctrine of “substantial equivalence,” used in the 1990s by the FDA to justify approval of genetically engineered plants. “Virtually indistinguishable” is not a scientific standard. The FDA acknowledges that cloned animals that are “virtually indistinguishable” to the human eye might be different in ways that impact food safety or nutritional quality. The public is not likely to accept similarity of appearance as the decisive food safety hurdle standing between animal clones and the American food supply.

Who Gains from Unregulated and Unlabeled Cloning?

The presence in the marketplace of unregulated and unlabeled meat and milk from cloned animals will help further differentiate organic products from unsegregated conventional livestock products. This will almost certainly increase demand for organic meat and animal products.

Corporations who control the technology and proprietary strains of cloned animals will likely profit if farmers are not concerned about the risk of market rejection.

The absence of tracking or labeling protects technology companies and users of cloned animals from liability. Without traceability, it will be difficult, if not impossible, to link consumption of cloned animal products to adverse impacts on human health.

No other country has approved food from cloned animals. The introduction of cloning has the potential to seriously diminish consumer confidence in U.S. animal products and will likely depress domestic and export markets for conventional livestock products. Export sales of organic livestock products will almost certainly grow at an accelerated rate.

A December 2006 poll by the Pew Initiative on Food and Biotechnology found that 64 percent of consumers said they were uncomfortable with animal cloning, with 46 percent saying they were “strongly uncomfortable.” Other polls have shown comparable levels of consumer reticence. As consumers learn more about the risks associated with animal cloning, it is hard to imagine a softening of consumer anxiety over cloning. For this reason, a comprehensive economic impact analysis should be conducted to examine the impacts of cloning technology on existing markets for conventional and organic livestock products.