

## *Food From Cloned Animals*

### Issue Background

The U.S. Food and Drug Administration (FDA) released a draft risk assessment and management plan on December 28, 2006, in which the agency preliminarily concluded that food derived from cloned animals is as safe to eat as conventionally produced food. The agency requested comments on the documents during a period now extended to May 3, 2007, but will accept comments at any time. Following a thorough review of all comments and any additional data that are submitted, the agency may issue final risk documents or determine that further work is necessary. Nonetheless, until a final determination is made, the voluntary ban that FDA implemented in 2001 to restrict food from cloned animals from entering the food supply will remain in place.

A December 2006 article by FDA scientists in the *Theriogenology* journal signals that at least some officials within the agency believe that sufficient data exist to conclude that food products from clones may be considered “generally recognized as safe” or GRAS.<sup>1</sup> Foods that are considered GRAS are not subject to FDA’s pre-market review authority under the Federal Food, Drug and Cosmetic Act (FD&C Act) and may be introduced into the food supply without any regulatory action or approval of any sort. A GRAS determination (which may be legally made by individual private companies) could place legal tension on the voluntary ban, although all of FDA’s statements have confirmed the agency expects the ban to remain in place.

Following are issues likely to be raised during the agency’s consideration of this issue:

- Whether the quality and quantity of the available scientific data are sufficient to conclude that food products derived from cloned animals are GRAS or whether such food products should be regulated under provisions of the FD&C Act that require pre-market approval.
- Whether food products derived from cloned animals present unique concerns that should result in new labeling requirements.
- Whether the existing regulatory structure is sufficient to regulate the introduction of foods produced by this technology.

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<sup>1</sup> Rudenko, Larisa, and Matheson, John C., “The U.S. FDA and Animal Cloning: Risk and Regulatory Approach,” *Theriogenology* 67, pp. 198-206 ([www.elsevier.com/locate/theriogenology](http://www.elsevier.com/locate/theriogenology) [subscription required]).

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Food Marketing Institute (FMI) conducts programs in research, education, industry relations and public affairs on behalf of its 1,500 member companies — food retailers and wholesalers — in the United States and around the world. FMI’s U.S. members operate approximately 26,000 retail food stores with a combined annual sales volume of \$340 billion — three-quarters of all retail food store sales in the United States. FMI’s retail membership is composed of large multi-store chains, regional firms and independent supermarkets. Its international membership includes 200 companies from 50 countries.



## 1. What is cloning?

Cloning creates a genetic twin of an organism. Breeders use the cells or embryos from their best livestock to reproduce animals that provide high-quality food. Scientists have used three principal methods over the past 25 years:<sup>2</sup>

**Embryo Splitting** — An early-stage embryo is divided, making available cells carrying the embryo's genetic blueprint in its nucleus. These cells are implanted into empty eggs, cultured into embryos and implanted into surrogate mothers.

**Blastomere Nuclear Transfer** — Later-stage embryos produce multiple cells (blastomeres) from a fertilized egg. These cells are implanted into eggs whose nuclei have been removed, cultured into embryos and implanted into surrogate mothers.

**Somatic Cell Nuclear Transfer** — Cells are taken from the tissue of adult animals, and grown and preserved in a culture. The nuclei of these cells are inserted into nucleus-free eggs, introducing the genetic blueprint of the donor adult. A small electric spark or chemical coaxes these eggs to form embryos. The embryos are implanted into surrogate mothers.

The birth of Dolly the sheep on July 5, 1996, was the first successful case of somatic cell cloning.<sup>3</sup> Cloning adults enables breeders to reproduce mature livestock whose high-quality traits are manifest. Scientists and breeders today are using somatic cell cloning for this reason.

Cloned offspring who survive the first one to two years of life mature with the qualities of their donors. Their meat and milk appear virtually identical to their genetic donors and are safe to consume, according to the FDA draft risk assessment. The offspring of these animals are reproduced using conventional methods. It is these offspring — one generation removed from the cloned source — whose meat and milk would be introduced into the food supply for human consumption. These facts propel the continued pursuit of somatic cloning, which, once refined, could dramatically improve livestock breeding.

The low success rate and scientific challenges of somatic cloning create cost hurdles that hinder the proliferation of cloning. The cost ranges from \$15,000 to clone a dairy cow to \$32,000 to clone a pet cat to \$150,000 to clone a champion horse.<sup>4</sup>

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<sup>2</sup> FDA, *Animal Cloning: A Draft Risk Assessment*, December 28, 2006, pp. 27-32 (<http://www.fda.gov/cvm/CloneRiskAssessment.htm>); Van Eenennaam, Alison, "Livestock Cloning," University of California, Davis, March 2006 ([http://animalscience.ucdavis.edu/animalbiotech/Outreach/Livestock\\_cloning.pdf](http://animalscience.ucdavis.edu/animalbiotech/Outreach/Livestock_cloning.pdf)).

<sup>3</sup> Dolly was euthanized on February 14, 2003, after contracting a lung infection unlinked to cloning, *National Geographic News*, July 5, 2006 (<http://news.nationalgeographic.com/news/2006/07/060705-dolly.html>).

<sup>4</sup> *National Geographic News*, *op. cit.*

## 2. Why clone?

Proponents of cloning say the technology accelerates the birth of the best livestock by allowing farmers to be certain of the genetic make-up of a particular animal.<sup>5</sup> Cloning livestock can foster the reproduction of animals that provide the leanest, most nutritious and best-tasting meat. It could enable ranchers to breed cattle that do not carry *E. coli* O157:H7 bacteria and are immune to mad cow and foot-and-mouth disease. Cloning minimizes the use of antibiotics, growth hormones and other chemicals by using the healthiest livestock.

This technology can protect endangered species from extinction. China is preserving the cells of pandas to protect this species from extinction.

## 3. Which animals have been cloned, and how many are there?

A wide variety of animals have been cloned, including cats, cattle, deer, dogs, frogs, goats, horses, mice, monkeys, mules, oxen, pigs, rabbits, rats, sheep and wildcats.<sup>6</sup>

Only about 150 dairy cows have been cloned, compared with the nine million now producing milk, and many of these cloned cows are show animals, according to the International Dairy Foods Association (IDFA).<sup>7</sup>

In all, fewer than 1,000 food-producing cloned animals were living on U.S. farms at the end of 2006.<sup>8</sup>

## 4. When will food from cloned animals be available in supermarkets?

It is difficult to predict exactly when these products will be sold. In 2001, the FDA imposed a voluntary ban on selling food from cloned animals in the marketplace. The food and biotechnology industries have complied. This ban will continue until the agency finalizes a draft major risk assessment and management plan. The draft was released for public comment on December 28, 2006. After a comment period ending May 3, 2007, the FDA will review the feedback and decide whether to lift the voluntary ban. Still, legal or congressional intervention could cause further delays. In fact, members of Congress already introduced legislation to require food from cloned animals to be labeled as such. A mandatory ban on human cloning will remain in effect regardless of what happens.

Concern has been expressed in some published reports that food from cloned animals may enter the food supply without government or public knowledge because products from cloned animals cannot be distinguished from products derived naturally.

Even if FDA concludes in 2007 that cloning is safe and efforts to reverse this determination fail, years will elapse before the offspring of cloned animals can bring a significant amount of meat and milk to supermarket shelves. Low consumer demand based on safety or ethical concerns could also delay or limit the introduction of these foods.

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<sup>5</sup> CloneSafety.org. "Why Clone?" ([www.clonesafety.org/cloning/facts/why/](http://www.clonesafety.org/cloning/facts/why/)).

<sup>6</sup> FDA, *Animal Cloning: A Draft Risk Assessment*, *op cit*; *National Geographic News*, *op. cit*; Van Eenennaam, Alison, *op. cit*.

<sup>7</sup> IDFA, "Cloning Fact Sheet, December 2006 ([http://www.idfa.org/reg/cloning\\_factsheet\\_12-06.pdf](http://www.idfa.org/reg/cloning_factsheet_12-06.pdf)).

<sup>8</sup> Weiss, Rick, "FDA Says Clones Are Safe to Eat," *Washington Post*, December 29, 2006.

## 5. What do consumers think about food from cloned animals?

More than six in 10 consumers (64 percent) are “uncomfortable” with the idea of animal cloning, including 46 percent who are “very uncomfortable,” according to a September 2006 survey of 1,000 people by the Pew Initiative on Food and Biotechnology.<sup>9</sup>

The International Food Information Council found comparable results in a survey of nearly 500 people in mid-2006: only 16 percent held a favorable impression of animals produced through cloning, 56 percent held an unfavorable view, including 33 percent who find it “not at all favorable.” In this survey, consumer attitudes improved “if the FDA determined that meat, milk and eggs from cloned animals were safe.” More than four in 10 consumers (42 percent) said they would buy these foods if the FDA deemed them safe.<sup>10</sup>

## 6. Where are the consumer advocates?

Most strongly oppose any animal cloning, citing moral, religious, scientific and animal welfare concerns. The Center for Food Safety, Consumer Federation of America (CFA), Food and Water Watch, Friends of the Earth, American Anti-Vivisection Society, Humane Society of the United States, Religious Coalition for Reproductive Choice and the Center for Environmental Health are opposed to any animal cloning. This coalition of groups has a history of litigating its policies.

When the FDA released its draft assessment suggesting food from cloned animals is safe, CFA’s Carol Tucker Foreman criticized the agency for “imposing these products on a public that opposes cloning technology and does not want to consume cloned foods.”<sup>11</sup>

Consumer advocates believe there is inadequate scientific data to support allowing the sale of food from cloned animals. They cite a 2004 *New England Journal of Medicine* report that stated, “[G]iven the available evidence, it may be exceedingly difficult, if not impossible, to generate healthy cloned animals,” and the 2004 National Academy of Sciences report that said the safety of cloned food could not be asserted because “the paucity of evidence in the literature on this topic makes it impossible to provide scientific evidence to support this position.”<sup>12</sup>

## 7. What is the industry’s position?

Different industry segments hold varying positions. The **biotechnology industry** strongly supports FDA approval. The industry argues that the science is safe, and the products of the offspring of cloning are nutritionally identical to conventionally produced products. The industry further suggests that the supporting scientific data that will be publicly released for examination by all parties will be convincing.<sup>13</sup> The FDA released a significant amount of data in raw form with its risk assessment.

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<sup>9</sup> The Mellman Group conducted the survey September 20-26 (<http://pewagbiotech.org/newsroom/releases/120606.php3>).

<sup>10</sup> IFIC, *Food Biotechnology: A Study of U.S. Consumer Attitudinal Trends, 2006* ([ific.org/research/biotechres.cfm](http://ific.org/research/biotechres.cfm)).

<sup>11</sup> CFA news release, “FDA Disdains Public Opposition, Promotes Animal Cloning,” December 27, 2006. (<http://www.consumerfed.org/pdfs/dec28pressrelease.pdf>).

<sup>12</sup> Center for Food Safety press release, “Groups Tell FDA, Keep Cloned Animals Off Our Dinner Plates,” October 12, 2006, ([www.centerforfoodsafety.org/cloning\\_petitionPR10.12.06.cfm](http://www.centerforfoodsafety.org/cloning_petitionPR10.12.06.cfm)).

<sup>13</sup> Biotechnology Industry Organization (BIO), Fact Sheet on Animal Cloning.

Led by IDFA, the **dairy industry** holds a less positive view. IDFA has called for a “thorough, deliberative and open process.”<sup>14</sup> Driving IDFA’s “go slow” approach is preserving public confidence in the wholesomeness of dairy products and respecting questions about ethical and moral issues, which are outside the scope of FDA’s risk assessment. “Cloning is a niche-market technology. It remains to be seen whether dairy farmers will choose to use it,” said IDFA President and CEO Connie Tipton when the FDA released its risk assessment, adding, “There currently is no consumer benefit in milk from cloned cows in this country....”<sup>15</sup>

**Food manufacturers**, represented by the Grocery Manufacturers Association-Food Products Association (GMA-FPA), have adopted a multi-step policy. It recognizes that consumer preferences will ultimately determine if meat, milk and other products from cloned animals will be sold in the marketplace. GMA-FPA believes these products do not need to be labeled. At the same time, manufacturers support labeling food “not from cloned animals.” GMA-FPA supports the development of guidance for manufacturers and marketers on how to substantiate and validate clone-free product claims.

The **organic food industry** strongly opposes allowing food from cloned animals to be considered organic. “The Organic Trade Association (OTA) only supports the use of natural processes for breeding and raising animals in the organic system,” said OTA Executive Director Caren Wilcox in a statement released on January 3, 2007. “We have never supported cloning as a part of the organic process. Organic animal products will not come from cloned animals. Consumers who seek to avoid cloned meat, dairy or other animal products should look for the organic label on products.”<sup>16</sup>

## 8. Who regulates these food products?

All foods, including foods of animal origin, are principally regulated by three federal agencies: the FDA, U.S. Department of Agriculture (USDA) and Environmental Protection Agency (EPA). These agencies collectively oversee food and environmental safety, as well as animal health. The available scientific reports and FDA’s draft risk assessment do not provide a basis to conclude that foods from cloned animals need to be regulated differently than other animal-derived foods for food safety reasons.<sup>17</sup>

## 9. What are the regulatory questions before the FDA?

The immediate regulatory issues before FDA relate to the quality and quantity of scientific data available to the agency and whether they are sufficient to support a conclusive final risk assessment that could lift the voluntary ban.

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<sup>14</sup> Commissioner of Food and Drug, Andrew C. von Eshenbach, M.D., November 29, 2005, letter to IDFA President and CEO Connie Tipton.

<sup>15</sup> The complete statement, along with additional background material, is posted at [http://www.idfa.org/reg/cloning\\_idfa\\_statement\\_12-28-06.pdf](http://www.idfa.org/reg/cloning_idfa_statement_12-28-06.pdf).

<sup>16</sup> OTA Statement on Cloning (<http://www.ota.com/pp/otaposition/cloning.html>).

<sup>17</sup> IFIC, Questions and Answers about Foods from Cloned Animals, December 2006.

As a related matter, late in December 2006, two FDA scientists wrote a scientific article that was published in the peer-reviewed journal *Theriogenology*. The article concluded that “food from cattle and swine was as safe to eat as food from animals of those species derived by conventional means.”<sup>18</sup> It made the same finding about food from the offspring of these cloned animals. This journal article and the draft assessment and plan released on December 28, 2006, provide the basis for the agency’s recommendation to regulate food from cloned animals as it regulates products from conventionally bred ones. The assessment and plan exclude sheep due to a lack of data.

The FDA science and safety review effort has not been free from scientific and public criticism. In 2004, the National Academy of Sciences forced the agency to seek more data.<sup>19</sup> Since then, the FDA received a large amount of additional data from the biotechnology industry. Much of this data was included in the draft assessment.

### **10. Will the food from cloned animals bear a label?**

Food is considered misbranded if it fails to include certain required information (such as the name or ingredients) or if the labeling is false or misleading. Labeling may be considered misleading if any material information is omitted. Information is considered “material” if its absence might pose a health risk or mislead consumers in a significant way.

FDA interpreted this requirement with respect to bioengineered foods and found that these products do not differ in any meaningful or uniform way from foods developed by any other means. The agency then declined to require foods produced through biotechnology to be labeled as such. In the absence of any scientific basis to distinguish foods derived from cloned animals from foods produced by conventional means, FDA may decline to require labeling in this case as well.

### **11. What about voluntary labeling?**

Food marketers and manufacturers may make voluntary statements regarding food products provided the statements 1) are not false or misleading in any particular and 2) are adequately substantiated. FDA has issued guidance interpreting this standard in the context of both rBST and bioengineered foods. Examples of potential truthful statements include:

- “This milk is not derived from cloned animals.”
- “We do not use meat from cloned animals.”
- “This product is made from milk that is not derived from cloned animals.”

Guidance that FDA issued in the rBST context suggests that additional qualifying language might be needed for the foregoing claims, such as “No significant difference has been shown between milk derived from cloned and non-cloned animals.”

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<sup>18</sup> “The U.S. FDA and Animal Cloning: Risk and Regulatory Approach,” *op cit*.

<sup>19</sup> National Academy of Sciences, *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects* ([www.nap.edu/books/0309092094/html](http://www.nap.edu/books/0309092094/html)).

### **12. What substantiation of claims will marketers need?**

Since it is not possible to distinguish between milk or meat from cloned and conventionally bred animals, the requirement for adequate substantiation could present special challenges in the context of food derived from cloned animals. Processors might have to implement steps similar to those outlined in FDA's rbST guidance, including physical segregation of milk or meat from non-cloned animals and documentation of the source of the products throughout the transportation and processing steps. A third-party certification program could outline and verify appropriate procedures. In some cases, affidavits may suffice.

### **13. What advertising claims will marketers be able to make?**

The Federal Trade Commission (FTC) governs truth in advertising and requires that advertising be truthful and not misleading; and, that companies adequately substantiate all objective product claims before disseminating an ad. The FTC would not require disclosure that milk is derived from clones, but would permit truthful, non-misleading and substantiated voluntary label statements about the origin of milk or milk products.<sup>20</sup>

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<sup>20</sup> IDFA Hotline, *Ibid.*