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Re: European Food Safety Authority (EFSA) Request for public comments on the "Implications of animal cloning on food safety, animal health and welfare and the environment" (April 27 – May 29, 2007)

Dear Dr. Kleiner:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to comment on the request by EFSA for public comments on the "Implications of animal cloning on food safety, animal health and welfare and the environment". BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products.

BIO members provide industry leadership for the ethical application of animal biotechnology to improve animal and human well-being. The industry seeks to improve global food supply and quality through the application of animal cloning, and thereby provide solutions to issues important to humankind—hunger, health and a sustainable environment. BIO appreciates the opportunity to comment on the request by EFSA for public comments on the "Implications of animal cloning on food safety, animal health and welfare and the environment".

U. S. Food and Drug Administration Draft Risk Assessment

BIO encourages the EFSA Scientific Committee to review the U. S. Food and Drug Administration (FDA) Draft Risk Assessment, released on December 28, 2006, as part of your deliberations on the implications of animal cloning. BIO supports and agrees with the science-based conclusions of the U. S. FDA Draft Animal Cloning Risk Assessment

(the Draft Risk Assessment). Edible products from healthy clones and progeny of clones of cattle, swine and goats, pose no additional food consumption risks relative to corresponding products from other sexually-derived animals. In this matter, U. S. FDA is in agreement with the National Academy of Sciences, which, in "2002 Animal Biotechnology: Science-Based Concerns," concluded that "The products of offspring of clone(s)…were regarded as posing no food safety concern because they are the result of natural matings," and "In summary there is no current evidence that food products derived from adult somatic cell clones or their progeny present a food safety concern." (www.nap.edu/books/0309084393/html/)

The Draft Risk Assessment includes detailed reviews of both the health of livestock clones to date, and the relative food safety risks of food produced from clones and their progeny compared with food produced from animals bred through other assisted reproductive technologies (ARTs). The conclusions of the Draft Risk Assessment were reviewed and accepted for publication in a scientific journal (Rudenko, L. and J. C. Matheson. The US FDA and Animal Cloning: Risk and Regulatory Approach. Theriogenology 2007; 67: 198-207).

BIO supports the two-pronged approach used by FDA in the risk assessment to evaluate the potential risks associate with the food products of animal clones. BIO has reviewed the Comprehensive Biological Systems Approach developed by the FDA and finds it to be a valid assessment approach to systematically evaluate all data on animals involved in cloning on a developmental stage basis. Additionally, BIO has critically evaluated and endorses the Compositional Analysis Method. These procedures were validated via peer review and acceptance for publication in a scientific journal (L. Rudenko, J. C. Matheson, A. L. Adams, E. S. Dubbin, K. J. Greenlees. Food consumption risks associated with animal clones: what should be investigated? Cloning Stem Cells, 2004; 6(2):79-93).

In BIO's estimation, the FDA has established the most extensive review to date of the publicly available animal health and food composition data on animal clones and their progeny. The agency's scientific review was a consideration of the weight of the evidence, evaluating all available information in the appropriate context, as the basis for the Draft Risk Assessment. These procedures were validated via peer review and acceptance for publication in a scientific journal (L. Rudenko, J. C. Matheson, S. F. Sundlof. Animal cloning and the FDA—the risk assessment paradigm under public scrutiny, Nature Biotechnology, January 2007; 25(1):39-43).

Additional Data

There are additional scientific data which EFSA should consider, and which have been published since the U. S. FDA completed their Draft Risk Assessment. These data include those recently presented at an international scientific symposium. The International Embryo Transfer Society held a symposium in Kyoto, Japan on January 6, 2007 that focused on cloning technology, "Assisted Reproductive Technologies and Food Safety in Farm Animals." The presenters were from seven different countries. All of the

data at that symposium are in agreement with the conclusions of the U. S. FDA Draft Risk Assessment conclusions, and include:

- H. Ortegon, D.H. Betts, L. Lin et al. Genomic Stability and Physiological Assessments of Life Offspring Sired by a Bull Clone, Starbuck II. Theriogenology 2007; 67: 116-126 ("Offspring of a cloned bull had a normal chromosomal stability, growth, physical, hematological and reproductive parameters.").

- Y. Heyman, P. Chavatte-Palmer, V. Berthlot et al. Assessing the Quality of Products from Cloned Cattle: An Integrative Approach. Theriogenology 2007; 67: 134-141 ("In clone and control groups, most parameters measured for health and development of the animals as well as evaluation of milk and meat products were within the normal range for the breed. ..Slight significant difference was observed in fatty acid composition… Nutritional evaluation of milk and meat using the rat model did not reveal any difference between products derived from clones versus controls.").

- M. Panarace, J.I. Aguero, M. Garrote et al. How Healthy are Clones and Their Progeny: 5 years of Field Experience. Theriogenology 2007; 67: 142-151 ("In conclusion, cloning had no risks qualitatively different from those encountered in animals involved in modern agricultural practices, although the frequency of the risks appeared to be increased in cattle during the early portion of the life cycle of cattle clones.").

- M. Yamaguchi, Y. Ito, S. Takahashi. Fourteen-Week Feeding Test of Meat and Milk Derived From Cloned Cattle in the Rat. Theriogenology 2007; 67: 152-165 (Long-term rat feeding study found "no significant differences in general conditions, death loss, growth, battery of functional observation tests and estrous cycles among groups given diets containing meat and milk powder from non-clone, embryonic clone and somatic clone cattle. Furthermore, no significant changes attributed to consumption of clone meat or milk were detected in urinalysis, hematological and blood chemical, gross pathological or histological examinations. Therefore, we concluded that the physiologic conditions of the rats were not affected by consumption of meat and milk from bovine clones.").

- G. Laible, B. Brophy, D. Knighton et al. Compositional Analysis of Dairy Products Derived from Clones and Cloned Transgenic Cattle. Theriogenology 2007; 67: 166-177 (Compositional differences, associated with milk and cheese derived from cloned and transgenic cows, were assessed. "Based on gross composition, fatty acid and amino acid profiles and mineral and vitamin contents, milk produced by clones and conventional cattle were essentially similar and consistent with reference values from dairy cows farmed in the same region under similar conditions.").

- S.C. Walker, R.K. Christenson, R.P. Reeves et al. Comparison of Meat Composition from Offspring of Cloned and Conventionally Produced Boars. Theriogenology 2007; 67: 178-184 ("Meat composition from offspring of cloned and conventionally produced boars was compared. The "data indicated that meat from the offspring of clones was not chemically different than meat from controls.").

Finally, BIO recommends that EFSA consider other risk assessments on the safety of food from cloned animals. Both New Zealand and France have released government risk assessments attesting to the safety of foods from livestock clones and their progeny. (New Zealand Food Safety Authority, 2007. Food from cloned animals. Available online at http://www.nzfsa.govt.nz/policy-law/publications/policy-statements/food-cloned-animals/food-from-cloned-animals-final.htm; Agence Francaise de Securitie Sanitaire des Aliments, 2005. Risks and benefits related to livestock cloning applications. Available online at www.afssa.fr/Ftp/Afssa/33773-33774.pdf).

Conclusion

The FDA recognizes somatic cell nuclear transfer (SCNT) as an ART that falls on a continuum of other technology-assisted breeding methods used today in animal agriculture, including artificial insemination, embryo transfer and in vitro fertilization. It is estimated that 75 percent of the milk and 80 percent of the pork produced in the United States comes from animals bred with the use of artificial insemination. The use of embryo transfer has been valuable in capturing the desirable traits of superior females. In vitro fertilization is increasingly being used in production of superior animals eventually used as founder sires. As these examples show, ARTs have been successfully practiced in the agriculture sector. Cloning is simply another ART, which will continue to improve the health of agricultural animals that produce safe meat and milk.

Animal cloning allows for the rapid distribution of the best genetics from proven animals to provide consistent, healthful, and safe meat and milk for human consumption in a reliable manner. Our respective food safety agencies, the FDA and EFSA, and the food industry are focused on maintaining the highest possible safety, quality, and affordability in the food supply; livestock cloning will contribute dramatically to that goal.

Companies that have developed cloning technology for agricultural animals recognize the importance of a rigorous, science-based risk assessment process designed to protect the safety of the food supply. The cloning technology providers have continuously improved the technology, collaborated in their research, shared data with federal agencies, and openly provided information about the animals and the technology to many different stakeholder groups. We understand that BIO member ViaGen, Inc. is offering to share data with EFSA.

BIO appreciates this opportunity to comment on EFSA's "Implications of animal cloning on food safety, animal health and welfare and the environment". We look forward to

further deliberation, and would be pleased to work with the EFSA to provide further input or clarification of our comments, as needed.

Sincerely,

Barbara P. Glenn, Ph. D.
Managing Director, Animal Biotechnology
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