



A study on current risk assessments and guidelines on the use of food animal products derived from cloned animals



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ABSTRACT

The author widely surveyed and analyzed the food safety issues, ethical issues, permits, and approval of animal products from animals cloned by somatic cell nuclear transfer worldwide. As a result of a 2-year survey, the author found that there is no evidence that meat and milk derived from cloned animals or their progeny pose a risk to food safety in terms of genotoxicity, adverse reproductive effects, or allergic reactions. Most countries have not approved meat and milk derived from cloned animals, and their progeny are entering the food supply. To establish the guidelines, the author suggests four principles of safety assessment for meat and milk derived from cloned animals. The four main principles for safety assessment are similarities of chemical composition, adverse reproductive effects, genotoxicity, and allergic reactions under the influence of meat and milk from cloned animals and noncloned counterparts. This principle means that meat and milk derived from a cloned animal are safe if there are no differences in the four safety assessments of meat and milk between cloned animal's progeny and noncloned counterparts.

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1. Introduction

Animal cloning is a biological process of producing genetically similar animals, and somatic cell nuclear transfer (SCNT) is the most common animal cloning technology because somatic cells can be easily obtained and cultured in vitro. Cloned animals are highly attractive to livestock breeders because cloning essentially produces an identical copy of an animal with superior traits (Butler, 2009). Nonetheless, safety of meat and milk derived from cloned animals and ethical issues in animal cloning are still controversial topics. In 2002, the National Academy of Sciences' National Research Council (NAS/NRC) report commissioned by the FDA concluded that there is no evidence that food products derived from adult somatic cell clones or their progeny pose a food safety risk. The US government has released a draft proposal declaring that food from cloned cattle, pigs, and goats is "likely to be as safe as" food from their noncloned counterparts. FDA has found no science-based reason to require labels to distinguish between animal products from cloned animals and commercial animal breeds.

In January 2008, FDA released a final assessment in which it concluded that meat and milk from cow, pig, and goat clones and the offspring of any animal clones are as safe as food we eat every day (FDA, 2008). Not only has animal cloning been widely done, but also the FDA has approved the use of meat and milk derived from clones; consumers and the government are seriously concerned about allowing cloned animals and their derived products into food chains (Panarace et al., 2007). Moreover, some of the questions are still unresolved, e.g., ethical and moral issues and the low success rates of SCNT. For these reasons, many developed countries except the United States will not allow the meat and milk derived from cloned animals or their offspring to enter the food supply in the near future. For instance, food derived from animal clones falls currently under the jurisdiction of the Novel Food Regulation of the EU. Although most countries have not issued a risk assessment guidance regarding meat and milk from cloned animals, a guideline study must address unforeseen situations in the future. Indeed, some Korean scientists asked and made SCNT a requirement for producing meat and milk derived from cloned animals. Therefore, the purpose of this study was to provide information on the risk of animal products derived from cloned animals and to establish guidelines for the use of meat and milk derived from animals cloned by SCNT. This study should be helpful for the establishment of other guidelines for novel foods derived from animals.

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2. Materials and methods

I surveyed more than 100 studies published in the past 10 years related to the link between the animal products derived from cloned animals and safety. This study includes electronic searches of the PubMed, Medline, Scopus, Wiley Online Library, Springer Link, AGRIS, CAB, and Google Scholar databases by means of the following search terms: SCNT, cloned animals, meat and milk derived from cloned animals, safety of animal products derived from cloned animals, guidance, guideline and regulation (in various combinations). Numerous reports released from the government and research institutes of the USA, EU, Japan, New Zealand, Australia, or Korea were analyzed in this study. Risk assessment tests for this study are cited from reports mentioned below, which extensively determined chemical composition, quality parameters, similarity of reproduction and adverse breeding effects, similarity of genotoxicity, and similarity of allergic reactions to consumed meat and milk between the progeny of cloned-animal origin and its noncloned counterparts in rodent models. These reports compared chemical composition and quality parameters of meat and milk between progeny of a cloned animal and noncloned counterpart, and they compared reproduction and adverse breeding effects, genotoxicity, and the allergic reaction in experimental animals that consumed meat and milk derived from the progeny of a cloned animal and from a noncloned counterpart. After analysis of differences or similarities, these previous researchers drew a conclusion whether meat and milk derived from the progeny of a cloned animal are safe or not. In the present study, risk assessment and tests for guideline establishment were cross-referenced from these other studies.

3. Risk assessment studies on animal products derived from cloned animals

This paper extensively surveyed the risk assessment studies on animal products derived from cloned animals and the summarized results are presented in Table 1. Most investigators found that chemical composition of meat and milk was similar between animals derived from clones and noncloned counterparts. The US FDA report in 2008 and Japan NARO Institute of Livestock and Grassland Science (NILGS) report in 2011a,b contain extensive analysis of the chemical composition of meat and milk derived from clones and noncloned counterparts, and then these reports concluded that chemical composition is similar between clones and noncloned counterparts. Although several studies [Takahashi and Ito (2004), Rudenko et al. (2004), and Tian et al. (2005)] found some differences in parameters, they reported that most parameters were within the normal range in terms of chemical composition of meat, milk, carcass, and blood between clones and noncloned counterparts. In terms of quality of meat and milk, the Japanese NARO NILGS report, an FDA report in 2008, and unpublished data from Korean National Institute of Animal Science concluded that quality parameters were similar in meat and milk between clones and noncloned counterparts. In terms of animal health and adverse effects, most studies found that consumption of clone-derived meat and milk did not affect the health and did not have toxic effects in experimental rodent animal models. Moreover, dietary meat and milk derived from clones did not cause genotoxicity, adverse reproductive effects, and allergic reactions in various experimental rodent animal models. As result of these studies, this author also concluded that meat and milk derived from cloned animals are as safe as food from their noncloned counterparts. According to these studies, meat and milk derived from cloned animals can be used as a novel food. Nevertheless, social consultation must be a prerequisite in terms of ethical and moral issues of animal cloning,

improving the success rate and standardization of SCNT; and alleviation of anxiety among consumers.

4. Definition of meat and milk derived from animals cloned by SCNT for the guidelines

A cloned animal is a creature representing a genetically identical copy of an animal because of SCNT, and the definition of cloned animals includes the progeny, which is children and grandchildren of the cloned animal. The definition of animal products derived from cloned animals are meat and milk derived from progenies (2nd and 3rd generation) of a cloned animal, not the cloned animal's lifetime (1st generation). The definition of progenies of cloned animals is second and third generation from the cloned animals, i.e., children and grandchildren of cloned animals. Due to a genetic dilution and mutation, it is hard to determine whether the fourth generation (great-grandchildren) are progenies of a cloned animal or not. In this regard, cloned animals (1st generation) should be represented only by parent animals (whether both parents or half-blooded) and by progenies (2nd and 3rd generation) of cloned animals; meat and milk should be produced by natural mating or artificial insemination not by SCNT in terms of the proposed guidelines.

5. Risk assessment procedures for meat and milk derived from a cloned animal

The risk assessment procedures are subdivided into two steps (before and after slaughtering), the first step is analysis and management of the animals and the farm before slaughtering, and the second step is analysis of differences in meat and milk between the progeny of cloned animals and their noncloned counterparts.

The first step for analysis and management of all animals and the farm before slaughtering can also be subdivided into four steps mentioned below.

The first step is establishment of a tracking system for all the animals and farm of origin.

The second step is standardization of SCNT and SCNT stability for meat and milk production. This step must be consider genome reprogramming or abnormally expressed.

The third step is to determine the health of cell donor animals and surrogate dams.

The forth step is to determine the health of cloned animals and their progeny.

Currently, there are no accurate ways to identify where animal products come from (cloned animals produced by SCNT or noncloned animals). For that reason, the use of meat and milk derived from cloned animals may be hard to control by the government in terms of enforcement of regulations against misuse or violation of labeling. Therefore, a tracking system of animals and farms of origin should be provided prior to establishing the guidelines. Moreover, the health condition of all the animals (cell donor, surrogate dams, cloned animals, and their progeny) must be consider in terms of ethical and moral issues. If we pass the first step (before slaughtering), then risk assessment moves on to the second step mentioned below.

The second step to determine the safety is subdivided into six steps as follows.

The first step is a survey of the experience of human consumption of meat and milk derived from cloned animals throughout the world.

The second step is analysis of similarity of chemical composition of meat and milk between the progeny of cloned animals and noncloned counterparts.

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