Food Directorate Interim Policy on Foods from Cloned Animals

FD-FSNP-075

Background

Assisted reproductive technologies, such as artificial insemination, embryo transfer and *in vitro* fertilization, have a long history of use as an integral part of domestic livestock breeding programs in Canada. More recently, it has become possible to produce copies of animals by asexual means, referred to as cloning. Based on current scientific understanding, the products of animals generated through cloning techniques that use embryonic cells, such as embryo splitting and embryonic cell nuclear transfer, are considered not to pose a food safety concern. There is generally no restriction on the marketing of either the animals produced using these techniques and their progeny, or the products or by-products of these animals, in Canada or elsewhere.

The recently developed method of animal cloning called somatic cell nuclear transfer (SCNT) has raised potential food safety concerns. This type of cloning, which produced Dolly the sheep, involves the transfer and fusion of a differentiated donor cell, for example one derived from an adult animal, with an enucleated egg cell. The nucleus of this donor cell now becomes the nucleus of the reconstructed embryo. As the donor cell is already specialized to perform a specific function, for example, to be a skin or a liver cell, the nuclear material of the donor cell must be reprogrammed to permit it to return to a state close to that of an embryonic, undifferentiated cell. At this time, it is unclear if the nuclear reprogramming that a differentiated cell undergoes to return it to a non-specialized state might impact on the safety and nutritional quality of foods derived from animals generated by SCNT. SCNT technology is still at the research and development stage, and as a result, very limited data are available to provide answers to these questions. On the other hand, the fact that significant health problems are observed in some animals cloned using this technology, reinforces the fact that questions need to be asked about food products derived from them. Without further investigation, however, it is difficult to determine what questions need to be asked.

Interim Policy

Until more is known about the products of this technology, Health Canada will consider foods produced from livestock developed using SCNT and the progeny of such livestock to be captured under the definition of "novel food" in the *Food and Drug Regulations* in that they have been obtained by a reproductive technology which has not previously been applied to generate animals that would be used to manufacture foods (meat, eggs, milk, etc.) and which may result in a major change in these foods. They are therefore subject to the regulations in Division 28, Part B, of the *Food and Drug Regulations (Novel Foods)*. Developers producing cloned animals through SCNT must, therefore, not sell the products or by-products of any cloned animals or their progeny in the human food supply in Canada unless they have been subjected to the pre-market safety assessment required of novel foods.

Additional Considerations

As there is currently insufficient data to guide the pre-market safety assessment of these products, **developers who wish to use SCNT technology for producing food livestock are requested to withhold novel food notifications** until requirements are determined and guidance is available. Nevertheless, in the event that they wish to discuss potential issues and information requirements related to a specific product of this technology, Health Canada encourages developers to contact the Department, preferably before conducting trials aimed at assessing the safety and nutritional quality of food products derived from these animals.

Health Canada is engaging in further study of this issue and will take part in international consultations as they occur. Once sufficient information has been gathered to determine suitable criteria, we will develop the guidance needed to conduct a thorough safety assessment of these products.

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