

## Safety Assessment of Novel Foods

Foods derived from cloned cattle and pigs produced by somatic cell nuclear transfer (SCNT) and their offspring

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### **Abstract**

The Food Safety Commission of Japan has conducted a food safety assessment related products derived from cloned cattle and pigs produced by SCNT (hereafter, referred as SCNT cloned cattle and pigs) and their offspring using available information and the data provided by the Ministry of Health, Labour, and Welfare.

SCNT is a technique in which a somatic cell nucleus or somatic cell is transferred into an ooplast, by direct injection and electrofusion, transfer of the reconstructed embryo into a surrogate dam, and the embryo is delivered as a newborn clone. The basic principle of this assessment was to assess whether the foods derived from SCNT cloned cattle and pigs or from their offspring have substantial equivalence when compared to foods of cattle and pigs produced by the conventional assisted reproduction technology, (ARTs: e.g. artificial insemination ) based on the current scientific knowledge.

It has been pointed out that SCNT cloned cattle and pigs have indicated increased mortality observed in the perinatal period compared to cattle and pigs produced by the conventional ARTs. SCNT cloned cattle are also reported to have a higher mortality rate in their juvenile period. However, this is thought to be a result of imperfect totipotency of embryo reconstructed from somatic cells. Indeed, the newborn death from the embryonic imperfection is a common cause of death not only in animals produced by SCNT but also in those produced by the conventional ARTs. Some SCNT cloned cattle and pigs show physiological instability during their perinatal period, but those traits tend to disappear and the animals become healthy as they grow.

When offspring of SCNT cloned cattle and pigs were compared to those by conventional ARTs, difference in their health status could not be observed.

All together, there appears to be no difference in normal cattle, pigs and their offspring for foods regardless of the used reproduction technologies; the SCNT or the conventional ARTs.

The main reason for these abnormalities displayed by the SCNT cloned cattle and pigs during perinatal and juvenile periods seem to be caused by the epigenetic dysregulation followed by inappropriate embryonic development and differentiation.

Nuclear DNA sequences of SCNT cloned cattle and pigs are a copy their donor animals, therefore, the SCNT itself is not a technology to create new protein when compared to the conventional ARTs.

Meat and/or milk of SCNT cloned cattle and pigs are no difference from those of cattle and pigs produced by the conventional ARTs when judged by nutritional compositions, genotoxicity, feeding studies, and allergenicity.

Therefore, judging by the currently available scientific data, it appears that foods from SCNT cloned cattle, pigs, and their offspring have substantial equivalence compared to cattle and pigs produced by the conventionally ARTs.

The SCNT is a developing technology, therefore, risk management authorities should continue to collect data/information in area of safety of foods derived from clone animals.