The Food and Drug Administration (FDA) may soon approve the use of bovine somatotropin (bST). When the product is injected into dairy cows they will increase the production of milk.

Naturally produced by a cow's pituitary gland, bST is one of the hormones involved in normal growth and development of the mammary gland and normal milk production. Its presence in cow's milk is normal.

Since 1985, FDA has affirmed that milk from bST supplemented cows presents no health risk to consumers. The hormone bST is a protein, not a steroid, and is biologically inactive in humans. It is digested just like any other protein in milk and food.

Milk is the principal source of minerals and protein required for the growth of infants and children. The use of bST by dairy farmers to increase milk production efficiency will not change the nutritional composition of milk.

Old Compound, New Technology
For over fifty years scientists have known that injection of pituitary extracts could increase milk production in lactating cows. However, development of these extracts, later identified as bST, for dairy management purposes was impractical. In the 1970's, the development of recombinant DNA technology led to the volume production of certain important pharmaceuticals.
Commercialization of recombinantly produced human insulin, introduced in 1982, spurred the development of other useful recombinant hormones. Among these hormones were human somatotropin and bST.

By 1985, the FDA had determined that milk and meat from bST-supplemented cows was safe for human consumption. As a result of their review of the safety data, FDA informed Congress and authorized the sale of food products from test cows. However, bST itself was not yet approved for public sale. This approval has awaited extensive review of data from continued studies, writing of draft regulations, and the final approval of the FDA Commissioner.

Increasing Milk Production
Cows genetically selected for higher production normally produce greater amounts of bST. When cows are supplemented with increased amounts of bST, the mammary gland takes in more nutrients from the bloodstream and synthesizes more milk. This increase is accomplished by bST's effects on the synthesis and secretion of insulin-like growth factors (IGF-I). To support this synthesis, the cow voluntarily increases feed intake during the period of bST supplementation. Since nutrient requirements for body maintenance remain virtually unchanged, the result is an increased efficiency in the conversion of feed to milk.

Milk Composition
The effect of bST on the concentration of milk nutrients is dependent on the nutritional status of the cows before and during bST supplementation. Nutrients including fat, protein, and calcium are generally not affected by bST administration. Fat, however, may vary somewhat in earlier stages of supplementation. With the use of proper feed management practices, milk production increases of about 10% may be expected.

Normal levels of bST in milk, about 10 ppb, are not significantly affected by administration of the hormone to the cow. The modest rise of IGF-I concentration is well within normal variation and at a level below its concentration in human milk.

Human Safety Considerations
Early clinical researchers studying bST were hopeful of its usefulness in treating human dwarfism. However, though the protein could be safely injected into humans, it was not biologically active. Growth hormones are species-specific. Since it is a protein hormone, it is digested by humans into peptides and amino acids like any other protein. In fact, when presented to a cow orally, bST is not active. The
cow's digestive system simply recognizes it as dietary protein.

Though the human safety of naturally-occurring bST had been established in the 1950's, many more extensive studies were required by FDA prior to the approval for marketing milk from test cows in 1985. Then, prior to approving the marketing of recombinant bST in the U.S., many other issues, such as animal health and labeling, had to be resolved.

**Will Milk Be Labelled Differently?**
There is presently no requirement for the dairy industry to label that milk is from bST-supplemented cows. Labeling this milk would set a precedence since this is not required of any other supplements. The safety of bST is well established and tests on milk cannot distinguish between milks from a supplemented and a nonsupplemented cow. Milk cannot be marketed if it is from a cow which is receiving any veterinary therapy which might produce a milk residue.

**Animal Health Issues**
Profitable milk production requires that cows are maintained in good health. Scientists have found that the health of bST-supplemented cows is similar to that of nonsupplemented cows producing similar amounts of milk. In any case, good management practices by dairy farmers together with regulatory monitoring of health and therapeutic treatments ensure quality milk for the consumer.

**Selected References**
- FDA 1989. FDA Reviewing bST for Cows, Safety Data Being Published. Talk Paper, FDA, Aug. 4, 5600 Fishers Lane, Rockville, MD 20857.

**Facts About Milk and bST**
- Dairy products are the most thoroughly tested and regulated products in the food industry and are safe and wholesome.
- The U.S. Food and Drug Administration (FDA) is likely to approve the use of recombinant bST after years of exhaustive studies showing it is safe for humans, animals, and the environment.
- Published scientific research and reviews, appearing, for example, in the Journal of the American Medical Association and Science) indicate that milk from bST-supplemented cows is safe, and that the nutritional value is unchanged.
- Milk from cows receiving bST has the same amount of the protein as milk from cows not receiving it.