**Situation**

- Bovine Somatotropin (BST) was approved by the Food and Drug Administration (FDA) on November 5, 1993. It was the first biotechnological product approved for animal production. The Food and Drug Administration determined that BST did not pose a risk to human health, animal health, or the environment. This decision was reaffirmed by FDA in January 1999, following review of newly reported research.

- BST was approved for use in cattle to increase milk yield and production efficiency. BST use can result in about a 9 to 13 pound increase in milk produced per cow per day. Importantly, milk composition is unaltered.

- Public concern about BST usage generally relates to the fact that the form of BST used to treat cows is recombinantly-derived. That is, it is derived from bacteria or yeast that have had the BST gene from cattle inserted into their genome. Some are concerned that the BST molecule is of different amino acid composition or different shape, or that it possesses different properties than BST. None of these concerns are warranted. All characteristics and properties of recombinantly-derived BST are identical to those of BST produced in the cow’s pituitary gland.

- In February 1998, a joint Food and Agriculture Organization and World Health Organization Committee on Food Additives again confirmed that treating cows with BST to increase milk production is safe.

**What We Know**

- BST is perhaps the most researched molecule in food animal production. There have been well over 2,000 publications about BST. These studies have demonstrated the benefits and safety of using BST in dairy production.

- BST results in a 9 to 13 pound or 10 to 15% increase in milk production per cow per day. This additional milk yield requires cows to consume additional feed, but there is approximately a 12% increase in efficiency.

- Somatotropin is the hormone that regulates growth, affects metabolism of all classes of nutrients, stimulates milk production, and improves productive efficiency. Dwarfism in humans can be treated with recombinantly-derived human somatotropin (HST).

- BST is a protein hormone. The term “hormone” has negative public perception because of numerous articles in the public press about side effects to athletes using steroid hormones. One major difference between protein and steroid hormones is that protein hormones are orally inactive and are completely digested in the stomach and small intestine, while steroid hormones are not as readily digested and may be absorbed intact.
Somatotropin is a naturally occurring protein hormone produced and secreted by the pituitary gland of mammals. Bovine somatotropin is not active in humans, and HST is not active in cows, even if directly injected into the bloodstream. In fact, BST and HST differ by about 35% in their amino acid composition, and somatotropin receptors on human cells do not recognize BST.

Milk from BST treated cows has nearly identical composition to milk from untreated cows. Any minor changes in milk composition are likely attributable to increased milk yield in treated cows. Variation of milk fat and protein content is of the same magnitude in milk from treated and untreated cows. Similarly no differences have been found for proportion of whey proteins and casein (which is important for cheese production), vitamin A, thiamin, riboflavin, pyridoxine, vitamin B-12, pantothenic acid, or choline. A slight increase in biotin has been observed.

BST is naturally present in cow’s milk in small quantities (.000006% of total milk protein), and the level is not affected by BST treatment.

Another protein hormone, insulin-like growth factor I (IGF-I), is regulated by BST. In milk of BST treated cows, the concentration of IGF-I is about twice that of untreated cows. Some concern has risen from the fact that IGF-I is active in humans and cattle. Like BST, there is no real safety concern because IGF-I is digested into its amino acid components, as with all proteins. Moreover, IGF-I is present in human breast milk at still higher levels.

BST does not alter milk flavor or its manufacturing properties for cheese, butter, and other products.

There is no significant difference in BST concentration in meat from treated or untreated animals. Improper injection of BST could result in injection site lesions in carcasses. This is alleviated if proper injection procedures are followed.

BST does not pose a risk to the health of treated dairy cows. This was demonstrated in the FDA approval process by treating cows with 60 times the approved dosage with no adverse health effects. There have been some claims in the popular press that BST increases the incidence of mastitis. In fact, any increase in milk yield is usually accompanied by increased mastitis incidence. Moreover, some recent research indicates that BST may play a role in speeding the recovery of milk secretion tissue after a mastitis infection.

Use of BST should have no adverse impacts on the environment. Indeed, improved productive efficiency by dairy cattle results in less manure for a given volume of milk produced.

BST has been approved for use in Brazil, Bulgaria, Costa Rica, Mexico, Russia, South Africa, and some other countries. It has not been approved for use in Canada or the European Union, which complicates export of US dairy products.

The only FDA approved BST product on the market is POSILAC’, by Monsanto. This product is a sustained release formulation that is active for 14 days. The active life of BST in the cow is very short.

BST is a management tool. Like other dairy management technologies, it must be evaluated on a herd by herd basis to determine if it can be used profitably, and at the same time maintain milk quality, animal health, and environmental safety.

What We Don’t Know

There may be implications for reproduction by dairy cows. These effects are not from BST injection per se, but are related to the increased milk production levels and the additional energy demands that the cow requires to meet those levels. Work remains to be completed to determine the optimal times during the lactation cycle that individual cows should be eligible for BST administration.

Prior to the possibility of BST usage, it was believed that the optimum interval between calvings for a cow was one year. With BST usage, cows may maintain milk production at profitable levels much longer. The optimum calving interval under BST usage is not known.

Some consumers prefer milk from non-treated cows. Certain milk bottlers are providing milk that is certified to be from non-treated cows. Certification can be achieved only by the pledge of the dairy producer, since no method is available to detect whether milk is from a treated cow. It is unclear how much additional money consumers are willing to pay.

What We Are Doing

We are monitoring the scientific literature and providing unbiased and science-based information about any potential impacts of BST usage on food safety and human health, animal well being, and safety of the environment.

We are continuing to provide dairy producers with up-to-date information to allow them to decide whether BST treatment is a management tool they can use profitably and safely in their herds.