

Use of Bovine Somatotropin in Dairy Production

Dale E. Bauman^a and Robert J Collier^b

^aCornell University and ^bUniversity of Arizona
deb6@cornell.edu; rcollier@ag.arizona.edu

Recombinant bovine somatotropin (rbST), among the first proteins produced through the application of biotechnology, has been marketed in the U.S. for 16 years and outside the U.S. for 24 years. Despite concerns and perceptions of some regarding animal and human health, there has been no evidence of health issues from its use. To date more than 30 million dairy cows have received rbST supplements and this represents a supply of about 70 billion gallons of milk.

Producer and consumer benefits from the use of rbST include two inter-related considerations — improvements in the utilization of productive efficiency (milk output/resource input) and reductions in the environmental impact of dairy production. The use of rbST is one reason today's carbon footprint to produce a gallon of milk is only one-third of that in 1944. Thus, rbST is a management tool that improves the sustainability of the dairy industry. The following addresses some of the common questions about the use of rbST.

Question: What is bST?

Answer: Bovine somatotropin (bST), also known as bovine growth hormone, is a protein hormone produced by the pituitary gland of cows. There are 20 amino acids that comprise the structure of all proteins and each specific protein has a unique sequence of amino acids similar to the use of letters in the alphabet to spell a word. These 20 amino acids are combined in specific sequences to form the more than 10,000 different proteins in the body.

The sequence of amino acids dictates the three-dimensional shape and properties of each specific protein; the sequence of the protein bST is 191 amino acids. Recombinant-DNA technology has allowed for the commercial production of rbST which is biologically equivalent to natural pituitary-derived bST and has the same amino acid sequence plus the essential amino acid methionine at one end.

Question: What is the history of bST?

Answer: The somatotropin story began in the 1920s and 1930s when it was discovered that an extract from the pituitary glands affected animal performance, including milk production by dairy cows. During the 1940s, U.K. scientists conducted an impressive series of studies that were driven by the food shortages associated with WWII. They identified somatotropin as the primary protein in the pituitary extract which was responsible for the increase in milk production, but found the availability of bST obtained from the pituitary glands of slaughtered cattle was too limited to significantly impact the UK milk supply.

Additional studies were conducted over the next several decades, but work was limited by the supply of pituitary-derived bST and the dogma that bST would only be effective in fat, low-producing cows. In the late 1970s advances in biology led to new concepts on the regulation of nutrient use during lactation, and studies showed bST markedly improved productive efficiency even in high-producing dairy cows. This coincided with advances in biotechnology that made it possible to produce recombinant bST.

This was done commercially by several companies, and a collaboration between Monsanto and Genentech provided the rbST that was used in 1981 by Cornell University scientists in the first studies with dairy cows in 1981. Thereafter, rbST investigations in dairy cows expanded to include university, government, and industry scientists worldwide. FDA approved Monsanto's rbST in 1993 and U.S. commercial sales began February 4, 1994, under the trade name "Posilac." Subsequently, in 2008 Elanco purchased the Posilac business and became the worldwide distributor for rbST.

Question: How does bST work and when is it used?

Answer: In lactating dairy cows, bST is a major regulator of milk production. It does this by coordinating metabolism to allow more nutrients for milk production. The net effect is that rbST-supplemented cows produce more milk and utilize nutrients more efficiently. This is referred to as an improvement in "productive efficiency" which is defined as milk output per resource input. Indeed, genetically superior cows make more bST and they have a greater productive efficiency.

Supplementation of the dairy cow with rbST is done in synchrony with a cow's natural lactation cycle. A cow's peak milk yield occurs about eight weeks after the calf is born, and thereafter daily milk production gradually declines through the remainder of the lactation cycle, as does the amount of bST she produces. The use of rbST is initiated during the 9th or 10th week of lactation and continues until the end of lactation. The rbST supplement (~1 milliliter) is injected subcutaneously (under the skin) at two-week intervals, and the milk response is about a 4.5 kg (10 pounds) increase in the daily milk yield. Thus, use of rbST makes all of a farmer's cows more like the best cows.

Question: What is the basis for the gains in productive efficiency?

Answer: Dairy cows are able to take feed resources and byproducts from the human food industry and convert them into a nutritious product — milk. One benefit from the use of rbST is that supplemented cows require less feed per unit of milk produced. This improvement in productive efficiency is a consequence of what is referred to as "dilution of maintenance." The feed used to maintain the cow is analogous to a fixed cost required for the dairy cow to live and carry out normal body functions, and a constant quantity of nutrients is required to meet the cow's maintenance requirement regardless of her performance. Additional feed is required to make the milk, with a constant quantity of nutrients required for each increment of milk produced.

The quantity of nutrients required for milk production increases as milk output increases, but the fixed costs of maintenance are unchanged. Thus, rbST-supplemented cows have a greater feed intake to support their increased milk output, but the entire extra nutrient intake is used to make milk. The overall effect is a lower proportion of feed intake used for maintenance, resulting in an improvement in the amount of milk produced per unit of feed.

Question: What are the environmental effects of rbST use?

Answer: All food production has an environmental impact, but the environmental impact of dairy production is reduced when milk yield per cow is increased. The use of rbST allows each cow to produce about 4.5 kg (10 pounds) of extra milk per day, and the net effect of this is an 8 to 9 percent reduction in the carbon footprint per gallon of milk. To put this in perspective, if just 15 percent of the U.S. dairy herd was supplemented with rbST, the reduction in the carbon footprint would equal taking about 400,000 cars off the road each year, or planting about 300 million trees annually.

The dairy industry has made remarkable increases in efficiency, and the carbon footprint for production of a gallon of milk has been reduced by almost two-thirds since 1944. The use of rbST helps continue this trend and allows the milk supply to be produced with fewer total cows and feedstuffs. Therefore, an adequate milk supply can be achieved, requiring less land and water to raise crops, which in turn means a reduction in soil erosion and the use of herbicides and pesticides.

The reduction in total cows and feedstuffs also means less fossil fuel and electricity are required for the dairy and cropping operations, and the output of manure and animal waste is reduced. Thus, rbST use in dairy production mitigates environmental parameters including eutrophication and acidification potentials, greenhouse gas emissions, and fossil fuel use.

Question: Is rbST harmful to cows?

Answer: The best indication of the health and well-being of a dairy cow is her own performance. If cows are stressed or ill, then milk yield is reduced. The performance of cows receiving rbST supplements is exactly the opposite — they produce more milk and are able to utilize nutrients more efficiently.

The livelihood of dairy farmers depends on the health and well-being of their animals. Therefore, potential effects on general health, including metabolic disorders and mastitis, reproductive performance, and culling rates, were key considerations in the evaluation of rbST. Prior to FDA approval, results from hundreds of controlled studies were published by university, government, and industry scientists around the world.

Following Food and Drug Administration (FDA) approval, scientists continued to evaluate rbST use on commercial dairy farms, and these results are available in scientific publications. The largest of these was an eight-year study on northeast dairy herds involving over 80,000 cows and 200,000 lactations. Controlled studies as well as field investigations on commercial dairy farms confirm that use of rbST raises no unique concerns, and that the required care and management of rbST-supplemented cows as well as their longevity and herd-life are comparable to those of cows not receiving supplements.

Question: Is the milk from rbST-supplemented cows safe for humans?

Answer: The safety of rbST use has been extensively investigated and comprehensively documented. In addition to FDA, regulatory authorities and their review panels in more than 50 countries, including Canada and the European Union, have concluded that milk and dairy products from rbST-supplemented cows are safe for human consumption.

As one of the first products of biotechnology, the safety of rbST was also evaluated and confirmed by many scientific and biomedical groups including the joint World Health Organization/Food and Agricultural Organization committee (WHO/FAO), National Institutes of Health (NIH Consensus Conference), American Medical Association (AMA), Royal College of Canadian Physicians, American Dietetic Association (ADA), American Society for Clinical Nutrition (ASCN), Institute of Food Technologists (IFT), and U.S. Department of Health and Human Services (USDHHS).

Somatotropin has been the subject of scientific studies for over 50 years and thus there is an extensive base of knowledge about its biology. In particular, in the 1950s attempts were made to use bovine somatotropin to induce growth in humans afflicted with dwarfism. These studies proved that although there were no negative side effects, humans do not respond to bovine somatotropin. There were many considerations in the evaluation of the human safety of milk from rbST-supplemented cows; major reasons for the conclusion that the milk was safe for humans included:

1. rbST is a protein and when consumed orally it is digested, just as occurs for all dietary proteins.
2. bST is not biologically active in humans even if injected directly into the bloodstream.
3. Milk from rbST-supplemented cows does not differ in composition from milk produced by unsupplemented cows.
4. All milk, whether cows are treated or not, contains trace amounts of somatotropin and this miniscule amount is not affected by the use of rbST. Likewise, the ranges for the trace levels of other hormones in milk, including IGF-1, are unchanged
5. Pasteurization destroys any somatotropin present in milk. If the milk is not pasteurized, then digestion in the stomach destroys the somatotropin present in milk.

Question: Isn't bST a hormone?

Answer: bST is a naturally occurring protein hormone. Hormones are chemical messengers that are transported in the blood to affect body processes like metabolism and reproduction. Hormones can be broadly divided into two types: protein hormones and steroid hormones. Protein hormones include somatotropin and insulin, and they are digested like other proteins and rendered inactive when consumed orally. This fact was confirmed in laboratory rats fed large quantities of bST. Just as diabetics must receive insulin injections for this protein hormone to be biologically active, cows have to receive injections of rbST for it to be active.

Humans also make somatotropin, referred to as hST (human somatotropin), and while it is similar to bST in structure there are differences in the amino acid sequence. As a consequence the three dimensional configuration of bST and hST differ, so that bST is not biologically active in humans even if injected directly into the bloodstream.

Question: What about the level of hormones in the milk?

Answer: Milk contains trace levels of somatotropin, less than one part per billion, and these levels don't differ in the milk from cows receiving rbST supplements and unsupplemented cows. As mentioned earlier, the protein hormones in foods are rendered inactive because they are digested similarly to other dietary proteins.

Milk also contains trace levels of other hormones and their concentration range does not differ between milk from cows supplemented with rbST and milk from unsupplemented cows. Insulin-like growth factor-1 (IGF-1) was of special interest because the amino acid sequence produced by cows is identical to that produced by humans. IGF-1 is produced by most cells and is critical for human health because of its role in cell maintenance and repair. Milk IGF-1 was deemed to be of no human health concern because levels are low (a glass of milk contains less than one-ten thousandth of the daily production by the human body) and when consumed orally it is digested like other dietary proteins, so that no appreciable amount would be absorbed from milk.

Question: Is there a test to detect milk from cows receiving rbST?

There is no reliable, validated test that can detect if the milk came from rbST-supplemented cows. The lack of a test is not surprising because there are no differences in the composition of the milk — neither the macro-components nor the micro-components. Consumer confidence in food tests is maintained knowing that FDA requires rigorous proof before certifying the validity of such tests.

Question: What about retail milk labeled as rbST-free?

Answer: Retail milk labeled as “rbST-free” or “no added hormones” or “no synthetic hormones” or “organic” is a niche product based on producers following a management system that does not include the use of rbST. There are no differences in the milk composition among conventional milk and milk labeled as rbST-free or organic; all represent milk that is wholesome and nutritious.

FDA requires that all food labels include certain items, e.g., information about the nutrient content of a serving size of the product. FDA also allows labels to include information relating to product branding and the development of a niche market, as long as the information is truthful. The requirement for truthfulness represents a special challenge to processors wishing to label retail milk as rbST-free or organic because there are no compositional differences in the milks and no tests that can verify the label claim. To deal with situations such as this, FDA generally follows a practice that allows producers to sign an affidavit or provides for a third-party certification system. However, there was still a concern that the label “rbST-free” might be misleading to consumers, so FDA required the label also to include a disclaimer statement that “no significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows.”

Question: Does use of rbST increase antibiotic residues and pesticide levels in the milk?

Answer: All milk is tested for antibiotics, and none with antibiotic residues is allowed to enter the food chain. The antibiotic testing occurs for samples of each milk load from individual farms, and additional tests occur at several points during the milk’s journey from farm to market. If antibiotic residues are detected, the milk is discarded and the producer receives a severe penalty.

The U.S. Department of Agriculture (USDA) analyzes foods, including retail milk and dairy products, for pesticide residues using the tests and standards set by the Environmental Protection Agency. Results are posted on the USDA website; results verify the rarity of violations.

Question: Why is rbST not commercially used in some countries?

Answer: rbST has been approved for commercial use in over 20 countries but some countries, such as Canada and countries in the European Union, do not allow its commercial use. Reasons for countries having not yet approved commercial use are varied, ranging from concerns about animal well-being, production quota-based marketing systems, general opposition to new technologies, social customs, and preference for traditional food production systems.

Nevertheless, these countries, including Canada and the countries in the European Union, have confirmed the human safety of milk from rbST-supplemented cows and allow imported dairy products from countries using rbST to be marketed with no restrictions or special labeling requirements.

Question: How does rbST relate to sustainability of the dairy industry?

Answer: Sustainability is an important consideration in agriculture, with emphasis on meeting human nutritional needs while mitigating the environmental impact of food production. Advances in agricultural productivity have allowed for the production of food that is safe, nutritious, and affordable. In particular, milk and dairy products are excellent sources of high-quality protein and many essential vitamins and minerals for the human diet. However, the U.S. and world population is growing, and our ability to maintain an adequate food supply and the sustainability of the dairy industry depends on continued improvements.

Recombinant bovine somatotropin is one of a long series of technologies which have improved the sustainability of the dairy industry; these include artificial insemination, estrus synchronization, and improved nutrition to name a few. The rbST technology is unique because of the magnitude of its interrelated effects of reducing feed and resource inputs (i.e., improvements in productive efficiency) and mitigating the environmental effects of milk production.

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