Just Say No To **rBGH**
recombinant bovine growth hormone

Bovine somatotropin

Bovine somatotropin or bovine somatotrophin (abbreviated bST and BST), or bovine growth hormone (BGH), is a peptide hormone produced by cows' pituitary gland. Like other hormones, it is produced in small quantities and is used in regulating metabolic processes. After the biotech company Genentech discovered and patented the gene for BST in the 1970s, it became possible to synthesize the hormone using recombinant DNA technology to create recombinant bovine somatotropin (rBST), recombinant bovine growth hormone (rBGH), or artificial growth hormone. Four large pharmaceutical companies, Monsanto, American Cyanamid, Eli Lilly, and Upjohn, developed commercial rBST products and submitted them to the US Food and Drug Administration (FDA) for approval. Monsanto was the first firm to receive approval. Other countries (Mexico, Brazil, India, Russia and at least ten others) also approved rBST for commercial use. Monsanto licensed Genentech's patent, and marketed their product as "Posilac". In October 2008, Monsanto sold this business, in full, to Eli Lilly and Company for $300 million plus additional consideration.

rBST has not been allowed on the market in Canada, Australia, New Zealand, Japan, Israel or the European Union since 2000. Argentina also banned the use of rBST.

The Food and Drug Administration, World Health Organization, and National Institutes of Health have independently stated that dairy products and meat from BST-treated cows are safe for human consumption. In the United States, public opinion led some manufacturers and retailers to market only milk that is rBST-free.

A European Union report on the animal welfare effects of BST states that its usage often results in "severe and unnecessary pain, suffering and distress" for cows, "associated with serious mastitis, foot disorders and some reproductive problems".

History

In 1937, the administration of BST was shown to increase the milk yield in lactating cows by preventing mammary cell death in dairy cattle. Until the 1980s, there was very limited use of the compound in agriculture as the sole source of the hormone was from bovine cadavers. During this time, the knowledge of the structure and function of the hormone increased. With the advent of biotechnology, one of the pioneering biotech companies, Genentech succeeded in cloning the gene for BST. Monsanto had been working along the same lines and struck a deal with Genentech in 1979 to license Genentech's patents and collaborate on development of a recombinant version of BST – a process on which Monsanto would invest $300 million. The two companies used genetic engineering to clone the rBST gene into E. coli. The bacteria are grown in bioreactors, then broken up and separated from the rBST, which is purified to produce the injectable hormone. They published their first field trial results in 1981.

Lilly, American Cyanamid, and Upjohn, and Monsanto all submitted applications to market rBST to the U.S. Food and Drug Administration (FDA), and the FDA completed its review of the human safety

component of the these applications in 1986 and found food from rBST-treated cows to be safe; however strong public concern led to calls for more studies, investigations, and public discussions, which included an unprecedented conference on the safety of rBST in 1990 organized by the National Institutes of Health (NIH) at the request of Sen. Patrick Leahy. FDA approved Monsanto's application in 1993. Monsanto launched rBST, brand-named Posilac, in 1994.

Mechanism of action

An average dairy cow begins her lactation with a moderate daily level of milk production. This daily output increases until, at about 70 days into the lactation, production peaks. From that time until the cow is dry, production slowly decreases. This increase and decrease in production is partially caused by the count of milk-producing cells in the udder. Cell counts begin at a moderate number, increase during the first part of the lactation, then decrease as the lactation proceeds. Once lost, these cells generally do not regrow until the next lactation.

Administration of rBST or BST prior to peak production, in cows that are well fed, prevents the number of mammary cells from decreasing, and increases the amount of nutrients directed away from fat and toward the mammary cells, leading to an extension of peak milk production. The effects are mediated by the insulin-like growth factor (IGF) system, which is upregulated in response to BST or rBST administration in well-fed cows.

Use on farms

From 2000-2005 the USDA National Agricultural Statistics Service (NASS) survey of dairy producers found that about 17% of producers used rBST. The 2010 USDA National Agricultural Statistics Service survey of Wisconsin farms found that about 18% of dairy farms used rBST.

To apply Posilac for maximum effect, farmers are recommended to make the first Posilac application about 50 days into the cow's lactation, just before she peaks. The Posilac then sustains already-present mammary cells, limiting the rate of production decrease after production peaks. After the peak, production declines with or without application of Posilac, but declines more slowly with Posilac than without. This decrease in the rate of production decline permits dairy cows to produce more milk over the span of a lactation. A FAQ document created by the FDA states that, when injected into dairy cattle, the product can increase milk production by an average of more than 10% over the span of 300 days, in cows whose feed levels are increased.

Controversy

Even though approved by the U.S. Food and Drug Administration (FDA) in 1993, rBST has been immersed in controversy since the early 1980s. Part of the controversy concerns potential effects on animal health.

Animal health

Two meta-analyses have been published on rBST's effects on bovine health. Findings indicated an average increase in milk output ranging from 11%–16%, a nearly 25% increase in the risk of clinical mastitis, a 40% reduction in fertility and 55% increased risk of developing clinical signs of lameness. The

same study reported a decrease in body condition score for cows treated with rBST even though there was an increase in their dry matter intake.

In 1994 a European Union scientific commission was asked to report on the incidence of mastitis and other disorders in dairy cows and on other aspects of the welfare of dairy cows. The commission's statement, subsequently adopted by the European Union, stated that the use of rBST substantially increased health problems with cows, including foot problems, mastitis and injection site reactions, impinged on the welfare of the animals and caused reproductive disorders. The report concluded that, on the basis of the health and welfare of the animals, rBST should not be used. Health Canada prohibited the sale of rBST in 1999; the external committees found that, although there was no significant health risk to humans, the drug presents a threat to animal health, and, for this reason, cannot be sold in Canada.

Monsanto-sponsored trials reviewed by the FDA asked whether the use of rBST makes cows more susceptible to mastitis. According to the U.S. Food and Drug Administration, which used data from eight Monsanto-sponsored trials in its decision in 1993 to approve Monsanto's rBST product (POSILAC), the answer is yes. The data from these eight trials, which involved 487 cows, showed that during the period of rBST treatment, mastitis incidence increased by 76% in primiparous cows and by 50% for multiparous cows. Overall, the increase was 53%.

Human health
Milk from rBST-treated cows is chemically similar to traditional milk. Both have very similar levels of protein, fat, and sugar, and comparable levels of vitamins and minerals. Milk from rBST-treated cows is not, however, chemically identical to traditional milk. Milk from rBST-treated cows contains slightly elevated levels of hormones such as BST, and Insulin-like growth factor 1 (IGF1).

Macronutrient composition
The overall composition of the milk including the fat, protein and lactose content are not altered substantially by the use of rBST in dairy cows. The milk may have a slight change in fat content within the first few weeks of rBST treatment as the cow is allowed to adjust their metabolism and feed intake. The changes in the fat content have been shown to be temporary. The composition of the milk has been examined in more than 200 different experiments. Natural variation within milk is normal with or without rBST treatment in cows. This is due to genetics, location, feed, age and other environmental factors. Protein in milk content has also been studied and was shown to have no apparent change in rBST treated cows. The vitamins and minerals that are normally in milk were also unaltered in milk from rBST treated cows. Freezing point, pH, thermal properties, and other manufacturing characteristics of milk were shown to be the same regardless of whether it came from rBST treated cows or not.

Hormones
The American Cancer Society has reviewed the evidence concerning IGF-1 in milk from rBST treated cows, and found that: "While there may be a link between IGF-1 blood levels and cancer, the exact nature of this link remains unclear. Some studies have shown that adults who drink milk have about 10% higher levels of IGF-1 in their blood than those who drink little or no milk. But this same finding has also been reported in people who drink soymilk. This suggests that the increase in IGF-1 may not be specific to cow's milk, and may be caused by protein, minerals, or some other factors in milk unrelated to rBGH. There have been no direct comparisons of IGF-1 levels in people who drink ordinary cow's milk vs. milk stimulated by rBGH. At this time, it is not clear that drinking milk, produced with or without rBGH treatment, increases blood IGF-1 levels into a range that might be of concern regarding cancer risk or

other health effects.... IGF-1 concentrations are slightly higher (to variable degrees, depending on the study) in milk from cows treated with rBGH than in untreated milk. This variability is presumed to be much less than the normal range of variation of IGF-1 in cow's milk due to natural factors, but more research is needed."

BST is present in milk from both rBST-treated and untreated cows, but it is destroyed in the digestive system and even if directly injected, has not been found to have any direct effect on humans.

FDA rBST labeling guidelines state, "FDA is concerned that the term 'rbST free' may imply a compositional difference between milk from treated and untreated cows rather than a difference in the way the milk is produced. Without proper context, such statements could be misleading. Such unqualified statements may imply that milk from untreated cows is safer or of higher quality than milk from treated cows. Such an implication would be false and misleading".

The Food and Drug Administration, World Health Organization, and National Institutes of Health have independently stated that dairy products and meat from BST-treated cows are safe for human consumption. The American Cancer Society issued a report declaring "The evidence for potential harm to humans [from rBGH milk] is inconclusive. It is not clear that drinking milk produced using rBGH significantly increases IGF-1 levels in humans or adds to the risk of developing cancer. More research is needed to help better address these concerns."

Environmental impact

Some studies show that rBST-treated cows reduce the impact of greenhouse gases in comparison with conventional and organic dairy operations. Furthermore, N and P excretion, two major environmental pollutants arising from animal agriculture, were reduced by 9.1% and 11.8%, respectively. Carbon dioxide is recognized to be the most important anthropogenic greenhouse gas, and livestock metabolism and fossil fuel consumption are the main sources of emissions from animal agriculture.

Livestock Metabolism-Use of rBST in lactating cows decreases the quantity of energy and protein needed in comparison to conventional dairy operations along with reducing the total feedstuff used. Fossil Fuel Consumption-Targets atmospheric pollution and resource sustainability environmental concerns. With cows treated with rBST, producing a higher milk yield reduces the feed requirement which in turn decreases with electricity for milk production and the energy required from fossil fuels for cropping.

When conventional, conventional with rBST, and organic dairy operations are compared 8% fewer cows are needed in an rbST-supplemented population, whereas organic production systems require a 25% increase to meet production targets. This is due to a lower milk yield per cow due to the pasture based system which is attributed with a greater maintenance energy expenditure associated with grazing behavior.:20–21

Lawsuit against WTVT

In 1997, the news division of WTVT (Channel 13), a Fox-owned station in Tampa, Florida, planned to air an investigative report by Steve Wilson and Jane Akre on the health risks associated with Monsanto's bovine growth hormone product, Posilac. Just before the story was to air, Fox received a letter from Monsanto saying the reporters were biased and that the story would damage the company. Fox tried to work with the reporters to address Monsanto's concerns; Akre stated that she and Wilson went through 83 rewrites over eight months. Negotiations broke down and both reporters were eventually fired. Wilson and Akre alleged the firing was for retaliation, while WTVT contended they were fired for

insubordination. The reporters then sued Fox/WTVT in Florida state court under the state's whistleblower statute. In 2000, a Florida jury found that while there was no evidence Fox/WTVT had bowed to any pressure from Monsanto to alter the story, Akre, but not Wilson, was a whistleblower and was unjustly fired. She was awarded a $425,000 settlement. At the time of the decision, "the station claimed it did not bend to Monsanto's letter and wanted to air a hard-hitting story with a number of statements critical of Monsanto." Fox appealed the decision stating that under Florida law, a whistleblower can only act if "a law, rule, or regulation" has been broken and argued that the FCC's news distortion policy did not fit that definition. On February 14, 2003, the appeals court overturned the verdict, finding that Akre was not a whistleblower because of the Florida "legislature's requirement that agency statements that fit the definition of a "rule" (must) be formally adopted (rules). Recognizing an uncodified agency policy developed through the adjudicative process as the equivalent of a formally adopted rule is not consistent with this policy, and it would expand the scope of conduct that could subject an employer to liability beyond what Florida's Legislature could have contemplated when it enacted the whistle-blower's statute."

Regulation

Use of the recombinant supplement has been controversial. The assessment of the United States FDA is that there is no significant difference between milk from treated and untreated cows. 21 other countries have also approved marketing of rBST: Brazil, Chile, Colombia, Costa Rica, Ecuador, Egypt, Guatemala, Honduras, Jamaica, Lebanon, Mexico, Panama, Pakistan, Paraguay, Peru, Salvador, South Africa, South Korea, Uruguay and Venezuela. However, regulatory bodies in several countries, such as the EU, Canada, Japan, Australia, New Zealand and Argentina rejected Monsanto's application to sell rBST because rBST increases the risk of health problems in cows, including clinical mastitis, reduced fertility, and reduced body condition. In Canada, bulk milk products from the United States that have been produced with rBST are still allowed to be sold and used in food manufacture (cheese, yogurt etc.).

In 1990, the European Union placed a moratorium on its sale by all member nations. It was turned into a permanent ban starting from 1 January 2000; the decision was based solely on veterinary concerns, laws, and treaties. An in-depth report published in 1999 analysed in detail the various human health risks associated with rBST.

Canada's health board, Health Canada, refused to approve rBST for use on Canadian dairies, citing concerns over animal health. The study found the occurrence of an antibody reaction, possible hypersensitivity, in a subchronic (90-day) study of rbST oral toxicity in rats that resulted in one test animal's developing an antibody response at low dose (0.1 mg/kg/day) after 14 weeks. However, the board stated that, with the exception of concerns raised regarding hypersensitivity, "the panel finds no biologically plausible reason for concern about human safety if rBST were to be approved for sale in Canada."

The Codex Alimentarius Commission, a United Nations body that sets international food standards, has to date refused to approve rBST as safe. The Codex Alimentarius does not have authority to ban or approve the hormone—but its decisions are regarded as a standard and approval by the Codex would have allowed exporting countries to challenge countries with a ban on rBGH before the World Trade Organization.

United States

In 1993, the product was approved for use in the U.S. by the Food and Drug Administration (FDA), and its use began in 1994. The product is now sold in all 50 states.

The FDA stated that food products made from rBST treated cows are safe for human consumption, and no statistically significant difference exists between milk derived from rBST-treated and non-rBST-treated cows. The FDA found BGH to be biologically inactive when consumed by humans and found no biological distinction between rBST and BST. In 1990, an independent panel convened by the National Institute of Health supported the FDA opinion that milk and meat from cows supplemented with rBST is safe for human consumption.

Labeling

The FDA does not require special labels for products produced from cows given rBST but has charged several dairies with "misbranding" its milk as having no hormones, because all milk contains hormones and cannot be produced in such a way that it would not contain any hormones. Monsanto sued Oakhurst Dairy of Maine over its use of a label which pledged not to use artificial growth hormones. The dairy stated that its disagreement was not over the scientific evidence for the safety of rBST (Monsanto's complaint about the label), but "We're in the business of marketing milk, not Monsanto's drugs." The suit was settled when the dairy agreed to add a qualifying statement to its label: "FDA states: No significant difference in milk from cows treated with artificial growth hormones." The FDA recommends this additional labeling but does not require it.[48] The settlement itself caused much controversy, with anti-rBST advocates claiming that Oakhurst had capitulated in response to intimidation by a larger corporation and others claiming that Oakhurst's milk labels were in and of themselves using misleading scare tactics that deserved legal and legislative response.[citation needed]

Kansas

In 2009 the Kansas Legislature passed a bill that would have required dairies that did not use rBGH to print disclaimers on their labels that stated, “The Food and Drug Administration has determined there are no significant differences between milk from cows that receive injections of the artificial hormone and milk from those that do not.” The bill was vetoed in the last days of the 2009 legislative session by then-Governor Kathleen Sebelius. The legislature removed the labeling language and passed the bill without the provision.

Pennsylvania

In 2007, the U.S. state of Pennsylvania adopted a regulation that would have banned the practice of labeling milk as derived from cows not treated with rBST. Pennsylvania's agriculture secretary Dennis Wolff made the following statement in support of the measure:

"Consumers are getting confused with the extra labels. They deserve a choice, and so do producers. But from the standpoint of safety, all milk is healthy milk. Our milk is a safe product. The Pennsylvania Department of Agriculture is not in a position to say use rBST or not. The key word is: choice. I used rBST from day one of its approval to the last day that I milked cows. It was an important management tool on my dairy farm. What we oppose is the negative advertising or the selling of fear. If producers are asked to give up a production efficiency, and if that efficiency nets them $3000 or $10,000 a year for their dairy farm… That's a lot of money.

This prohibition was to go into effect 1 January 2008, but after the comment period the guidelines were adjusted to only ban "rBST-free" claims and instead allow claims that farmers had pledged not to use

rBST and accompany such claims with a disclaimer such as, "No significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows."

Response from milk producers and retailers

In response to concerns from consumers and advocacy groups about milk from cows treated with rBST, some dairies, retailers, and restaurants have published policies on use of rBST in production of milk products they sell, while others offer some products or product lines that are labelled "rBST-free" or the like. Other dairies and industry groups have worked to assure the public that milk from rBST-treated cows is safe.

- Costco has no overall rBST policy, but sells brands such as "Kirkland" with labels pledging that no rBST was used in milk production.
- Wal-Mart announced in March 2008 that its private label Great Value milk will be "sourced exclusively from cows that have not been treated with artificial growth hormones like recombinant bovine somatotropin (rBST)"
- Kroger announced in April 2007 that "it will complete the transition of milk it processes and sells in its stores to a certified rBST-free supply by February 2008."[citation needed]
- Dean Foods has no overall rBST policy, but has brands, such as "Oak Farms", with labels pledging that no rBST was used in milk production.
- Winder Farms, a home delivery dairy and grocer in Utah and Nevada, sells milk from rBST-free cows.
- Guernsey Farms, a dairy farm and distributor located in Northville, Michigan, sells and distributes rBST-free dairy products in Southeastern Michigan. Its milk has been labeled rBST-free for a number of years.
- Safeway in the northwestern United States stopped buying from dairy farmers that use rBST in January 2007. The two Safeway plants produce milk for all Safeway stores in Oregon, Southwest Washington, and parts of northern California. Safeway's plant in San Leandro, California has been rBST-free since 2005.
- Chipotle Mexican Grill announced in June 2012 that it will serve rBST-free sour cream at its restaurants.
- Publix supermarket chain states on its website: "Publix milk is rbST-free. (No added artificial hormones.) However, the FDA has stated that no significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows"
- Braum's, a dairy and ice cream retailer in the midwest with a private herd, says on its website that it does not administer rBST to its cows.
- Starbucks's website, as of August 2012, has no statement about use of milk from cows treated with rBST. For example, its Animal Welfare policy is silent on the issue. It announced in January 2008 that it would no longer sell milk from cows treated with rBST in its stores in the US. The Organic Consumers Association, an advocacy group, claimed that Starbucks' change was due to their advocacy work.
- Ben & Jerry's ice cream uses milk and cream from dairy farms that have pledged not to use rBST.
- Tillamook County Creamery Association, a co-operative made up of 110 dairy farms, indicates on its website that its cows are not treated with hormones.

- Yoplait In 2009 General Mills announced it would stop using milk from cows treated with rBST, and stated "While the safety of milk from cows treated with rBST is not at issue, our consumers were expressing a preference for milk from cows not treated with rBST, and we responded."
- In reaction to these trends, in early 2008 a pro-rBST advocacy group called "American Farmers for the Advancement and Conservation of Technology" (AFACT), made up of dairies and originally affiliated with Monsanto, formed and began lobbying to ban such labels. AFACT stated that "absence" labels can be misleading and imply that milk from cows treated with rBST is inferior. The organization was dissolved in 2011.

The International Dairy Foods Association has compiled a list, last updated in 2009, of state regulations in the US for referencing use of growth hormones on milk labels.

http://en.wikipedia.org/wiki/Bovine_somatotropin

Frequently Asked Questions About rBGH

What is rBST or rBGH?

Bovine somatotropin (BST) is a protein hormone naturally produced in the pituitary glands of cattle. Monsanto developed a recombinant version, rBST, by using a genetically engineered E. coli bacteria. Sold under the brand name “Posilac,” it is injected into cows to boost milk output in the short term. This practice is coming under increasing scrutiny. rBST is also known as rBGH (recombinant Bovine Growth Hormone).

How does rBST affect the animals that receive this drug?

Posilac packaging lists many possible side effects of the drug, including reduced pregnancy rates, visibly abnormal milk, hoof disorders and a need for more drug treatments for health problems. Cows treated with rBST face a nearly 25% increase in the risk of clinical mastitis, a 40% reduction in fertility, and 55% increase risk of lameness. (The Canadian Journal of Veterinary Research, 2003)

Why is increased chance of infections like mastitis a problem?

In addition to the needless suffering of the animal, increased incidence of infections could lead to increased use of antibiotics and an increased risk of antimicrobial residues in milk and to antibiotic resistant bacteria.

("Report on Public Health Aspects of the Use of Bovine Somatotropin," issued March 15-16, 1999, p.16, and available from The European Commission—Food Safety.)

The United States Centers for Disease Control and Prevention recommend that "Decreasing unnecessary or inappropriate antibiotic use, in humans and animals, will decrease the resistance pressure on the treated organisms. Ongoing efforts. . .are needed. . .so that the efficacy of antibiotics is preserved as long as possible."

Is rBST allowed for use in other countries?

The product is already prohibited in Canada, Japan, Australia, New Zealand, and in the 27 countries of the European Union.

How does rBST affect milk production?

rBST is known to increase the levels of insulin-like growth factor 1 (IGF-1) in cows, which can lead to increased IGF-1 in milk. ("Report on Public Health Aspects of the Use of Bovine Somatotropin," issued March 15-16, 1999, and available from The European Commission—Food Safety.)

What are the concerns about IGF-1 in milk?

Many studies have noted some links associated between IGF-1 levels and increased risk of cancer, especially breast and prostate cancer. (Holmes, Pollak, et. al. "Dietary Correlates of Plasma Insulin-like Growth Factor I and Insulin-like Growth Factor Binding Protein 3 Concentrations" Cancer Epidemiology, Biomarkers, and Prevention, Sept. 2002, p. 852-861; Chan, Stampfer, et. al."Plasma Insulin-like Growth Factor-I and Prostate Cancer Risk: A Prospective Study," Science, January, 1998, p 563-566; Yu, Jin, et. al, Insulin-like Growth Factors and Breast Cancer Risk in Chinese Women, Cancer Epidemiology, Biomarkers, and Prevention, August 2002, p. 705-712.)

What other potential problems have come up?

Studies of animals exposed to rBST raise concerns about potential changes in milk protein that could lead to allergies. ("Report on Public Health Aspects of the Use of Bovine Somatotropin," issued March 15-16, 1999, p. 17, and available from The European Commission—Food Safety.)

What do milk and milk product labels need to say about not using rBST?

Labels must be truthful and not misleading. To avoid misleading consumers, Food and Drug Administration (FDA) guidance from February 1994 suggests a label statement such as: "from cows not treated with rbST" or other truthful description.

As recently as August 2007, the Federal Trade Commission (FTC) and FDA rejected a request for new restrictions on rBST marketing claims at the federal level. The FTC stated "food companies may inform consumers in advertising, as in labeling, that they do not use rBST."