Milk and Biotechnology: Maintaining Safe, Adequate Milk Supplies

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Amid unparalleled coverage of the introduction of a new technology for milk production, the U.S. Food and Drug Administration (FDA) approved in late 1993 a synthetically produced hormone for cows—called recombinant bovine somatotropin, or rbST—for commercial sale in the United States.

Consumer-watch groups questioned the safety of milk and dairy products for human consumption from dairy cows receiving rbST, and some dairy suppliers and grocery stores indicated that they would not sell the products. Many want products made with milk from cows receiving rbST to carry labels.

FDA, the Federal agency primarily responsible for determining the safety of new animal drugs and for labels on milk and dairy products, says these fears are unfounded. After considerable testing (the first study reporting results of rbST-supplementation of dairy cows was in 1982), they found rbST use to be safe to dairy cows and they found dairy products made with milk from treated cows to be safe for human consumption.

The FDA Commissioner, David A. Kessler, has stated, "This has been one of the most extensively studied animal drug products to be reviewed by the agency. The public can be confident that milk and meat from bST-treated cows is safe to consume."

The Biotechnology Hits the Market

rbST is an artificially synthesized copy of a naturally occurring protein hormone in cattle (called bovine somatotropin, or bST). The hormone is naturally secreted by a cow’s pituitary gland, directing how energy and nutrients from feed are used for growth, milk production, and other body functions (see box).

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**rbST: Genetically Copied Hormone**

rbST is an artificially synthesized copy of a naturally occurring protein hormone in cattle called bovine somatotropin, or bST. Four variants of natural bST, based on the number and location of amino acids, exist.

Hormones serve as chemical links between cells and organs within the body. bST is naturally secreted by a cow’s pituitary gland, directing how energy and nutrients from feed are used for growth, milk production, and other body functions. The hormone is then transported in the cow’s bloodstream to other organs, where its biological effects occur. For example, bST reaching the cow’s udder stimulates the production of milk.

The sequence of amino acids comprising bST gives it a unique three-dimensional “shape.” For bST to induce a biological effect in the cow, it must bind with specific receptors on the cell membrane of tissues or body organs. These receptors have a three-dimen-

The genetically copied hormone can be administered to dairy cows to boost milk production. Studies have reported milk production increases of 10 to 20 percent per cow during a 245-day treatment period. However, percentage estimates can be misleading, especially if the base levels of production are not reported. USDA analyses of the effects of rbST assume a production response of 1,800 pounds of milk per cow, or an 11.5-percent increase (based on a 1993 average output of 15,610 pounds per cow), over a 305-day lactation period.

Because rbST is considered an animal drug, FDA approval is required before it can be distributed commercially in the United States. Four pharmaceutical companies have been seeking approval for their rbST products. On November 5, 1993, FDA approved the sale of the Monsanto Company product (trade name Posilac). FDA’s approval applied to the Monsanto product only—such products of other firms are being evaluated individually.

FDA’s review procedures for animal drugs emphasize effective-

### Human Safety

FDA’s findings on human safety of rbST are based on two sets of information: the general characteristics of bST and the results of studies (conducted in accordance with FDA rules and guidelines) by the firms offering the products.

The major human-safety issues raised to date are: 1) the safety of consuming milk and meat from cows receiving rbST, 2) risks related to insulin-like growth factors (IGF), and 3) risks associated with possibly greater antibiotic use.

### Safe Milk and Meat

Based upon research indicating that rbST was not active in any species tested if given orally, plus the fact that bST was shown in the 1950’s to be inactive in humans even if injected, FDA concluded early in the investigational period (mid-1980’s) that milk and meat from test animals receiving rbST were safe for human consumption.

Several groups—including the American Medical Association, the National Institutes of Health, the Congressional Office of Technology Assessment, the World Health Organization, and the Food and Agriculture Organization of the United Nations—later supported FDA’s findings.

### Insulin-Like Growth Factors

Scientists raised concerns in the 1980’s about the effect of rbST on levels of insulin-like growth factors (IGF) in milk. IGF’s, in particular IGF-I, mediate many of the biological actions of somatotropins. Bovine IGF-I was found to be

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identical in structure to human IGF-1. Therefore, scientists wanted to be sure that milk and meat from dairy cows receiving rbST would not enhance human IGF-1 effects. Because there was limited information available, FDA requested more data from companies concerning the connection between rbST use and IGF-1 levels and effects.

IGF-1 levels in milk were found to vary widely among cows and herds. rbST use slightly raised IGF-1 levels, but not beyond the ranges found in cows and herds not receiving the products.

It also was found that IGF-1 in milk is biologically inactive when ingested through the mouth. IGF-1 levels in milk from both test animals and animals not receiving the drug were 100 to 1,000 times below the level naturally occurring in human blood. Indeed, it has been shown that IGF-1 is a natural protein required for normal growth and possibly health maintenance in humans. It is normally present in almost all human body tissues and fluids, including human breast milk and saliva. FDA concluded that the milk and meat from dairy cows receiving rbST presented "no increased health risk to consumers."

**Antibiotic Usage**

A 1992 U.S. General Accounting Office (GAO) report concluded that rbST could present an indirect risk through possible increases in the incidence of mastitis (an udder infection common among lactating dairy cows) and the expected increased use of antibiotics to treat the condition.

A fact often ignored in the controversy surrounding the use and safety of rbST is the existence of measures to prevent milk with unsafe levels of antibiotic residues from reaching the public. An extensive system of monitoring by both State and Federal agencies exists to detect residues of illegal drugs in milk. Farmers face severe financial penalties if they are found to have shipped milk containing these residues.

FDA reviewed the data provided by Monsanto to address the mastitis issue. The incidence of mastitis cases in test animals was slightly greater, but did not appear any more difficult to treat than mastitis in non-test animals. Also, the effect of Monsanto’s rbST product on the incidence of mastitis was found to be substantially less than other factors, such as herd-to-herd variation, environment, season, age of the cow, and stage of lactation. FDA concluded that the human health risk posed by the potential increase in antibiotic use was not significant (FDA’s findings apply to Monsanto’s product only—other rbST products must be reviewed individually for their risks of clinical mastitis).

Monsanto voluntarily developed a program, in consultation with FDA, to monitor effects of its approved rbST product. The program includes: 1) evaluation of rbST use on small and large commercial dairy farms, focusing on the health of dairy cows, especially mastitis, animal drug use, and milk losses due to mastitis or drug treatment; 2) collection of information on farmer acceptability and any problems encountered; 3) a 2-year tracking of milk production and drug residues, and 4) a 1-year study of producer-supplied milk to compare the amounts discarded due to positive drug tests between rbST and non-rbST herds.

The fact that rbST is a near exact copy of naturally occurring bST presents a significant regulatory issue. rbST is not detectable in dairy products because current scientific procedures cannot easily differentiate between the artificial rbST and the natural bST. It should be noted that a test method to determine whether milk or meat was derived from rbST-treated cows was not required by FDA; such regulatory methods are not required for animal drug products for which there are no human food-safety concerns. The “no residue” standard employed by FDA to evaluate animal drug safety becomes an issue in itself when such differentiation is not possible.

**Consumers Want Labeling**

Surveys show consumers overwhelmingly desire special labeling of milk products from cows receiving rbST products. FDA held an open joint meeting of its Food Advisory and Veterinary Medicine Committees in May 1993 to consider the labeling issue. Interested parties were invited to present testimony and make statements.

Sound scientific evidence must exist for FDA to make mandatory labeling decisions—consumer preferences alone are not sufficient. With input from the advisory committees plus the testimony provided at the May meeting, FDA...
concluded that it had no legal basis under the Federal Food, Drug, and Cosmetic Act, as amended, for mandating special labeling of products processed or manufactured of the milk from cows receiving rbST. This decision was announced November 5, 1993.

FDA has ruled that food companies could voluntarily label milk and dairy products with respect to rbST, provided the information is "truthful and not misleading." An interim guideline was published in February 1994 by FDA concerning such labeling, but no final decisions have yet been made public. Many consumer and industry groups and individuals have sent in comments regarding the labeling guidelines. FDA must evaluate these comments prior to making a final decision.

**Economic Ramifications**

Consumers, the dairy industry, and Federal budget watchers share concerns about the economic ramifications of rbST use. The effects of rbST on milk production and prices received by dairy farmers, the subsequent impacts on retail prices for milk and milk products, and the effect these changes will have on Federal outlays for dairy support and domestic food assistance programs are just some of the issues raised.

**Milk Production Will Rise Slightly**

Since the product has just recently become commercially available, economic analyses have depended on the assumptions of analysts. A recent study, based in part on USDA analyses, indicated a 1-percent average annual increase in U.S. milk production due to rbST use over fiscal years 1994-99. Prices farmers receive for their milk would decline by about 2 percent per year over the study period, which pushes down total dairy income by about 1 percent per year.

These estimates presume: a continuation of current USDA milk price-support policies, an 1,800-pound-per-cow increase in milk production due to rbST and the appropriate change in feeding to support that increase, an adoption rate by producers resulting in 34 percent of the cows receiving rbST by fiscal year 1999, and no reduced consumption of milk and dairy products once rbST milk is marketed more widely.

Greater milk production would cause prices for farmers to fall and lead to more dairy product purchases by the Federal Government to support farmers' incomes. Federal dairy price-support program costs would increase, peaking at approximately $150 million in fiscal 1996, and then would decline in later years as the industry adjusts to rbST use. This would represent a 1.8-percent increase in the total projected Federal farm commodity subsidies in fiscal 1996. The projected increase in dairy price-support program costs over the entire fiscal 1994-99 period of $510 million represents about 1 percent of Federal farm commodity subsidies for that period.

At the same time, however, lower milk prices would lower the Government's cost of providing fluid milk, cheese, and infant formula to participants in the Special Supplemental Food Program for Women, Infants, and Children (WIC). Lower fluid milk prices would also lower the cost of the Government's Thrifty Food Plan, the basis for calculating food stamp benefits.

Savings in the costs of Federal food assistance programs would begin in fiscal 1997, averaging $18 million per year for WIC and $53 million per year for food stamps over fiscal 1997-99. These savings could completely offset increases in dairy price-support program costs within 10 years.
rbST Expected To Be “Size Neutral”

One concern raised is whether rbST will force small dairy farmers out of business. Analysts generally characterize rbST as a “size neutral” technology. That is, on the basis of cost per cow, farmers with small herds will benefit as much as farmers with larger herds if managerial ability is equal.

No significant capital or equipment expenditures are required to use rbST. For example, Monsanto has offered rbST in a 25-dose package for $140. Such small-dose availability means no dairy farmer should be precluded from using rbST on the basis of herd size. On a per-cow basis, with a 215-day treatment period, the cost of rbST would amount to $86, or 40 cents per day of treatment.

However, if rbST is heavily adopted and milk prices are reduced, at least some of the smaller farmers that do not use rbST might be forced out of the dairy business, because they would not be producing economically sufficient volumes of milk. This situation would arise with other cost-saving technologies, too.

But Will Consumers Buy It?

Surveys have shown a generally positive outlook on agricultural biotechnology by consumers. However, surveys of milk consumers have shown a wide range of reaction to rbST use. The consumption issues related to rbST are fundamentally concerned with fluid milk, which represents about 40 percent of total milk use. Rennet, a bioengineered protein hormone which has been in use in cheese production since 1990, has raised few concerns to date.

Prior to rbST approval, it had been reported that anywhere from 4 to 20 percent of consumers said they would stop buying milk altogether if rbST were approved and used. Translated into sales, these results suggest a 2- to 8-percent decline in total milk demand. However, fluid milk sales actually strengthened in early 1994 and have had the first sustained growth since 1991.

Concerns raised by consumers regarding rbST are similar to issues that have been raised for other foods. Biotechnology in agricultural production is a sensitive issue. The availability of clear, concise information to both farmers and consumers will play a major role in the acceptance of rbST.

References


