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# TED Case Studies

**CASE NUMBER: 399**

**CASE MNEMONIC: BST**

**CASE NAME: Bovine Growth Hormone (rbST) and Dairy Trade**

## A. IDENTIFICATION:

### 1. Issue

Science has created a synthetic form of bovine growth hormone (BGH) that can increase milk output from cows. Recombinant bovine somatotropin (rbST) is a synthetic duplicate of BGH that is a natural protein supplement in cows. BGH can be found naturally in milk. There is controversy that surrounds the sale of rbST-supplemented products. Since the early 1980s, consumers and environmentalists have fought the government and the Food and Drug Administration (FDA) in prohibiting the use of rbST in milk production. Consequently, there has been extensive testing and social and economic studies to quell consumer, environmental, and farmer fears. These groups fear the effects that rbST can have on humans, cows, and small farmers. The FDA concluded in 1985 that beef and dairy products from rbST-supplemented cows were safe for human consumption. The four main pharmaceutical companies that support the sale of this synthetic hormone are Monsanto, Eli Lilly, Upjohn, and American Cyanamid. The sale of rbST would affect the domestic and international sales of dairy products. In November, 1993, FDA approved the rbST product by Monsanto, Posilac, to be used for milk production in dairy cows. RbST was not included in dairy products until February, 1994 after the 90-day moratorium issued by President Clinton. There are still bitter feelings concerning the labeling guidelines of rbST products. Consumers want to know which products are tainted with rbST despite the approval of the FDA and other health organizations. At the domestic level, small cow farms cannot compete with large cow farms if they do not participate in using this drug. Furthermore, there is already an overabundance of milk production in the United States. At the international level, there also exists a controversy concerning the sale and production of rbST. Most dairy farmers of U.S. products trust the actions and procedures undertaken by the U.S. government. In Europe, there has been a ban on growth hormone-infused meat since 1989. Consequently, this happened after an incident relating to tainted beef with the steroid hormone diethylstilbestrol (DES) and the mad cow disease scare. The U.S. is pressing a case against the European Union (EU) in the World Trade Organization (WTO). Due to socioeconomic and political reasons, EU has temporarily banned or issued a moratorium of the marketing and use of rbST-treated products until the year 2000. The U.S. has not retaliated against the EU concerning rbST at this time.

### 2. Description

A background of the hazards to the animals, humans, and environment is now detailed. Also, the economic and international implications of rbST use are explored. Bovine Somatotropin is a type of BGH or protein that is naturally produced by the pituitary gland of all cattle. Traces of bST can be found in milk production. Biotechnology has allowed scientists to produce a synthetic form of this protein-based hormone called recombinant bovine somatotropin (rbST). This synthetic hormone is periodically injected into the cows and makes the mammary glands of dairy cows take in more nutrients from the bloodstream, therefore, producing more milk. (1) Milk production can increase from 10%-40%. (2) Since 1985, this hormone has fueled tremendous controversy by environmentalists, lawmakers, consumers, and pharmaceutical companies in the national and international arenas. The FDA tested the product beginning in the early 1980s by investigating various rbST-supplemented cow herds throughout the U.S. FDA must prove that the drug is safe to humans, dairy cows, and the environment. Subsequently, the National Institute of

Health and the American Medical Association have approved the safety of rbST.(3) Controversy arises in the issues concerning human health, animal cruelty, environmental impacts, and economic impacts. Pasteurization destroys approximately 90% of rbST and bST that is present in milk.(4) There are no biological side effects for humans, but there are minimal side effects for the cattle injected with rbST such as an increased risk of mastitis. Many of the issues that the U.S. has combated are now being dealt with by the EU.



### **Animal and Human Health Concerns**

There is fear by environmentalists that rbST is causing cruelty to animals and concerns by consumers that traces of antibiotics can taint milk for human consumption. The lactation process is a very strenuous activity for the cattle, therefore requiring careful monitoring and high quality of herd management at all stages. If the use of rbST is administered by farmers, then extra precautions are necessary to ensure the safety of humans and the cattle. Increased bST production can cause a condition called mastitis or udder infections that produces puss-laden milk. Environmentalists think that it is cruel to animals to increase the risk of mastitis, but increased antibiotics can ameliorate the condition. Careful monitoring by the agricultural sector will have to be performed to ensure the legality of administering antibiotics.(5)

Despite FDA approval in 1985, several consumer groups have expressed concern over the unforeseen medical problems, traces of antibiotics in milk and meat products and the effect of the increase of insulin-like growth factor (IGF-1). Some consumers doubt the credibility of government organizations, thus doubting FDA reports. Another health concern pertains to penicillin-based drugs (bactum-lactam), the most commonly used, to treat mastitis. The FDA will have to monitor the illegal use of these drugs to prevent allergic reactions in humans. IGF-1 is present in the human dietary process and is identical to cow IGF-1. Both rbST and IGF-1 are orally inactive. Consumers fear the potential carcinogenic affects of higher concentrations of IGF-1 in milk. IGF-1 stimulates intestinal cell growth, thus increased the risk of abnormal intestinal growth. The levels of IGF-1 are 100-1000 times lower than endogenous blood levels in humans, therefore, if IGF-1 is not completely digested, there will be insignificant physiological effects on humans and infants.

BGH as well as other biotechnological hormones have been called Frankenfoods or crack for cows. Jeremy Rifkin, head of the Foundation on Economic Trends (FET), has led a unsuccessful seven- year campaign against the use of rbST in dairy products. The Pure Food Campaign, a public interest group, also boycotted major dairy and grocery companies supporting rbST products. The group dumped milk across the U.S. to symbolize their opposition to perceived human and animal health hazards.(6) Numerous supermarkets, including Krogers, have refused to buy dairy products treated with rbST due to the adamant opposition by consumers.(7) FET has unsuccessfully filed three petitions with the FDA on the grounds of human and animal cruelty.(8) Groups also protested when three current FDA employees were found to have connections to Monsanto when the firm developed Posilac. The FDA and the General Accounting Office have investigated the claims and have found that there was no basis for the claims. There is still a heated debate concerning the labeling of products from rbST-supplemented cows. FDA only requires

labeling of products when foods are significantly altered. FDA requires warning labels when foods are nutritionally altered or introduce allergens. The genetically engineered rbST is almost identical to naturally occurring rbST, therefore, requiring no necessary labels. On February 8, 1994, the FDA established guidelines for labeling rbST products because of increased consumer protests and concerns. No label can state that the product is bST-free because all milk contains the natural form of bST. Acceptable labels can read: "from cows not treated by rbST" accompanied by "no significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows."(9) States, however, are expected to enforce labeling rules by establishing third-party certification and the clear separation of rbST herds and non-rbST herds and products. The following states have enacted laws regarding rbST: Maine, Minnesota, Vermont, West Virginia, and Wisconsin. Maine requires farmers who use rbST to register this information with the dairies that they supply. Maine, Wisconsin, and Minnesota require voluntary labeling. Vermont and West Virginia are still in the process of establishing labeling laws and regulations.(10)

### **Environmental concerns**

In order for a product to be approved by the FDA, the environmental effects must be assessed. Numerous studies have been conducted by environmentalists to detect whether toxins are harmful to farms from continuous use of if the use of rbST would reduce the number of cows needed to produce milk. Consequently, the same quality of milk can be produced with fewer cows, therefore, putting less stress on the environment. There is reduced water and air pollution from manure and methane production and less soil erosion from the decrease of feed production. RbST is administered by syringe dosages and after usage, the rbST-laced syringes become waste. Monsanto has provided safe and legal disposal instructions so that there is no environmental contamination. Furthermore, Monsanto provides a waste management system through a postage-paid mail-back kit. Used syringes can also be mailed to a medical waste treatment facility where the contents are destroyed by incineration or by sterilizing and shredding. Increased or accidental environmental contamination pose no hazardous risk to air, soil, or water



### **conomic concerns**

Four pharmaceutical companies, Monsanto, American Cyanamid, Eli Lilly, and Upjohn, raced to have commercial

rights to rbST. On November 5, 1993, the FDA gave its approval to Monsanto to sell rbST under the name Posilac. Injections of Posilac must be administered in 14-day intervals.(12) Pharmaceutical companies, particularly Monsanto, fully support the sale of rbST. A Monsanto spokeswoman projects that BGH sales will reach \$100 million in 1994. Furthermore, in the next five years, profits will reach \$500 million.(13) The other four companies are currently awaiting FDA approval.(14) President Clinton then issued a 90-day moratorium on the commercial sale of the product until February 3, 1994. This temporary delay was issued to assess the economic and social impact of the new hormone drug on the U.S. dairy industry.(15) According to the American Medical Association, it is expected that increased milk production could benefit third world countries suffering from hunger. Labeling could cost Monsanto a 10% loss in sales. Monsanto supports labeling in order to protect the firm from potential lawsuits that could occur from possible adverse health effects. The FDA also requires that Monsanto include precautionary warnings in their rbST product, Posilac. Monsanto has already filed two lawsuits against milk processors that have falsely labeled their products rbST-free.(16)

The economic impact on the dairy market is significant to dairy farmers. According to Manny Ratafia, a spokesman for Technology Management Group, the estimated potential worldwide sale of milk with rbST supplements could reach as much as \$3.5 billion. There is already a surplus of milk on the market and the scope of government price supports is only based on an estimate. In order to equalize demand and supply in the milk market, farmers will have to reduce rbST dosages.(17)

The Congressional Budget Office has projected that rbST use could cost the government about \$15 million a year in the purchase of surplus milk and dairy products.(18) More exact government estimates, based on a report put out by the Clinton Administration in 1994, can be found under category 16, **economic data**(19) Large farms will benefit over small farms due to the production variables required to support rbST-supplemented cows. These variables include a more concentrated feed, antibiotics, and computer-oriented monitoring equipment for the cows to optimize milking conditions.

### **International concerns**

The same health and animal concerns exist in the Europe. More studies have been conducted by the European scientific community to confirm the U.S. results. The sale of growth hormone treated products has been opposed by the EU ever since the beef market scare over the illegal and biologically harmful drug DES and mad cow disease. The ban was enacted on January 1989 and still exists. The U.S. is currently establishing a case against the EU in the WTO. RbST is under a moratorium until the year 2000 due to political and socioeconomic reasons. This moratorium has been re- extended from 1994. The EU supplies about 50% of the world's dairy products.(21)

The moratorium only concerns the marketing and the use of rbST in the EU, but not BST production in the EU for export to other countries or imports from countries that approved bST.(22) The EU Committee for Veterinary Medicinal Product (CVMP) and the UK Medicines Commission have approved the safety, quality, and efficacy of rbST. Rbst meets the EU guidelines for the new animal cruelty laws. The ban also exists to prevent the surplus of milk production in Europe. Despite the ban against hormones, several European countries can acquire illegal growth hormones on the black market.(23) Under the Common Agricultural Policy (CAP), the EU established marketing quotas since until 2000 to limit production. The Commission says that rbST will disrupt the dairy balance. The EU conducted a survey that concluded that large farms would benefit from rbST use which is unfair to small farms under CAP legislation. The U.S. will not take this case to the WTO unless the moratorium is extended again. If the moratorium continues, the EU will be violating the Sanitary and Phytosanitary (S & P) code of the General Agreement on Tariffs and Trade (GATT) of the Uruguay Round. The code elaborates on Article XX which allows members to discriminate against products that are harmful to humans, animals, or plants. Decisions must be based on scientific reasons from consistent research. The U.S. has already established a case against the EU for banning beef injected with hormones.

There is significant domestic support for the continuous banning of rbST in Europe. There are sixty organizations ranging from supermarkets like Safeway, Co-op, Sainsbury, and Waitrose to Scottish cheese-makers who are supporting the moratorium against Monsanto's Posilac. The only organizations to oppose the ban are biotechnology companies and scientific institutions. Environmental pressure groups like the Genetic Forum are demanding that more research be performed.(24)

### **Keywords**

(1) Trade product: Bovine Growth Hormone

(2) Bio-Geography: DRY

(3) Environmental Problem: HEALTH

**4. Draft Author: Tish Falco (February 1997)**

## **B. LEGAL Clusters**

**5. Discourse and Status:** DISagreement and INPROGess

The controversy over rbST in the U.S concerning consumer and animal protection is complete. The sale of rbST-supplemented products occurred in February 1994. There is a moratorium on the marketing and use of rbST, however, in the EU until the year 2000.

**6. Forum and Scope:** GATT/WTO and MULTILATERAL

At a domestic level, the case involves the United States and its consumers and environmental groups. On an international level, the European Union and its members are involved. Other countries that import U.S. dairy products are currently dealing with the environmental and trade controversy of rbST. Countries are more willing to accept rbST dairy products than they are other BGH meat products. So far, the U.S. has not retaliated against countries that have enacted a moratorium on rbST products.

**7. Decision Breadth:** 16 (USA, EU)

**8. Legal Standing:** LAW

The use of rbST has been regulated by the FDA and approved by Congress in the U.S. while there is a moratorium until the year 2000 in the EU.

## **C. GEOGRAPHIC Clusters**

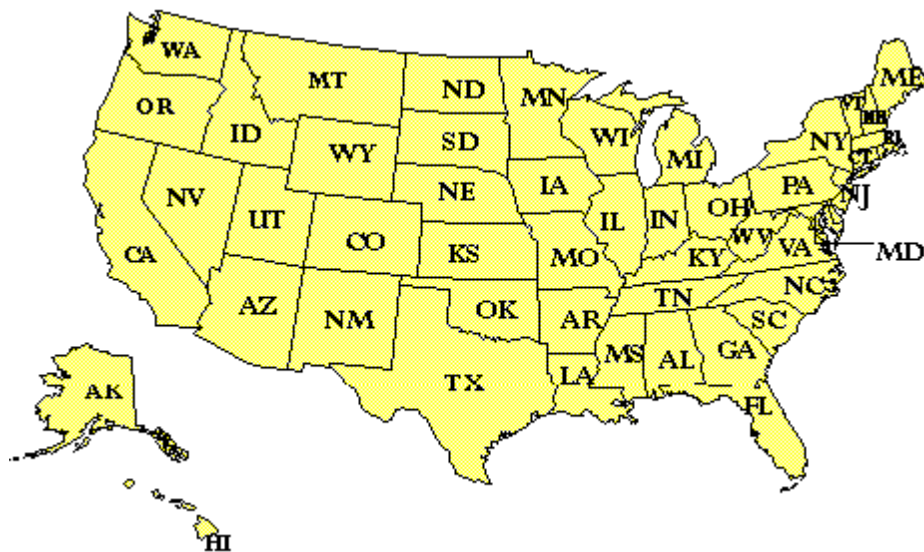
**9. Geographic Locations**

Geographic Domain: Europe [EUROPE]

Geographic Site: Western North America [WNAMER]

Geographic Impact: USA [USA]

The use of rbST affects all of the US specifically California, Texas, Vermont, Wisconsin, and Georgia. The use of rbST affects all of Western Europe or EU member countries.



**10. Sub-National Factors:** NO

**11. Type of Habitat:** TEMPerate

## **D. TRADE Clusters**

**12. Type of measure** Import ban [IMBAN]

The United States has regulated the use of rbST under federal law while the EU has issued a temporary moratorium until the year 2000 in order to investigate the biological effects of the protein hormone.

**13. Direct vs. Indirect Impacts:** DIRrect [DIR]

Currently, there are estimated impacts of the use of rbST based on consumer perception and farmer enthusiasm for the drug. Without government support, the use of rbST could affect small farms and flood the dairy market. The effects would be the same in Europe. If other markets are found for the surplus of milk, as in the developing world, then rbST could increase American and European milk sales. It is hard to measure consumer perceptions at this

time. In 1992, U.S. dairy exports to the EU were \$37 million or 5% of the U.S. dairy product exports. The changes in annual milk production will increase to .5 billion pounds in FY 1994 to 3 billion in pounds in FY 1996. Over a six year period (FY 1994-96), annual milk prices will decrease by 2%. Aggregate farm income will range from \$30 million in 1994 to \$110 million in 1996. Approval of rbST will have little effect on dairy exports. Potential future growth is expected in developing countries in Asia, Central-Eastern Europe, and Latin America.

**14. Relation of Measure to Environmental Impact**

- a. Directly Related: YES rbST production and sales
- b. Indirectly Related: YES dairy products
- c. Not Related: NO
- d. Related to Process: YES, Health

**15. Trade Product Identification:** Dairy products

**16. Economic Data**

Most economic data is based on estimations provided by the Clinton administration in January, 1994. It is estimated that farmers who adopt rbST will increase productivity and profit per cow. Milk production will also increase by one percent through FY 1999, therefore, decreasing consumer milk prices by two percent. Federal price supports are expected to increase by \$150 million in FY1996. Alternately, welfare support for nutritional programs is expected to decrease. Monsanto, the only company to have their rbST product, Posilac, approved by the FDA, will provide Posilac in packages of 25 doses on a 14-day interval. The cost of this package will be \$140. The amount of milk produced from each cow with rbST dosages depends on the point of injection during lactation cycle (305 days where peak is 63-90 days), age and health of the cow, and quality of herd management. It is speculated that milk production will increase by 1800 pounds per year per treated cow or 11.5% increase.

The government forecast of the milk the impact of rbST on the dairy industry based on the Farm Costs and Return Survey of 1989 (FCRS). This detailed survey is representative of the nation's farmers and their entire production costs. Accordingly, farmers will receive a cash balance of 15%-22%. Lower price supports by the CCC would occur due to the increase in milk production. The table below summarizes estimated economic cost associated with the use of rbST to the consumer and the government. Monsanto will profit from the sale of rbST at the domestic and international levels. Pharmaceutical competitiveness will affect Posilac sales.

**Estimated Economic Costs of rbST use (1994-1999)**

	<b>Cow decrease</b>	<b>Increased Milk production</b>	<b>Farm Income</b>	<b>Increased Consumer costs</b>	<b>USDA price supports</b>
<b>1994</b>	n/a	n/a	\$30 million	n/a	n/a
<b>1995-1999</b>	3%	4%	\$250-\$680 million	44 billion-\$770 million	\$510million

**17. Impact of measure on trade competitiveness:** HIGH No major dairy producing country, except Argentina, has banned the use of local and international rbST hormones. Nearly 25 countries have approved the use of rbST. Among the top U.S. dairy importers with rbST approval are Algeria, Brazil, Bulgaria, Costa Rica, the Czech Republic, the former Soviet Union, Honduras, India, Jamaica, Mexico, Namibia, Pakistan, Romania, the Slovak Republic, South Africa, and Zimbabwe. The three leading dairy producers, the EU, New Zealand, and Australia have delayed the use. The temporary ban is due to economic, not scientific reasons, therefore, violating the S & P Code of GATT. The international approval is not expected to have any affect on US exports. Since 1992, dairy exports have progressively increased, especially in the former Soviet Republics and Central-Eastern Europe. Competition in the international dairy market might become fierce due to possible allegations that US milk is not natural due to the use of rbST. A ban of rbST is seen as a non-tariff trade barrier. The international criteria for animal products includes safety, quality, and efficacy. Social and economic considerations are invalid. The moratorium could have certain impacts on US dairy farmers. Monsanto will definitely lose sales overseas of Posilac and run the risk of competitors entering the market in the future. In general, short-term actions could have an affect on other biotechnological products.

**18. Industry Sector:** FOOD

**19. Exporter and Importer:** USA and EUROPE

**V. ENVIRONMENT Cluster**

**20. Environmental Problem Type:** HEALTH

**21. Name, Type, and Diversity of Species Name:** Dairy Products Type: Animal/Bovine/Cattle

**22. Impact and Effect:** LOW and REGULatory

**23. Urgency and Lifetime:** LOW and 10 years

Numerous scientific studies conducted by the US and the EU have proven that rbST has no life-threatening effects on humans or cattle. Consequently, hormonal injections will unlikely cause the extinction of humans or cattle in the near future.

**24. Substitute:** SYNTHetic The development of synthetic alternatives can replace the currently marketable Posilac. Three other companies are developing such alternatives.

**VI. OTHER Factors**

**25. Culture:** YES

The current European moratorium is socioeconomic in origin. The mad cow scare and the DES scare have weakened consumer strength in hormone-supplemented products. Consequently, the EU is extremely cautious in establishing such guidelines. Furthermore, the EU does not want to overflow the European milk market. Since the moratorium on the marketing and use of rbST is temporary, the US is not establishing a trade dispute case. The US, however, is in the process of bringing the EU up against the WTO pertaining to their ban on rbST-supplemented beef.

**26. HUMAN RIGHTS:** NO

The affect of rbST on humans shows that consumption is biologically safe. This includes the residues from antibiotics used on the cows for mastitis.

**27. Trans-Boundary Issues:** YES

The FDA and the US government have fully supported and approved the use of rbST. The EU, however, is still experimenting and studying the affects of the hormone on humans and particularly animals. Extensive research has been conducted on the use and social and economical effects of rbST.

**28. Relevant Literature**

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