Market Sours on Milk Hormone

Controversy over bovine growth hormone reaches a boil, fueled by allegations that it is unsafe and will drive family farms out of business

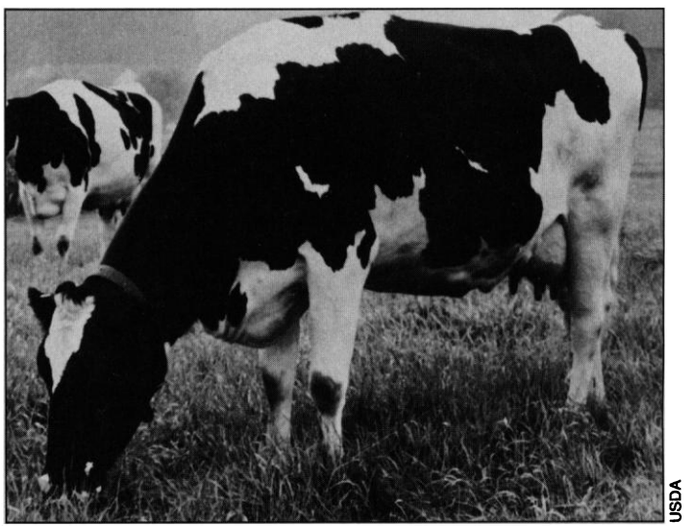
TWO YEARS AGO, bovine growth hormone (BGH) seemed set to become agricultural biotechnology's first billion-dollar product. Companies had spent as much as $200 million developing it, tests had shown that it boosts milk production by 10 to 20%, and the Food and Drug Administration (FDA) had declared that its use would pose no risks to human health. But over the past few months, BGH's commercial prospects have soured so badly that some analysts are now predicting that its market debut—expected sometime next year—could be a costly flop.

The reason: BGH has become the target of a highly effective campaign waged by genetic engineering critic Jeremy Rifkin and grass-roots organizations supporting family farms. Although the critics' main concern is economic—they contend that it will benefit big milk producers and drive family farms out of business—Rifkin is also playing on the public's health fears by raising questions about the safety of milk from BGH-treated cows. By raising the specter of a consumer revolt, he has succeeded in getting some major food processors and retailers to announce that, for the time being, they will not take milk from herds treated with BGH. And a bill is now moving through the Wisconsin state legislature that would require dairy products from BGH-treated herds to be clearly labeled.

Industry officials are plainly exasperated by the mounting controversy. "This country has got an excellent market for fear," says Upjohn's BGH project leader James Lauderdale. Jerry Caulder, president of the Industrial Biotechnology Association and chief executive of Mycogen, says that the BGH safety debate "is a result of living in a society that's relatively scientifically illiterate."

But, with the country already awash in surplus milk, Rifkin knows he has picked an easy target, one that is far easier to shoot at than, say, a lifesaving drug. "It's not like anyone is screaming for more milk," Rifkin says. Industry "picked a real doozy for their first big agricultural biotechnology product."

And BGH's prospects are not helped by the fact that it is currently in a kind of regulatory no-man's land. FDA—which under federal law must assess both the safety and efficacy of animal biologics and drugs—decided 2 years ago that the hormone's use would pose no health hazards to people. But the agency has not yet issued final approval to market BGH because it is still evaluating the hormone's effects on the health of cows. For example, it is assessing BGH's impact on the period of time between a cow's lactations and it is still determining the optimum dose of BGH. While FDA finishes its assessment of the hormone's effectiveness, the agency has said that milk from cows being tested with the hormone can be sold.



USDA

Treated or not? *Milk from cows injected with BGH cannot be distinguished from milk produced by untreated cows.*

BGH is a naturally occurring bovine hormone that increases lactation. It will be commercially manufactured by splicing the BGH gene into bacteria, which will be grown in large quantities in fermentation tanks. The four companies vying for the BGH market—American Cyanamid, Elanco (a subsidiary of Eli Lilly), Monsanto Company, and Upjohn Company—each make slightly different versions of BGH that are identical to the natural hormone or vary from it by one to eight amino acids.

The natural hormone is always present in milk in low concentrations, and studies have shown that, even when cows are injected with synthetic BGH, the hormone levels in the milk do not increase. Indeed, milk produced by treated cows is indistinguishable from milk produced by untreated cows.

But the fact that the product is a hormone has "scary" connotations to consumers, says Gerald Guest, director of FDA's Center for Veterinary Medicine. FDA is convinced that BGH is safe because it is broken down in the gut and inactivated before being absorbed into the blood stream. Robert Collier, Monsanto's director of dairy research, notes that BGH is a relatively simple protein that should not be confused with steroid hormones, which are formed by carbon-ring structures that are not easily digested. John Welser, vice president for agricultural research at Upjohn, says that BGH is digested like any other protein found in food.

Moreover, there is evidence that BGH would not be biologically active even if it did get into the blood stream. Welser says that during the 1960s, when human growth hormone was in short supply, BGH was injected into children as a possible treatment for dwarfism. It had no effect.

Nevertheless, FDA required manufacturers to conduct feeding studies to test the biological activity of BGH. Rats were chosen as the test model because they grow faster when BGH is injected into them. The feeding studies demonstrated that the hormone is not absorbed through the gut, Welser says. FDA adds that the studies demonstrated that BGH had no effect even at daily doses equivalent to 2.3 million times the amount a human would be exposed to in five 8-ounce glasses of milk a day.

Undaunted by these results, Rifkin has seized on a report written by University of Illinois scientist Samuel Epstein to raise safety concerns. Epstein is a physician and professor of environmental science and occupational health who has been a vocal environmental activist for decades. Last spring, he released a report and subsequent-

ly wrote an opinion piece in the *Los Angeles Times*, charging that BGH poses "grave consumer health risks that have not been investigated by the industry or FDA."

Epstein's report, which has not been published in a peer-reviewed journal, contends that BGH could indirectly stimulate premature growth in infants and breast cancer in women. In an interview, Epstein says that this is an opinion "based on my own inference," not on direct experimental findings. He also asserts that BGH treatment has adverse effects in cows, including a reduction in their fertility, and argues that because some of the synthetic versions of BGH differ slightly in molecular structure from the natural hormone, their long-term effects should be more fully investigated. He contends FDA should require long-term testing of BGH in cows and laboratory animals, including primates, before approval.

The report has been vigorously denounced by industry and FDA officials. Henry Miller, a top aide to outgoing FDA commissioner Frank Young, says that Epstein's paper "is a gross distortion of fact." Lauderdale of Upjohn calls the Epstein paper "an atrocity."

But, since the safety issue keeps coming back, FDA has decided to take an unusual step to try to quell concerns. The agency has prepared a scientific paper that it will submit to a peer-reviewed journal, laying out the evidence to support its conclusion that milk from treated cows is harmless. Guest says that FDA has been reluctant to go to extra lengths to proclaim the safety of milk from BGH-treated cows because it wanted to avoid criticism that the agency is an advocate of the product. But in this case, the agency was driven to move out of its role of impartial regulator at the urging of members of Congress and the dairy products industry because of their concern that consumers would rebel against milk from BGH-treated cows.

Economic concerns have already prompted a revolt among farmers and others. The labeling bill in Wisconsin was passed last month by the state senate committee and is expected to be voted on by the full senate in January. Industry representatives say the bill, which would go into effect July 1991, is tantamount to a ban on BGH because consumers will avoid the labeled products. The Vermont company Ben & Jerry's Homemade, Inc., made a media splash this summer when it began stamping its ice cream cartons with a symbol opposing BGH and an appeal, "Save family farms! Call Ben & Jerry 802-BGH-FARM."

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Fear of a consumer backlash was enough to frighten Kraft USA, Borden, Inc., Dannon, Inc., and other food processors to announce that they will not sell BGH milk products while the hormone is still under FDA review. And in August, four of the nation's largest grocery chains, including Safeway Stores, Inc., and Kroger Company, and a major milk cooperative, adopted a similar position.

Monsanto spokesman Larry O'Neill puts the best face on the decision by the food companies not to sell dairy products from BGH-treated herds for now. "They're not challenging the [product's] safety," O'Neill says. "They say they'll reassess their positions" once it clears FDA approval.

BGH's reputation in Europe isn't much better. In September, the Commission of the European Communities proposed legislation that would bar the use of BGH in Europe through the end of next year except for scientific purposes while the potential economic impact is more fully studied.

Remarking on the global status of BGH, Charles Benbrook, staff director of the National Academy of Sciences' Board on Agriculture, describes the controversy over BGH as a "confused mess." To Benbrook, it would seem that only the Europeans are debating the right issue. The arguments over safety, he says, are "obscuring the real issue—the economic impact of BGH once it hits the market."

Ice cream crusade. *The Vermont firm Ben & Jerry's sends its customers a message.*

The BGH manufacturers tout the hormone as a tool to cut farmers' production costs because the same amount of milk can be produced by fewer cows, which cuts feed costs. They contend that the marketplace should be allowed to decide the commercial fate of the hormone. But Rifkin and supporters of small family farms believe that the social costs of this innovation will be too great: family farms will be driven out of business because use of the hormone will create a surplus of milk that will drive down prices.

The debate among the economists centers on two main uncertainties: How many farmers will adopt BGH and will the federal government increase its subsidy of milk prices if a surplus develops? A lengthy economic report released last year by researchers at the University of Wisconsin at Madison concluded that there is "a very high probability" that BGH will cause milk prices to drop—or, alternatively, prompt an increase in dairy price supports. But the study, part of a report entitled "The Social and Economic Impact of Biotechnology on Wisconsin," which was led by agricultural economist Bruce Marion, also said that "it is difficult to predict" the extent to which BGH will be adopted by Wisconsin farmers.

A 1985 study by Cornell economist Robert Kalter said there "will be clear winners and losers" as BGH is adopted (*Science*, 11 July 1986, p. 150). But he added that use of the hormone will simply speed up a trend in which medium- to large-size farms are outcompeting small ones.

To many observers who see the future of BGH as a high stakes game, that future looks grim. Peter Drake, a biotechnology analyst at Vector Securities, remarks, "BGH has run up against a high-pitched political environment" that spells doom for the hormone. Drake contends that FDA may drag out its review of BGH for years.

Benbrook is even more pessimistic. "Without reform of national dairy policy, BGH will ultimately run aground," he says, because farmers, fearful of the economic consequences on the whole industry, will not use BGH.

If the pessimists are right and BGH is doomed, is the future dim for agricultural biotechnology—at least as it might affect the dairy farmer? Benbrook thinks not. Other technologies and methods derived from biotechnology that boost milk output are on the horizon. These include improved genetic manipulation in breeding, the creation of new types of animal feed in which bacterial additives help the animals digest faster, and improved treatment of mastitis (inflammation of the udder), a common ailment that reduces cows' milk output.

So with or without BGH, the squeeze on inefficient farms, whether large or small, is likely to get tighter in the near future. Meanwhile, the impact of biotechnology on dairying will only become more expansive.

■ **MARJORIE SUN**