LIVESTOCK GROWTH HORMONES

THEY'RE SAFE

by Terry D. Etherton

During the past ten years an unprecedented biotechnology has been developed involving the treatment of dairy cows and growing meat animals with somatotropin (ST). Despite the advantages afforded by the use of somatotropin for animal agriculture and the scientific research which affirms that somatotropin poses no increased health risks for either the consumer or the target animal, there are groups that actively oppose the use of this biotechnology.

The Food and Drug Administration is considering approval of somatotropin for commercial use in the dairy and swine industries in 1992. Therefore, a summary of the benefits to animal agriculture and a review of the scientific evidence affirming that somatotropin poses no increased risk to either the consumer or the target animal is in order.

Somatotropin is a naturally occurring protein hormone made in the anterior pituitary gland which is attached to the base of the brain in all mammals. It is the master hormone that regulates growth. In addition, ST regulates the metabolism of all classes of nutrients (e.g., proteins, carbohydrates, lipids, minerals, and vitamins).

In humans, an insufficient production of ST markedly retards growth resulting in short stature at maturity (dwarfism). In advanced countries dwarfism is not a common occurrence because it can be diagnosed and treated. The treatment entails administering recombinantly derived human ST to children who suffer from ST deficiency.

The technology developed involves treating dairy cows and growing meat animals with recombinantly derived somatotropin. When administered to dairy cows, bovine ST (bST) increases milk yield as much as 20 percent and improves productive efficiency as much as 10 percent. Likewise, administration of porcine ST (pST) to pigs increases growth rate by as much as 10 to 20 percent, improves productive efficiency 15 to 35 percent (i.e., increases body weight gain/unit feed consumed), decreases adipose tissue (fat) mass by as much as 80 percent and concurrently increases muscle growth rates by as much as 50 percent. To realize these benefits, it is important to emphasize that the management skills of the producer will be a key factor in determining the production responses attributed to bST and pST.

An additional benefit to consumers is the reduction in fat content of pork from pigs treated with pST. Since numerous studies have established that the quantity of saturated fatty acids in the diet is a major risk factor for coronary heart disease (CHD), a reduction in fat content of meat by pST may provide a health benefit to consumers who are concerned about CHD.

➢ There is widespread evidence that the use of somatotropin or growth hormone to improve milk and pork production is safe. An independent committee appointed by The National Institutes of Health concluded that, "The evidence clearly indicates that the overall composition and nutritional quality of milk and meat from bST-treated cows is equal to that from untreated cows." Similarly, the FDA has concluded that the use of bST presents no increased health risk to consumers. In addition, there is compelling evidence to indicate that somatotropin poses no increased health risk to the target animal. Thus, treatment of farm animals with somatotropin is not only an effective technology for increasing productive efficiency but one that poses no increased health risk for either the consumer or the target animal.

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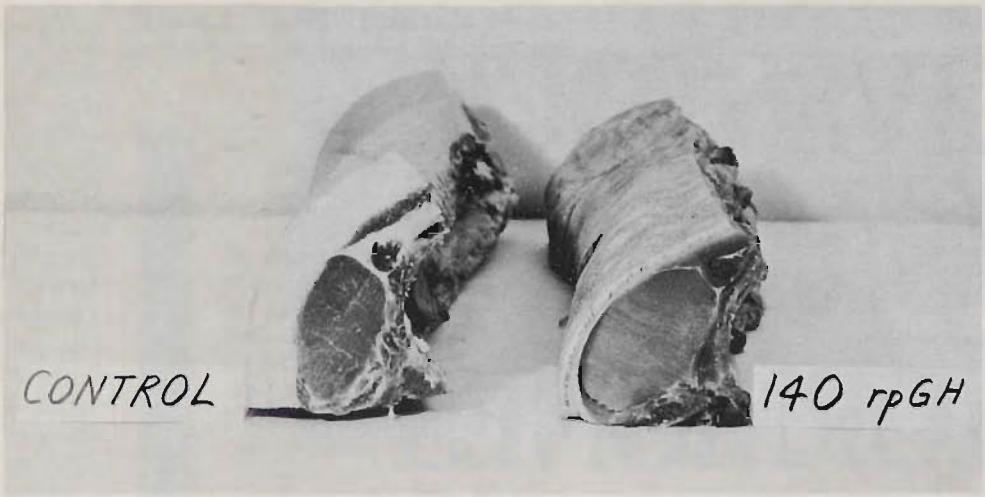

Porcine somatotropin (pST) affects muscle growth in pigs. The pork loin on the right shows the effects of pST on muscle and subcutaneous adipose tissue growth. It is from a pig treated with 140 µg of pST/kg body weight/day for 77 days. The pork loin on the left is from a control pig.

The Public Discussion

This technology perhaps represents the most important recent scientific advance in animal agriculture. However, there is widespread misunderstanding about the safety of somatotropin.

Although ST has been received with great excitement in the scientific community, some public groups are actively attempting to block commercialization of ST and other products produced by biotechnology. Public discussion of ST, in particular bST, has been controversial and in large part a response to misinformation disseminated by groups who oppose the technology. Lesser points out that the intent of these groups is to examine new products and technologies for their social and economic effects to ascertain their political meanings and to find ways to have society oppose technical innovation. It seems that many of their claims are designed to scare the public rather than address the scientific, economic, and social facts as we know them. One example of this is Epstein's outlandish and unfounded assertion that bST would lead to antibiotic-resistant infections in the general public, create infections in man similar to AIDS and increase carcinogens in milk and cancer in humans.

The public discussion also is affected by the scientific illiteracy of the public which makes it difficult for many individuals to understand what ST is, evaluate the risks/benefits of any biotechnology and appreciate the important role that the FDA plays in establishing the safety of pharmaceutical products for both the animal and consumer. In the context of the public campaign waged by the groups opposed to the use of bST and pST, it is relatively easy to understand how consumers, who are uninformed about science and the scientific method, can form perceptions about the technology and their potential economic and social effects that are not based on sound, scientific information.

Absence of Oral Activity

One assertion raised by opponents of ST is that it is "orally active" and that this could lead to health problems for consumers. There is no evidence at all to support this claim. Somatotropin is a protein hormone comprised of different animo acids. Upon consumption, all animal and plant proteins in the diet are degraded to single amino acids and oligopeptides through a combination of the low pH conditions of the stomach and the digestive enzymes found in the stomach and upper small intestine. This degradation process has been confirmed for ST in studies reviewed by the FDA in which bST was administered (by gavage) to rats for 90 days at doses up to 50 mg/kg/day. In these oral toxicity studies with rates, bST did not cause a growth response; furthermore, no gross or microscopic histologic changes were identified in any tissue or organ examined. In addition, no toxicologically significant changes were noted in the clinical chemistry, hematology or urinalysis parameters measured in the rats administered bST orally. It is important to note that each study reported by Juskevich and Guyer met the FDA's minimum requirement of treating rats for at least 14 days with up to 100 times or more of the bST dose projected to be used commercially for the target animal (based on a mg/kg/ bodyweight basis). These findings indicate that ST has no oral activity, a finding which is not at all surprising.

It has been known for almost 40 years that ST from farm animals and other non-primates is inactive in children and adults even when injected. Thus, in addition to ST being rendered biologically inactive by the digestion process, ST is species-specific; non-primate ST has no biological activity in humans. Based on this, it can be concluded that any bST present in milk or pST present in meat would have no adverse effect in the consumer. In fact, the scientific evidence about the safety of bST is so convincing that the FDA has recently published a review in which they conclude that bST presents no increased health risk to consumers. This is an unprecedented move because FDA has not yet given regulatory approval for the commercial sale of bST in the United States.

ST Residues in Meat and Milk

Because ST is present in meat and milk, some opponents of adopting ST for commercial use have suggested that this could pose various human health problems. A number of studies have established that milk normally contains trace quantities of bST (1 to 10 ng/ml); however, administration of bST to dairy cows does not alter milk ST concentration. On a protein basis, a concentration of 10 ng/ml of bST represents only 0.00002 percent of all the proteins found in milk. For example, one quart of milk would contain only ≈ 11 µg of endogenous bST. Because bST is not orally active and is biologically inactive in humans, the FDA has adopted the position that bST in milk does not present a human food safety concern. Other reports have shown that ST treatment for 28 days does not significantly increase ST concentration in meat. Even if there were an increase in ST concentration in meat as the result of ST treatment, this would not be expected to be a human food safety concern. Furthermore, the cooking process would denature ST and, therefore, render it biologically inactive.

IGF-I Concentrations in Meat and Milk

Many of the effects that ST has on cell proliferation in animals are mediated by a protein hormone called insulin-like growth factor-I (IGF-I). Extensive information in the literature shows that ST treatment increases the blood concentration of IGF-I in animals and humans. For example, when pigs are treated with pST there is a one- to three-fold increase in serum IGF-I concentrations and a similar response is observed in dairy cows treated with bST (two- to four-fold increase). ST treatment also increases IGF-I con-

centration in milk and tissues of cows. These observations have prompted some opponents to argue that an elevation of IGF-I in either milk or meat is a safety concern. Although IGF-I in milk survives the pasteurization process (heating to 175°F for 45 seconds), it is destroyed by the conditions used to prepare some infant formulas. It is important to emphasize, however, that these changes in milk IGF-I concentration do not pose any increased health risk to the consumer whatsoever. IGF-I is not orally active in rats. This strongly suggests that ingestion of IGF-I poses no increased health risk to consumers. Furthermore, since IGF-I is a protein, it is digested in the gastrointestinal tract like other dietary proteins and rendered biologically inactive. It's also of interest to note that IGF-I is found in human breast milk at concentrations which are as high or higher than that found in bST-supplemented cows' milk. Thus, infants who are breast-fed have been consuming IGF-I since we evolved as a species without adverse effects.

Summary

Beyond the current controversy is the issue of consumer understanding (literacy) and acceptance of other agricultural products produced as a result of emerging biotechnologies. To date, professional scientific organizations have not developed effective programs to inform the public about the benefits and safety of the emerging biotechnologies. Any promotional or educational efforts undertaken by a company before a product is granted regulatory approval by the government is prohibited. Thus, it is important that professional scientific societies and governmental agencies develop proactive programs to inform the public about the safety and benefits of the emerging agricultural biotechnologies.

The public discussion which has taken place for bST and pST illustrates the strategies used by opponents of technological advancement that will likely be directed toward other emerging agricultural biotechnologies. It is important that the scientific community and society understand the ramifications if technological advancements are hindered. Non-implementation of new agricultural biotechnologies will hinder the United States' ability to maintain economic competitiveness in the global community and impede the rate of technological advancement needed to allow food production to keep pace with the growing food needs of an ever expanding world population.

For More Information

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