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PRB 98-1E

RECOMBINANT BOVINE SOMATOTROPIN (rbST)

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In September and October 1998, there were two important developments regarding recombinant bovine somatotropin (rbST).

First, at the request of the Health Protection Branch, Health Canada scientists studied the rbST risk assessment process and found that the evaluation of the risks of rbST for humans had not been conducted in compliance with the requirements of the *Food and Drugs Act*. They also noted shortcomings in the scientific data and some uncertainty about the long-term effects of rbST on human health.

These scientists also expressed fears about the data provided by Health Canada to the two groups of independent experts currently conducting an assessment. These two groups of experts, under the auspices of the Canadian Veterinary Medicine Association with respect to animal health, and under the auspices of the Royal College of Physicians and Surgeons of Canada with respect to human health, are to publish their report in early 1999.

Next, the conference of the *Codex Alimentarius* Commission's Committee on general principles was held in September 1998. This Committee began a study on the possibility of taking into account other than scientific criteria (for example, social and economic criteria) in setting *Codex* standards for rbST. This study will probably be of assistance in determining whether criteria other than public health criteria should be taken into account in registering new products.

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INTRODUCTION

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Recombinant bovine somatotropin (rbST) is a veterinary medication produced by genetic engineering. When administered to lactating cows, it can increase their milk production by between 10 and 15%.

Approval of this product has been subject to controversy in this country since the early 1990s, primarily because of its possible effects on human health. The various House of Commons and Senate committees with an interest in the subject have regularly examined the issue and held hearings on it. In 1994, the House of Commons Standing Committee on Agriculture and Agri-Food published a report entitled *rbST in Canada*. The first request for approval of an rbST-based product was made in 1988; however, no decision has yet been made on whether to authorize or to ban this medication. Health Canada, the department responsible for approving the product, is currently reviewing its process for evaluating rbST.

This document presents various issues relating to rbST and considers its effects on health and the dairy industry, its regulation in Canada, and its use abroad.

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WHAT IS rbST?

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Bovine somatotropin (bST), which is also called bovine growth hormone, is a natural hormone produced in the pituitary glands of cattle, which stimulates growth in calves and lactation in adult cows. A relationship has been found between the quantity of bST present in cows and their milk production.

The hormone bST, which is present in milk, is, like any other protein, broken down in the digestion process. It is also destroyed to a large extent by pasteurization.

Until the 1980s, the only means of obtaining rbST was to produce an extract from the pituitary glands of dead animals -- just as the insulin required by individuals suffering from diabetes was originally taken from the pancreas of human cadavers. However, the limited amounts of the product obtained in this way and its impurity meant that it could never be used commercially.

Recombinant bovine somatotropin (rbST) is simply bST produced "outside the animal." The gene that expresses bST is inserted into a bacterium using the recombinant DNA technique.(1) This bacterium can then produce a hormone identical to bST, which is called rbST. This process, which is the same as that used to produce insulin, makes it possible to obtain large quantities of a very pure product.

When the diet of lactating cows is supplemented with rbST, as a veterinary medication, milk production can be increased by between 10 and 15%; however, the cows' appetite is also stimulated and they have to eat more in order to support this increased production.

The rbST produced by pharmaceutical companies differs only very slightly from naturally occurring bovine somatotropin. Although it is possible in theory to detect the presence of rbST in cattle, it is very difficult to do so in practice. At the present time there is no practical method of testing for its presence in milk or blood serum, either directly or indirectly.

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(1) The recombinant DNA technique involves the manipulation of genetic material (DNA or deoxyribonucleic acid) and can be used, for example, to transfer genes from one species to another in order to create transgenic hybrids of plants, animals or micro-organisms.

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THE IMPACT OF rbST ON HEALTH

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Human Health

The effects of rbST on human and animal health are still controversial. The following facts are generally accepted.

- Where the overall composition of milk is concerned (mineral, vitamin, protein and lactose content, for example), no difference has been observed between milk from rbST-treated cows and milk from untreated cows. Nor has a higher concentration of rbST been observed in the milk of rbST-treated cows. Thus the quantity of rbST contained in milk is the same whether or not the cows have been given rbST. Furthermore, most rbST is destroyed by pasteurization.

- In cows, rbST influences the production of Insulin-like Growth Factor 1 (IGF-1), a hormone occurring naturally in humans and cows' milk. A slightly higher concentration of IGF-1 has been observed in the milk of rbST-treated cows. According to the 1992 conference of the Joint FAO-WHO Expert Committee on Food Additives, the higher concentration of IGF-1 in milk after rbST treatment is still within the range of concentrations among a test group of cows. However, according to the 1993 Monsanto submission in the United Kingdom, IGF-1 concentrations in the milk of rbST-treated cows could be five times higher than concentrations in the milk of untreated cows. Although IGF-1 is not destroyed by pasteurization, heating milk for the production of baby foods reduces its concentration by 50%; rbST and IGF-1 are both destroyed during yogurt production.

The following organizations have concluded that milk from cows treated with rbST in accordance with sound veterinary practices does not constitute a risk to human health:

- the United States National Institute of Health, in December 1990;

- the Joint FAO-WHO(1) Expert Committee on Food Additives, in February 1992;

- the Commission of the European Community, in January 1993;

- the Center for Veterinary Medicine of the United States Food and Drug Administration, in November 1993;

- the Joint FAO-WHO Expert Committee on Food Additives, in February 1998.

Also, the Human Safety Division (HSD) of Health Canada initially recommended that rbST be registered, judging that it did not constitute a risk to human health.

Nevertheless, some points are worth considering, particularly the activity of rbST and IGF-1 in the human body.

Some observers claim that rbST, like any other protein, is broken down in the digestive tract where, since it is specific to cattle, it is inactive in humans. It is also claimed that IGF-1 is broken down in the digestive tract and thereby becomes biologically inactive.

According to the Health Canada internal report entitled "rbST (Nutrilac) Gaps Analysis Report," dated 10 June 1998, however, the theory that neither rbST nor IGF-1 is biologically active when given orally does not appear accurate in all circumstances. A 90-day study on sub-chronic exposure in rats was submitted by Monsanto; it showed that, after high doses were given orally, rbST could be absorbed intact from the digestive tract and cause an immune response. The consequences of this observation have not been fully assessed by the HSD.

Also according to the Health Canada report, recent experimental data indicate that IGF-1 can survive in the digestive tract and be absorbed intact, particularly when ingested with milk proteins. The report asks that the local effects of IGF-1 residues present in the milk of rbST-treated cows be studied in greater depth and that the findings on IGF-1 submitted in February 1998 to the Joint FAO-WHO Expert Committee on Food Additives be verified among newborns.

In February 1998, the FAO-WHO Committee on Food Additives concluded that the higher concentration of IGF-1 in the milk of rbST-treated cows was in fact lower than the concentration found in the digestive tract and other parts of the human body. IGF-1 absorption after milk consumption should not increase IGF-1 concentration in the body or its organs, even if all the IGF-1 present in the milk is absorbed within the digestive tract.

The effects of the increased use of antibiotics for cows to counter the increased incidence of mastitis caused by rbST use are also a subject of concern (see the section entitled Animal Health). In February 1998, the Joint FAO-WHO Expert Committee on Food Additives studied the possible contamination of milk as a result of the increased incidence of mastitis and the resulting increased use of antibiotics for cows. It concluded that the use of rbST does not increase the risk to human health when antibiotics are used to treat mastitis, and that possible higher concentrations of antibiotic residues in milk can be managed using existing dairy industry practices.(2)

According to the Health Canada internal report, however, the apparent link between rbST use and increased incidence of mastitis (as pointed out on Monsanto's product labels) could have effects on human health. The possibility of emerging resistance to antibiotics in pathogens transmissible to humans has not been studied.

The Health Canada study continues. At present, two groups of experts, one with respect to animal health, under the auspices of the Canadian Veterinary Medicine Association and the other, with respect to human health, under the auspices of the Royal College of Physicians and Surgeons of Canada, are assessing rbST. Their assessment will be part of the decision-making process.

Animal Health

The most important negative effect on the health of rbST-treated animals is the possibility of increased incidence of mastitis.(3)

A number of factors can promote mastitis: lactation, the environment, the herd, the season and so on. Studies have shown that there is a connection between the level of milk production and the incidence of mastitis, whether or not the cattle have been treated with rbST. Since rbST-treated cows produce more milk, it has been suggested that the increased incidence of mastitis could be due to this higher level of production, rather than to the hormone treatment.

It is difficult to determine the role of the rbST treatment in the increased incidence of mastitis. In the United States, the Food and Drug Administration (FDA)(4) has concluded that the use of PosilacÒ (the rbST-based product marketed by Monsanto) is not biologically significant in the incidence of mastitis per unit of milk produced since, when compared with mastitis caused by other major factors, the effects of rbST were not great. On the other hand, the European Union Committee on Veterinary Medications has concluded that classical statistical techniques do not allow us to conclude that the rbST treatment has no direct impact on the incidence of mastitis.

Monsanto does acknowledge that the use of rbST can increase the risk of mastitis but points out that other factors, which can be managed, may also play a role. The product label carries a message recommending that farmers assess their mastitis-prevention practices before using the product.

On the other hand, in a study published in 1997, the Virginia Polytechnic Institute and State University questioned the method used by the FDA to assess the impact of rbST on the incidence of mastitis. The University stated that the findings of the FDA contradicted the results analyzed in this study and suggested that the labelling indicating that good management practices were effective in preventing mastitis should be reviewed. The University study also noted the weakness of certain conclusions in the scientific literature used to assess the effect of rbST on the incidence of mastitis in the United States. This effect is therefore still open to discussion.

Where other effects of rbST on animal health are concerned, Monsanto's proposed product label indicates a number of undesirable effects including digestive problems, lameness and other foot problems, and reproductive problems. These effects were confirmed by the Health Canada internal report dated 10 June 1998, which concludes that the first assessments of the risks of rbST to cows, although of poor quality, indicate that rbST can have results including congenital defects, reproductive problems, and increased incidence of lameness.

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(1) United Nations Food and Agriculture Organization (FAO); World Health Organization (WHO).

(2) Each Canadian province has monitoring programs. Before a producer's milk is pooled, it must be certified free of antibiotic residues.

(3) Mastitis is an inflammation of the teat.

(4) In the United States, the FDA is responsible, among other things, for assessing and approving veterinary products for animals intended for use as food.

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THE IMPACT OF rbST ON THE DAIRY INDUSTRY

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In September 1994, Agriculture and Agri-Food Canada set up a task force on rbST, made up of representatives of industry, producers, consumers, and government. The task force examined the potential impact of this product on the dairy industry in Canada in its May 1995 report entitled *Review of the Potential Impact of Recombinant Bovine Somatotropin (rbST) in Canada*.

In this report, the task force considered the costs and benefits of adopting rbST for the dairy industry as a whole, for the supply management system, for dairy farms and for the dairy processing industry. It also studied the impact of rbST on the genome and on the genetic evaluation of dairy cattle in Canada. The following paragraphs are based on this report.

Supply Management and the Processing Industry

According to the task force report, the use of rbST would have only a relatively modest impact on the production calculations used to determine the target price for milk, unless its use became widespread among producers. Similarly, the value of production quotas would change very little in the long term.

A dual marketing system in which a distinction was made between rbST-free milk and undifferentiated milk(1) would be very expensive in Canada. The differentiation of these products would involve a complete reorganization of the Canadian supply management system and substantial costs for the dairy processing industry.

Dairy Operations

According to the task force report, prices would fall, regardless of whether milk consumption remained unchanged or whether a negative reaction by consumers led to a decline in sales. Consumers would benefit if all the savings achieved were passed on to them. If there were a 3% decline in sales, the profitability of the industry would decline by 2.4% on average; however, net revenues from dairy operations would be maintained.

Since rbST is a management tool, it is unlikely that its use will become very widespread. Farm management is a more important factor in profitability than the use of rbST. Unlike the construction of a building, for example, the use of this product does not require any major additional investment. However, there would be certain additional costs in the administration of this product, for example the cost of additional feed. It would be up to each farmer to make the choice on the basis of his or her own economic calculations.

According to studies, the influence of this product on the number of dairy operations in Canada would be minimal and its use would be cost-effective for most commercial dairy operations. The quality of the dairy operation, rather than its size, would determine the increase in dairy production.

Animal Genetics

Scientists who have assessed the impact of rbST on the genetic assessment of dairy cattle have concluded that approval of the product must not be dependent on its impact on animal genetics. However, they have made 15 recommendations designed to reduce the impact of the product on genetic upgrading programs; in particular, they recommend continuation of the research into the relationship between rbST and animal genetics.

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(1) "Undifferentiated milk" would be milk from cows that might or might not have received rbST.

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THE REGULATION OF rbST IN CANADA

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Approval

Recombinant bovine somatotropin (rbST) is a veterinary medication produced with the assistance of genetic engineering. When it is used on lactating cows, it can help to increase milk production by between 10 and 15%. Approval of such a medication falls under the *Food and Drugs Act* and Regulations.

Health Canada is the only department responsible for approving rbST in Canada. Approval would be based on a finding that the product is harmless for both the animals and for human consumption. Regulations also evaluate the purity, effectiveness, potency and stability of a medication. When the medication meets the regulatory requirements, Health Canada issues a notice of compliance. As long as rbST has not received this notice, it may not be legally sold in Canada.

Use of rbST

Somatotropin is referred to in Schedule F, Part I of the *Food and Drugs Regulations*. A medication included in this Schedule may be sold only by an authorized practitioner in Canada. If rbST receives a notice of compliance, it may be sold to a dairy producer only by an authorized veterinarian, who will be responsible for recommending to his or her client how best to use the product. The practice of veterinary medicine is governed by the provincial organizations responsible for issuing the licence that every veterinarian must have in order to practise. Thus, the fact that only authorized practitioners may sell veterinary medicines constitutes a control over the sale of these products and acts as a means of restricting any abuse of them.

Labelling

Health Canada is responsible for mandatory labelling requirements dealing with such health issues as the presence of allergenic products or changes in the nutritional composition of a product. The Canadian Food Inspection Agency (CFIA) is responsible for any labelling that does not relate to food safety; that is, voluntary labelling and labelling designed to protect consumers against fraud. Thus, the CFIA ensures that Canadian and imported dairy products comply with the regulations governing quality and labelling.

It is very likely that products such as cheese and yogurt made from milk produced by rbST-treated cows have been imported into Canada. In fact, the use of rbST has been approved in the United States since February 1994. In that country, milk from treated cows is considered to be as safe as milk from untreated cows and there

is no labelling requirement concerning rbST on dairy products. Furthermore, according to the CFIA, there is no means of identifying these products.

However, because dairy products are identified by their country of origin, the consumer can decide whether to purchase products from countries that have already approved rbST. On the other hand, products in which milk is only one ingredient among many (ice cream, for example) are classified as Canadian products, no matter where their raw materials may have originated.

If rbST is approved for use in Canada, the issue of a notice of compliance would imply that the product had been found not to pose any particular threat to human health. When a product does not pose a threat, Health Canada does not require any mandatory labelling, but voluntary labelling is permitted if the information is verifiable.

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SITUATION WITH RESPECT TO rbST IN CANADA

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Provel, a division of Eli Lilly Canada Inc., submitted an application for approval of its product based on recombinant bovine somatotropin (rbST) in March 1988. At Provel's request, the application was put on hold in May 1996.

In 1990, Monsanto Canada made an application for approval of its rbST-based product (sometribove, marketed under the name "Nutrilac").

In April 1994, the Standing Committee on Agriculture and Agri-Food published a report entitled *rbST in Canada*. The Committee made seven recommendations including the imposition of a one-year moratorium for conducting a detailed review of the impact of rbST and creation of a task force to carry out that review.

A one-year moratorium on the sale of rbST was put in place in July 1994. This moratorium is still in effect.

In September 1994, the Minister of Agriculture and Agri-Food created an rbST Task Force; this task force includes a representative from each of the following organizations: Agriculture and Agri-Food Canada, Consumers Association of Canada, Dairy Farmers of Canada, Industry Canada, Monsanto Canada inc., the Council for the Dairy Industry of Canada and Provel (a division of Eli Lilly Canada Inc.).

In May 1995, the rbST Task Force published its report entitled *Review of the Potential Impact of Recombinant Bovine Somatotropin (rbST) in Canada*. (See Section on Impact of rbST on the Dairy Industry.)

In May 1997, an article in the *Globe and Mail* reported that some Health Canada scientists had questioned the process for assessing the impact of rbST on human health.

In July 1997, the Dairy Farmers of Canada asked that the Auditor General review the rbST approval process, that the *Codex alimentarius* Commission(1) express an opinion on whether the hormone is harmless, and that Health Canada inform the public of the process for assessing the approach used in deciding whether to grant approval.

In July 1997, the Netherlands proposed a motion to the *Codex alimentarius* requesting that establishment of a maximum limit for residues be delayed while data relating to human health were reassessed by the Joint FAO-WHO Expert Committee(2) on Food Additives and the application of "legitimate factors other than the scientific

analysis" was reviewed. Canada voted against the motion.

The assessment of rbST is still on-going. Health Canada has asked Monsanto for further information on the impact of rbST on the animals treated. There have also been two major developments:

- An internal Health Canada team made up of renowned scientists has examined the process for assessing rbST following the questioning of this process by scientists from the department (some criticisms had appeared in the press). The study has revealed certain flaws in the evaluation process and its scientific findings.

- An evaluation by a third party, which will be included in the decision-making process, is under way. Two groups of experts -- under the direction of the Canadian Association of Veterinarians for the animal health aspect and the Royal College of Physicians and Surgeons of Canada for the human health aspect -- are currently evaluating the product. The report is scheduled to appear in the fall of 1998.

As long as rbST has not received a notice of compliance, it cannot be sold legally in Canada.

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(1) The *Codex alimentarius* (the Latin term for food code) Commission is part of the World Health Organization (WHO) and the United Nations Food and Agriculture Organization (FAO) and has 146 member countries. Since it was established in 1962, one of its goals has been to define food standards and codes governing hygiene and technology in light of the safety of food additives and contaminants (it has evaluated more than 700 additives and determined more than 3,200 maximum levels of pesticide residues).

(2) United Nations Food and Agriculture Organization (FAO) and the World Health Organization (WHO).

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rbST IN OTHER COUNTRIES

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United States

Sales of recombinant bovine somatotropin (rbST) have been permitted in the United States since February 1994. American law does not require the milk from rbST-treated cows to be labelled as such, although it is possible to label milk as being rbST-free. Where this is done, however, it must also be indicated that the Food and Drug Administration has determined that there is no significant difference between the milk from cows treated with rbST and milk from cows that have not been so treated.

American consumer reaction has been studied by Georges Brinkman, an economist at the University of Guelph.

In the year following the introduction of rbST, milk consumption remained steady. It would appear that this trend can be explained primarily by the fact that the product available did not make distinctions: in the United States, milk is not identified as coming or not coming from cows treated with rbST. Milk may be labelled as rbST-free, provided that it is also specified that there is no significant difference in the milk of cows that have been treated with rbST and cows that have not. During the period from January to August 1996, milk consumption even increased by 0.9% over the figure for the same period in 1995.

It is thought that sales of milk recognized as being rbST-free account for less than 2% of total milk sales in the United States. The milk identified as being rbST-free sells at prices between 10 and 15% higher than those for milk that is not identified in this way.

In markets where the introduction of rbST caused serious concerns, the sale of milk identified as being rbST-free has declined; in 1995 it accounted for at most only 5% of total sales in the state of New York and in Minneapolis. In Wisconsin and Vermont, however, buying habits are different. In Wisconsin, milk identified as being rbST-free was the choice of most consumers in 1995; however, in 1996, most milk sold for consumption in that state was unlabelled and could have come from cows treated with the hormone. In Vermont, consumer milk from companies known to produce rbST-free milk represented most of the sales in 1996. In these two States, a double system offering both and undifferentiated milk seems to have been necessary to maintain sales. However, opposition to rbST apparently resulted in part from concerns about a threat to the rural way of life and came as much from producers as consumers.

Across the country, studies conducted in 1996 showed that rbST was no longer of concern to American

consumers. Milk consumption in the United States seems to vary more according to price increases, advertising and fat content than to the use of this hormone.

European Union

Even though it claims that rbST has no impact on human health, the European Union has imposed a moratorium on the use of this hormone until 31 December 1999. This decision was based essentially on social and economic considerations such as a fear of penalizing small farmers, the existence of milk surpluses and the fear of consumer reaction. The European Union also apparently declared that use of rbST was contrary to the Common Agricultural Policy (CAP). However, there is no ban on the importation of dairy products from countries that have approved the use of rbST.

In March 1993, the Group of Advisers on the Ethics of Biotechnology (GAEB), appointed by the European Commission, stated that a decision on whether or not to market rbST in the European Union was primarily a political matter. In June 1998, the Institute of Food Science and Technology in Great British announced that there was no scientific or moral reason to require labelling identifying between milk or meat from rbST-treated cows. In July 1997, the Netherlands, speaking for the European Union, proposed a motion to the *Codex alimentarius*(1) requesting a postponement of the establishment of a maximum limit for residues in order to allow for a reassessment by the Joint FAO-WHO Expert Committee on Food Additives of the data concerning human health and a review of the "application of factors other than the scientific analysis." The European Union is also seeking to legitimize its approach to assessing the product using other than scientific criteria.

Other Countries

Besides the United States, the following countries have authorized the use of rbST: South Africa, Brazil, Colombia, Korea, Costa Rica, Egypt, United Arab Emirates, Honduras, Israel, Jamaica, Kenya, Mexico, Namibia, Peru, Russia, Slovakia, Turkey and Zimbabwe.

After a 12-month-long study, Australia decided in September 1992 not to approve rbST for purely commercial reasons. In fact, most Australian exports of dairy products are to countries that have not approved rbST. The issue has not been reopened since that time.

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(1) See footnote (6).

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WHAT SHOULD BE THE DECISION ON rbST?

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Recent developments relating to recombinant bovine somatotropin (rbST) on the international level raise a number of questions concerning its approval in Canada.

First of all, in February 1998, the Joint FAO-WHO Expert Committee on Food Additives concluded that milk and meat from rbST-treated cows did not pose any danger to human health. The Committee's report was sent to the *Codex alimentarius*,(1) which will examine it during the summer of 1999.

The World Trade Organization (WTO) is making increasing use of the decisions of the *Codex alimentarius* as a technical and scientific reference when it has to resolve trade disputes between countries (see the decision of the Canada-Europe panel on bans of imports of beef from Canada to Europe). Nevertheless, participating countries are not obliged to abide by decisions of the *Codex alimentarius*.

In fact, in accordance with its human health approach, the *Codex alimentarius* is dealing with the rbST problem solely in terms of the change in the composition of milk (residues of rbST, IGF-1 and so on). When the question of whether standards should be adopted for maximum levels of somatotropin residues was examined by the *Codex alimentarius* in July 1997, consumer representatives and the representatives of several countries argued that the use of rbST would meet with opposition from consumers and that the hormone did not improve the quality of the milk or its health characteristics. In Canada some people object to the use of rbST because they have reservations about its long-term effects on human health. Others oppose its use on the grounds that we already have more milk than we need, the economic effectiveness of rbST has not been proven in all cases, and it is not wanted by consumers, producers, or the dairy industry. The European Union (EU), for its part, has requested that "legitimate factors other than scientific analysis" be taken into account.

In Canada, some groups have argued that it would be difficult to justify a ban on the use of rbST on the basis of criteria other than public health, since this would make it necessary to review the approach taken to all the other products of biotechnology.

Given the uncertainty about the effects of rbST on human health, the debate remains inconclusive.

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(1) The Codex alimentarius (the Latin term for food code) Commission is part of the World Health Organization

(WHO) and the United Nations Food and Agriculture Organization (FAO) and has 146 member countries. Since it was established in 1962, one of its goals has been to define food standards and codes governing hygiene and technology in light of the safety of food additives and contaminants (it has evaluated more than 700 additives and determined more than 3,200 maximum levels of pesticide residues).