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RECOMBINANT BOVINE SOMATOTROPIN (rbST)

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RECOMBINANT BOVINE SOMATOTROPIN (rbST)

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INTRODUCTION

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*, **and in March 1999 the Standing Senate Committee on Agriculture and Forestry published its interim report entitled *rbST and the Drug Approval Process*.**

In January 1999, Canada decided not to approve the sale or use of rbST in Canada, having concluded that rbST had harmful effects on the health of animals to which it was given. From 1988, from this the time of the first application for approval of an rbST-based product until the decision by Health Canada, the department responsible for approval, 11 years had passed.

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.

WHAT IS rbST?

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.

THE IMPACT OF rbST ON HEALTH

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.

- 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[2] 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

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

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.(3)

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.

In mid-1998, Health Canada commissioned an expert panel, working under the auspices of the Royal College of Physicians and Surgeons of Canada, to evaluate whether rbST was harmful to human health. In its January 1999 report, the panel reached the following conclusions.

- **If the results of the 90-day study on rats carried out by the rbST manufacturer are valid, there is a possibility of an allergic reaction in humans who consume products from animals that have been given rbST. The panel therefore recommended that the study be carried out again in order to clarify this point.**

- **There is no plausible biological basis for concluding that an increased concentration of IGF-1 in milk causes immune responses, changes in the intestinal development of newborns, or risks of cancer among consumers of products from animals that have been given rbST. At present there is no evidence that oral absorption of IGF-1 is carcinogenic. Although IGF-1 plays a**

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

role in the development of certain forms of cancer, Health Canada has not asked the rbST manufacturer for an additional study on risks of cancer.

- **Any increased exposure of bacteria to antibiotics resulting from mastitis related to use of rbST is marginal in comparison with the exposure resulting from other agricultural and human uses. Thus it is unlikely that rbST has an impact on increased resistance to antibiotics.**

On the basis of these conclusions, Health Canada decided that consumption of products from animals that have been given rbST does not present significant risks to human health.

In March 1999, the European Commission's Scientific Committee on Veterinary Measures Relating to Public Health published its evaluation of the effects of rbST on human health. This report identified risks similar to those studied by the experts appointed by Health Canada: risks of cancer caused by lifelong exposure to IGF-1; allergic reactions caused by possible changes in the composition of milk proteins; and resistant bacteria caused by possible antibiotic residues in milk. Unlike the Canadian experts, the European committee did not evaluate the level of risk but recommended that an evaluation be carried out in greater depth. Some scientists appearing before the Standing Senate Committee on Agriculture and Forestry in April and May 1999 also considered the risk evaluation inadequate and called for long-term studies.

In June 1999, the *Codex Alimentarius* Commission met in Rome; one of its tasks was to set an international standard (a Maximum Residue Limit) for rbST. If established, this standard would imply scientific consensus on the effects of rbST on human health. Since the various delegations were unable to reach agreement, the Commission decided to postpone setting this standard until a consensus could be reached.

Animal Health

The most important negative effect on the health of rbST-treated animals is the possibility of increased incidence of mastitis.(4)

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)(5) has concluded that the use of Posilac® (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.

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(4) Mastitis is an inflammation of the teat.

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

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.

In 1999, two reports supplemented the knowledge of the effects of rbST on animal health. As it had done to evaluate whether rbST was harmful to human health, Health Canada commissioned a second expert panel, working under the auspices of the Canadian Veterinary Medical Association, to evaluate whether rbST was harmful to animal health. In its January 1999 report, this panel concluded that rbST use causes "an increased risk of mastitis of up to 25%, of infertility by 18%, and of lameness by up to 50%. These increased risks and overall reduced body condition lead to a 20-25% increased risk of culling from the herd." On the basis of these conclusions, Health Canada decided not to approve the sale of rbST in Canada. Furthermore, in March 1999 the European Commission's Scientific Committee on Animal Health and Animal Welfare published a report fully supporting this view and recommending that rbST not be used because it causes mastitis, lameness, and reactions at injection sites in animals that are given it.

THE IMPACT OF rbST ON THE DAIRY INDUSTRY

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, according to the report, 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[(6)] 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. **At the October 1998 hearings of the Standing Senate Committee on Agriculture and Forestry, the National Dairy Council of Canada estimated that segregating milk would cost approximately $500,000 per dairy and "could only be done at a smaller plant."**

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

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. **Although there are other ways to increase production, United States producers consider rbST a particularly useful tool for small dairy producers.**[(7)]

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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(7) Standing Senate Committee on Agriculture and Forestry, interim report, *rbST and the Drug Approval Process*, March 1999.

THE REGULATION OF rbST IN CANADA

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. **On 14 January 1999, Health Canada announced that it would not approve the sale of rbST 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.

SITUATION WITH RESPECT TO rbST IN CANADA

In October 1985, Health Canada issued the first Experimental Studies Certificate for an rbST-based product, concluding that the milk of animals given the product did not present risks to human health.

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 to review the rbST approval process, that the *Codex alimentarius* Commission[8] express an

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(8) 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).

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 on Food Additives and the application of "legitimate factors other than the scientific analysis" was reviewed. Canada voted against the motion.

In January 1998, Health Canada set up an internal review team made up of four evaluators, including two scientists who had worked at the office responsible for evaluating an rbST-based product and had challenged the evaluation process in the press. The team's mandate was: to consider the data provided to Health Canada on whether rbST was harmful to human health; and to identify methodological and scientific shortcomings in the evaluation process. The team produced two reports: the first, dated 21 April 1998, on the analysis of shortcomings in the evaluation process, is unanimous; the second, dated June 10, 1998, is signed by the two Health Canada evaluators who did not work for the office responsible for evaluating the rbST-based product. Both reports state that the rbST evaluation process had methodological and scientific shortcomings.

On 7 September 1998, Health Canada announced that a decision on whether to approve rbST would be made only after the June 1999 meeting of the *Codex Alimentarius* Commission in Rome.

At its October 1998 hearings, the Standing Senate Committee on Agriculture and Forestry heard from the members of Health Canada's internal review team. These hearings indicated that the rbST evaluation process had not always been correctly followed. Witnesses told the Committee of management problems at Health Canada, claiming that there had been pressure, coercion, theft of documents on rbST, and a rule of silence with respect to rbST.

Meanwhile, two expert panels, one working under the auspices of the Royal College of Physicians and Surgeons of Canada and a second working under the auspices of the Canadian Veterinary Medical Association, evaluated whether rbST was harmful to human and animal health respectively. This was done at the request of Health Canada, which wanted to include the panels' conclusions in its

decision-making process. Both panels submitted their reports in January 1999. The panel on rbST's effects on human health concluded that consumption of products from animals that have been given rbST does not present significant risks to human health. The panel on rbST's effects on animal health, however, concluded that rbST use causes "an increased risk of mastitis of up to 25%, of infertility by 18%, and of lameness by up to 50%. These increased risks and overall reduced body condition lead to a 20-25% increased risk of culling from the herd."

On the basis of the panels' conclusions, on 14 January 1999 Health Canada announced that it would not approve the sale of rbST in Canada.

In March 1999, the Standing Senate Committee on Agriculture and Forestry published its interim report entitled *rbST and the Drug Approval Process*. Despite Health Canada's decision, one recommendation contained in the report is "that no Notice of Compliance be issued for rbST until the manufacturer submits the long-term studies identified by Health Canada's rbST internal review team as data missing from its submission and until a review of those studies more precisely determines any risks to human safety."

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

rbST IN OTHER COUNTRIES

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. **However, in light of the information published by the Senate of Canada concerning scientific shortcomings in the rbST evaluation process, two United States Senators and a number of public interest groups have urged the Food and Drug Administration to review its conclusions on rbST.**

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*(9) 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

(9) See footnote (8).

European Union is also seeking to legitimize its approach to assessing the product using other than scientific criteria.

In March 1999, two of the European Commission's Scientific Committees (Directorate 24, Consumer Policy and Protection of Consumer Health) published their opinions on rbST. The Scientific Committee on Animal Health and Animal Welfare recommended that rbST not be used because it causes mastitis, lameness, and reactions at injection sites in dairy cows.

The Scientific Committee on Veterinary Measures Relating to Public Health identified various risks: risks of cancer caused by lifelong exposure to IGF-1; allergic reactions caused by possible changes in the composition of milk proteins; and resistant bacteria caused by possible antibiotic residues in milk. Unlike the Canadian experts, the European committee did not evaluate the level of risk but instead recommended that an evaluation be carried out in greater depth.

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.

CANADA'S DECISION: WHAT NOW?

Recent international and Canadian developments relating to rbST raise a number of questions.

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*,[10] **and in June 1999, the *Codex Alimentarius* Commission met in Rome. One of its tasks was to set an international standard (a Maximum Residue Limit) for rbST. Since the various delegations were unable to reach agreement, the Commission decided to postpone setting this standard until a consensus could be reached.**

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 making its January decision 1999 on rbST, Health Canada noted that consumption of products from animals that have been given rbST does not present significant risks to human health; it banned the sale and use of rbST in Canada for reasons of animal health. Thus Canada does not ban dairy products imported from countries where rbST is used, and is thus unlikely to be the subject of a complaint to the WTO in this matter. The lack of international agreement on the effects of rbST on human health and the resulting lack of an international standard make the likelihood of a complaint to the WTO even more remote.

If Health Canada is to review its decision, manufacturers of rbST-based products must submit a further New Drug Submission (NDS). Although Monsanto seemed to want to do so, in August 1999 it had not yet taken steps to submit a further NDS. In this regard, the April and May 1999 hearings of the Standing Senate Committee on Agriculture and Forestry indicated that there is still disagreement in Canada on whether rbST is harmful to human health.

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(10) See footnote (8).