

Recombinant Bovine Growth Hormone

**How its licensing contradicts existing policies, rules and regulations
and sets Canadian agriculture on the wrong course**

Position Paper

of the

TORONTO FOOD POLICY COUNCIL

August 1997

This is a work in progress. The Toronto Food Policy Council is interested in discussing the issues and strategies presented here as part of its on-going efforts to improve the food and agriculture system in Canada, and to help create food security. Please forward any comments and requests for additional copies, to the Toronto Food Policy Council, 277 Victoria Street, Suite 203, Toronto, ON, M5B 1W1, phone 416-392-1107, fax 416-392-1357

TABLE OF CONTENTS

EXECUTIVE SUMMARY	1
Flow Chart 1	3
Flow Chart II	4
Flow Chart III	5
Flow Chart IV	6
Flow Chart V	7
Flow Chart VI	8
1. Contrary to industry and government claims, levels of BGH and IGF-1 will be present in the milk supply as research does not prove that they are mostly denatured by commercial pasteurization	10
Summary	10
Details	11
2. There are no chronic safety data assessing the impacts of humans consuming milk from rBGH-modified cows	13
Summary	13
Details	13
3. The regulatory system has failed to properly evaluate the potentially negative health impacts of IGF-1	15
Summary	15
Details	16
4. Milk from rBGH-modified cows will be in contradiction of legal definitions of milk	18
Summary	18
Details	19
5. Independent analysis of industry data shows that rBGH use increases mastitis in herds using rBGH, and such increases may result in increased antibiotic use and pressure on the milk quality control system	21
Summary	21
Details	21
6. rBGH licensing will compromise existing rules of scientific breed improvement, a cornerstone of long-term progress in milk production	24
Summary	24
Details	25
7. Government and industry opposition to labelling means that the market will not be able to tell us whether consumers find biotechnology products acceptable	31
Summary	31
Details	32
CONCLUSIONS	35
Appendix A	37

Appendix B 39
 Appendix C 43

EXECUTIVE SUMMARY

Recombinant Bovine Growth Hormone (rBGH) has for a decade been a very controversial product. Although not yet licensed for use in Canada, its costs and benefits have been the subject of much debate among farmers, dairy processors, public health authorities and consumers. Proponents of the drug have claimed it can increase milk production in many cows and provide farmers with more management options. Critics believe the drug poses human and animal health problems, and that its widespread use will cause a significant and undesirable restructuring of the Canadian dairy sector.

It is the view of many in the agriculture and health sector that the licensing and **non-therapeutic** use of rBGH **will not conform** with both established scientific procedures or government policies, rules and regulations that give direction to the Canadian dairy sector. Consequently, dramatic changes to such procedures and policies would be required to bring them into compliance with the new realities imposed by rBGH licensing.

The drug’s manufacturers and the drug review process have been consistently criticized for:

- C incomplete regulatory evaluation and controls;
- C questionable scientific and statistical analysis of potential human and animal health impacts of the drug;
- C incomplete analysis of the implications for the dairy sector;
- C contradictory regulations governing milk and the dairy industry;
- C contradictory arguments regarding labelling of milk rBGH-modified cows.

More specifically, seven fundamental weaknesses are apparent in the position favouring rBGH licensing.

1. Contrary to industry and government claims, levels of BGH and IGF-1 will be present in the milk supply as research does not prove that they are mostly denatured by commercial pasteurization.
2. There are no chronic safety data assessing the impacts of humans consuming milk from rBGH-modified cows.
3. The regulatory system has failed to properly evaluate the potentially negative health impacts of IGF-1.
4. Milk from rBGH-modified cows will be in contradiction of legal definitions of milk.
5. Independent analysis of industry data shows that rBGH use increases mastitis in herds using rBGH, and such increases may result in increased antibiotic use and pressure on the milk quality control system.

6. rBGH licensing will compromise existing rules that scientific breed improvement, a cornerstone of long-term progress in milk production.
7. Government and industry opposition to labelling means that the market will not be able to tell us whether consumers find biotechnology products acceptable.

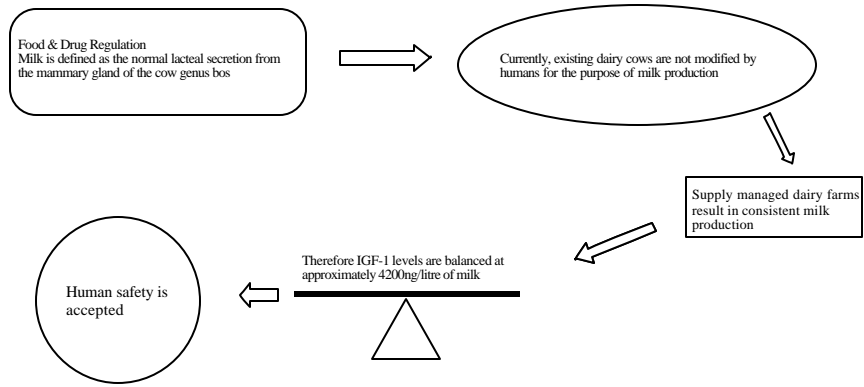
Further elements of our arguments are outlined in 6 flow charts (see pages 3-9).

It is the view of the Toronto Food Policy Council that NO license for rBGH be granted at this time, pending resolutions of these issues.

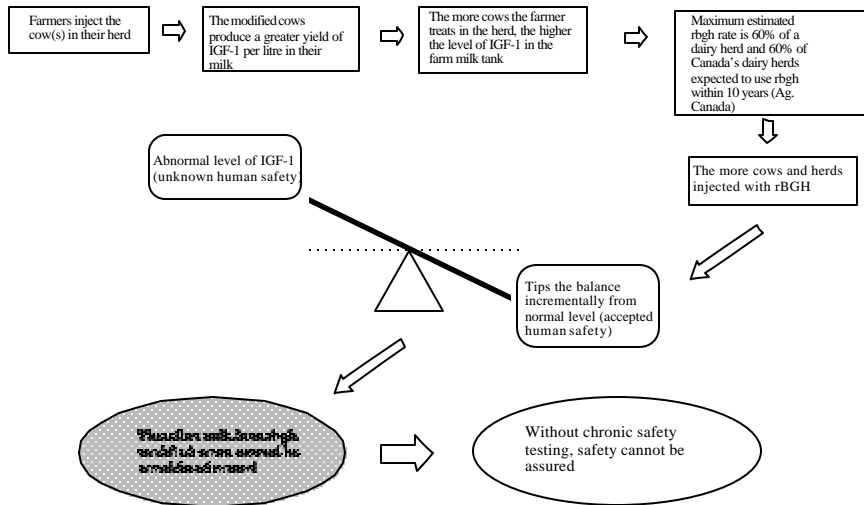
Instead, the federal government should consider the following options for the dairy sector:

- 1) Dairy farmers should have a long-term dairy policy based on the financial and environmental sustainability of the sector, and that as part of this policy, no hormones should be permitted for the expressed purpose of modifying an existing dairy cow (either inherently, genetically, or through transgenic manipulation) so that it produces more milk than its inherent capacity in a normal Canadian dairying environment.
- 2) Any new technologies should focus only on improving the therapeutic or environmental aspects of dairying, for example, alternative approaches to managing animal health, feeding regimes, pasture and crop management, and animal housing designs.
- 3) Dairy processors and retailers should be more accountable to consumers, and product labelling of processes used in dairy farming and processing should be part of such accountability.
- 4) New products should be screened for their potential broad social benefits prior to the review process undertaken by Health Canada, to determine whether the product has sufficient merit in terms of long-term health and sustainability to warrant a detailed review of its efficacy and specific health impacts.

Flow Chart 1
IGF-1 Logistics in the Canadian Milk market
Pre rBGH License



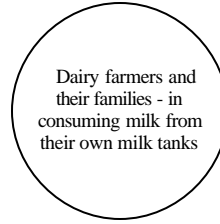
However to license rbgh as a non-therapeutic drug means:



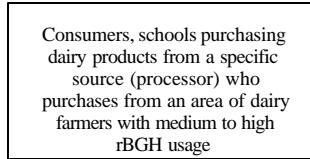
Flow Chart II
IGF-1 Exposure Target Group

*Rated in order of concentrated exposure

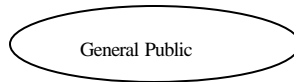
Primary Exposure Group



Secondary Exposure Group

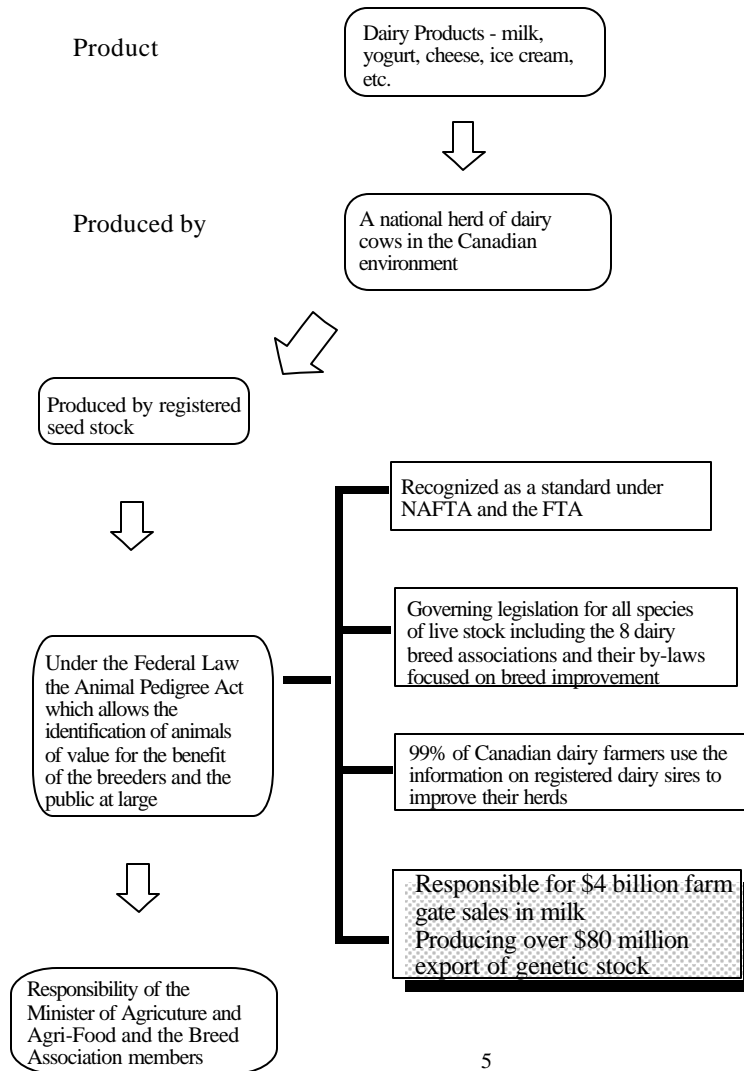


Third Exposure Group

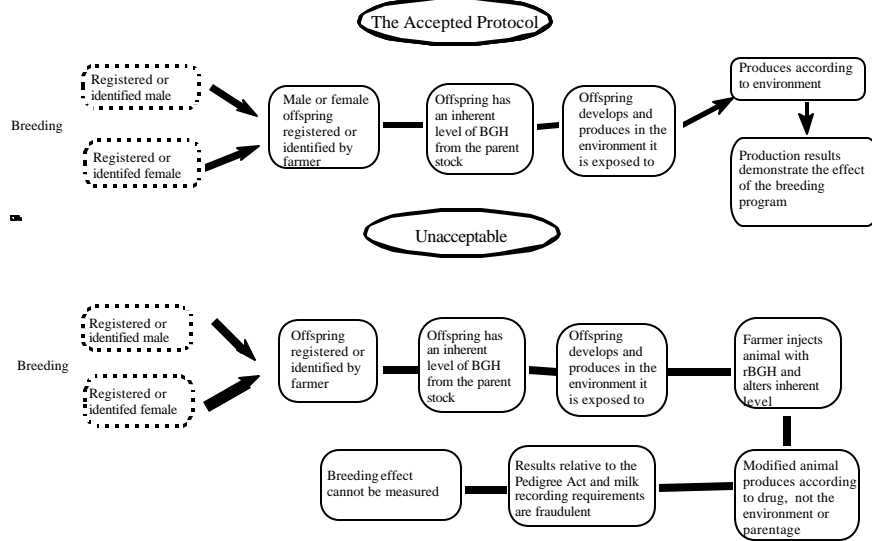


Flow chart III - Food Security

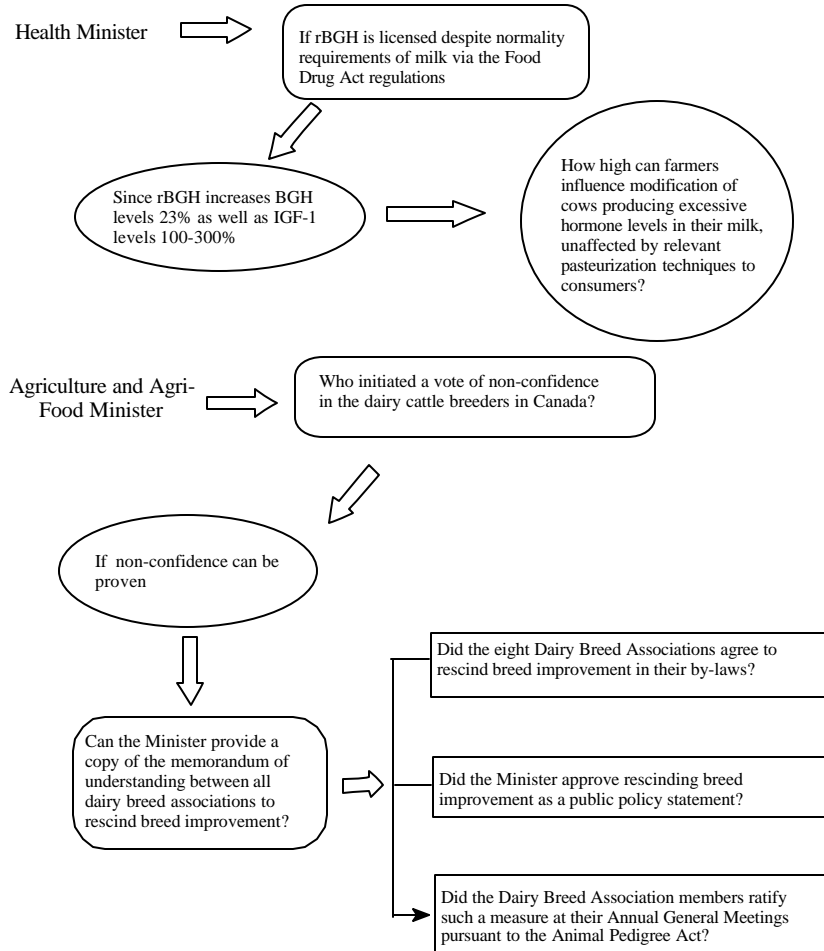
In order to gauge degrees of success or failure one must not lose the ability to measure what is produced and how



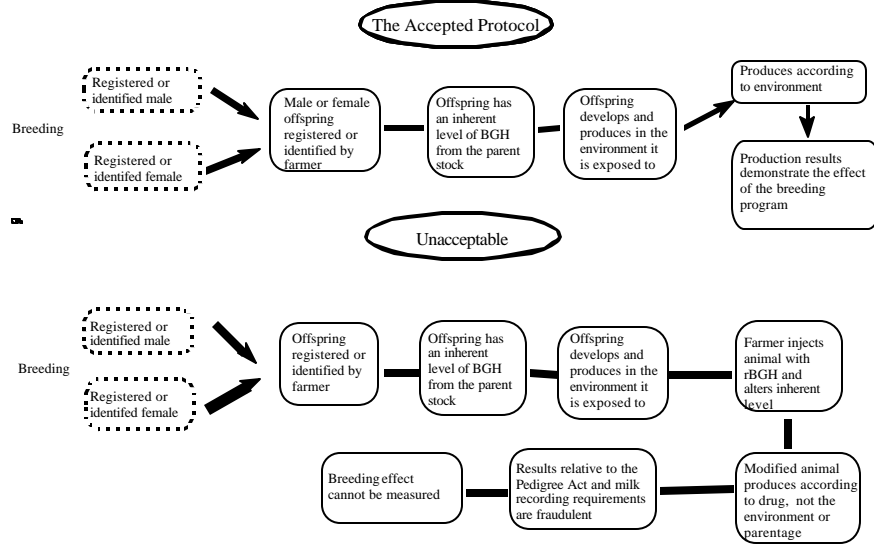
Flow Chart IV
How rBGH undermines genetic
improvement and milk recording
programs



Flow Chart V
Question chart for Cabinet Ministers
(Health and Agriculture & Agri-Food)



Flow Chart IV
How rBGH undermines genetic
improvement and milk recording
programs



Time Frame Recognition of Breed Improvement By Noted Personages as a Recognized Protocol

1760 A.D. - 1896 A.D.

- Breeding to standard was created by Robert Bakewell of England. He is recognized as the creator of Breed Improvement (Bakewell's Ten Rules) (1760-1795).

1880 - 1930

- Ontario Agricultural Commission Report (1881)
- Creation of Primary Dairy Breed Associations (purpose: breed improvement using recorded genealogy)
- Constitutions, by-laws and herd books established.
- Pioneers who published books involving breed improvement:

S Duncan Marshall (Alberta Agriculture Minister)
S H.H. Dean - University of Guelph (Professor Dairy Husbandry)
S G.E. Day - University of Guelph (Professor/Agriculture/Farm Superintendent)
S J.H. Reed - University of Guelph (Professor Veterinary Science)
S U.P. Graham - University of Guelph (Manager)

- Record of Merit Program started
- Record of performance program created by the Federal Government

1931 - 1950

Government people who acted on what the pioneers advised:

- Honourable James G. Gardiner, Minister of Agriculture, Ottawa
- Stanley Wood, Superintendent of Livestock, New Brunswick Department of Agriculture
- J.H. King, Dominion Livestock Branch
- George Muir, Experimental Farm, Ottawa
- W.D. Davies, Assistant Chief Production Services Dominion Department of Agriculture

1950 - 1997

- by-laws of the Dairy Breed Associations still stand for recording registered animals and breed improvement
- Pedigree Act binds the members (Section 17) to obey the by-laws, and to identify animals of value
- 99% of Canadian dairy farmers use that information
- Pedigree Act Recognized as a standard under the Free Trade Agreement (FTA) and the North American and Free Trade Agreement (NAFTA)

Conclusion

Stability in the dairy sector is based on cooperative farm research and development by as many dairy farmers as possible and is the intent of breed improvement. Therefore, is the current Minister of Agriculture prepared to set a precedent by publicly revoking the direction followed by his predecessors and departmental advisors of previous administrations?

1. **Contrary to industry and government claims, levels of BGH and IGF-1 will be present in the milk supply as research does not prove that they are mostly denatured by commercial pasteurization**

Summary

A key research paper for the pro-rBGH position was published by Juskevich and Guyer, then both employees of the US Food and Drug Administration, in Aug. 1990 in the reputable journal "Science"¹. The paper detailed a research study as well as summarized data from many sources to prove whether or not human health could be compromised by consuming milk from rBGH-modified cows. The report specifically dealt with the milk hormones, rBGH and Insulin Growth Factor-1 (IGF-1).

Their position was, in part, based on a conclusion by Groenewegen, et al. 1990, that 85-90% of rBGH would be destroyed following pasteurization of milk. The paper contains 2 major errors:

- a. Their 90% figure results from a situation that does not actually occur in the milk supply. They placed additional rBGH in milk samples and found after pasteurization that 90% of what they added had disappeared. But when you compare their data on regular milk, and milk from rBGH-modified cows, **pasteurization has limited effect on elevated BGH levels.**
- b. The study also used inaccurate, according to regulations, pasteurization temperatures/time frames, effectively overcooking the milk samples, and provided a greater opportunity for the heat treatment to destroy BGH.

Juskevich and Guyer stated in their report that the need to pursue more definitive studies was unnecessary because of Groenewegen's figures and the fact that human growth receptor do not recognize rBGH. Thus, their study provides the longest evaluation of human safety data (90 days). It cannot, however be considered chronic safety data.

Consequently, a cornerstone of the pro-rBGH position, that there are no potential health impacts from consuming milk from rBGH-modified cows, is based on practices that are irrelevant to regulations and the milk consumers drink. The implication is that people would consume more rBGH and IGF-1 than the research suggests, and policy makers may currently believe. Two groups would be particularly affected by this:

1. Farm families, the only ones allowed by law to drink milk directly from their milk tank;

¹ **Bovine Growth Hormone: Human Food Safety Evaluation**, Juskevich and Guyer, Science, Vol 249, Aug. 1990

2. Consumers who receive milk and some milk products from a processor who is receiving milk from an area of concentrated rBGH use².

Details

1. The actual pasteurization processes used by Canadian dairy processors are not the same as the temperatures used in the key research reports³.
2. The key research studies also report that IGF-1 is ninety percent destroyed by infant formula pasteurization process⁴. But the pasteurization process used in infant formula is dramatically different than that used for fluid and industrial milk, the forms in which most Canadians consume dairy products. That pasteurization does not have any affect on Insulin-like Growth Factor-1 levels.

The regulations regarding pasteurization of fluid milk are a provincial jurisdiction, while manufactured dairy products are governed federally by the Food and Drug Act.

Pasteurization of milk by law must achieve two things:

1. destroy any pathogenic organisms⁵;
2. destroy the phosphatase enzyme⁶;

The heat treatments and time frames for dairy products are themselves variable according to product specifications.

² There is pooling of milk in Ontario, so who would be affected and to what degree would depend on the degree of blending of milk from treated and untreated herds.

³ **Evaluation of Certain Veterinary Drug Residues in Food**, World Health Organization, Fourtieth report of the Joint FAO/WHO Expert Committee on Food Additives; **Bovine Growth Hormone: Human Food Safety Evaluation**, Juskevich and Guyer, Science, Vol. 249, Aug. 1990; **Clinical review 21, The Efficacy and Safety of Growth Hormone of Animal Agriculture**, Etherton, Journal of Clinical Endocrinology and Metabolism, Vol. 72, Number 5.

⁴ **Bovine Growth Hormone: Human Food Safety Evaluation**, Juskevich and Guyer, Science, Vol. 249, Aug. 1990; **Clinical review 21, The Efficacy and Safety of Growth Hormone of Animal Agriculture**, Etherton, Journal of Clinical Endocrinology and Metabolism, Vol. 72, Number 5; **Bovine Somatotropin Supplementation of Dairy Cows**, Daughaday and Barbano, Journal of the American Medical Association Volume 264, August 1990.

⁵ Alberta Dairy Regulations, Reg. 131/83 pg. 28.

⁶ Alberta Dairy Regulations, Reg. 131/83 pg. 28; Ontario Dairy Regulations, Reg. 761, pg. 40,41; United States Food and Drug Regulations.

They are not constant as the investigators assumed when drawing the conclusion that destruction of elevated rBGH and IGF-1 levels in milk from rBGH modified cows would occur.

For instance, the following pasteurization categories are FDA (U.S.) legal minimums:

	Vat ⁷		HTST ⁸		HHST ⁹		UHT ¹⁰	
	Time	Temp.	Time	Temp.	Time	Temp.	Time	Temp.
Fluid Milk	30 min.	145°F	15 sec.	161°F	1.0 sec.	191°F	2.0 sec.	280°F
			16 sec.	(Canada)	0.5 sec.	194°F		
					0.1 sec.	201°F		
					0.05 sec.	204°F		
					0.01 sec.	212°F		

Most dairy processors use High Temperature-Short Time (HTST)

These pasteurization categories can be compared with those used in the scientific experiments:

Groenewegen ¹¹	Pasteurization 160°F	25-30 min
---------------------------	-----------------------------	------------------

⁷ Vat- pooled milk in batch

⁸ High Temperature, Short Time

⁹ High Heat, Short Time

¹⁰ Ultra Heat Treatment, sometimes called UP or Ultra Pasteurized

¹¹ **The Bioactivity of Milk from BST-Treated Cows**, Groenewegen, Burton, McBride, Elsasser, Journal of Nutrition, 120, 514-520, 1990

Juskevich and Guyer ¹² Etherton ¹³ Daughaday and Barbano ¹⁴	Infant Formula Pasteurization 250°F	15-20 min
--	--	------------------

The pasteurization processes used in the research do not conform with standard practice. The process used in the Groenewegen study would definitely overcook the samples and result in much higher BGH destruction than that found in standard pasteurization.

2. There are no chronic safety data assessing the impacts of humans consuming milk from rBGH-modified cows

Summary

It is generally accepted that a legitimate assessment of the long-term impacts on humans of a product would include the following:

1. Birth defect testing: two generation rodent and rabbit assays.
2. Two year feeding studies and toxicological testing.
3. Periodic gel electrophoresis analysis of the plant or animal food.

Such tests are required to ensure that the product doesn't have a latency period. For example, there is already some evidence that the effects of IGFs do not appear until after 18 months of exposure. Tests would be based on maximum proposed usage of rBGH with a herd and groups of herds within a region (60% of cows within 10 years).

None of this testing has been done by the industry or regulatory bodies. The longest test, according to Health Canada, for human exposure is only 90 days.

Details

¹² **Bovine Growth Hormone: Human Food Safety Evaluation**, Juskevich and Guyer, Science, Vol. 249, Aug. 1990

¹³ **Clinical review 21, The Efficacy and Safety of Growth Hormone of Animal Agriculture**, Etherton, Journal of Clinical Endocrinology and Metabolism, Vol. 72, Number 5;

¹⁴ **Bovine Somatotropin Supplementation of Dairy Cows**, Daughaday and Barbano, Journal of the American Medical Association Volume 264, August 1990.

We believe that the process by which Health Canada reviews the safety of drugs is deeply flawed¹⁵. The problems include:

- C Reliance on industry data to make determinations of safety and efficacy. Even Dr. Sol Gunner¹⁶ then Director General of the Food Directorate of Health Canada made the following statement in Ottawa at a Committee Hearing¹⁷ regarding rBST and other products brought before Health Canada, "... then let me say, first of all, that we have to take the [industry] results in good faith. Whether this is troubling to the committee... It is certainly troubling to the regulatory agencies as well."
- C Reviews that take place in secret because the product data is considered proprietary. The industry's right to privacy is viewed as more important than the public's right to an open evaluation of the utility and safety of the products that the public may choose to buy.

The public has been made aware by the media of:

- C Reviews that regularly bypass the opinions of reviewers¹⁸
- C Excessively cosy relations between senior managers and the pharmaceutical industry¹⁹

We believe it is absolutely essential that Health Canada provide the Canadian public evidence from chronic safety evaluations of the safety of milk from rBGH-modified cows. It must be based on the equivalent of the maximum proposed usage rates within both a herd and groups of herds in a region

¹⁵ In fact, the Toronto Food Policy Council believes the entire policy apparatus of biotechnology regulation is a major cause for concern. In our view, the larger policy questions are ignored in favour of detailed technical analyses that fail to account for the broad potential impacts that these new technologies may impose on our economy, society and environment. We have documented these broader concerns about the review of rBGH in a discussion paper entitled, "Setting a New Direction: changing Canada's agricultural policy making system." Our point here is that even were these broader questions to be properly addressed by the policy system, we would still have no assurance of sound decisions given the weak safety reviews undertaken by the department.

¹⁶ currently retired from Health Canada

¹⁷ Hansard of the House of Commons, Issue 3, March 7, 1994, 3:56- 1830-1835, 1st Session of the 35th Parliament Minutes of Proceedings and Evidence of the Standing Committee on Agriculture and Agri-Food, respecting Consideration of Second Report on the Steering Committee, Pursuant to Standing Order 108(2), consideration of issues relating to the bovine somatotropin hormone(BST)

¹⁸ **Drug-approval process criticized: some Health Canada managers passed products despite reviewers' concerns, insiders say.** Eggertson, Globe and Mail, May 28, 1997.

¹⁹ **Drug-approval process criticized: some Health Canada managers passed products despite reviewers' concerns, insiders say.** Eggertson, Globe and Mail, May 28, 1997. **Bureaucrat withholding research data five Health Canada drug Scientists say,** Kennedy, Ottawa Citizen, July 4, 1997.

(60% of Canada's cows within 10 years)²⁰.

Chronic safety toxicological investigation requires two year evaluations (standard practice).²¹ This is to ensure that the effects of new products have no latency or dormancy periods. Such latencies have been reported in the literature. One study found an 18 month latency for IGF-II effects before biological activity was noted²².

We believe a trustworthy assessment procedure includes²³:

1. birth defect testing: two generation rodent and rabbit assays;
2. two year feeding studies;
3. periodic gel electrophoresis analysis of the plant or animal food showing that it was the same as approved for sale (no mutational events occurred of hazardous or unknown nature).

In addition, much more comprehensive protocols for reviewing the complex of factors that may influence health and efficacy must be implemented. Such protocols have been developed by a respected group of scientists concerned about product assessment. Some of their protocols are outlined in Appendix A, taken from the first draft of their report, "Assessment of Genetically Engineered Organisms in the Environment: The Puget Sound Workshop Biosafety Handbook"²⁴. Such stringent protocols are not currently followed by Health Canada.

The Council also wishes to put forward the following group of references which are more current to elevate the understanding of the role of growth factors, for Health Canada to evaluate (see appendix B).

Consensus on the value of rBGH cannot be built without chronic (long-term) safety data.

²⁰ **BST and the Dairy Industry**, A National, Regional, and Farm level Analysis, United States Department of Agriculture, Economic Research Service, October 1987; **Farm Analysis Bulletin; Bovine Somatotropin**, A Preliminary Impact Analysis with Emphasis on Farm Level Aspects, Farm Economics and Regulatory Policy Division, Agriculture and Agri-Food Canada pg. 16,1994

²¹ Letter from Fairview Industries, Von Meyer, independent biochemist, 1994

²² **Altered Body Composition and increased frequency of diverse malignancies in Insulin-Like Growth Factor II transgenic mice**, Rogler, Yang, Rossetti, Donohoe, Alt, Chang, Rosenfeld Neely, Hintz, Journal of Biological Chemistry, May, 1994, 269 (19)

²³ Adopted from Von Meyer, independent biochemist, Fairview Industries, 1994

²⁴ **Assessment of Genetically Engineered Organisms in the Environment**: The Puget Sound Workshop Biosafety Handbook, The Edmunds Institute, July 1996

Given the intense scrutiny this product has received, to license rBGH without that quality of data would be a step in the wrong direction.

3. The regulatory system has failed to properly evaluate the potentially negative health impacts of IGF-1

Summary

The official position of regulators and many academic and medical bodies remains that IGF-1 levels, although elevated in milk from rBGH-modified cows, do not pose a health threat²⁵. This conclusion has been reached despite recognition that we do not fully understand how IGF-1 functions²⁶, and contradictory evidence in the scientific literature regarding its biological activity in the human gut. It seems possible, however, that IGF-1 is not broken down by stomach enzymes and is therefore orally active.

Because bovine and human IGF-1 are identical and because IGF-1 appears to play a useful role in newborns, elevated levels of IGF-1 in older children and adults could trigger biological activity not normally found in older humans. IGF-1 appears also to play a role in cancer tumour growth.

Public health scientists have concluded that we should be far more prudent about the possible negative effects of IGF-1 than regulatory bodies have demonstrated to date, and that a substantial research agenda should be actively pursued to answer the remaining questions about IGF-1. Industry and government regulators are not currently following such an agenda.

Details

The basis for the license of rBGH by the Food and Drug Administration was that, while acknowledging elevated levels of IGF-1, they considered it to be orally inactive with no effect on humans²⁷. This same

²⁵ **Bovine Growth Hormone: Human Food Safety Evaluation**, Juskevich and Guyer, Science, Volume 249, August 1990.

²⁶ Page, M.D., Dieguez, C. and Scanlon, M.F. 1989. Neuroregulation of Growth Hormone Secretion. In: R.B. Heap, C.G. Prosser and G.E. Lamming (eds.). **Biotechnology in Growth Regulation**. Butterworths, London, UK. Pp. 47-55.; Wallis, M. 1989. Species specificity and structure-function relationships of growth hormones. In: R.B. Heap, C.G. Prosser and G.E. Lamming (eds.). **Biotechnology in Growth Regulation**. Butterworths, London, UK. Pp. 3-14.

²⁷ **Bovine Growth Hormone, Human Food Safety Evaluation**, Juskevich and Guyer, Science, 1990

conclusion appears in Health Canada's preliminary response²⁸.

We question the validity of that hypothesis, given the evidence that IGF-1 may be orally active and may increase the potential for local mitogenic effects on gut tissues.

Insulin-Like Growth Factor-1 is a member of the somatomedin family²⁹. IGFs are known to mediate many of the effects of growth hormones³⁰. It is also a mitogen³¹ (an agent that causes mitosis in cells, which is a type of cell division). The insulin-like growth factors are members of a family comprising insulin, IGF-1, IGF-II and relaxin.

Bovine IGF-1 is a protein of 70 amino acids and is structurally identical to human IGF-1³². IGF-1 is a normal constituent in milk, human saliva, blood and is a necessary part of life. It has a wide range of actions in the body. For example, it regulates transport processes (ion fluxes, glucose and amino acid uptake by cells); macromolecular synthesis (of RNA, DNA, proteins and lipids); and cell division and differentiation³³.

Two reviews by Mepham³⁴ and Feenstra³⁵ concluded that this IGF-1 might survive the human digestive tract and be absorbed through the gut wall. A study by Xian et al.³⁶ suggests that IGF-1 is not

²⁸ **Response by Health Canada** to the Motion of the Standing Committee on Agriculture and Agri-Food regarding rBST, page 11, June 21, 1995

²⁹ **Response by Health Canada** to the Motion of the Standing Committee on Agriculture and Agri-Food regarding rBST

³⁰ **Bovine Growth Hormone: Human Food Safety Evaluation**, Juskevich and Guyer, Science, Volume 249, August 1990; **National Institute of Health Consensus Development**, 1990

³¹ **FairView Industries**, independent biochemist, Von Meyer, 1992

³² **Response by Health Canada** to the Motion of the Standing Committee on Agriculture and Agri-Food regarding rBST, June 21, 1995; **FairView Industries**, independent toxicologist, Von Meyer, 1992.

³³ **Public Health Implications of Bovine Somatotropin use in Dairying**, a discussion paper, T.B. Mepham Journal of the Royal Society of Medicine, Volume 85, December 1992.

³⁴ **Public Health Implications of Bovine Somatotropin use in Dairying**, a discussion paper, T.B. Mepham Journal of the Royal Society of Medicine, Volume 85, December 1992.

³⁵ Feenstra, G. 1993. **Is BGH sustainable? the consumer perspective**. In: B. Liebhardt (ed.). **The Dairy Debate: consequences of Bovine Growth Hormone and Rotational Grazing techniques**. University of California, Davis, CA. Pp. 1-63.

³⁶ **Degradation of Insulin Like Growth Factor-1 in the rat gastrointestinal tract and prolongation of IGF-1 survival by an antiserum and casein**, Xian, Shoubridge, and Read, Journal of Endocrinology, 146, 215-224, 1995

destroyed in the human gut because of the protective effects afforded by both milk casein and milk alkalinity. This affords unbound forms of IGF-1 the opportunity to enter the intestinal tract and produce mitogenic effects on gut tissue.

IGF-1 is also required for the establishment and maintenance of tumors³⁷. Recombinant human IGF-1 has been reported to have mitogenic effects on the adult duodenal mucosa. The levels implied were higher than what would be found in rBGH-modified cows milk, but lower levels also increased crypt epithelial cell proliferation in preliminary dose-response studies. The researchers in this study concluded that the combination of IGF-1 in BST-milk and IGF-1 normally secreted into the human gastrointestinal lumen would augment intraluminal concentrations of this hormone, increasing the possibility of local mitogenic effects on gut tissues³⁸.

Mepham³⁹ concluded that "it would be imprudent to assume that the increased concentration of IGF-1 in milk of bST[rBGH]-modified cows presents no risks to human health until more information has been obtained on a number of issues. These include: (i) accurate determinations of the effect of BST on concentrations of total IGF-1 in milk; (ii) the effect of BST on the percentage of IGF-1 in the free form in milk, and its physiological significance; (iii) the effect of BST on the concentration of -3N:IGF-1 (a metabolite) in milk; (iv) the local action of IGF-1 on tissues of the upper gastrointestinal tract of consumers; (v) the degree to which IGF-1 is absorbed across the gut wall in consumers." Mepham's concerns echo that of the National Institute of Health which had declared further research is needed to "Determine the acute and chronic local action of IGF-1, if any, in the upper gastrointestinal tract."⁴⁰

The references provided by Health Canada⁴¹ suggest their reviews are out of date given recent growth factor research. Of 61 references provided, 67 percent predate 1992. Only 21 percent of the references dealt with current (1993 to 1994) information. There has been a tremendous amount of research going on relating to growth factors in the past three years. Yet Health Canada continues to insist there are no human health risks associated with licensing the product. Interestingly, they claim no risks associated with rBGH, however, they are more cautious in their statements about IGF-1, yet still fail to acknowledge that the critics may have valid concerns.

³⁷ **Cancer Research**: 55, 2463-2469, June 1995, reference from letter of G. Tritsch, PhD, Biochemistry

³⁸ **Safety of Milk from cows treated with Bovine Somatotropin**, D.Challacombe, E. Wheeler, Somerset Children's Research Unit, Taunton and Somerset Hospital, U.K., the Lancet, Volume 344, September 17, 1994

³⁹ **Public Health Implications of Bovine Somatotropin use in Dairying**, a discussion paper, T.B. Mepham Journal of the Royal Society of Medicine, Volume 85, December 1992, p.738.

⁴⁰ The National Institute of Health, Technology Assessment Conference Statement, Bovine Somatotropin, December 5-7, 1990

⁴¹ **Response by Health Canada** to the Standing Committee on Agriculture and Agri-Food regarding rBST, June 21, 1995

4. Milk from rBGH-modified cows will be in contradiction of legal definitions of milk

Summary

In the Food and Drug Act, milk is defined as the normal secretion from the mammary gland of the cow.

It is highly misleading to state, as proponents do, that milk from rBGH-modified cows is the normal lacteal secretion of the cow, because:

- C the milk contains elevated yields of IGF-1 (from 100-360%), and these levels substantially exceed normal secretion of IGF-1 at particular periods of the lactation cycle (see details below);
- C IGF-1 is not destroyed by pasteurization and may be orally active in humans because it may survive the human digestive tract due to the protective effect of milk casein (a protein), and the alkaline nature of milk (which reduces stomach acidity). (see previous discussion);
- C the commercial pasteurization process used for consumers does not destroy elevated levels of BGH, rBGH and IGF-1 (see previous argument).

Details

The definition of milk is expressed in Division 8 of the Food and Drug Act. This section of the FDA deals with definitions of dairy products⁴².

Section B.08.003 (S) Milk or Whole Milk

- (a) shall be the normal lacteal secretion obtained from the mammary gland of the cow, genus bos, and
- (b) shall contain added vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D.

Is the milk from rBGH-modified cows “normal” pursuant to the definition under the Food and Drug Act? Our answer is no. We base this on the reviews and data available including those key reports

⁴² Departmental Consolidation of the Food and Drugs Act and of the Food and Drug Regulations, with amendments to Dec. 15, 1995, issued by the Department of National Health and Welfare.

that were put before Health Canada by the manufacturers and Health Canada's database⁴³. Our discussion has focussed on IGF-1 levels in the milk supply, as the other infrastructures have been addressed in earlier sections.

The research documents state pasteurization protocols for milk products without reference to the legal or regulatory definition of milk from a cow in the country in which the research was done. Therefore, the research conclusions cannot conform to human exposure as allowed by public policy in each country.

A common theme of the scientific literature used to justify rBGH licensing is that elevated IGF-1 levels are within the normal range of variation of milk and are within, or are lower than, normal variations in human breast milk⁴⁴. Proponents also claim that, since the blood levels of IGF-1 in humans is of greater magnitude than what is found in milk, the contribution to total body IGF-1 from treated milk is insignificant.

The claim that rates of IGF-1 within rBGH-modified cows' milk are within normal variances of standard cows milk is false. The effect of rBGH in elevating IGF-1 levels in dairy cows has been the subject of peer reviewed and unpublished reports. The elevated levels range from 2 ng/ml increase in one study to 3.7 ng/ml to 13.6 ng/ml in another⁴⁵.

Importantly, the levels found within 100 bulk tanks of unmodified dairy herds expressed a mean average of 4.32ng/ml.(ranging from 1.0 ng/ml to 8.1 ng/ml)⁴⁶. On average, rBGH injection elevates IGF-1 up to 3.6 times (maximum)⁴⁷, but this average hides even more extreme increases at specific times in the lactation cycle. It is during these periods when consuming may be excessively exposed to IGF-1. A cow, like all mammals, produces colostrum milk in the first week after parturition. IGF-1 is produced in that week at a level of 150 ng/ml dropping to 25 ng/ml by the end of the week. It drops to

⁴³ **Response by Health Canada** to the Motion of the Standing Committee on Agriculture and Agri-Food regarding rBST, June 21, 1995

⁴⁴ **Bovine Growth Hormone: Human Food Safety Evaluation**, Juskevich and Guyer, Science, Vol. 249, Aug. 1990; **Recombinant Bovine and Porcine Somatotropin, Safety and Benefit of these technologies**, T. Etherton, K. Etherton and Mills, et al 1993 Perspectives in Practice.

⁴⁵ **Recombinant Bovine and Porcine Somatotropin, Safety and Benefit of these technologies**, T. Etherton, K. Etherton and Mills, et al 1993 Perspectives in Practice

⁴⁶ Posilac Manual, Monsanto

⁴⁷ **Increased Secretion of insulin-like growth factor 1 into milk of cows treated with recombinantly derived bovine growth hormone**, C. Prosser, I. Fleet, A. Corps, 1989

as low as 1.0 ng/ml in mid to late lactation⁴⁸. rBGH is injected at day 90 to 105 in a cow's 305 day lactation cycle, when the cow normally is at her lowest level of IGF-1 per litre of milk. These injections put the levels of IGF-1 back up for the rest of her lactation. This is an abnormal situation, contrary to the definition of normal milk.

We also reject the inference that IGF-1 associated with rBGH injection is not a problem because levels are inherently higher in humans and that IGF-1 levels in human breast milk are higher than rBGH-modified cows⁴⁹. The comparison is inappropriate because of profound differences in exposure time. Infants may nurse their mother's breast milk from birth to 1 year of age. And IGF-1 appears to play a critical role in gut development for that age. Milk is consumed for a lifetime in some cases, most of it at times when IGF-1 may be completely inappropriate for gut activity. Similarly, the body's inherent and self-regulating use of IGFs cannot be compared to external oral administration. The location of the IGF is critical to its use and impacts. Clearly IGFs in the blood stream play some purpose that in no way parallels action in the gut (see section 3 for more on potential health concerns associated with oral IGF-1 intake).

5. Independent analysis of industry data shows that rBGH use increases mastitis in herds using rBGH, and such increases may result in increased antibiotic use and pressure on the milk quality control system

Summary

The key to any livestock farmer's success is a healthy herd. Mastitis is an infection of the cow's udder and has a serious negative economic impact on dairy farming. Although proponents of the drug claim that research shows no significant negative impacts on animal health, critics claim that the industry's own data show that rBGH application causes increased levels of mastitis and infertility in cows, particularly when viewed over an animal's lifetime.

⁴⁸ **BST Treatment of Dairy Cattle: Milk and Human Health: an Assessment of Risk**, Paper presented at the International Dairy Federation Conference, Johannesburg, South Africa, October 23, 1996, Schofeld, Mephram

⁴⁹ **Bovine Growth Hormone: Human Food Safety Evaluation**, Juskevich and Guyer, Science, Vol. 249, Aug. 1990; **Clinical review 21, The Efficacy and Safety of Growth Hormone of Animal Agriculture**, Etherton, Journal of Clinical Endocrinology and Metabolism, Vol. 72, Number 5; **Bovine Somatotropin Supplementation of Dairy Cows**, Daughaday and Barbano, Journal of the American Medical Association Volume 264, August 1990.

Critics believe that such health problems mean higher costs for farmers for maintaining animal health, greater costs for replacing less fertile animals, and greater pressure on the food safety system resulting from increased use of antibiotics to control mastitis.

Details

Evaluation of animal drugs is the responsibility of the Central Nervous System, Endocrine and Antiparasitic Drugs Division of the Health Protection Branch. It is responsible for conducting the animal safety and efficacy evaluation. The health of dairy animals injected with rBGH has had extensive review, yet questions remain about herd health. These questions are significant and are reflected in Health Canada's request of Monsanto in 1996 requesting additional data on herd health effects.

We are particularly concerned about 2 matters: mastitis incidence and the related issue of probable increases in antibiotic use to treat elevated somatic cell counts (SCC's are an early indication of mastitis) and related mastitis incidents⁵⁰. This problem has been raised by respected veterinarians, universities and scientists, however the hormone manufacturers cite other peer reviewed documents to support their claim that rBGH injections do not cause any more mastitis

than found in normal dairying. Their argument is that any increase in mastitis is due to management and/or the increased milk yield that results when cows respond to rBGH injections⁵¹.

Cows in most Canadian dairy farms operate under a regular calving interval (approx. 12 - 14 months). In milk recorded herds, the standard lactation length is 305 to 365 days⁵². If initial treatment of cows is to start at day 90, then many cows will be just past their peak production. Some of the new feeding regimes allow animals that normally peak lower in early lactation, to milk at higher levels later in the lactation. In short, a cow may not be at full production at proposed rBGH injection time.

⁵⁰ **Posilac Manual**, Monsanto's rBGH is marketed under the trademark Posilac; **Clinical Mastitis in Cows Treated with Sometribove** (Recombinant Bovine Somatotropin) and its relationship to milk yield, White, Madsen, Hintz, Sorbet, Collier, Hard, Hartnell, Samuels, A compilation Paper of fifteen full lactation trials from Europe and the United States, Journal of Dairy Science, Volume 77, 2249-2260.1994; **The Effect of Recombinant Bovine Somatotropin on Udder Health**, Lissemore, Leslie, McBride, Burton Willan and Bateman, Ontario Agricultural College publication number 0688, June 1988; **Safety of Bovine Somatotropin in Dairy Cows**, Results and Recommendations, Veterinary Medicine Teaching and Resource Centre, University of California, Osburn, Holmberg and Weaver, April 12, 1993.

⁵¹ **Clinical Mastitis in Cows Treated with Sometribove** (Recombinant Bovine Somatotropin) and its relationship to milk yield. White, Madsen, Hintz, Sorbet, Collier, Hard, Hartnell, Samuels, A compilation Paper of fifteen full lactation trials from Europe and the United States, Journal of Dairy Science, Volume 77, 2249-2260.1994

⁵² Canadian Milk Recording Board Regulations.

A cow's udder only has so much space to hold milk. It gradually expands to accommodate extra milk production but there is a point when the udder becomes too full. The cow then reduces milk production by absorption or leaks milk onto the floor or field. This is her way of regulating. But, to force the cows to eat and produce more than she is inherently capable of, will lead to mastitis by creating a condition called "overstocking"⁵³ of the udder. It means quite simply, overloading of normal capacity.

Once overstocked, mastitis takes over. " Non-specified mastitis may be caused by irritation, trauma, injury or any similar stress condition."⁵⁴ It is worth noting that dairy farmers already have a clearly defined policy⁵⁵ on reducing external injury on the cow's udder, but forgot internal risks and a pre-established precedent regarding internal risks⁵³.

The treatment of mastitis requires the use of antibiotics. Currently there are stringent controls and tests at the processing plant and for on-farm use to ensure no harmful antibiotic residues are present in milk. All provincial milk control agencies take samples of bulk(milk) tanks on a monthly or bi-weekly basis. Tanker loads are screened daily to test for beta-lactams, and random samples are taken for drugs such as sulfamethazine, tetracyclines, gentomycin, ceftiofur, erythromycin and other sulfas⁵⁶. Dairy farmers in Ontario are financially liable for milk load spoilage.

The contention that rBGH application has no direct effect on mastitis incidence has been criticized in two ways:

1. The industry has pooled its data in order to fulfill requests for more cow population proving effects regarding mastitis. However, the pooling of results and by presenting population averages, the variability of rBGH effects on cows is harder to identify⁵⁷. It is now clear from

⁵³ **Special Report, Diseases of Cattle**, United States Department of Agriculture, Bureau of Animal Husbandry, 1904

⁵⁴ **Bovine Mastitis**, Publication Number 525, Neubold, Ontario Veterinary College, Ontario Department of Agriculture

⁵⁵ Recommended code of practice for the care and handling of dairy cattle, Section 1.1.9., publication 1853\E, Agriculture Canada, 1990

⁵⁶ Peter Oosterhoff, then President of Dairy Farmers of Canada, Hansard of the House of Commons, Minutes of Proceedings and Evidence of the Standing Committee on Agricultural and Agri-Food, pursuant to Standing Order, 108(2), Consideration of issues relating to the bovine somatotropin hormone (rbST) issue 3, March 7, 1994, 3:10, 1545:1550.

⁵⁷ Kronfeld, D.S. 1993. **Recombinant Bovine Growth Hormone: cow responses delay drug approval and impact public health**. In: B. Liebhardt (ed.). **The Dairy Debate: consequences of Bovine Growth Hormone and Rotational Grazing techniques**. University of California, Davis, CA. Pp. 65-111

much evidence that rBGH impacts on cows are unpredictable; therefore cows that have a high incidence of mastitis can not be considered “outlier” effects and then either dismissed from the data set or pooled with animals not so affected.

2. Because the effects of rBGH are so unpredictable, it is virtually impossible for a farmer to properly manage the application of the drug. All cows have **varying** levels of growth hormone due to genetic differences⁵⁸. The effect on each cow’s metabolism of rBGH administration varies depending on the dosage and the inherent levels⁵⁹. The influence of herd variables on the effect of BST are largely unknown as pointed out in earlier study⁶⁰. Some cows suffer metabolic disorders, some do not react to the drug⁶¹ and some cows have no problems whatsoever.

How is a manager expected to make sound management decisions and avoid mastitis problems and other noted animal health problems?

Ultimately, whether the increased mastitis found in herds injected with rBGH is a direct result of rBGH administration, or a result of management/milk yield, the fundamental problem is the increase in mastitis, antibiotic use, and added pressure on the monitoring system.

Permitting such additional pressure is contradictory with current efforts to **decrease** high somatic cell counts in milk⁶². Why would the regulatory system permit on the market, a drug that will make this policy objective more difficult to achieve?

The Council appreciates the efforts of the drug manufacturers and the dairy industry as a whole to ensure that no currently licensed antibiotics enter the milk supply. However, the concern still remains

⁵⁸ **Faster Better Proofs**, Khumnirdpetch, Schaefer and Hacker, Department of Animal and Poultry Science Ontario College, Ontario Dairy Farmer Article, August 1994.

⁵⁹ **Posilac Manual; The Effect of Bovine Somatotropin on Udder Health**, Lissemore, Leslie, McBride, Burton Millan and Bateman, Ontario Agricultural Publication 0688, June 1988; **Safety of Bovine Somatotropin in Dairy Cows**, Results and Recommendations, Veterinary Medicine Teaching and Research Centre, University of California, Osburn, Holmberg and Weaver, April 12, 1993.

⁶⁰ **The Effect of Bovine Somatotropin on Udder Health**, Lissemore, Leslie, McBride, Burton, Millan and Bateman, Ontario Agricultural Publication 0688, June 1988.

⁶¹ **Adverse Drug Reaction Summary**, Department of Human Health and Services, United States, March 17, 1995.

⁶² Ontario Dairy Regulations 761, Consolidation of Regulations under the Milk Act, November 1993

that farmers will resort to extra label use of drugs⁶³ to combat chronic mastitis problems associated with rBGH administration, and antibiotics that may end up in milk. This problem was addressed in part by the General Accounting Office of the United States⁶⁴.

6. rBGH licensing will compromise existing rules of scientific breed improvement, a cornerstone of long-term progress in milk production

Summary

Three and a half billion dollars (farm gate price) is produced by the dairy breeds in Canada. Since 1881 Canada has adopted the principle of breed improvement to ensure the attempt toward continual improvement in the dairy sector. Each generation of animals has been evaluated for performance. Guided by federal law (the Animal Pedigree Act), scientific principles apply in order to prove this genetic performance. The rules allow breeders to evaluate how environmental conditions (feed, management, ventilation, housing conditions) improve the cow's ability to produce milk. But injecting into the animal a substance that the animal itself produces can not be considered an environmental condition. Therefore, the injections contravene established legally prescribed protocols and regulations.

The modified animals production performance is therefore, according to the rules, statistically invalid because the inherent capabilities of the animal born as a result of breeding (male x female) no longer exist. Consequently, it would be impossible for the industry to prove breed improvement if rBGH were licensed.

Details

Three and a half billion dollars (farm gate) of milk is produced by the dairy breeds in Canada. Further processing of that milk (ice-cream, butter, yogurt, etc.), including the spinoff industry accounts for over **nine billion dollars** to the Canadian economy (**125,000 jobs**)⁶⁵.

⁶³ Extra label use describes drugs that are used either singly or in combination to treat drastic situations in animal care but not conditions for which the drugs are licensed. Current testing procedures would not necessarily be able to detect these unknown drugs.

⁶⁴ **Food Safety and Quality, FDA Strategy Needed to Address Animal Drug Residues in Milk**, United States General Accounting Office, Report to the Chairman, Human Resources and Intergovernmental Relations Committee on Government Operations, House of Representatives, August 1992

⁶⁵ Dairy farmers of Ontario, Information Folder, October 1995

Canada already accounts for between 40-45 percent of global export activity in dairy genetic material (animals, semen, embryos). Yet Canada has only 1,267,300 dairy cows⁶⁶ (one half of one percent of the world dairy cow population). From this stock, comes nearly 100 percent of our dairy products, making Canada essentially self sufficient⁶⁷.

All the retailers, packagers, advertisers, processors, milk and cattle truckers, truck plants, construction, dairy equipment, inspectors, auctioneers, exporters, artificial insemination studs, hoof trimmers, nutritionists, feed mills, veterinarians, dairy breed associations, and many more who all work to put a glass of milk or dairy products on a consumer's table would be unemployed without a national herd of dairy cows.

Despite changes in technology, from which the Canadian dairy industry is not exempt, certain things do remain the same, i.e., basic scientific laws, such as gravity, mathematics, and a dairy cow (to get cow's milk).

Dairy cows come in many shapes and sizes, colours, attitudes, breeds and production levels all of which depends on their heritable traits. Being the female, a dairy cow has a unique role. She has to calve to provide milk, become pregnant between days 45-90 in her lactation, eat enough to maintain her body, the growing calf in her womb and produce enough milk to justify her standing in the stall or grazing in the pasture. Then she has to do it again next year after a rest of maybe 50 - 70 days between lactations⁶⁸ (approximately 305 to 365 days).

To create a new generation of offspring, dairy farmers have three choices for impregnating cows:

1. Natural service by a bull: 25 percent of Canadian dairy farms currently use this method
2. Artificial insemination (the use of frozen semen collected from a licensed bull stud): 75 percent of Canadian dairy farms currently use this method⁶⁹
3. The implantation of fresh or frozen embryos from superior donor cows: this is not a widely accepted practice due to cost and management requirements.

Dairy farmers, though diverse in ideology, practices and focus, are connected by one common thread: the use of the information provided by genetic improvement programs. These programs provide the

⁶⁶ Dairy Animal Improvement Statistics, 1994, Agriculture and Agri-Food Canada, Market and Industry Services Branch

⁶⁷ Supply management

⁶⁸ Standard practices, although there are exceptions in farm philosophy, ie buy cows, milk and cull, no calves

⁶⁹ Canadian Dairy Network Statistics. Jersey Breeder Journal, March 1996

assessment of an animal's heritable traits or breeding pattern in the environment to which the animal is exposed.

By co-relating the data on each individual animal and comparing it with herd mates on an individual farm and with other individual animals of the same sire on other individual farms, the farmers as a group create a picture of the breeding pattern of the sire's daughters in two areas: the daughter's body conformity, and her production levels. Those two areas are evaluated by independent evaluators, in essence third party verification.

To improve a cow or cows in their herd, the farmer's selection of sires is based on the achievements of the daughters from evaluated herds. This tremendous co-operation has been in Canada since 1881⁷⁰. These programs are vital to maintain the credibility and the effectiveness of the Canadian dairy industry.

It has been claimed that rBGH is a management tool to produce milk and would have no effect on the genetics of a cow given that milk production in a cow is variable anyway. But rBGH is designed for the expressed, non-therapeutic purpose of modifying a cow to produce more milk than she is inherently capable of producing in any normal environment. (see Appendix C)

The deliberate act of injecting growth hormone into an animal causes the animal to produce at a level that it was inherently incapable of achieving. Given that dairy cows are measured for their genetic milk production patterns, injecting growth hormone bastardizes agreed upon standards and measurements.

Breed improvement protocols are the roots from which the current dairy industry has emerged. A protocol is a procedure that must be used when performing specified measurements or related operations in order for the result to be acceptable to the specifying agency⁷¹. The protocol with dairy animals is designed to prove genetic value and stability. You must have a male and a female to breed together in order to get offspring. If later in life you then inject an inherent material (rBGH) into said offspring, how can one claim that the results of that animal's production is that of the animal bred by the original parents?

The genealogical records of all dairy cows since the inception of breed improvement⁷² in the late 1700's have been a result of breeding. Each generation of cows has been measured in comparison to its mother and herd mates to indicate whether the animal is better than or below average. The specifying

⁷⁰ Ontario Agricultural Commission Report, report of the Commissioners, 1881

⁷¹ Dictionary of Scientific and Technical Terms, Fifth Edition, MacGraw Hill, page 1595, 1994

⁷² The founder of breed improvement according to a standard, was Robert Bakewell of Leicestershire, England whose work was carried out between 1760 until his death in 1795.

agencies (breed associations in this case)⁷³, exist through the Animal Pedigree Act, 35-36-37, Queen Elizabeth II, Chapter 13⁷⁴.

The Animal Pedigree Act allows the establishment of breed associations under section 6 of the Act, provided the following requirements are met:

1. **An association may be incorporated under this Act only if the Minister is satisfied**
 - (a) that the animals of each distinct breed and evolving breed in respect of which the association sought to be incorporated have significant value;
 - (b) that the persons submitting articles of incorporation in respect of the association represents the breeders throughout Canada of the animals of each distinct breed in respect of which the association is sought to be incorporated;
 - (c) that the keeping of pedigrees and other records in respect of the animals of each distinct breed and evolving breed in respect of which the association is sought to be incorporated would be beneficial to the breeders thereof and the public at large.

2. **Scientific Principles**

An association may be incorporated in respect of a distinct breed only if the Minister is satisfied that the breed determined is **in accordance with scientific genetic principles**.

3. **Special Requirements with respect to evolving breeds**

An association may be incorporated in respect of an evolving breed only if the Minister is satisfied that the requirements referred to in sub-section 1 exist and that the creation, with genetic stability, of the new breed into which the animals of the evolving breed are intended to evolve is possible.

This act gives direction to breed associations regarding association format, by-law formula, annual general meeting protocol, constitution requirements and the legal, sole right to issue certificates of registrations (pedigree), and genealogical information to their respective members. It also legally binds any member of an association to obey the by-laws within their respective constitutions (section 17) as well as protects the interests of Canadians who chose to become breed association members (section 3-(b)).

⁷³ Dairy Breed Associations, of which there are eight in Canada

⁷⁴ The Animal Pedigree Act, Queen Elizabeth II, Chapter 13, Assented May 25, 1988, now expressed as Chapter 8(4th supplement) Revised Statutes of Canada, 1985, with amendments expressed in the Canada Statute Citorator, A5-5, December 1995

Part of dairy cattle genealogy is the milk production of each animal's individual lactation. This evaluation is performed by inspectors from the provincial milk recording associations approximately ten times per year. The farmer receives an update on each animal's current lactation production after each test (usually 2 milkings or one day). That information is forwarded to each dairy breed association to be incorporated into the database or genealogy file.

rBGH has been researched in Canada since 1984 at the University of Guelph for the purpose of evaluating the drug's performance on animals. What is curious to the Council is that during that time all owners of milk recorded animals had the following regulations to abide by:

Under section 1.1.6 - **Practices not allowed under the Canadian Milk Recording Standards** (1992).

The following practices are not allowed:

- 1.1.6.1 Any action by a person who, by an act or voluntary omission, knowingly and with intent to mislead, impairs or attempts to impair the reliability of any information about an animal or herd.
- 1.1.6.2 Any practice or the administration of a product (stimulant, drug, Oxytocin), to an animal during test day. This rule does not forbid proper medical attendance on an animal at any time.
- 1.1.6.3 Any practice that is intended to create an abnormal yield of milk or components in the milk.

The Council questions the motivation to consider rBGH given this breach of scientific discipline and Animal Pedigree Act regulation:

- < Given the evaluation figures are shared amongst dairy breeders and put into their database which extends back over 100 years of scientific protocols;
- < Given that exclusion of animals injected with rBGH would lead to fewer animals evaluated from a sire, creating genetic regression⁷⁵ and less effective focus;
- < Given that the efforts of dairy breed members are pooled, compiled and given to the bull studs who disperse semen of bulls whose daughters were evaluated to prove the sire's breeding pattern;

⁷⁵ **Review of the Potential Impact of Recombinant Bovine Somatotropin (rbST) in Canada**, Full Report; Report of the rbST Task Force, Presented to the Minister of Agriculture and Agri-Food Canada, May 1995

- < Given that 99 percent of Canadian dairy farmers base decisions on that information when selecting a sire;
- < Given that the dairy farmers want as accurate a pattern as possible;

Therefore, the Toronto Food Policy Council requests, as allowed by section 6 -1-(c) of the Animal Pedigree Act (an enablement class statute), as representatives within the general public:

that the Federal Minister of Agriculture and Agri-food act on the public's behalf to ensure that no practice will be allowed on registered dairy cattle by the dairy breed associations that modify existing animals' inherent qualities, for the expressed purpose of milk production, thus, protecting and assuring the safety of the food supply via statistical controls pursuant to the scientific determinations laid down in public policy documents and;

that any genetically engineered animals be banned from entering the herd books; instead, they be declared an evolving breed, until such time as their genetic stability and purpose have been validated to the point where they may receive recognition as a new breed under section 34 and section 6, sub-section 3 of the Animal Pedigree Act.

Finally, it is important to note that the provisions of the Animal Pedigree Act are recognized under the Canada - US Free Trade Agreement and the NAFTA. Given that such protocols are recognized as scientific under these international trade agreements, Canada should thereby be provided grounds to ban rBGH licensing under Article 712, Section B of the NAFTA, Sanitary or Phytosanitary Measures. This provision allows countries to apply a sanitary measure that is more stringent than international practice if it is demonstrably based on scientific principles. Since rBGH licensing violates the scientific principles of breed improvement, a national standard, it is our view that sufficient grounds exist to warrant use of this measure, without fear of trade retaliation.

The FTA statues, under Schedule 1, "Customs Tariff" section 1, Live Animals, Animal Products, is the following:

"Schedule 1, Chapter 1, Live Animals Supplementary Note:

1. *For the purposes of the headings number 01.01 to 01.04 inclusively, the expression "purebred breeding animals" applies only to animals certified by the director of the Canadian National Livestock Records or the secretary of any other governing association incorporated under the **Livestock Pedigree Act** as being "purebred" imported especially for breeding purposes."*

For the readers benefit sections 01.01 to 01.04 are the tariff items under the FTA and NAFTA which

include purebred breeding animals of the following species: Live horses, asses, mules and hinnies, live bovines, live swine, live sheep, and live goats. (See Article 401, of NAFTA, rules of origin).

Animals as goods, defined under the FTA and NAFTA are within the NAFTA Customs Procedures Manual⁷⁶. This means animals are within the Canada Customs Procedures (Glossary), United States Customs Procedures, and Mexico's Custom Procedures.

The Canadian government was part of an action plan⁷⁷ which states in part; "to this end governments in partnership with all actors of civil society, as appropriate will apply measures, in conformity with the agreement on the application of Sanitary and Phytosanitary Measures and other relevant international agreements that ensure the quality and safety of food supply, particularly by strengthening normal and control activities in the area of human, animal and plant health safety."

It is our view that the Rome Summit statement opens the door for statistical controls providing the guidelines for sustainable food production being amended into NAFTA⁷⁸. In short, if a country has a pre-existing public policy, scientifically proving a direction in a sector of the food industry (in this case breed improvement) then Article 712 of NAFTA could legitimately be used to prevent products being licensed that create a double standard. Hence, this is the basis for our conclusion on page 36, number 4.

Article 712, Section B., Section 1

(1) Each party may, in accordance with this section, adopt, maintain or apply any sanitary or phytosanitary measure necessary for the protection of human, animal, or plant life in its territory, including a measure more stringent than an international standard, guideline, or recommendation.

The Right to Establish Level of Protection

(2) Notwithstanding any other provision of this section, each party may, in protecting human, animal or plant life establish its appropriate levels of protection with Article 715.

Scientific Principles

⁷⁶ Revenue Canada's Information Manual for Importers and Exporters, March 1995.

⁷⁷ World Food Summit, Rome Declaration of World Food Security and World Food Summit, Plan of Action page 15, Section 21, objective 2.3, 1996.

⁷⁸ **Canadian Statement on Implementations**, North American Free Trade Agreement, Canada Gazette, part 1, January 1, 1994; North American Free Trade Agreement, parliamentary Committee Working Version, December 17, 1992

(3) Each party shall ensure that any sanitary or phytosanitary measure that it adopts, maintains or applies is: (a) based on scientific principles, taking into account relevant factors including where appropriate different geographic conditions.

The Council now refers to article 715 of NAFTA:

Article 715 - Risk Assessment and Appropriate Level of Protection

When conducting a risk assessment, each party shall take into account:

- 1(a) relevant risk assessment techniques and methodologies developed by International or North American standardizing organizations;
- (b) relevant scientific evidence;
- (c) relevant processes and production methods;
- (d) relevant inspection, sampling and testing methods.

The Toronto Food Policy Council concurs that the genealogical study of dairy animals is scientific evidence relevant to food supply. It is based on relevant production methods in the Canadian environment and that such evidence is based on acknowledged independent milk recorded inspection, animal conformity inspection recognized by International and North American standardizing organizations.

7. Government and industry opposition to labelling means that the market will not be able to tell us whether consumers find biotechnology products acceptable

Summary

The federal government has consistently opposed labelling of biotechnology foods, on the grounds that they are no different from conventional foods regarding issues that consumers are

concerned about - composition, nutrition and food safety. They also claim that it is up to the market place to determine whether biotechnology products are useful and desirable.

But many claim that biotechnology products are different. They have the potential to produce negative health consequences that are not associated with their conventional equivalents (see earlier discussions). They are also an expression of different values about food. Biotechnologists do not appear to share the same set of ethical concerns held by many in the population regarding manipulation of the basic building blocks of life. Many consumers believe biotechnology foods are different products. By not allowing the products to be labelled, what the government is really saying is that it will

not respect consumer's conception of what creates product differences. There is extensive opposition amongst Canadian consumers to unlabelled foods of biotechnology.

The government's claim that the market place will decide if biotechnology products are acceptable is also suspect. If consumers are unable to tell at the moment of purchase whether they are buying food products from genetic engineering, how can their purchasing behaviour be seen as acceptance of this technology?

Details

“Earned trust means: “Trust me because I'll show that you can trust me”, which means you'll have to keep earning that trust. Blind trust says "trust me because I know what's best for you and I have the status, authority and power and I'll tell you what to do.” That sort of trust will not work with the public with biotechnology.”⁷⁹

There is significant opposition amongst Canadian consumers to milk from rBGH-modified cows. Poll results include:

Protegez-Vous, September 1994 (carried out July 1994, 1001 persons 18 years of age and older, margin of error 3.71 percent, 19 times out of 20)

78 percent oppose use
69 percent oppose strongly
93 percent want labelling
83 percent would buy non-rBGH milk
67 percent do not have faith in FDA decision

Optima, completed for Industry Canada November 1994 (carried out May 1994, 2000 adults, margin of error 3.0 percent, 19 cases out of 20)

29 percent indicate unlikely to purchase milk that is pooled
96 percent want labelling

Angus Reid, Public Opinion on Food Safety (re BST) July 1995 (based on over 1100

⁷⁹ Margaret Somerville, Professor, Faculty of Law and Faculty of Medicine, McGill University, Roundtable participant in the report to the House of Commons, **Biotechnology Regulation in Canada, A Matter of Public Confidence**, Report of the Standing Committee on Environment and Sustainable Development, November 1996.

respondents)

40 percent are extremely concerned
46 percent would pay 10 percent extra for milk
from cows not treated with rBGH.

The National Dairy Council believes a 15% reduction in milk sales is likely within a few years of rBGH licensing and has passed resolutions calling on the federal government to indemnify the dairy industry against financial losses associated with declines in milk sales due to negative consumer reaction to rBGH.

Despite this opposition, government and industry continue to press for rBGH licensing, believing that consumers are misinformed. With the appropriate marketing strategy, they believe consumers can be made to see the value of biotechnology and foods derived from it.

Paradoxically, however, they are opposed to mandatory labelling, arguing that since the products are identical then there is no need to label. For free market capitalists, this is a particularly odd position to take. The government has been supporting the deregulation of markets to ensure their proper functioning and to increase private sector competitiveness. A central assumption of efficient market function is that all market actors are fully informed about the products they are buying. In the absence of such information, imperfect market function results. Consumers can not be fully rational actors in the market unless they are provided with full information about the products they buy. To deny them information on the use of genetic engineering, is to distort the functioning of that market place. Such distortions also reduce the ability of firms to be competitive because they encourage them to engage in activities that ultimately distort efficient resource allocations.

Claims of consumer acceptance in the USA, based on a rise in milk consumption of one-half of one percent one year after rBGH introduction, are misleading given that figures released on milk consumption are aggregated figures and do not identify trends in sales of milk labelled rBGH-free and organic milk. Reports out of California show dramatic increases in sales of organic milk, in large part because of consumer rejection of rBGH.

Europe however, has worked diligently on labelling of novel foods. In mid-March, 1997, EuroCommerce, which represents international retailers and wholesalers in 20 countries rejected a claim in February, 1997, by the London based, Grain and Feed Trade Association (GAFTA) that labelling was impractical. In its statement, EuroCommerce said “There is a growing demand in Europe for labelling of genetically modified foodstuffs and retailers insist that raw materials should be separately identifiable⁸⁰.”

⁸⁰ Article in the Manitoba Co-Operator, page 23, March 13, 1997.

Biotechnology proponents are failing to observe the essence of trust. If genetically modified foods are not identified as such then the general public will have incomplete information. Particularly with regard to allergies this will leave health officials blind regarding diagnosis treatment.

The essence of selling a product is marketing or advertising. We cannot forget that base products that have even slight variations from the original product can have damaging effects in further processing. Further processing depends on knowing heat concentrations, time frames, addition of other products and how they interact. But with biotechnology, much is unknown and manufacturer's performance specifications may be inaccurate.

The public in Ontario is represented by the provincial government which has two excellent statutes: the Consumer Protection Act and the Sale of Goods Act. The consumer Protection Act has the section regarding false advertising (section 38) which states in part:

“Where the Registrar believes on reasonable and probable grounds that a seller or lender is making false, misleading or deceptive statements in any advertisement, circular, pamphlet or similar material, the Registrar may order the immediate cessation of the use of such material...”⁸¹

The Sale of Goods Act moves the above point further if a seller has made a warranty on said product. Part V deals with breach of contract. Section 50 of this Act states:

“In an action for breach of contract to deliver specific or ascertained goods, the court may, if it thinks fit, direct that the contract be performed specifically, without giving the defendant the option of retaining the goods on payment of damages, and may impose such terms and conditions as to damages, payment of the price, and otherwise, as to the court seems just.”⁸²

Given the uncertainties surrounding biotechnology products, can a case be made that they are in violation of these statutes?

The Toronto Food Policy Council views the labelling of genetically modified food as progressive and necessary to ensure consumer confidence in allowing consumers' right to vote with their dollar by assuring product specificity in the market place.

⁸¹ Consumer Protection Act, office Consolidation, Revised Statutes of Ontario, 1990. Chapter C.31. As amended by 1993, Chapter 27, Sched. And the following Regulation (as amended): General (R.R.O., 1990, Reg. 176), March 1995, printed by the Queen's Printer for Ontario.

⁸² Sale of Goods Act, Office consolidation, Revised Statutes of Ontario, 1990. Chapter S.1 as amended by 1993, Chapter 27, Sched.; 1994. Chapter 27, s. 54, June 1995, Printed by the Queen's Printer for Ontario.

CONCLUSIONS

There remains significant concern about:

- C how increased and potentially orally active levels of IGF-1 might impact on the human gut and cancer tumour development;
- C the likelihood of elevated levels of mastitis and fertility problems associated with rBGH administration;
- C the negative impact on the financial health of the dairy industry - due to genetic regression documented in this report and the rbST Task Force report in May 1995;
- C the public's health if consumers reduce their consumption of dairy products.

Given these potential problems and the confusion that would exist for the dairy sector in the event of licensing, we believe it is folly to permit this drug on the market. There are no obvious benefits to its introduction, and the negative health consequences may be very significant. Public concern is very high and over 350 school, health, farm, business and community organizations oppose its introduction.

Recombinant Bovine Growth Hormone should not be approved for sale in Canada. Instead, the federal government should consider the following options for the dairy sector:

- 1) Dairy farmers should have a long-term dairy policy based on the financial and environmental sustainability of the sector, and that as part of this policy, no hormones should be permitted for the expressed purpose of modifying an existing dairy cow (either inherently, genetically, or through transgenic manipulation) so that it produces more milk than its inherent capacity in a normal Canadian dairying environment.
- 2) Any new technologies should focus only on improving the therapeutic or environmental aspects of dairying, for example, alternative approaches to managing animal health, feeding regimes, pasture and crop management, and animal housing designs.
- 3) Dairy processors and retailers should be more accountable to consumers, and product labelling of processes used in dairy farming and processing should be part of such accountability.
- 4) New products should be screened for their potential broad social benefits prior to the review process undertaken by Health Canada, to determine whether the product has sufficient merit in terms of long-term health and sustainability to warrant a detailed review of its efficacy and specific health impacts.

Appendix A

Appendix A p. 2

Appendix B

List of Currently Applicable References

1. Ambrose, D., Resnicoff, M., Coppola, D., Sell, C., Miura, M., Rubin, R., Jameson, S., Baserga, R. (1994) Growth regulation of human glioblastoma T98G cells by Insulin-Like growth factor-1 and its receptor., *Journal of Cell Physiology*, April, 159(1): 92-100
2. Atiq, F., Garrouste, F., Remacle-Bonnet, M., Sastre, B., Pommier, G., (1994) Alterations in serum levels of insulin-like growth factors and insulin-like growth factor binding proteins in patients with colorectal cancer. *International Journal of Cancer*, 57(4) 491-497
3. Bang, P., & Hall, K. (1992) Growth Factors as endocrine and paracrine hormones. (Pp. 151-178). In the *insulin-like growth factors: structure and biological functions*. Ed. Schofield, P.N. Oxford university Press, Oxford.
4. Bates, P., Fisher, R., Ward, A., Richardson, L., Hill, D.J., and Graham, C.F., (1995) Mammary Cancer in Transgenic mice expressing insulin like growth factor II, *British Journal of Cancer*, (72) 1189-1193
5. Baumrucker, C.R., Blum, J.W., (1994) Effects of dietary recombinant human insulin-like growth factor 1 on concentrations of hormones and growth factors in the blood of newborn calves. *Journal of Endocrinology*, January, 140(1) 15-21
6. Bengtsson, B.A., (1993), Acromegaly and Neoplasia, *Journal of Paediatric Endocrinology* (6) 73-78
7. Burton, J.L., McBride, B.W., Block, E., Glimm, D.R., and Kennelly, J.J. (1994), A review of bovine growth hormone, *Canadian Journal of Animal Science*, (74) 167-201
8. Chen, J.C., Shao, Z.M., Sheikh, M.S., Hussain, A., LeRoth, D., Roberts, C., (1994) Insulin-like growth factor-binding protein enhancement of insulin-like growth factor 1 (IGF-1) mediated DNA synthesis and IGF-1 binding in a human breast carcinoma cell line. *Journal of Cell Physiology*, January, 158(1) 69-78
9. Christofori, G., and Hanahan, D., (1994) Molecular dissection of multistage carcinogenesis in transgenic mice, *Seminars in Cancer Biology*, (5), 3-12
10. Deleon, D.D., Wilson, D.M., Powers, M., Rosenfeld, R.G., (1992) Effects of insulin-like growth factors (IGFs) and IGF receptor antibodies on the proliferation of human breast cancer cells., *Growth Factors*, 6(4), 327-336
11. D'Errico, A., Grigoni, W.F., Fiorentino, M., Baccarini, P., Lamas, E., DeMitre, S., Gozzetti, G., Mancini, A.M., Brechot, C. (1994) Expression of insulin-like growth factor II (IGF-II) in human hepatocellular carcinomas; an immunohistochemical study., *Pathology International*, February, 44(2) 131-137
12. Figueroa, J.A., Sharma, J., Jackson, J.G., McDermott, M.J., Yee, D., Hilsenbeck, S.G., (1993) Recombinant insulin-like growth factor binding protein-1 inhibits IGF-1 serum, and estrogen-dependant growth of MCF-7 human breast cancer cells. *Journal of Cell Physiology*, November, 157(2) 229-236
13. Frodin, M., Gammeltoft, S., (1994) Insulin-like growth factors act synergistically with basic fibroblast growth factor and nerve growth factor to promote chromaffin cell proliferation. *Proc. National Academy, Science, USA*, march 1, 91(5) 1771-1775

Appendix B Continued
List of Currently Applicable References

14. Frystyk, J., Skjaerbaek, C., Dinesen, B., Orskov, H., (1994) Free insulin-like growth factors (IGF-1 and IGF-11) in human serum. *FEBS. Letter*, July 11, 348(2); 185-191
15. Gillespie, J., Dye, J.F., Schachter, M., Guillou, P.J., (1993) Inhibition of Pancreatic cancer cell growth in vitro by the tyrphostin group of tyrosine kinase inhibitors. *British Journal of Cancer*, December, 68(6) 1122-6
16. Glick, R.P., Unterman, T.G., Lacson, R., (1993) Identification of insulin-like growth factor (IGF) and glucose transporter-1 and -3 mRNA in CNS tumors. *Regul. Pept.* October 20, 48(1-2) 251-256
17. Guler, H.P., Zapf, J., Froesch, E.R. (1987) Short term metabolic effects of recombinant human IGF-1 in health adults, *New England Journal of Medicine*, 317, 137-140
18. Heinz-Erian, P., Kessler, U., Funk, B., Gais, P., Kiess, W., (1991) Identification in situ localisation of the insulin-like growth factor II receptor in the rat gastrointestinal tract: comparison with the IGF-1 receptor. *Endocrinology* 129, 1769-1778
19. Jones, D.I., Clemmons, D.R., (1995) Insulin-like growth factors and their binding proteins biological actions. *Endocrine Rev.*, 16, 3-34
20. Juul, A., Main, K., Blum, W.F., Lindholm, J., Ranke, M.B., Skakkebaek, N.E., (1994) The ration between serum levels of insulin-like growth factor IGF-1 and the IGF binding proteins, (IGFBP-1,-2, and -3) decreases with age in healthy adults and is increased in acromegalic patients. *Clinical Endocrinology*, 41-85-93
21. Kachra, Z., Yang, C.R., Posner, B.I., (1994) The augmentation of insulin-like growth factor 1 messenger ribonucleic acid in cultured rat hepatocytes: activation of protein Kinease-A and -C is necessary but not sufficient. *February Endocrinology* 134(2) 702-708
22. Kappel, C.C., Velez-Yanguas, M.C., Hirschfield, S., Helman, L.J. (1994) Human osteosarcoma cell lines are dependant on insulin-like growth factor 1 for invitro growth, *Cancer Reserach*, May 15, 54(10) 2803-2807
23. Kleinman, D., Roberts, C.T., Jr., LeRoith, D., Schally, A.V., Levy, J., Sharoni, Y., (1993) Regulation of endometrial cancer cell growth by insulin-like growth factors and the luteinizing hormone-releasing hormone antagonist. *Regul. Pept.* October 20, 48(1-2) 91-98
24. Krasnic, A., Menczer, J., Pariente, C., Kanety, H., (1994) Insulin-like growth factor 1(IGF-1) and IGF binding protein II are increased in cyst fluids of epithelial ovarian cancer. *Journal of Clinical Endocrinology-Metabolism*, February, 78(2)
25. Kwok, C.F., Ho, L.T., Jap, T.S., (1993) Insulin-like growth factor 1 receptor increases in aortic endothelial cells from diabetic rats. *Metabolism*, November, 42(11) 1381-1385
26. Langford, K.S., Miell, J.P., (1993) The insulin-like growth factor 1/binding protein axis: physiology, pathophysiology and therapeutic manipulation. *Eur-Journal-Clin-Invest.* September, 23(9), 503-516

Appendix B Continued
List of Currently Applicable References

27. Lee, A.V., and Yee, D., (1995) Insulin-like growth factors and breast cancer. *Biomedicine and pharmacotherapy*, 49, 415-421
28. LeRoith, D., Kavsan, V.M., Koval, A.P., Roberts, C.T., (1993) Phylogeny of the IGF's and receptors, a molecular approach, *Molecular Reproduction Development*, 35, 332-338
29. LeRoith, D., Baserga, R., Helman, L., Roberts, C.T. (1995) Insulin-like growth factors and cancer, *Annals of internal medicine*, 122, 54-59
30. Li, X.S., Chen, J.C., Sheikh, M.S., Shao, Z.M., Fontanna, J.A., (1994) Retinoic acid inhibition of insulin like growth factor 1 stimulation of c-fos mRNA levels in a breast carcinoma cell line. *Exp-Cell-Research*, March, 211(1) 68-73
31. Lippman, (1991) Growth factors, receptors and breast cancers. IGF-1 and related growth factors are critically involved in aberrant growth of human breast cancer cells. *Journal National Institute of health, Res.* 3 59-62
32. Martin, D.M., Singleton, J.R., Meghani, M.A., Feldman, E.L., (1993) IGF receptor function and regulation in autocrine human neuroblastoma cell growth. *Regul. Pept.* October, 48 (1-2), 225-232
33. Mephram, T.B., Schofield, P.N., (1995) Health aspects of bST milk, *International Dairy Federation Newsletter*, 4, 36-38
34. Minniti, C.P., Tsokos, M., Newton, W.A., Helman, L.J., (1994) Specific expression of insulin growth factor-II in rhabdomyosarcoma tumor cells. *American Journal of Clinical Pathology*, February, 101(2) 198-203
35. Miura, M., Li, S.W., Dumenil, Z.G., and Baserga, R. (1994), PDGF induced expression of PCNA mRNA requires a functional receptor for IGF-1. *Cancer Research*, 54, 2471-2477
36. Musgrove, E.A., Sutherland, R.L., (1993) Acute effects of growth factors on t-47D breast cancer cell cycle progression. *Eur. Journal Cancer*, 29A (16) 2273-2279
37. Nielson, F.C., Orskov, C., Haselbacher, G., Ramlau, J., Rehfield, J.F., Christiansen, J., Schmiegolow, K., (1994) Insulin-like growth factor II mRNA, peptides, and receptors in a thoracopulmonary malignant small round cell tumor. *Cancer*, February, 15, 73(4) 1312-1319
38. Oster, K.A., Ross, D.J., Shamick, S.W., (1980) Liposomes as a proposed vehicle for the presorption of bovine xanthine oxidase. *Proc. Soc. Experimental Biology and Medicine* Volume 163, Number 1, January
39. Prager, D., Li, H.L., Asa, S., Melmed, S., (1994) Dominant negative inhibition of tumorigenesis in vivo by human insulin-like growth factor 1 receptor mutant. *Proc-national Academy Science, USA*, March 15, 91(6) 2181-2185
40. Raille, K., Hoflich, A., Kessler, U., Yang, Y., Pfuender, M., Blum, W.F. Kolb, H., Schwarz, H.P., Kiess, W. (1994) Human Osteosarcoma (U-2 ps) cells express both insulin-like growth factor II/mannose-6-phosphate (IGF-II/M6P) receptors synthesized IGF-II:autocrine growth stimulation by IGF II via the IGF-1 receptor. *Journal of Cell Physiology* June, 159(3) 531-541

Appendix B Continued

List of Currently Applicable References

41. Rao, R.K., Lam, K., Phillips, A.F., Williams, C., Lake, M., Koldovsky, O., (1993) Presence of multiple forms of peptidase inhibitors in rat milk. *Journal of Paediatric Gastro-intestinal Nutrition*, November, 17(4) 414-420
42. Rechler, M.M., (1993) Insulin-Like growth factor binding proteins. *Vitamins and Hormones*, 47, 1-114
43. Robbins, K., McCabe, S., Schiener, T., Strasser, J., Clark, R., Jardieu, p., (1994) Immunological effects of insulin-like growth factor 1 enhancement of immunoglobulin synthesis. *Clinical Exp. Immunology*, February, 95(2) 337-342
44. Rogler, C.E., Yang, d., Rossetti, L., Donohoe, J., Alt. E., Chang, C.J., Rosenfeld, R., Neely, k., Vandaele, W., (1994) Altered body composition and increased frequency of diverse malignancies in insulin-like growth factor II transgenic mice. *Journal of Biological Chemistry*, May 13, 269 (19)
45. Romagnolo, D., Akers, R.M., Wong, E.A., Boyle, P.L. McFadden, T.B., Byatt, J.C., Turner, J.D., (1993) lactogenic hormones and extracellular matrix regulate expression of IGF-1 linked to MMTV-LTR in mammary epithelial cells. *Molecular Cell Endocrinology* October, 96(1-2) 147-157
46. Schofield, P.N., Engstrom, W., (1992), *Insulin-like growth factors and human cancer. The Insulin-like growth factors; structure and biological function*, ed. Schofield, P.N., (OUP)
47. Stiles, C.D., Capone, G.T., Scher, C.D., Antoniades, H.N., VanWyk, J.J. (1978) Dual control of cell growth by somatomedins and PDGF, *Proc. National Academy Science*, 76, 1279-1283
48. Stoll, B.A., (1993) The growth hormone/IGF axis and breast cancer risk, *Breast* 2, 130-133
49. Taylor, R.G., Fuller, P.J., (1994) Hormonal regulation of intestinal adaption. *Baillieres-Clinical Endocrinology Metabolism*, January, 8(1) 165-183
50. Tremble, J.M., McGregor, A.M., (1994) Epidemiology, complications and mortality. *Treating Acromegaly*, ed. Wass, J.A.H., (Endocrine Society) Bristol, U.K., 5-12
51. Wimalasena, J., Meehan, D., Dostal, R., Foster, J.S., Cameron, M., Smith, M., (1993) Growth factors interact with estradiol and gonadotropins in the regulation of ovarian cancer cell growth and growth factor receptors, *Oncol. Research*, 5(8) 325-327
52. Xian, C.J., Shoubridge, C.A., Read, L.C., (1995) Degradation of insulin-like growth factor 1 in the rat gastrointestinal tract and prolongation of IGF-1 survival by an anti-serum and casein. *Journal of Endocrinology*, 146, 215-224
53. Yashiro, T., Arai, M., Shizume, K., Obara, T., Murkami, H., Hizuka, N., Emoto, N., Miyakawa, M., Ito, K., Tshushima, T., (1994) Increased activity of insulin-like growth factor binding protein in human thyroid papillary cancer tissue. *Japanese Journal Cancer Research*, January, 85(1) 46-52
54. Yun, K., Molenaar, A.J., Fielder, A.M., Mark, A.J., Eccles, M.R., Becroft, D.M., Reeve, A.E. (1993) Insulin-like growth factor II messenger ribonucleic acid expression in Wilms tumor, nephrogenic rest, and kidney. *Lab-Invest*. November, 69(5) 603-615

Appendix C

Our case to prove inherent modification is demonstrated in the following scenarios:

Scenario No. 1		
<p>If we had the ability to move a cow to the three basic management programs available in Canada: The energy needed to produce these management scenarios increases from 1 being lowest to 3 being highest.</p>		
Management No. 1	Management No. 2	Management No. 3
<ul style="list-style-type: none"> - Seasonal pasture - Mixed grain ration - Mixed first cut hay 	<ul style="list-style-type: none"> - Zero Grazing - Prepared feed - Ensiled Forages 	<ul style="list-style-type: none"> - Total Confinement - Total Mixed Ration
<p>She produces 7000 litres of milk</p>	<p>She produces 8500 litres of milk</p>	<p>She produces 9800 litres of milk</p>
<p>Question: Did the cow change?</p> <p>Answer: No. The environment was modified, not the cow. The argument of production variability as an expression of genetic influence is null and void. The cow clearly showed she was genetically capable of withstanding the production system and able to produce according to environment.</p>		

- The original ease for Appendix C scenario was adopted by the Toronto Food Policy Council-1996 as part of a negotiation paper.
- Approved by the Toronto Board of Health - 1996

Appendix C (continued)

Scenario No. 2		
Taking the same three management approaches mentioned above and three different cows of equal body conformity, butterfat and protein content.		
Management No. 1	Management No. 2	Management No. 3
- Seasonal pasture - Mixed grain ration - Mixed first cut hay	- Zero Grazing - Prepared feed - Ensiled Forages	- Total Confinement - Total Mixed Ration
Cow A	Cow B	Cow C
Makes 9000 litres of milk	Makes 9000 litres of milk	Makes 9000 litres of milk
<p>Question: Which is the superior cow?</p> <p>Answer: Cow A. Though the level of production is constant in variable environments, Cow A proves superior NET (Net Energy Transfer) due to the lowest input of energy (relating to time for cropping, fuel, maintenance) to produce a litre of milk; therefore a more desirable cow to breed from for profit.</p>		

To inject rBGH into any of the above cows produces inherent modification. The human intervention of injecting a production hormone will make her milk more than was genetically (via breeding) possible under any environmental level of management.

Other hormones used in dairy cattle are for therapeutic use only and for specific problems and are not a concern to us due to the milk withdrawal time listed on the labels.