

### **Bovine somatotropin and the regulatory process for veterinary drug approval — Open letter**

Dear Sir:

In Canada, for a new veterinary drug to be approved, it must be investigated by Health Canada. A demonstration must be made that there is no risk to humans who consume animal products from treated animals, that animal health is not adversely affected, and that the drug is effective. If these questions are answered satisfactorily, Health Canada approves the drug. The Minister of Health and the Minister of Agriculture and Agri-Food then formally approve the products for sale or use.

With respect to bovine somatotropin (BST), the approval process has become considerably more complex. The Standing Committee on Agriculture and Agri-Food, a committee of MPs appointed by the Minister of Agriculture and Agri-Food to review relevant agricultural issues, recommended to the Minister that a BST Task Force be struck to oversee the carrying out of 4 specific information gathering tasks. Its mandate was to review in greater detail the impact of BST on the costs and benefits for the Canadian dairy industry, on animal health, on animal genetics, on U.S. consumer reaction, and any other outstanding human health questions. Because human health was already the responsibility of Health Canada, the Task Force did not duplicate this undertaking.

The BST Task Force reported back to the Minister on May 10, 1995, with its findings. On June 13, 1995, the Standing Committee on Agriculture and Agri-Food met with the BST Task Force to discuss these findings, and on June 15, 1995, it met with Health Canada officials to determine the status of their investigation. Both hearings were open to the public.

During the hearing with Health Canada, the majority of the MPs present attempted to undermine the credibility of the regulatory process. They became frustrated that Health Canada was not more forthcoming with

information. Several MPs suggested that Health Canada was not capable of performing its functions effectively and efficiently, and that the entire regulatory process should come under review by Parliament. The Chairman made a motion that Parliament legislate the procurement of the information in question from Health Canada. It is important to note that Health Canada officials are prevented **by law** from disclosing information, until their investigation is complete, at which time their methods and findings become part of the public record. Certainly, members of the Standing Committee were aware of this.

It is clear the Standing Committee on Agriculture and Agri-Food is dominated by MPs strongly opposed to BST. Additionally, there is a direct association among several of these influential MPs and the Animal Defence League, the Council of Canadians, and other special interest of lobbying groups. These organizations have absolutely no direct interest in the health and welfare of the dairy industry.

How significant will this attack on the regulatory process be? It will depend on the relative weight of the recommendations of the Standing Committee on Agriculture and Agri-Food, in comparison to Health Canada's eventual decision, and the BST Task Force's findings. Canada's regulatory process is recognized as arguably the best in the world. If the Standing Committee has great influence in the process, then special interest or lobbying groups could have a direct and significant voice in present and future agricultural issues. Currently, less than 2% of the Canadian population is directly involved in agriculture.

Consider carefully the implications of a change in our present drug approval process, which to date is based on sound science. Also consider the possible influence of various well funded and organized special interest groups in the decision making process, if a precedent is set on the BST issue.

The credibility of Health Canada is being challenged. We urge all veterinarians to strongly support our regulatory system.

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## **Bovine somatotropin and the regulatory process for veterinary drug approval — A reply**

Dear Sir:

I am responding to the letter from the group of veterinarians and dairy producers who claimed, among other things, that the rBST issue was somehow skewed by special interest groups with no direct connection to agriculture having direct access to the decision-making apparatus on Parliament Hill.

Committees of the House of Commons assist the Government by providing issue-specific information, obtained through a system of public hearings where individuals, groups, and organizations present briefs and answer MPs' questions. Members of Parliament who are Committee members are not appointed by Ministers. Each party fields its own membership on the House Committees, which work at arm's length from the Government. In the case of the Standing Committee on Agriculture and Agri-Food, its membership includes farmers or representatives of rural ridings where agriculture is a priority.

This Committee, like the other House Committees, is a democratic forum. With any issue, all interested parties are encouraged to appear or send a brief. As in any democratic forum, opinions, both pro and con, are heard. Members then draw their own conclusions. It is misleading to imply that it is only Committee members who are not farmers who are questioning the use and need for rBST or that Canada's dairy industry unequivocally supports its use. It was, after all, Canada's dairy industry itself that originally asked for a moratorium on the use of rBST.

The Government-Industry Task Force set up to investigate certain aspects of rBST use in the USA met with

the Standing Committee in June this year. The Task Force had not been successful when it asked Health Canada to provide information on certain human and animal health and safety aspects. The Committee reiterated the request and achieved a response. At **no time** was any attempt made by the Committee to circumvent Canadian laws respecting disclosure of proprietary information. While Committee members are well aware of the stringency of Canada's regulatory processes, they also believe that safety-study results that **are not** proprietary information should be made available to the concerned public in user-friendly form.

Had the authors checked the proceedings of the hearings, they would have learned that not only is Canada's dairy industry divided, but increasing numbers of Canada's consumers are voicing their doubts as to the use of and need for rBST. They are protesting collectively through various organizations and individually by contacting MPs, the Ministers involved, and even the Prime Minister. I hope that the authors accept Canadian consumers as bonafide stakeholders in Canada's agricultural industry.

The Members of the Agriculture Committee were inundated with information from the broadest possible spectrum of sources. They did what they were sent to Parliament to do: namely, to come to a well-informed decision and act accordingly. It is regrettable that the Committee's conclusions were perceived so negatively by the authors, since the final position was not arrived at in the interest of just **one** group, nor yet **one** organization, but in the interest of all Canadians.

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