

# **BST - A DISTRESSING PRODUCT**

AN ANALYSIS OF THE HEALTH AND WELFARE  
PROBLEMS OF DAIRY COWS INJECTED WITH BST

A

COMPASSION IN WORLD FARMING

Report by

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“BST is a cynical abuse of both the dairy cow and the dairy farmer”

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## Summary of Report Findings and Conclusions

BST can increase milk yield. It is associated with a range of adverse health conditions:

- It can double the length of the period of catabolic stress endured by cows after calving.
- It may increase the risk of cows suffering from negative energy balance, chronic hunger and severe loss of condition.
- It results in an increase in mastitis incidence in treated cows.
- It may have a negative effect on reproductive performance.
- New evidence from the USA shows that BST may have a profound effect on the cow's digestive system, which may be accentuated during second/subsequent lactations on BST.
- BST injections can result in painful injection site reactions.

## Conclusions

**BST can and often does cause significant tender and long-lasting swellings on the injection site. It doubles the length of the period of catabolic stress experienced by lactating cows after calving. It will result in mastitis cases which would not otherwise have occurred. Figures from the US FDA suggest that there is a real possibility that cows receiving BST on a second lactation develop an increased number of digestive problems.**

**Compassion in World Farming believes that in view of the health and welfare problems caused by BST administration, the product should not be licensed for use in the EU.**

**Compassion in World Farming believes that licensing of BST by the European Union would run counter to the terms of the 1997 Amsterdam Protocol on Improved Protection and Respect for the Welfare of Animals.**

**Compassion in World Farming believes that the Codex Committee on General Principles should pay due attention to the animal health and welfare concerns outlined in this Report when making recommendations on BST to the Codex Alimentarius Commission.**

**Compassion in World Farming believes that, should the UK Minister vote in favour of BST and allow its commercial use in the UK, s/he would surely be endorsing an infringement of Section 1 of the Agriculture (Miscellaneous Provisions) Act 1968 which makes it an offence to cause unnecessary pain or unnecessary distress to livestock.**

## **Introduction**

For several years, four major pharmaceutical companies tested and sought official authorisation to market bovine somatotropin, commonly called BST, the recombinant version of the cow's own growth hormone. These new versions of BST are genetically engineered in the laboratory by recombinant techniques and the subsequent products have different chemical structures to the natural product, with varying amino acid sequences.

The first two BST licensing applications in the UK were turned down by the Veterinary Products Committee due to concerns about animal health and welfare (VPC, 1990). On subsequent appeal to the Medicines Commission, approval was granted. BST is not yet on sale in the UK as EU approval is necessary before it can be licensed in Member States.

However, EU approval has not yet been granted and a series of moratoria on BST licensing have succeeded each other. The current moratorium ends in December 1999 when the Council of Ministers will have to decide whether to extend it, ban BST indefinitely, or approve commercial use of the product. When the last moratorium was debated, only the (previous) UK government voted in favour of licensing. The new Labour government in the UK says it will oppose licensing of BST.

In February 1993 the EU's Committee for Veterinary Medicinal Products produced its final Reports on two of the BST products: Somatech (Monsanto) and Optiflex 640 (Eli Lilly) (CVMP, 1993). The Committee recommended that authorisation of BST could take place, but only if accompanied by strict conditions of administration and monitoring over an extended time period.

The Committee's conclusions were reached in spite of the fact that in their own Report they admitted increased mastitis, anaemic conditions and raised stress indicators in BST-treated cows.

BST use has broad implications for: dairy farmers' livelihoods, the reform of the Common Agricultural Policy and possible ill-effects on vulnerable groups of consumers from the higher levels of IGF-I (Insulin Growth Factor) in BST-milk.

All the above are important considerations in their own right, but fall outside the scope of this Report, which is written solely with animal health and welfare in view.

### **Sentient Beings**

Since the last Council of Ministers vote on BST (December 1994) there has been another important development. A legally binding Protocol on Improved Protection and Respect for the Welfare of Animals was agreed by the EU Member States at the Amsterdam Summit in 1997 and is now annexed to the European Treaty. This Protocol says:

“THE HIGH CONTRACTING PARTIES;

DESIRING to ensure improved protection and respect for the welfare of animals as sentient beings;

HAVE AGREED UPON the following provision which shall be annexed to the Treaty establishing the European Community,

In formulating and implementing the Community's agriculture, transport, internal market and research policies, the Community and the Member States shall pay full regard to the welfare requirements of animals, while respecting the legislative or administrative provisions and customs of the Member States relating in particular to religious rites, cultural traditions and regional heritage."

It is Compassion in World Farming's view that injecting a cow regularly to increase her milk yield fails to recognise her sentience and certainly fails to pay full regard to her welfare requirements. Moreover, new evidence from the US on adverse reactions to BST strengthens the case that this product has the potential to increase animal disease and reduce the welfare (well-being) of treated cows. CIWF believes that there is now sufficient evidence on these issues for the EU at the very least to maintain the current moratorium, and preferably to transform the moratorium into a permanent ban on the commercial licensing of BST.

### **Why BST?**

When administered to a lactating cow, BST increases milk yield. The product was first promoted as a method of increasing the return from each treated cow, but in view of growing opposition, the companies now tend to claim that it will help farmers meet quota (by increasing milk production if farmers have yet to meet their full quota towards the end of the annual quota period) or produce more milk at seasons when productivity is lower and financial returns higher.

Generally it is alleged that milk yield may increase from 10-20% with BST use.

### **What BST does to the cow**

After calving, cows undergo a period when tissues are broken down by catabolic\* processes to produce energy and nutrients for milk synthesis. This period normally lasts for 12 weeks, and is followed by a phase of tissue build-up through anabolic\* processes. The catabolic phase, or rising phase of lactation, is generally associated with higher rates of morbidity (disease) and mortality as well as infertility.

BST produces its own phase of catabolic stress in the cow, lasting for 8-12 weeks. BST directs or partitions nutrients away from other body tissues towards the udder. The companies now recommend that BST is not given until the cow has conceived again after calving - around 60 days into lactation. Thus administering BST to cows extends the normal period of catabolic stress from 12 to 24 weeks.

Catabolic stress involves mobilisation of fat reserves and to a lesser extent tissue protein. This results in loss of body condition or failure to gain weight compared to control cows - both of which have been noted in several BST trials (Whitaker 1988, Phipps 1988).

Losing weight and condition are signs that the cow is likely to be in a state of negative energy balance - giving out more energy in milk production than she is taking in through feed. Such a cow will probably not be feeling "well" - or certainly not as well as she might be without BST injections.

\* Anabolic: describes a building up process affecting tissue such as muscle.

\* Catabolic: the opposite of anabolic - describes the breaking down or destruction of tissue.

## **Evidence on Mastitis**

Mastitis is an extremely painful inflammation of the udder. There is a growing body of evidence that BST injections result in an increased incidence of mastitis in treated cows.

### **Willeberg**

Preben Willeberg's 1993 paper also contains fundamental criticism of the companies' BST trials, both for the small number of animals in each trial and for their design, which was not "to evaluate the occurrence of clinical mastitis". He points out that if you pool the results of these small studies you find an "increase in clinical mastitis incidence of 15-45% in BST-treated over non-treated control cows" (Willeberg, 1993).

He points out that if all cows in a herd were injected, 20-30% of all clinical mastitis cases after day 60 would be attributed to BST.

He concludes "The fact that BST injections have an indirect, but significant and undesirable side effect on cow health and welfare should be weighted with other risks and benefits in the final decision of whether or not to make use of BST in dairy production" (Willeberg, 1993).

### **Farm Animal Welfare Council**

In July 1994, the UK Farm Animal Welfare Council (an independent body which gives advice to the government) issued a public statement on BST, calling for the continuation of the moratorium. The Council declared "BST can have severe effects on welfare, particularly in relation to the occurrence of mastitis and other diseases ... various reports exist suggesting increased lameness and other production-related diseases, impaired conception, and tender injection sites" (FAWC, 1994). In their 1997 Report on the Welfare of Dairy Cattle, the Farm Animal Welfare Council reiterated their belief that "The use of BST is unacceptable on welfare grounds". (FAWC, 1997).

### **Millstone**

In the October 1994 issue of 'Nature', Millstone, Brunner & White wrote about their mega-analysis of Monsanto BST trial data.

They claim that the company data shows "that the milk from cows treated with BST contains significantly increased levels of somatic cells (or, more prosaically, pus)" (Millstone, 1994). Somatic cell count (SCC) is an indicator of the level of inflammatory response of the udder. Where the count is raised, there is an increased risk of mastitis.

Millstone et al found "that on average, BST treatment produces a 19% increase in milk SCCs relative to controls; this effect is highly statistically significant" (Millstone, 1994).

### **Monsanto : White**

In August 1994, Monsanto published an analysis of its data and admitted an increase in SCCs in treated cows. 30% of treated cows developed mastitis (some more than once) and only 21% of controls. (The authors of the Monsanto paper claimed that neither the increase in SCCs nor the increased incidence of mastitis was statistically significant). The company continued to claim that the increase was due to the higher milk yields and not to the BST injections per se (Monsanto, 1994). **Yet it seems obvious that the higher yields are the intended and actual result of the BST injections.**

The company's specious argument was also used by the Committee for Veterinary Medicinal Products, but has been succinctly shot down by Willeberg, who points out "To the welfare of the cow it is of little relevance, however, to discuss whether the BST treatment is a direct or an indirect cause of the increased incidence of clinical mastitis" (Willeberg, 1993).

### **Kronfeld**

Professor David Kronfeld claimed this whole Monsanto argument was rejected by the FDA because the percentage increase in milk production in 8 herds being treated with BST was much less than the percentage increase in mastitis incidence (Kronfeld, 1994).

Kronfeld also analysed the length of time antibiotic therapy was used in seven of the BST trials where an increased mastitis level occurred. He showed that BST-treated cows needed antibiotic therapy for longer (Kronfeld, 1994). Obviously the greater the amount or duration of antibiotic therapy, the greater the possibility of antibiotic residues in the milk from treated cows.

### **The American Experience**

When the FDA approved the use of Posilac, they established a post-approval monitoring programme (PAMP). The initial PAMP monitored 28 herds (1,128 cows) for health problems. The overall increase in mastitis of BST-treated cows over controls was 32%. The duration of antibiotic treatment for mastitis in these cows was also increased to a statistically significant degree (Kronfeld 1997).

## **Conclusion**

Compassion in World Farming believes it is false logic to deny BST's role in the increased mastitis incidence. The truth of the matter is that if these particular cows were not receiving BST injections, the number of cases of mastitis in the group would be substantially reduced.

**We cannot emphasise too strongly that mastitis is a highly painful condition. As BST use increases the incidence of mastitis in a herd, it therefore causes unnecessary suffering in those cows who would not have developed the condition if they had not been injected with BST.**

**It is our opinion therefore that in the UK, BST use would contravene Section 1 of the Agriculture (Miscellaneous Provisions) Act 1968, which makes it an offence to cause unnecessary pain or unnecessary distress to livestock.**

## **Other BST-related health problems**

### **Webster**

Professor John Webster (Head of the Veterinary School, Bristol University) is recognised as a leading expert on cattle welfare. In an article published in December 1994 in the *Holstein Friesian Journal*, he discussed BST. He explained that if the treated cow has low genetic merit or is given high quality nutrition, then she may be able to consume and digest more nutrients than she needs to secrete milk. But, he explains, “In the far more common circumstances where the capacity of the udder to synthesise milk exceeds the capacity of the cow to supply it with nutrients then regular injections of BST will make things worse and increase the risk that cows may suffer from chronic hunger and severe loss of condition.” (Webster, 1994).

### **Broom**

Since the CVMP report (Feb 1993), new papers have been published which raise serious welfare concerns about BST. Professor Donald Broom, the Colleen Macleod Professor of Animal Welfare at Cambridge University, has claimed that the BST studies to date have concentrated on improving productivity, which he finds “a rather short-sighted approach” which betrays a “lack of concern for the animals”. He believes studies should be much longer and continue for at least the maximum farm life (Broom, 1993).

Broom points out that the high-yielding cow already has a greatly reduced life expectancy as a “consequence of increased metabolic rate and feed conversion efficiency leading to more production-related disease, reproductive problems and actual mortality”. He concludes, “Any further factor which increased metabolic pressure on the cow, as bovine somatotropin injections would, would probably reduce life expectancy still more” (Broom, 1993).

Broom is also concerned at the acknowledged increase of Insulin-like Growth Factor I (IGF-I) in BST-treated cows. Blood concentrations of IGF-I may be increased 2- to 5-fold in BST-treated cows, depending on the dosage. (Schams et al, 1989). As Broom points out, IGF-I is “a potent mitogen” (a substance which causes cells to divide) and we do not know what effects such raised levels of it will have on the cow, let alone the consumer of milk products (Broom, 1993). (IGF-I is identical in cows and humans. A 1995 National Institutes of Health Conference found that “IGFs are important mitogens in many types of malignancies” (LeRoith 1995)).

### **Burton**

In a major review article published in 1994, J. Burton et al reported “General conclusions to date are that reproductive performance is compromised during negative energy balance and lower body condition” (Burton, 1994). BST is known to result in an increased and/or prolonged negative energy balance. The paper concludes that BST use “could compromise reproduction” (Burton, 1994).

### **Huber**

In 1997, Huber et al published the results of a study of cows treated with BST over 4 lactations. (Two Monsanto scientists were part of the team). Of the 39 cows given BST over four lactations, only 6 animals completed the whole four. The paper reports that cows were culled from the herd in a normal manner “principally for failure to conceive or for low milk yields” (!). This was a careful study where feed and management were of high quality.

Interestingly, in this study cows on BST showed a 37% higher body weight gain over the 4-year period than control cows. However body condition score was unchanged. If the cows had been fatter, their body condition score would have gone up. They weren't. So how could this weight gain be explained? The authors speculate "the gain might reflect a larger digestive tract or muscular tissues". This is an interesting observation, as one of the concerns over BST is that it could increase the weight of body organs. (In finishing pigs treated with rPorcine Somatotropin, increased growth of muscle and of visceral tissues has been seen. (Kramer, 1993) ).

## **The American Experience**

When Monsanto's BST product Posilac went on sale in the US in February 1994, the company literature which arrived with it on farmers' doorsteps warned of a host of possible adverse side effects from treatment. The advice admitted that treated cows were "at an increased risk for clinical mastitis" (Posilac, 1994).

It went on to list the possible problems: "The use of Posilac may result in an increase in digestive disorders such as indigestion, bloat and diarrhoea ... cows injected with Posilac have increased numbers of enlarged hocks and lesions of the knee ... and second lactation or older cows have more disorders of the foot region".

In addition, the advice admitted that "use has been associated with reductions in haemoglobin and haematocrit values during treatment". This tallies with the CVMP Report (Feb.1993) on Monsanto's product which referred to "the observed anaemia" which "was due to a slowing down, caused by the treatment, of the physiological compensation of the constitution of the blood during lactation" (CVMP).

Having seen that farmers were warned, the US Food & Drug Administration encouraged them to report all adverse reactions associated with the use of BST. They could report to Monsanto, to their veterinary surgeon or to the FDA's Center for Veterinary Medicine.

In the first year of use, 806 adverse reactions were reported. The FDA accepted only 496 of these as being possibly associated with BST use. Each of these clinical manifestations (CMs) relates to more than one animal and the FDA estimated the numbers of cows reported with each CM. The number of cows in this first year with mastitis problems was 2,211, the number with increased somatic cell counts (SCCs) - a precursor to mastitis infection - was 3,332, the number with udder swelling or abnormal milk was 953. Away from obvious milk production problems, the number of cows with foot or leg problems was 1,619 and injection site reactions 763. None of these was unexpected - neither perhaps were the 1,194 cows with digestive disorders (defined as "includes anorexia, weight loss and other digestive tract signs").

When the adverse reactions for the second year of use, Feb. 1995 - Feb. 1996, were analysed, many of the figures for both CMs and number of cows were fairly similar in number to the first year. (As we do not have exact figures for the actual number of cows being injected with BST at any one time, it is impossible to say what percentage of treated cows were showing problems).

## **Startling new evidence**

One figure in the adverse reactions for the second year of use shows a highly significant difference. **The figure for cows with digestive disorders leaps from 1,194 in the year Feb.1994 - Feb. 1995 to 3,642 for the year Feb. 1995 - Feb. 1996 - a 205% increase!**

What could be happening out there on the farm? We do not yet have all the answers. It would be reasonable to conjecture that the second year figures include many cows on their second lactation on BST treatment. Could it be that problems with digestion were significantly increased under the metabolic pressures of a **second** lactation on this strong partitioning agent? Could the possible weight gain of the digestive tract (or other visceral tissues as suggested by Huber) also be starting to manifest during a second lactation?

## **Conclusion**

**Compassion in World Farming believes that the FDA should carry out a thorough investigation into this huge increase in digestive problems. The EU should take note of this previously unremarked problem when considering the health and welfare of cows treated with BST.**

## **Evidence on BST Injection Site Problems**

BST injections can also cause problems for the cow at the injection site. From early trials it was known that tender swellings frequently arose on the site of BST injections, but not on the site of placebo injections in control cows. Therefore the BST itself was the cause of the swellings.

By the time the companies were making their second attempt to get CVMP approval for BST, they had recommended moving the injection site from the flank to the tailhead.

The farmers' advice issued with Posilac says the injection site swellings may be as large as 4 inches in diameter and remain for 6 weeks or more. Not surprisingly perhaps, the advice suggests that "use of Posilac in cows in which injection site swellings repeatedly open and drain should be discontinued" (Posilac, 1994).

There is a danger that the moving of the injection site from flank to tailhead masks the resulting swellings. The tailhead area is often encrusted with dung which could disguise the swellings.

Figures from the FDA on reported adverse reactions show 763 cows with injection site problems in the first year of commercial use (Feb.'94-Feb.'95) and a 55% increase in the second year (Feb.'95-Feb.'96) to 1,183 (CVM, 1995, 1996).

## **Conclusion**

**Once again we can only conclude that the act of injecting BST and thereby causing the swellings would contravene the Agriculture (Miscellaneous Provisions) Act 1968, in that it causes unnecessary suffering. In the context of the EU, CIWF believes it would be unlawful for the EU**

**to allow BST injections under the 1997 Amsterdam Protocol on Improved Protection and Respect for the Welfare of Animals.**

### **The Ethical Issue**

BST is injected on a regular basis. Injecting an animal causes stress, likely momentary pain and quite likely continuous pain or discomfort at the injection site for some time to come. The product itself does not improve cow health or welfare. If it did, the infliction of some pain might be ethically justified. But in fact BST may inflict on the cow a range of health and welfare problems.

CIWF believes it is totally unethical to subject animals to some suffering and a risk of further suffering just so that their productivity can be enhanced by a product which is not therapeutic, nor even prophylactic, but may actually have an adverse effect on the treated animal.

### **SUMMARY CONCLUSION**

**BST can and often does cause significant tender and long-lasting swellings on the injection site. It doubles the length of the period of catabolic stress experienced by lactating cows after calving. It will result in mastitis cases which would not otherwise have occurred. Figures from the US FDA suggest that there is a real possibility that cows receiving BST on a second lactation develop an increased number of digestive problems.**

**Compassion in World Farming believes that in view of the health and welfare problems caused by BST administration, the product should not be licensed for use in the EU.**

**Compassion in World Farming believes that licensing of BST by the European Union would run counter to the terms of the 1997 Amsterdam Protocol on Improved Protection and Respect for the Welfare of Animals, which requires that in formulating and implementing the Community's agriculture policies, the Community and the Member States shall pay full regard to the welfare requirements of animals.**

**Compassion in World Farming believes that the Codex Committee on General Principles should pay due attention to the animal health and welfare concerns outlined in this Report when making recommendations on BST to the Codex Alimentarius Commission.**

**Compassion in World Farming believes that, should the UK Minister vote in favour of BST and allow its commercial use in the UK, s/he would surely be endorsing an infringement of Section 1 of the Agriculture (Miscellaneous Provisions) Act 1968 which makes it an offence to cause unnecessary pain or unnecessary distress to livestock.**

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## **Appendix: Anecdotal Evidence**

Reports circulate that not all adverse reactions reported in the USA are being logged with the FDA. This casts some doubt on the published figures and leads to the supposition that in fact adverse reactions may be underestimated.

We give this brief summary of anecdotal evidence of adverse effects of BST. We do not claim scientific veracity for it:

Speaking on the BBC Radio 4 programme *Farming Today* on 9/6/95, farmer John Kinsman from Wisconsin said that in addition to the increases in cases of mastitis and leg and hoof problems in cows treated with BST, “the cows become very emaciated ... and many go down ... There was one more problem .. the incidence of multiple births - many, many twins and triplets ... and many of these calves died.” He went on to talk of cows bursting blood vessels and “as many as 50 cows in some of the herds had to be sold ... when they reached the market some were unable to get off the truck, they had to be dragged off”.

The respected UK journal *Farmers Weekly* reported on 23/8/96 that sales of BST in the USA were falling already, with less than 10% of dairy cows being injected with the product in the USA. The article, by Richard Wright, goes on “Farmers have also cited management problems such as heat stress and calving problems”.

### **The Vermont Reports**

Rural Vermont (a rural advocacy group) published a Report in 1995 “Down on the Farm: The Real BGH Story” by Mark Kastel. This Report tells of a dairy farmer who reckoned he lost \$100,000 in lost milk production and in replacing cows that became unproductive or had severe health problems after just a few months on BST.

The Report refers to a hotline set up by the Wisconsin Farmers Union and the National Farmers Union in Denver in late summer 1994. The hotline was set up to allow farmers to record their experiences in using BST. By late summer, Texan farmers were phoning in complaining of problems with BST-treated cows during the then heatwave. The hotline brought to light another farmer who said the majority of his treated cows had “some health problems - mastitis, lumps/open sores at injection sites, stress, etc.”.

The Report refers to another farmer who claimed that not only did he have to cull nearly all the cows that had increased their milk yield after starting on BST, but he had had 3 severely deformed calves born within 6 weeks of each other. Another farmer reported 90% twin births to BST-treated cows.

Another 1995 Report from Rural Vermont is entitled “Recombinant Bovine Growth Hormone: Alarming Tests, Unfounded Approval” by state representative and dairy farmer Andrew Christiansen. This refers to BST experimental work being carried out at the University of Vermont over a 4-year period to 1990. According to this Report, a university employee gave Rural Vermont and the local legislature photos and information showing that cows involved in the BST trial at the University of Vermont were giving birth to severely deformed calves and experiencing severe health problems. (The FDA subsequently challenged the identity of two of these cows).

The Report says that the Vermont legislature hired a veterinarian to analyse the University health records and Rural Vermont sent these results to BST expert Dr David Kronfeld for statistical analysis. He found statistically significant higher rates of retained placenta and ketosis, dead and deformed calves and of culled cows from animals on BST.

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