



December 1, 2008

Governor Kathleen Sebelius
Office of the Governor
Capitol, 300 SW 10th Ave., Ste. 212S
Topeka, KS 66612-1590

Dear Governor Sebelius,

Consumers Union, publisher of Consumer Reports, is writing to oppose proposed rule K.A.R. 4-7-723 that restricts labels on dairy products from cows not treated with recombinant bovine growth hormone (known as rbGH). This proposed rule would ban labels such as "rbGH-free," "rbST free," or "no artificial growth hormones," on dairy products and would require a disclaimer in certain font size when a label states "from cows not treated with rbGH." We feel that the proposed rule puts unnecessary obstacles in the way of consumers getting the information they want, restricts free speech rights of dairies and processors, interferes with the smooth functioning of free markets and could lead to increased costs for the state.

RbGH (recombinant bovine growth hormone, also referred to as recombinant bovine somatotropin, or rbST) is an animal drug manufactured by Monsanto (and now made by Elanco) that some farmers inject into dairy cows to increase milk production.

We object to a number of sections in this proposed rule, which would make it much more difficult for farmers to inform consumers that they are *not* using this hormone on their cows.

We oppose Section d, which would classify all claims about the composition of milk with respect to hormones as false and misleading. We agree that certain claims, e.g. "No Hormones," "Hormone Free," or "BST Free" are misleading as all milk contains hormones, including bovine growth hormone. But not all milk contains synthetic, artificial growth hormones. Thus, it is not misleading to say milk from cows not treated with *recombinant* bovine growth hormone (rbGH) is "rbGH-free." As the Food and Drug Administration (FDA) has pointed out, rbGH is not identical to the naturally produced bGH but differs by one amino acid: "Monsanto Agricultural Company's product has a single amino acid substitution of Met for Ala on the NH₂-terminus end."¹ Furthermore, research in Europe has clearly shown that antibodies can distinguish

Consumers Union

Headquarters
101 Truman Avenue
Yonkers, New York 10703-1057
914-378-2000
fax: 914-378-2900

¹ Juskevich, JC and CG Guyer. 1990. Bovine growth hormone: Human food safety evaluation. *Science*, 249: 875-884.

between Monsanto's rbGH product and naturally produced bGH.² Thus, since rbGH is a synthetic molecule that does not occur in nature, if a cow has *not* been treated with rbGH then its milk will *not* contain rbGH. By definition, such milk is "rbGH-free." The label claim "this milk is from cows not treated with rbGH" is permitted in this rule because it is not false and misleading. It logically follows that the claims "rbGH-free" or "rbST-free" are not false and misleading on dairy products from untreated cows and so should be allowed as well.

Consumers believe such labels are appropriate. In October, 2008, the Consumer Reports National Research Center polled over 1,000 people nationwide on various food labeling issues; some 93 percent agreed that "dairies that produce milk and milk products without artificial growth hormones should be allowed to label their products as being free of these hormones."³ In addition, some 57 percent of Americans were willing to pay more for milk and milk products produced without artificial growth hormones. These results clearly show that the vast majority of consumers want to know whether the milk they buy contains artificial growth hormones such as rbGH. Consumers want to know this information because of unanswered questions about the safety of milk from rbGH-treated cows, and adverse effects on the safety of the animal including increases in mastitis, reproductive effects, and foot problems.

Finally, last year, Monsanto asked FDA to declare these labels to be misleading, but FDA refused. In a letter that the FDA sent to Monsanto in late June, 2007, FDA made it clear that the only labels they considered to be misleading were ones that stated that the milk contained no hormones. FDA also clearly stated that they would not revise their labeling guidance as Monsanto had requested: "FDA issued warning letters when milk labels contained false statements that milk from cows not treated with rBST contained no hormones. . . . we will issue warning letters when milk labeling regarding rBST is false or misleading. With respect to your request that we revise the 1994 guidance . . . we do not intend, at present, to invest the substantial amount of time necessary to revise the guidance"⁴ Clearly, prohibiting farmers, dairies and processors from making the truthful label claim "rbGH-free" interferes with their free speech rights under the first Amendment.

We also oppose Section c(2), which requires an additional, contextual statement ("The FDA has determined that no significant difference has been shown between milk derived from rbST-supplemented and non-rbST-supplemented cows") in the same font, style, case, size, color and location as the main label claim (e.g. "this milk is from cows not supplemented with rbST"). First, the contextual statement is not necessary as the US Food and Drug Administration (FDA) has explicitly said that it is not required. In a July 27, 1994 letter to the New York Department of Agriculture and Markets, FDA stated "the

² Erhard, MH, Kellner, J, Schmidhuber, S, Schams, D and U Lösch. 1994. Identification of antigenic differences of recombinant and pituitary bovine growth hormone using monoclonal antibodies. *Journal of Immunoassay*, 15: 1-19. and Castigliego, L, Iannone, G, Grifoni, G, Rosati, R, Gianfaldoni, D and A Guidi. 2007. Natural and recombinant bovine somatotropin: immunodetection with a sandwich ELISA. *Journal of Dairy Research*, 74: 79-85.

³ See pp. 13 in: <http://www.greenerchoices.org/pdf/foodpoll2008.pdf>

⁴ Letter, dated June 27, 2007, from Sheldon Bradshaw, Chief Counsel for FDA, to Brian Lowry (Monsanto)

bottom line is that a contextual statement is not required, that in many instances a statement like “from cows not treated with rbST” would not be misleading, and in no instance is the specific statement “No significant difference . . .” required by FDA.”⁵

Second, we know of no other government agency, state or federal that requires such a contextual statement to be in the same font, style, case, size and color as the main label claim. This constitutes undue interference with the exercise of free markets and is not necessary to inform the consumer. To have such a detailed requirement will interfere with interstate commerce since adjoining states may have different requirements. Missouri has no requirement for the contextual statement (also called a “disclaimer”) and also does not outlaw labels such as “rbGH-free” or “contains no artificial growth hormones.” Thus, a label that is legal in Missouri could be illegal in Kansas and could mean that that product would not be marketed in Kansas. Also, companies that sell products nationally, such as Ben & Jerry’s ice cream or Tillamook cheese, would either have to not market products in Kansas or change labels on all their products to comply with the regulation.⁶ A likely scenario is that, faced with a myriad of state labeling regulations, national companies would stop any kind of rBGH-free labeling at all. This would deprive them of a very valuable marketing tool, since more and more consumers are looking for these labels. The net effect is that consumers would know less about what’s in their food at the same time they are expressing a desire to know more.

Third, a requirement that the font size be the same for the claim and the disclaimer is not necessary, and will take up an excessive amount of space. Nutrition labels, which are very important to consumers and widely read, are generally in a smaller font size than label claims and often are located on the back or sides of the package.

Fourth, we urge you not to require the contextual statement because it is misleading. There are, in fact, significant differences between milk from cows treated with rbGH and from cows not treated. FDA’s own publications have demonstrated that milk from cows treated with rbGH show statistically significant increases of the hormone insulin-like growth factor 1⁷ (IGF-1) (which has been linked to breast⁸, colorectal⁹, and

⁵ Letter dated July 27, 1994 from Jerold Mande, Executive Assistant to the Commissioner of FDA, to Harold Rudnick, Director, Division of Milk Control, New York Department of Agriculture and Markets

⁶ International Dairy Foods Association Files Suit to Stop Ohio’s Labeling Law. At: http://www.rffretailer.com/CDA/Articles/Industry_News/BNP_GUID_9-5-2006_A_1000000000000370285

⁷ Freedom of Information Summary POSILAC (sterile sometribove zinc suspension), November 5, 1993 At: <http://www.fda.gov/cvm/4390.htm#bst6j>

⁸ Hankinson, S.E., Willett, W.C., Colditz, G.A., Hunter, D.J., Michaud, D.S., Deroo, B., Rosner, B. Speizer, F.E. and M. Pollack. 1998. Circulating concentrations of insulin-like growth factor-1 and risk of breast cancer. *Lancet*, 351(9113): 1393-1396.

⁹ Giovannucci, E., Pollack, M.N., Platz, E.A., Willett, W.C., Stampfer, M.J., Majeed, N., Colditz, G.A., Speizer, F.E. and S.E. Hankinson. 2000. A prospective study of plasma insulin-like growth factor-1 and binding protein-3 and risk of colorectal neoplasia in women. *Cancer Epidemiology, Biomarkers & Prevention*, 9: 345-349.

prostate¹⁰ cancer, although whether the increased IGF-1 levels due to rbGH in milk would affect health has not been established). The milk of treated cows also shows increases in average somatic cell counts (indicative of mastitis infections in cows and an indication of the quality of the milk).¹¹ The additional antibiotic required to treat these infections can't help but contribute to the overall problem of antibiotic resistance in humans, a major national health problem.

In sum, we urge you to rescind this proposed rule and issue a final rule that makes the requested changes—drop the requirement for the disclaimer and permit use of the claims “rbGH-free” or “rbST-free”. If the disclaimer must remain, we urge you to drop the detailed requirements for the font, size, color and location.

Finally, we note that Ohio passed a substantially similar, but less stringent version of K.A.R. 4-7-723 (the Ohio regulation doesn't require the contextual statement to be the exact same size, font, etc. as the label claim) earlier this year. On June 30, 2008, the International Dairy Foods Association, sued the state of Ohio, maintaining that “the Ohio rule interferes with the First Amendment right of its members to communicate truthful information to Ohioans and with interstate commerce.”¹² Since Kansas' proposed rule is so similar to Ohio's, Kansas could also be liable to a lawsuit from the dairy industry.

If the proposed rule remains unchanged, it will negatively impact Kansan consumers' ability to make an informed decision about the dairy products they buy. It interferes with farmers and dairies' rights to free speech. In this era of increased concern about what's in our food and how it is produced, Kansas should be making more information available not less.

Yours,



Michael Hansen, Ph.D.

Senior Scientist

¹⁰ Chan, J.M., Stampfer, M.J., Giovannucci, E., Gann, P.H., Ma, J., Wilkinson, P., Hennekens, C.H. and M. Pollack. 1998a. Plasma insulin-like growth factor-I and prostate cancer risk: a prospective study. *Science*, 279: 563-566.

¹¹ Millstone, E, Brunner, E and I White. 1994. Plagiarism or protecting public health? *Nature*, 371: 647-648

¹² International Dairy Foods Association Files Suit to Stop Ohio's Labeling Law. At: http://www.rffretailer.com/CDA/Articles/Industry_News/BNP_GUID_9-5-2006_A_1000000000000370285