Department of Agriculture Notice of Hearing on Proposed Administrative Regulations

A public hearing will be conducted at 10:00 a.m. Tuesday, December 2, 2008, in the 4th floor training room of the Kansas Department of Agriculture, 109 S.W. 9th St., Topeka, Kansas to consider the adoption of proposed regulation for the dairy program.

This 60-day notice of the public hearing shall constitute a public comment period for the purpose of receiving written public comments on the proposed rule and regulation. All interested parties may submit written comments prior to the hearing to the Secretary of Agriculture, 109 S.W. 9th, 4th Floor, Topeka, 66612, or by e-mail at leslie.garner@kda.ks.gov. All interested parties will be given a reasonable opportunity to present their views orally on the adoption of the proposed regulation during the hearing. In order to give all parties an opportunity to present their views, it may be necessary to request that each participant limit any oral presentation to five minutes. This regulation is proposed for adoption on a permanent basis. A summary of the proposed regulation and its economic impact follows:

K.A.R. 4-7-723 - The proposed regulation is intended to provide clarification on what is false or misleading labeling as it pertains to milk and dairy products. Specifically, this proposed regulation provides guidance to the dairy industry with respect to label claims concerning the use of recombinant bovine somatotropin commonly known as "rBST".

Economic summary:

The additional record / document review in the proposed regulation would have a very minimal impact on the time required to do an inspection by the department. It is estimated that thirty minutes of inspection time would be required at each dairy manufacturing plant during their quarterly inspections, it is estimated to be an additional twenty hours per year at an average cost of \$23.32 per hour or approximately \$466.40.

The proposed regulation will significantly impact dairy manufacturing plants which choose to make production claims concerning rBST on their labels. Existing milk and dairy product labels that do not comply will need to be brought into compliance within the time frames specified in the regulation. The cost of new labels or new containers will vary.

- There are no direct or indirect costs for those dairy manufacturing plants whose labels are in compliance or who do not make any claims relative to rBST use.
- The cost to dairy manufacturing plants of maintaining required verification documents is minimal.
- Plants which use adhesive labels that must be changed can expect an estimated one-time cost of approximately \$3800 per product label for a typical three-color printing plate and artwork change. This can be a significant cost for a major manufacturing plant with as many as 80 to 120 different labels. Any existing label inventory remaining after the specified date in the regulation must be disposed of.
- Plants utilizing re-useable glass bottles will need to replace their entire inventory within timeframes established in the proposed regulation since label information is permanently printed on each glass container. Cost to replace glass bottles is approximately \$2.50 each.
- The regulation applies to any dairy manufacturing plant offering product for sale in Kansas. The regulation applies to both in-state and out of state plants.

Any individual with a disability may request accommodation in order to participate in the public hearing and may request the proposed regulation and impact statement in an accessible format. Requests for accommodation should be made at least five working days in advance of the hearing by contacting Leslie Garner at (785) 296-4623 or fax (785) 368-6668. Handicapped parking is located at the southwest corner of 9th and Kansas Ave., and the north entrance to the building is accessible to individuals with disabilities.

Copies of the regulation and its economic impact statement may be obtained by contacting the Department of Agriculture, Leslie Garner, 109 SW 9th St., 4th Floor, Topeka, KS 66612 or (785) 296-4623 or by accessing the department's Web site at http://www.ksda.gov. Comments may also be made through the department's website, under the proposed regulation.

Adrian J. Polansky Secretary of Agriculture

KANSAS DEPARTMENT OF AGRICULTURE ECONOMIC IMPACT STATEMENT DAIRY REGULATION

Proposed regulation 4-7-723

I. Summary of the proposed regulation and what is to be accomplished by its adoption:

K.A.R. 4-7-723 - The proposed regulation is intended to provide clarification on what is false or misleading labeling as it pertains to milk and dairy products. Specifically, this proposed regulation provides guidance to the dairy industry with respect to label claims concerning the use of recombinant bovine somatotropin commonly known as "rBST".

II. Financial impact of the adoption of the proposed amendments for the Kansas Department of Agriculture.

The proposed regulation would require that the dairy inspection program of the Kansas Department of Agriculture verify rBST use labeling claims by examining records and other documents maintained by the dairy manufacturing plants. Many of the required records are already reviewed during routine inspections currently being done by inspectors. The additional record / document review in the proposed regulation would have a very minimal impact on the time required to do an inspection. It is estimated that thirty minutes of inspection time would be required at each dairy manufacturing plant during their quarterly inspections. Financial impact to the department is estimated to be an additional twenty hours per year at an average cost of \$23.32 per hour or approximately \$466.40.

III. Financial impact of the adoption of the proposed amendments for other governmental agencies or units, regulated entities, private citizens including consumers of the products or services that are subject to the regulations or their enforcement.

The proposed regulation will significantly impact dairy manufacturing plants which choose to make production claims concerning rBST on their labels. Existing milk and dairy product labels that do not comply will need to be brought into compliance within the time frames specified in the regulation. The cost of new labels or new containers will vary.

- There are no direct or indirect costs for those dairy manufacturing plants whose labels are in compliance or who do not make any claims relative to rBST use.
- The cost to dairy manufacturing plants of maintaining required verification documents is minimal.
- Plants which use adhesive labels that must be changed can expect an estimated one-time
 cost of approximately \$3800 per product label for a typical three-color printing plate and
 artwork change. This can be a significant cost for a major manufacturing plant with as
 many as 80 to 120 different labels. Any existing label inventory remaining after the
 specified date in the regulation must be disposed of.

- Plants utilizing re-useable glass bottles will need to replace their entire inventory within timeframes established in the proposed regulation since label information is permanently printed on each glass container. Cost to replace glass bottles is approximately \$2.50 each.
- The regulation applies to any dairy manufacturing plant offering product for sale in Kansas. The regulation applies to both in-state and out of state plants.
- Two in-state plants utilizing glass bottles will need to make changes in their bottles. One, known out-of-state glass bottling plant will need to make changes in their bottles. The regulation will allow existing inventories of glass bottles to be used. Any new glass bottles ordered after the effective date of the regulation will need to comply.

IV. Less costly or less intrusive methods considered by the Kansas Department of Agriculture.

Realizing the potential for the significant financial impact this regulation could have on dairy manufacturing plants selling milk and dairy products in Kansas, the Department held a stakeholders' meeting on April 22, 2008 to hear comments and concerns. As a result of the stake holders' meeting and because of the possible financial impact of this regulation, allowances as described above were written into this proposed regulation. Compliance dates given in the proposed regulation were set with the purpose of allowing existing inventories of labels and containers to be utilized.

V. Anticipated impact on cities, counties or school districts.

This change will not increase or decrease revenues of cities, counties or school districts. It does not impose functions or responsibilities on cities, counties or school districts.

ENVIRONMENTAL BENEFITS STATEMENT

An environmental benefits statement is not required since the proposed regulation, while proposed for adoption by the secretary of agriculture, deals with false or misleading information displayed on milk and dairy product labels and does not have as its primary purpose the protection of the environment.

K.A.R. 4-7-723. Accurate labeling of milk, milk products, and dairy products. (a) As used in this regulation, the following terms shall have the meanings specified in this subsection:

- (1) The term "rBST" means recombinant bovine somatotropin.
- (2) The term "rBGH" means recombinant bovine growth hormone.
- (3) The term "BST" means bovine somatotropin.
- (b) "Milk," "milk products," and "dairy products" shall be deemed "misbranded," as defined in K.S.A. 65-771 and amendments thereto, if the labels on the containers in which the products are sold or offered for sale contain any false or misleading statements as specified in this regulation.
- (c) Each milk, milk product, or dairy product label that contains a production claim that "this milk is from cows not supplemented with rBST," or a substantially equivalent statement, shall be deemed misleading unless both of the following conditions are met:
- (1) The owner or operator of each "dairy manufacturing plant," as defined in K.S.A. 65-771 and amendments thereto, verifies that the claim is accurate and has in its possession a milk producer's affidavit that the milk is from cows not supplemented with rBST and any other written records deemed necessary by the dairy manufacturing plant owner or operator to support the claim, and these documents are made readily available to the department for inspection.
- (2) The label contains, in the same label panel immediately after the production claim and in exactly the same font, style, case, size, and color as used in the production claim, the following qualifying statement: "the FDA has determined that no significant difference has been shown between milk derived from rBST-supplemented and non-rBST-supplemented cows." The color of the qualifying statement shall be of sufficient contrast to the background color to be easily read.
- (d) Each milk, milk product, or dairy product label that has a statement regarding the composition of milk with respect to hormones, including "No Hormone," "Hormone Free," "rBST Free," "rBGH Free," and "BST Free," shall be deemed false and misleading. The statement shall not be permitted.
- (e) If a milk, milk product, or dairy product label contains a statement indicating the absence of a compound that is not permitted by the United States food and drug administration to be present in the product, including antibiotics and pesticides, the label shall be deemed false and misleading. The statement shall not be permitted on milk, milk product, and dairy product labels.
- (f) The provisions of this regulation shall not be construed to prohibit any seals or marks authorized by a federal law or Kansas statute.
- (g)(1) On and after January 1, 2010, this regulation shall apply to the labels on all nonreusable containers of milk, milk products, and dairy products.
- (2) Each reusable container for milk, a milk product, or a dairy product purchased by the owner or operator of a dairy manufacturing plant before January 1, 2011 that includes on the label the production claim that "this milk is from cows not supplemented with rBST," or a substantially equivalent statement, shall include the qualifying statement specified in paragraph (c)(2) affixed to the container. The qualifying statement shall not be required to be on the same label, immediately after the production claim on the label, or in exactly the same font, style, case, size, and color as used in the production claim.
- (3) On and after January 1, 2011, this regulation shall apply to the labels on all reusable containers of milk, milk products, and dairy products purchased by the owner or operator of a dairy processing plant on or after that date. (Authorized by K.S.A. 2007 Supp. 65-772; implementing K.S.A. 65-665 and K.S.A. 65-789; effective P-