**Massachusetts Department of Public Health**

Bureau of Environmental Health

305 South Street

Jamaica Plain, MA 02130-3597

(617) 983-6712 (617) 983-6770 - Fax

**Food Protection Program**

**Policies, Procedures and Guidelines**

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| **Issue:** Guidelines for rBST Labeling of Fluid Milk and Milk Products DU-02 |

In 1994 the U.S. Food and Drug Administration (FDA) issued guidelines for the labeling of milk and milk products derived from cows that had not received recombinant bovine somatotropin (rBST). Additionally, FDA stated that rBST is safe, both for the cows to whom it is administered and for humans who consume milk and milk products derived from said cows. These Guidelines outline the operational and labeling requirements established by the Massachusetts Food Protection Program (FPP) for Massachusetts processors of fluid milk and milk products that choose to make rBST and/or bovine hormone claims. Any MA processor seeking to make such labeling claims must petition the FPP, in writing, for approval. Approvals are valid for twelve (12) months and must be renewed annually. Failure by a MA processor to comply with this guideline may result in administrative action being taken against the processor’s permit.

Out-of-state processors of milk and milk products that bear a label with a claim related to the presence or absence of rBST or bovine hormones may only sell their product(s) in Massachusetts if the state in which they are located has an established program capable of verifying the use or non-use of rBST or other bovine hormones in producer cows (“Verification Program”). Milk and milk products, bearing a label with a claim related to the presence or absence of rBST or bovine hormones, sold in MA but processed in a state without a Verification Program will be deemed “misbranded” and may be subject to an administrative action, including but not limited to, seizure and disposal.

**Milk Source**

Any processor of fluid milk or milk products seeking to make labeling claims relative to the absence of rBST or other added bovine hormones shall only use raw milk produced in a State whose responsible agency, e.g., Department of Agriculture, has an established Verification Program.

**Verification of rBST Claims**

A processor shall have on-site and readily available, signed affidavits from all raw milk sources used in the production of products labeled with an rBST or hormone claim. Said affidavit(s) shall state:

1. That no animals on the farm are currently being treated with rBST or added bovine hormones;
2. That no animals on the farm have received rBST or added hormonal treatments within the past 90 days;
3. That the producer will provide advanced written notice to the processor if the producer intends to use rBST or added hormones. Written notice will be up to 90 days prior to the intended use of rBST or added hormones.
4. That the producer will not knowingly allow animals to be brought into the herd which have received rBST or added hormone treatment within the past 90 days; and
5. That the producer is responsible for any liability claim that may arise against the processor of said milk should the producer be found to be using or has used rBST or added hormones without providing prior written notice to the processor of producer’s intent to use rBST or added hormones.

All affidavits shall be signed, dated and renewed at least annually.

**Receipt of Raw Milk for Product with rBST Labeling Claims**

Prior to allowing any raw milk into the facility intended for the production of fluid milk or milk products with rBST or hormone labeling claims, the processor shall:

1. Ensure that all delivery slips and farm tickets accompanying each raw milk tanker state that all producer milk contained in the tanker is appropriate for its intended purpose, i.e., conforms to the rBST or hormone labeling claims;
2. Ensure that it has in its possession at the time of delivery, a current affidavit for all raw milk sources contained in the tanker;
3. Ensure that tankers containing raw milk from a non-verified source is rejected for product intended for rBST or hormone labeling claims; and
4. Rejected raw milk may be used for product not intended for rBST or hormone labeling so long as required temperature and bacteriological standards are met.

**General Processing Requirements**

All raw milk intended for products with rBST or hormone labeling claims must be transported, received and processed through clean, i.e., Clean in Place (CIP) lines, pumps, pasteurizers, tanks/silos and fillers.

* Raw milk intended for product with rBST or hormone labeling claims is received through clean and sanitized raw milk receiving lines and pumps;
* Raw milk is processed on a clean, CIP’d HTST pasteurization system and pumped to a clean CIP’d pasteurized storage tank;
* Pasteurized milk is processed on a clean CIP’d filler; and
* Once processing of rBST or hormone labeled product is complete, processing and packaging of non-rBST or hormone labeled product may begin.

**Specific Processing Requirements**

* 1. Upon arrival and prior to off-loading the contents of any tanker transporting raw milk intended for product with rBST or hormone labeling claims, the processor shall ensure that the raw milk is:
  + From a producer with the proper verification; and
  + Tested for compliance with required temperature, antibiotic, and bacteriological standards;
  1. Immediately prior to off-loading, all lines, pumps, pasteurizers, tanks/silos and fillers shall be subject to a thorough CIP;
  2. Upon completion of processing, the finished product shall be isolated in a clean pasteurized storage tank(s); and

**Documentation**

The processor shall maintain and provide upon regulatory review, the following:

1. Master list of producers providing raw milk for product intended for rBST or hormone labeling;
2. Signed and dated producer affidavits stating that the raw milk meets the rBST or hormone labeling requirements;
3. Copies of delivery tickets and farm slips that accompany tanker loads;
4. CIP charts for raw receiving lines and pumps, HTST systems, pasteurized tanks, and fillers; and
5. Filler CIP charts and logs.

**Labeling**

* 1. The statements “BST free”, “rBST free” “hormone free”, or similar such wording are not allowed on product processed and/or sold in Massachusetts.
  2. The statement “from cows not treated with rBST” or “from cows not treated with additional hormones” may be used so long as it is accompanied by the statement: “No significant difference has been shown between milk derived from rBST treated and non-rBST treated cows.” The accompanying statement must appear on the same display panel as the rBST statement and may be no less than ½ the type size.
  3. If an approved processor ceases to produce products with rBST or hormone labeling, the processor shall destroy all remaining rBST or hormone labels in stock under the supervision of a FPP Food and Drug Inspector.