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December 29, 2010

Commissioner Margaret Hamburg, M.D.  
US Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993

Dear Commissioner Hamburg:

As the chief executive officers in our respective states for agriculture and, in some cases also for food safety, we wish to express our grave concerns regarding the program announced by the FDA Center for Veterinary Medicine (CVM) for the sampling of milk tanks of milk produced by dairies across the country.

In particular, we are concerned that this proposed testing program is designed without adequate consideration for the mechanics and economics of the dairy industry, which has unique characteristics and which forms the underpinning of the local economies in our rural communities. The disruption of the flow of milk to markets, in particular, can have serious repercussions for farmers, processors, and consumers. There may also be serious damage to our dairy exports, which comprise approximately 12% of US dairy sales, and are a key element in stabilizing the dairy economy in the United States.

The potential disruption of the flow of milk to markets may present a disposal issue of milk on farms that are ill equipped to manage this disposal without negative environmental impacts. For example, one such disposal method would be to the manure storage pit. However, this methodology is not allowed in every New England state. Furthermore, there is a winter manure spreading ban on manure in several New England states and storage capacity is limited in manure pits. Where it is allowed, if milk is to be disposed of on the farm, the capacity of the manure pits may be an issue for proper disposal of milk during the winter months. In addition, most dairy farms do not have the equipment to pump the milk in question from the bulk tank and the equipment to transport it to the designated disposal site. They would incur even further costs to have to pay a firm with the equipment to provide this service. Similarly, ground water protection regulations in certain New England states would also limit on farm disposal opportunities and potentially lead to significant costs to the farm.

We are also concerned about the process under which this program was developed. While we cannot speak for dairy producers or processors, we can report that CVM has rolled out this program without duly consulting the state regulatory agencies. For instance, on 12/13/2010 an inquiry was submitted by NYS

Division of Milk Control to CVM, only to receive the response that FDA was waiting for final clearance of the assignment, and no details could be provided. Instead, we learned about the proposed project through our industry contacts.

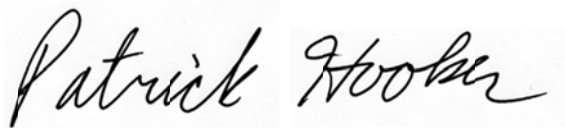
We are concerned that the proposed program does not consider the current systems in place to control milk safety, a system which has been developed to provide consumers with one of the safest and best inspected foods in the world. In short, the testing procedure outlined by CVM conflicts with the protocol currently required in the 2009 Pasteurized Milk Ordinance (PMO) which requires that a recheck or milk "clearing sample" be obtained and analyzed to determine if there is a continued presence of inhibitory substances. Upon a negative result the producer is reinstated and allowed to resume shipment of milk into the marketplace.

Both of these programs are administered by FDA but the proposed program by CVM does not take into consideration the regulatory uncertainty for dairy farms and state regulators. It has been proposed that the bulk tank of milk be disposed of on the day of sample by CVM. If that sample is found to be positive, the PMO requires that no further milk is shipped until a confirming sample is negative. The testing protocol from CVM may not provide that answer until further milk is produced and potentially shipped from the farm. It is still not clear what the status of the milk and potential dairy products produced with that milk between the initial sample date and the final result date if the sample is positive. This is too much uncertainty between CVM proposed program and the PMO regulations for an industry the size and scope of the Northeast dairy industry.

We are also concerned about the appropriateness of CVM's proposed program. CVM has stated that 7.7 % of the cattle slaughtered in the US are adult dairy cattle, and these have a 67% tissue residue violation rate. Yet when we review the FSIS Residue Violation Tissue lists from which these figures are drawn, they have a high number of violative bob veal calves. In fact, the list we reviewed contains eight times as many bob veal calves as cows labeled as 'dairy cows.' Of course, bob veal calves are neither lactating animals nor adult dairy cattle. We are also concerned whether the list's 'dairy cows' meet a reasonable standard to constitute a cow that contributes milk to milk supply. Thus it is hard to understand why a large number of repeat residue offenders in the form of bob veal calves from dairy farms and cows loosely labeled as 'dairy cows' should be construed to justify a correlation to milk residues. We respectfully suggest that CVM should revise its violator list to be comprised of animals whose violation would be covered by the testing of milk.

We are eager to cooperate with the CVM to help address the problem of medicinal residues in dairy culls. Like you, we wish to ensure that the food supply is safe for all consumers. We believe that an open dialogue between state agencies and the FDA can create a reasonable program that accommodates the specific economic needs of the dairy supply system and which also meets your agency's public health goals.

Sincerely,



Patrick Hooker  
Commissioner, New York State Department of  
Agriculture & Markets



Philip Prelli  
Commissioner, Connecticut Department of Agriculture



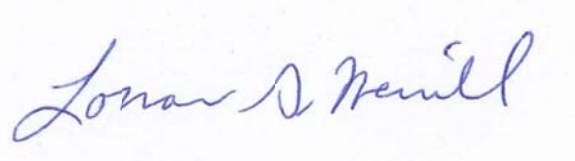
Ed Kee  
Secretary, Delaware Department of Agriculture



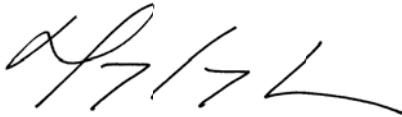
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