

THE DAIRY PRACTITIONER AND THE AMERICAN VETERINARY MEDICAL ASSOCIATION/NATIONAL MILK PRODUCERS FEDERATION QUALITY ASSURANCE PROGRAM FOR MILK AND DAIRY BEEF

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The Milk and Dairy Beef Quality Assurance Protocol (MDBQAP)¹ began as a collaborative effort on the part of the American Veterinary Medical Association (AVMA) and the National Milk Producers Federation (NMPF) to overcome unfavorable publicity, which was scientifically unsubstantiated, regarding pharmaceutical residues in milk which had been sold in certain areas of the United States. In addition there existed concern over the incidence of pharmaceutical residues occurring in cull dairy cows as reported by the U.S. Department of Agriculture, Food Safety Inspection Service. Since both veterinarians and producers were implicated in these issues, it was logical that the two organizations cooperate and respond in a proactive manner.

Representation on the MDBQAP committee which drafted the document consisted of four individuals from the NMPF who were directly involved with milk marketing farmer owned cooperatives, a dairy farmer and director, a director of a quality control laboratory, a veterinarian who is a dairy farmer and a director, and a practicing veterinarian who also serves as an on-farm quality control consultant for a milk marketing cooperative. The committee's AVMA component had representation from the AVMA's Executive Board and the association's Council on Biological and Therapeutic Agents and a member representing an AVMA allied organization, the American Association of Bovine Practitioners (AABP). This broad base of expertise afforded a management and production medicine perspective unique to dairying. Excellent staff support was provided by both organizations.

The outcome of this effort was a comprehensive milk and dairy beef chemical residue avoidance program designed to provide and educate dairy farmers with fundamental knowledge regarding responsible use of pharmaceuticals in animals on their farms. The approach to achieve this goal was to employ a hazard analysis critical control point (HACCP) concept. The HACCP concept programmatically identifies and focuses on those areas which are of primary importance in achieving the identified goal(s) which in this instance is residue avoidance. These HACCP criteria, when implemented and followed, should prevent violative drug residues from occurring in milk or dairy beef. To assist the producer to implement this program, there is provided supportive material in narrative form which is applicable to each of the 10 control points. The producer manual also provides the opportunity for the dairy farmer to answer a series of questions which provide an awareness of and sensitivity to specific control points which interface with his/her dairy operation.

A companion, more adequately documented, parallel version of the manual is available for use by veterinarians. This provides the veterinarian with reference material regarding all aspects of residue prevention, milk production regulations pertaining to dairy animal drug therapy and other related matters for which veterinarians and dairymen are responsible. Each of the 10 HACCP areas identified in the producer manual interfaces with the topics in the expanded veterinarian's manual.

Although the MDBQAP was originally intended to be implemented on a voluntary basis, the dairy industry proposed that it be included in the

Pasteurized Milk Ordinance (PMO). To comprehend how the MDBQAP became directly involved in regulatory activity, one needs to understand that the interstate movement of fluid Grade A milk in the U.S. is regulated by uniform standards and requirements set forth in the PMO. The PMO is authorized by the U. S. Health and Human Services Department, Food and Drug Administration's (FDA), Center for Food Safety and Applied Nutrition (CFSAN), Milk Safety Branch (MSB). The FDA's Center for Veterinary Medicine provides input regarding animal drug matters. The PMO is promulgated through the cooperative effort of the MSB, state milk regulatory officials, representatives of the dairy industry and others who biennially convene as the National Conference of Interstate Milk Shipments (NCIMS). It is the NCIMS that introduces proposed changes in the PMO. The enactment of such changes is ultimately determined by the MSB. At the 1991 NCIMS, a change in the PMO required that a dairy farmer from whose farm milk containing violative drug residues had been sold, would be fined, assigned a "temporary" permit to ship Grade A milk and be required to enroll in the AVMA-NMPF MDBQAP prior to being reinstated with a permanent permit to ship Grade A milk. This requirement took effect 1 July 1992.

In addition, effective 1 January, 1992, the 1991 NCIMS effected a PMO change which required that all bulk tanker loads of Grade A milk be screened for drug residues (initially for Beta lactam drugs) prior to milk entering the human food chain. All positive residue occurrences result in the identification of the dairy farm on which the violative residue occurred. This drug residue monitoring activity has caused an increased level of sensitivity on the part of both dairymen and veterinarians regarding proper drug use on dairy farms.

The AVMA-NMPF Milk and Dairy Beef Residue Prevention Protocol 10 Hazard Analysis Control Points are:

1. PREVENTIVE HERD HEALTH MANAGEMENT

A properly functioning dairy herd health management program lessens the need for and should cause a reduction in the use of pharmaceuticals by dairy farmers thus reducing the opportunity for violative drug residue occurrences.

2. ESTABLISH A VALID VETERINARIAN/CLIENT/PATIENT RELATIONSHIP (VCPR)

Establishing and maintaining a working relationship with a veterinarian expands the focus of those who treat animals on the dairy farm. Clinical judgments regarding animal health, medical treatment, and drug withholding times, appropriate residue test methodologies and other pertinent matters relating to responsible drug therapy are addressed in a manner which brings all of the key players together as a team. Because many pharmaceuticals which do not have official FDA approval for use in the lactating dairy cow, veterinarian's may find it necessary to use pharmaceuticals in an extra label manner. Since the FDA restricts extra label drug use only to veterinarians who have a valid VCPR, this control point is extremely important to residue avoidance and also it speaks to the issue of the health and welfare of animals in the dairy herd. Giving adequate consideration to the matter of extra label drug use and the role of the VCPR plays in this scenario is an important facet in a violative residue prevention program.

3. USE ONLY FDA APPROVED OVER THE COUNTER (OTC) OR PRESCRIPTION (Rx) DRUGS

This control point provides information to assist dairymen to understand the difference between OTC drugs which can be used according

to the restrictions on the label without a veterinarian's authorization and Rx drugs which require a veterinarian's authorization to be used. It also addresses the extra label drug use issue and the restrictions applicable thereto as well the matter of the compounding of drugs.

4. ALL DRUG LABELS COMPLY WITH GRADE A MILK CONTROL LABELING REQUIREMENTS

By complying with the pharmaceutical labeling requirements required by the regulatory mandates of the PMO, State and Federal agencies, there is provided a level of awareness with respect to proper drug use which helps to assure that harmful residues do not enter the human food chain.

5. ALL DRUGS ARE STORED IN COMPLIANCE WITH THE PMO LABELING REQUIREMENTS.

The PMO provides for specific drug storage requirements and as in control point 4, provides a level of awareness regarding proper use.

6. ALL DRUGS ARE ADMINISTERED PROPERLY AND TREATED COWS ARE PROPERLY IDENTIFIED.

In the event that animals must be treated, maintaining the identity of such animals, provides a mechanism which helps to assure that undesirable residues do not enter the human food chain. The proper administration of pharmaceuticals encompasses the entire spectrum of drug use and impacts on residue avoidance.

7. TREATMENT RECORDS ARE PROPERLY MAINTAINED AND TREATED ANIMALS ARE ADEQUATELY IDENTIFIED.

The tracking of treated animals is an important facet of violative residue avoidance, as milk and dairy beef for treated animals can be prevented from leaving the farm until it is safe for human consumption.

8. PROPER DRUG RESIDUE TESTING CAPABILITIES READILY AVAILABLE ON AND OFF FARM.

When animals are treated, the proper use and interpretation of appropriate milk and urine test(s) on and off the farm prevents dairy products with violative residues from leaving the farm and interfaces with control point 7.

9. EMPLOYEES DEMONSTRATE AWARENESS AND KNOWLEDGE OF PROPER DRUG USE AND METHODS TO AVOID MARKETING ADULTERATED PRODUCTS.

The information contained in the MDBQAP must be made available to of all those involved with the treatment of animals on the dairy farm. The importance that proper drug use plays in avoiding violative residues should be emphasized to all those on the farm involved with milk production.

10. QUALITY ASSURANCE CHECKLIST COMPLETED ANNUALLY.

This is intended to maintain the program as an ongoing effort in violative residue avoidance. This intention actually addresses two HACCP considerations. Not only will the MDBQAP have to be reviewed annually by the producer and his/her veterinarian, but the MDBQAP be kept current by those responsible for doing so.

If the information is available, the author will attempt to provide information as to reaction of those who have had to participate in the regulatory aspect of this quality assurance program during the time span from its implementation and the presentation of this paper.

- (1) **Milk & Dairy Beef Quality Assurance Program;
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