

# Drug usage hazard analysis and critical control points (HACCP)

**David A. Rhoda, DVM**

*Chairman, Wisconsin Veterinary Medical Association Drug Residue Task Force, Evansville, WI 53536*

## Abstract

The Wisconsin Veterinary Medical Association has prepared a six-step process for developing an on-farm HACCP plan for drug usage on a dairy. The six steps are to define the roles and responsibilities of the veterinarian-client-patient relationship (VCPR) team, evaluate the complete list of drugs purchased, develop protocols for use of the drugs, consider standard operating procedures used by the dairy, develop the treatment records plan, and establish an oversight strategy for monitoring drugs used on the dairy by the veterinarian.

## Résumé

La Wisconsin Veterinary Medical Association a préparé un processus en six étapes pour élaborer sur place un plan HACCP pour l'utilisation de médicaments sur une ferme laitière. Les six étapes consistent à définir les rôles et responsabilités de l'équipe chargée de la relation vétérinaire-client-patient (VCPR), à évaluer la liste complète des médicaments achetés, à mettre au point des protocoles d'utilisation des médicaments, à prendre en compte les procédures normales d'exploitation utilisées par la laiterie, à mettre au point le plan d'enregistrement des traitements et à établir une stratégie de supervision pour faire le suivi des médicaments utilisés par le vétérinaire sur la ferme.

## History

The food products we produce as a dairy industry are high quality, both from a food quality and a food safety perspective. The proportion of tissue residues discovered by screens established to prevent residues reaching the market is small, but the expectation by both consumers and regulators is zero tolerance. Our products are berated by the media, consumers, and opponents of animal food production for any detected residues, even though test sensitivities are well above established tolerance levels.

To address this expectation, we need an on-farm drug usage Hazard Analysis and Critical Control Point (HACCP) plan that improves our accountability toward drug use. Even if the expectation of zero errors

seems unachievable, we can demonstrate with tangible information our commitment to balance animal welfare and food production by reaching oversight of drug usage.

As an organization, the Wisconsin Veterinary Medical Association (WVMA) developed information about how to comply with the Animal Medical Drug Usage Clarification Act (AMDUCA) when the act was passed. It summarized the regulatory information for the WVMA membership from a practitioner's standpoint, and the information was shared in multiple states and with the American Association of Bovine Practitioners (AABP) after the act was passed. AMDUCA is a well-written act, which regulates our responsibilities for extra-label use of drugs. AMDUCA was the foundation for the work that followed, as the WVMA developed software with emphasis on supervision of drug usage on dairies called Best Practices Wisconsin (BPW).

BPW was to be a four-piece program: drug usage reconciliation; drug prescription writing; a protocol development tool; and a records plan for not only extra-label drug usage (ELDU) but also label drug usage (LDU). Two issues with this work have limited its application by practitioners. First, there is a complexity level to accomplish the mandatory requirements for labels, records, and prescriptions that makes this tool labor-intensive to initiate on a dairy and maintain through the changes that occur in protocols and drug options. Secondly, we never accomplished a records plan that was simple and readily adopted with the Best Practices work.

With the creation of the WVMA HACCP for Proper Drug Use, the WVMA Drug Residue Task Force feels we have accomplished the records portion, not with templates, but with a plan adaptable to the management style diversity in the industry, which will be detailed with the HACCP plan. Currently we have a different mood by regulators, consumers, processors, veterinarians, and producers about the importance of getting this phase of drug usage recording right.

The WVMA HACCP for Proper Drug Use process continues the AMDUCA work by focusing on identifying all ELDU on the dairy; eliminating that which is unnecessary; and developing oversight of drug usage—regardless of whether ELDU or LDU by practitioners—by utilizing management level records.

## Meat Residues

The number of tissue residues in 2009 for dairy cull cows and bob veal calves revealed that ELDU without proper withdrawal application was a significant problem.

The top tissue violator drugs for cull cows were penicillin, flunixin, sulfas, desfurouylceftiofur, and gentamicin.

The top tissue violator drugs for bob veal were, neomycin, sulfas, gentamicin, and flunixin.

Consideration of labels for these drugs clearly indicates the likelihood that ELDU without proper withdrawal was the issue. The FDA summarized their drug residue dairy farm investigations by identifying these on-farm issues:

- No on-farm treatment records
- Increased dosages without adjusting withdrawal times (ELDU)
- No individual animal ID

They considered all of these as a failure of the veterinarian-client-patient relationship (VCPR). The WVMA's solution is to address the use of drugs one dairy at a time at the VCPR level. The WVMA developed an informational presentation to explain the likely mistakes residue violators had made to producers, veterinarians, and other stakeholders.

A study of the tissue residue results also clearly demonstrated that the targeting of likely treated animals with a very sensitive screening test by the Food Safety Inspection Service (FSIS) was effective in detecting and removing animals from the food supply. The next step for the WVMA was to consider what risks needed to be addressed to give the same confidence to consumers of milk.

## Milk Residues

Milk has been tested routinely for beta lactams, and maintaining our world markets for milk means we must meet the testing demands of milk purchasers. We have historic information about the residue level from beta lactam testing. In 2012, testing for a large spectrum of drugs was initiated by the FDA for 900 herds that had previously been positive for a tissue residue, and 900 herds that had not had a tissue residue.

Drug residues in meat clearly indicated that while AMDUCA has been an effective law and has changed drug usage on dairies, ELDU should be the focus for the process of establishing a drug usage HACCP plan. The meat residue investigations also demonstrated that this renewed effort also needs to focus on the VCPR. A VCPR that addresses care of animals is present on most dairies. We determined a plan needed to be implemented on

our dairies to define a VCPR that also addresses drug usage oversight.

## Hazard Analysis and Critical Control Points (HACCP) for Drug Usage

The process for establishing a drug usage HACCP plan requires identifying and defining six areas significant to drug usage that are unique for each individual dairy:

- Identifying roles and responsibilities of the team of people represented in the VCPR with emphasis on consistency of work, compliance with the written plan, and competency in the skills required.
- Identifying all drugs used on the dairy in protocols, with emphasis on identification of ELDU and clear, concise condition definitions for on-farm usage.
- Writing protocols matching drug usage to defined conditions with emphasis on label treatments with known withdrawal times and Food Animal Residue Avoidance Databank-derived withdrawal times and AMDUCA algorithm satisfaction when ELDU is needed for animal welfare.
- Writing standard operating procedure instructions for the people of the VCPR team including health care delivery and animal care processes, with emphasis on the SOP for returning a treated animal to food production.
- Developing a records plan which at a minimum gathers the fundamental information needed for food safety, but preferably captures management level information usable by the VCPR team for establishing appropriate drug usage, then using it as a guide for oversight of drug usage.
- Establishing a plan to oversee treated animals that verifies food safety, appropriate drug usage, and animal welfare of treatments which is useful to manage not only medical effectiveness of treatment, but economic effectiveness of the plan.

Development of a HACCP plan needs to be accomplished one dairy at a time by the VCPR team due to the unique situation relative to the people, drugs, conditions, and specifics of each individual dairy.

### 1. VCPR team

The VCPR is identified by most writers and speakers as the solution because drug residues in meat and milk are people mistakes rather than a drug problem. The VCPR can be defined as the people represented:

- Patient – represented by cow-side people as well as the cow. Consistency, competency of techniques and compliance with written instructions are required in drug protocol application.

- Client – represented by the owners and managers responsible for cow care. They make decisions on care policies to follow, and then need to oversee compliance and competency of cow-side people.

- Veterinarian – dairies have multiple veterinarians involved who need to be communicating so that the responsible veterinarian is aware of all drug recommendations. Most modern dairies have three categories of veterinarians: attending veterinarians, referral veterinarians, and consultants.

Identifying roles, responsibilities, and consensus of opinion about drug usage on the dairy is a challenge within this group. We also need to satisfy statutory requirements of the VCPR.

Identification of potential risks within the VCPR is significant to hazard analysis. Use of records by the members of the VCPR team is necessary for first accomplishing food safety and ultimately reaching the goal of appropriate drug usage.

## 2. Drug list

The complete list of drugs used on a dairy needs to be assessed: first, to look for drugs that would be considered high-risk because their use could only be extra-label, or there is no tolerance for any residue for them; to find ELDU of either over-the-counter (OTC) or prescription drugs; and to determine the definition of conditions being treated to prepare for protocol writing.

This step is critical for hazard analysis relative to the drugs used, but it is even more important for identifying drug usage based on people's feelings instead of being science-based. Protocol development and treatment decisions are based on everyone involved in the process sharing the same definitions for conditions and drug usage. The first two steps need to have identified what drug usage needs to be changed and who needs be trained in science-based, appropriate drug usage with protocols.

## 3. Protocols

One objective of the drug list portion was identification of ELDU use to make certain that withdrawal times were accurate, but there is also the objective of identifying defined conditions where label protocols should be written.

Some mindsets should be considered when writing protocols: the attitude that label treatment is minimal treatment and that extra-label is somehow maximum treatment. This perception is unjustifiable, but effective treatment needs to be defined and demonstrated through the records and oversight to overcome this mindset. This perception seems to have developed because label treatments

are not always effective. If we use mastitis as an example, many isolates are untreatable pathogens; of course label treatments will not be effective, but extra-label treatments also will not be effective. Treatable pathogens are also not effectively treated every time.

The protocol needs to clearly state the condition definition, drug protocol, withdrawal information, and the information to record. Definitions of effective treatment and proportions of successful treatment can then be used to satisfy the VCPR team that label treatments are effective using the herd's own data.

An additional challenge in protocol writing is attempting to identify conditions where the use of drugs is unlikely to be effective. Establishing the permanent record sets the stage for science-based, appropriate drug usage with consideration of medical history. The challenge with protocol writing is including instructions for the proportion of cows that should have a non-treatment decision made, not simply repeatedly following the treatment plan. A major objective of the WVMA HACCP for Proper Drug Use process is to assure science-based drug use. It also calls for every drug found on the dairy to be included in a protocol.

## 4. Standard Operating Procedures (SOP)

These are the steps on how we want a task completed by those who are performing the task. The objective with the writing of both protocols and SOPs is to insure consistency in how a task is performed. This is no less true with the treatment of medical conditions than it is for any task performed on the dairy. When there is consistency in the animals that are presented for treatment decisions and consistency in the drug protocols used, there is also predictability in what we can expect in convalescence and rate of recovery.

One of the main objectives of working on a HACCP program is the prevention of meat or milk residues, which makes the SOP for detailing who has responsibility for returning an animal to food production and the steps for accomplishing this task a priority.

## 5. Records

Records are obviously a critical piece for the HACCP plan and for providing each person included in the VCPR team with the information they need for completing their responsibilities. The WVMA recognizes that there are three levels of record keeping available on dairies.

- **No records** - This is the highest risk, because it relies on the memory of the drug user for determin-

ing withdrawal times. Since a record requirement is a tenet of AMDUCA, all treatments would be limited to label and the attending veterinarians for these dairies would oversee that there was no ELDU. From the standpoint of HACCP there is little opportunity for verification of drug usage.

•**Fundamental records** - AMDUCA's records requirement is an example of a fundamental recording plan:

- Identify the animals, either as individuals or a group
- Animal species treated
- Number of animals treated
- Condition being treated
- The established name of the drug and active ingredient
- Dosage prescribed or used
- Duration of treatment
- Specific withdrawal, withholding, or discard times, if applicable for meat, milk, eggs, or animal-derived food
- Keep records for two years
- FDA may have access to these records to estimate risk to public health

Many fundamental record templates have been developed which are useful for managing the treatment of the case, including its withdrawal time. This meets our first objective of food safety, but to meet the objective of achieving appropriate drug usage we need records which include the medical history of an individual animal that identifies cows that are less likely to cure.

•**Management level records** - are taking the step of developing a permanent record for each individual animal that contains the cow's medical history. This level of record keeping is not only effective for making the treatment decision, but can also be collated for management of the herd situation. The two halves of our health care responsibilities are to first, manage the care of the individual sick cow by utilizing her medical history and second, to manage the herd epidemiology for various medical conditions through recognition of herd patterns by organizing individual records into groups of animals that need to be assessed.

The key for achieving value for this level of records is training the members of the VCPR team to use the records as part of their health care management. As veterinarians, our opportunity is to use whatever level of written record is achieved to oversee drug usage, and encourage management-level records to achieve proper drug use.

## 6. Oversight

The final step is to develop an oversight strategy that meets the needs of the dairy. As with the VCPR, we will need a non-regulatory approach due to the unique needs on the dairy. One strategy for this process is to have records available that allow:

- Oversight of the individual animals currently under treatment
- The group of primary cases of a condition to determine the pattern of cases
- The group of repeat or relapse cases to identify the pattern of cases of problem cows
- A group of past cases to measure the outcomes of treatments for conditions treated

The objective of oversight is timely evaluation of compliance, competency, and consistency of health care delivery by the VCPR team, meeting the welfare needs of the sick, and assurance of appropriate drug usage. The value is in detecting training opportunities at teachable moments when issues are occurring.

## Conclusion

This six-step process can be revisited as needed to evolve the HACCP plan to changing medical situations on the dairy and its VCPR personnel. A byproduct of this HACCP plan is transparency and accountability of our drug use, which the consumers want. The accountability of appropriate drug usage should allow market access to the drugs needed to meet the welfare needs of the sick. Finally, there is tangible value for the dairy in the management of the economic factors involved in drug usage.