

# Developing treatment protocols

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## Abstract

The Food Armor® HACCP for Proper Drug Use program is a 6-section program for implementing HACCP for proper drug use plans on our nation's dairy farms. The 6 sections include (1) proactively assigning roles and responsibilities between all members of the VCPR team, (2) creating a farm-specific drug list which includes all drugs on the farm and defines exactly how each drug will be used in specific situations or management groups, (3) developing treatment plans for commonly occurring, easily recognizable conditions, (4) precisely defining procedures for animal care, including animal identification, residue avoidance, drug administration, and euthanasia, (5) ensuring a recording method which includes a treatment log for every treatment and a permanent medical history for every animal, and (6) establishing a continuous monitoring plan of drug use hazards and identification of potential improvements to the animal care plan. The focus of these proceedings is on the creation, implementation, and oversight of on-farm treatment protocols.

**Key words:** treatment protocols, compliance, oversight, drug use, Food Armor®

## Résumé

Le programme Food Armor® HACCP pour l'utilisation responsable des médicaments se divise en six sections et sert à implanter dans les fermes laitières de notre pays des plans d'utilisation des médicaments basé sur le système HACCP. Les six sections incluent : (1) l'attribution proactive de rôles et de responsabilités entre tous les membres de la relation vétérinaire-client-patient, (2) la création d'une liste de médicaments propre à la ferme qui incluent tous les médicaments de la ferme et définit comment chaque médicament sera utilisé dans des situations spécifiques ou dans des groupes de régie, (3) le développement de plans de traitement pour des conditions fréquentes et facilement identifiables, (4) la définition précise des procédures pour le soin des animaux incluant l'identification des animaux, la prévention des résidus, l'administration des médicaments et l'euthanasie, (5) la mise en place d'un système d'inscription incluant un registre de chaque traitement et les antécédents médicaux de chaque animal sous forme permanente, et (6) l'établissement d'un plan de suivi continu des dangers reliés aux médicaments et l'identification d'améliorations potentielles dans le plan de soin des animaux. L'accent dans cette présentation sera mis sur la création, la mise en place et la surveillance des protocoles de traitement à la ferme.

## Introduction

The process for establishing a drug usage HACCP plan requires identifying and defining 6 areas significant to drug usage that are unique to each individual farm:

**VCPR** (veterinarian/client/patient relationship) – The veterinarian of record (as defined by the AABP) and the farm owner proactively assign roles and responsibilities which establish the lines of communication between all members of the VCPR team.

**Drug list** – This list includes all drugs on the farm and defines exactly how each drug will be used in specific situations or management groups.

**Protocols** – Protocols are treatment plans developed by the veterinarian of record for commonly occurring, easily recognizable conditions where instructions can be left by the veterinarian of record for the care of these conditions in his/her absence.

**SOPs** – Standard Operating Procedures precisely define procedures for animal care, including animal identification, residue avoidance, drug administration, and euthanasia.

**Records** – Records provide the veterinarian of record and the farm owner a means for oversight of drug usage on the farm. A recording method must be present which includes a treatment log for every treatment and a permanent medical history for every animal. The permanent record should provide information that allows farm management to make medical decisions for the individual animal and the entire herd.

**Oversight** – Veterinary oversight includes continuous monitoring of hazards and identification of potential improvements to the animal care plan. Oversight is an integral component for validation of the VCPR and provides accountability, ultimately resulting in increased consumer confidence.

The development of a HACCP plan needs to be accomplished 1 farm at a time by the VCPR team. Each farm is a unique situation relative to the people, drugs, conditions, and management. While all of the sections are important to implement an on-farm antimicrobial stewardship plan, the focus of these proceedings will be on the formation of treatment protocols and how proper construction and communication are crucial for success.

## Creation and Implementation

As one begins the process of writing or revising treatment protocols for a client, the first thing that should be considered and prioritized is compliance. The perfectly written

protocol, with the “best” drug for the disease being treated, is 100% ineffective if the treatment personnel disregard it. Protocols don’t have to be complicated or lengthy. It is actually recommended to keep them shorter, more direct, and to the point to improve end-user compliance.

Food Armor<sup>®</sup> suggests on-farm protocols include 5 sections: condition definition (with or without severity subsets), treatment directions, milk and meat withdrawal period, recording directions and expected outcomes/what to do next.

*Condition definition:* describe the condition being treated in farm-specific terms. Avoid complicated medical language and focus on laymen terms. The condition definition should be short, but allow the cow-side personnel to match the animal’s clinical signs to the treatment protocol.

*Treatment directions:* this is the section where the veterinarian should be very specific. The exact drug, dose, route, duration, and frequency should be detailed clearly so the person administering treatments knows exactly what the treatment is.

*Withdrawal periods:* include the appropriate withdrawal times associated with the specific drug treatments. If extra-label drug use is included in the protocol, remember to justify the usage through AMDUCA, and include extended withdrawal times to ensure food safety.

*Recording directions:* for a veterinarian to do oversight on drug use and treatment outcomes, records are critical. In order to capture the needed information to monitor outcomes, provide clear directions on what information the cow-side personnel should be writing down, and where to do so.

*Expected outcomes/what to do next:* whenever we give directions for a treatment, we need to detail what end result is expected. Decrease in fever? Resolution of clinical signs? Increase in milk production? If these items are clearly detailed and the animal responds as expected, the cow-side personnel can recognize a successful treatment. However, what if the animal does not respond in the way we expect? Unless we include directions on “what to do next”, we risk the cow-side personnel attempting a second round treatment without veterinarian approval. This could result in an increased residue risk, increased drug costs, and/or failure of the treatment. But what if the veterinarian anticipated a few “non-responders” or “treatment failures”? If so, there would already be directions within the protocol telling the cow-side personnel how they need to follow up. Those directions could be as simple as “call the veterinarian”.

## **A Sample Protocol Template is included as Appendix A of these Proceedings**

When writing new or revised protocols for a farm, it is important to train the appropriate employees on those protocols. It should never be assumed that just because a veterinarian wrote the protocol and left it on the farm, employees are complying with the protocol. The veterinarian should communicate directly with employees, or through a trusted manager or supervisor, to educate the farm’s treatment crew on any new protocols or changes to existing protocols. Using training videos, live demonstrations, and/or having the employee perform the task under supervision are all methods the veterinarian can use to ensure the employees understand the protocol being provided to the farm.

### **Record Keeping: The Backbone of Veterinary Oversight**

Writing and training on a treatment protocol is just the first step in protocol creation and implementation. The ongoing review, training, and revision (as needed) of protocols is all part of a valid VCPR and demonstrates the veterinarian and farm’s efforts towards continuous improvement in antimicrobial stewardship.

As a veterinarian, one should work closely with the farm to review their treatment records and improve them, as necessary, for the benefit of the farm and to maintain all FDA requirements.

### **Conclusion**

Food Armor<sup>®</sup> is the first-of-its-kind antimicrobial stewardship program, resulting in actionable change on the farm. The program is more than just a checklist or a signature, it requires the farm to work with their veterinarian to put in place customized drug lists, protocols and SOPs, and maintain a high level of record keeping. The plan is ongoing and requires regular veterinary oversight to ensure drugs are used responsibly and stewardship principles are met. Treatment protocols are an important piece of any on-farm HACCP program, creating a system to allow animal treatment under the supervision of a veterinarian. In order to maintain this type of freedom, veterinarians must be able to demonstrate a valid VCPR through ongoing oversight of treatments and monitoring of compliance.

# Appendix A

Farm Name \_\_\_\_\_

Clinic Name \_\_\_\_\_

## **Farm Condition**

### **Treatment Protocol**

#### **Condition definition:**

*Describe the condition definition in farm-specific terms.*

#### **Treatment plan**

*Include specific details about the treatment plan.*

#### **Dosage table: (Example)**

Drug	Dose	Per	Route	Frequency	Duration

#### **Withdrawal times:**

*Include withdrawal times for all medications used.*

#### **Records plan:**

#### **Expected results of treatment:**

#### **When to call the veterinarian:**

Farm Owner Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Veterinarian of Record: \_\_\_\_\_ Date: \_\_\_\_\_

Expiration date: \_\_\_\_\_