PEER REVIEWED

Important Elements of the HACCP Process to Control Johne's Disease, BVDV, and BLV

Mel Pence, *DVM, MS, PAS, DABVP (beef cattle)*[1]; **John U. Thomson,** *DVM, MS*[2]; **Dana Cole,** *DVM, PhD, DACVIM*[3]

[1]*Veterinary Diagnostic and Investigational Laboratory and Department of Large Animal Medicine, University of Georgia, Tifton, GA 31793*

[2]*Dean, College of Veterinary Medicine, Mississippi State University, Mississippi State, MS 39762*

[3]*Large Animal Medicine, College of Veterinary Medicine, The University of Georgia, Athens, GA 30602*

Abstract

The hazard analysis critical control point (HACCP) program was developed to address food safety issues and has been mandatory in all cattle harvest plants since January 2000. HACCP process control procedures provide a systematic approach to the identification and control of a variety of biological, physical and chemical hazards within a food-production system. In addition, the seven steps of HACCP offer a proven systematic approach that addresses biological problems.

This approach can be adapted to on-farm production problems of a non-food safety nature. The risk a disease poses to a production unit is assessed, critical control points (CCP) for a specific disease are identified, these risk factors are addressed and best management practices are applied to reduce or eliminate disease risk. Limits are established for each disease, monitoring procedures are applied to each CCP, and corrective action is applied when disease level surpasses the set limit. Thus, a record system is created that documents the plan, and verification procedures are established to ensure the plan is working. Together, practitioners and producers can use this method to systematically address specific production problems related to disease control.

This paper describes how HACCP might be used to address bovine viral diarrhea persistent infection (BVD PI), bovine leukosis virus (BLV) and *Mycobacterium avium* subspecies *paratuberculosis* (Johne's disease), and to prevent introduction or systematically reduce or eliminate the impact of these diseases on the production unit.

Résumé

Le système d'analyse du risque et de maîtrise des points critiques (HACCP) a été développé pour le contrôle de la salubrité des aliments et est maintenant obligatoire dans toutes les usines de transformation du bétail depuis janvier 2000. Ce système permet une approche systématique dans l'identification et le contrôle d'une grande variété de risques, autant biologiques que physiques ou chimiques, dans un système de production. De plus, les sept étapes du système offrent une démarche systématique établie pour faire face aux problèmes biologiques.

Cette approche peut être adaptée aux problèmes de production à la ferme qui ne sont pas reliés à des risques alimentaires. Le système permet d'examiner le risque qu'une maladie pose dans une unité de production et d'identifier les points critiques de contrôle pour une maladie en particulier. Les facteurs de risque sont identifiés et les meilleures pratiques de régie sont mises en place pour réduire ou éliminer le risque de maladie. Des limites sont établies pour chaque maladie, des mesures de surveillance sont appliquées à chaque point critique de contrôle et des ajustements sont faits lorsque le niveau de la maladie dépasse la limite établie. Un système est créé pour documenter les étapes du plan et des mesures de vérification sont établies pour s'assurer que le plan soit suivi. Les producteurs et les praticiens peuvent donc utiliser cette méthode ensemble pour faire face systématiquement à des problèmes de production associés au contrôle de maladies.

Cet article décrit comment le système de contrôle pourrait être utilisé pour contrecarrer l'infection persistante associée à la diarrhée virale bovine (BVD PI), le virus de la leucose bovine (BLV) et *Mycobacterium avium* sous-espèce *paratuberculosis* (Maladie de Johne) et de plus pour prévenir l'entré de ces maladies ou éliminer ou réduire systématiquement leur présence dans l'unité de production.

Introduction

Discovery of bovine spongiform encephalopathy in the United States underscored the need for a system to establish the origin of individual cattle. With the advent of trace-back systems, it may become more beneficial to validate the health status of producers' herds and validate processes intended to limit zoonotic or contagious diseases. This validation may enhance the value of those cattle production units that can demonstrate they are disease-free or have limited the prevalence of specific diseases.[31] Hazard analysis critical control point (HACCP) is a logical, scientific-system approach that has been used to control safety problems in food-production systems affected by biological, chemical and physical hazards.[4] Originally developed and implemented to provide a mechanism of risk assessment and process control for safe food, current federal regulations require all beef harvest plants to have a working HACCP plan.[4,27] Development of biosecurity procedures for biological hazards in HACCP-compliant cattle herds could help protect the human food chain and other cattle production systems. Additionally, practitioners and cattle producers could use HACCP protocols to validate the health status of their production units, adding value to their production.

HACCP plans enhance team cooperation. Practitioners and producers work together to identify risks to production, devise a plan to address the problem, set goals and validate their completion. Based on the influence that veterinary practitioners have on beef producers, a HACCP model could be used to build controls for threatening diseases like bovine viral diarrhea persistent infection (BVD PI), bovine leukosis virus (BLV) and Johne's disease. These diseases were chosen as a model in this paper since they all impact profitability to varying degrees. These three diseases are similar in that testing can identify a reservoir, and identification and elimination of the reservoir is the critical control point (CCP) for each disease. The three diseases vary in cost effectiveness of testing programs because of the differing economic cost of each disease, disease herd prevalence, and sensitivity and specificity of the testing protocols that identify the reservoir. Thus, HACCP plans would vary for different production units based on the marketing and production goals of a specific producer. The local practitioner is uniquely qualified to assist producers to devise HACCP plans that are biologically sound and meet the producer's goals.

Materials and Methods

A significant disease may be defined as disease-causing, or capable of causing a major economic or public health impact.[31] This definition allows qualitative principles of hazard identification to be utilized that identify significant cattle diseases.[6] Diseases may be significant to the population of cattle, but may not be zoonotic. Alternatively, the disease may have minor impact on the production of meat or milk but could represent a significant level of concern among the consuming public. As an industry, we must be prepared to address diseases affecting either production or consumer concerns. Once a significant beef cattle disease hazard is identified, epidemiologic approaches are used to define the interactive factors that maintain a disease agent in a production unit (critical control points).[4] A critical control point is defined as a point, step or procedure in a production process at which control can be applied, and as a result the production hazard can be prevented, eliminated or reduced to an acceptable level.[4] Although control models for different diseases may vary, the principles are similar. Epidemiology can be employed to identify the critical control points that increase the risk of disease introduction into a beef herd or contribute to spread of a disease within an infected herd. Veterinarians are uniquely trained to apply principles of pathogen biology, epidemiology and disease control to facilitate implementation of a HACCP plan. The following seven principles of HACCP can be applied by veterinarians to assess risk and severity, identify hazard critical control points, and control and/or eradicate specific diseases within a specific production unit based on the goals of the producer:

1. Assess risk or hazards associated with the enterprise. If no risks are identified, or if hazard to the enterprise is minimal, no further action would be necessary.
2. Determine critical control points required to control identified hazards or risks.
3. Establish critical limits that must be met for each critical control point.
4. Implement procedures to monitor critical control points.
5. Determine corrective action to be taken when there is a deviation from the established critical limits identified by monitoring a critical control point.
6. Set up effective record keeping systems that document the HACCP plan.
7. Establish procedures for verification that the HACCP system is working correctly.

HACCP plans must be individualized for specific problems on each production unit. The producer's veterinarian, with unique knowledge of that production unit and the disease process, can assist in developing and implementing a specific HACCP plan. In this article we identify three significant beef cattle diseases (BVD, Johne's disease, and BLV) and outline the general principles of HACCP that can be used by practitioners and their producers to address these diseases.

Protocol for BVDV PI

Bovine viral diarrhea virus (BVDV) continues to be a major source of infectious disease and economic loss in the cattle industry, which makes BVD a significant disease and hazard to cattle production. BVDV vaccines have been extensively utilized since 1959 in dairy and beef cattle operations.[14] However, the current frequency of vaccine use, vaccination protocols and/or biosecurity practices in the dairy and beef industries lack the rigor to prevent or control bovine viral diarrhea virus persistent infection (BVDV PI), as demonstrated by the continued prevalence of BVD PI in cattle ranging from 0.13% to 1.7%.[8,17,19,35]

The presence of BVD PI cattle increases potential continued transmission of BVDV in a cattle herd.[9] BVDV PI calves are produced *in-utero* when the fetus is infected between 30 and 120 days of gestation, which is prior to development of the immune system and results in an immunotolerant animal.[24] The frequency of BVDV isolation from bovine fetal serum indicates that PI calves may be more common than was previously assumed.[10] In a survey of 1000 pooled bovine fetal serum samples (1-3 fetal sera per sample), BVDV was isolated in over 20% of the samples.[10] BVDV PI cattle have the potential to continuously shed BVDV from every body orifice and may constitute 1.7% of the cattle population at birth.[8] This continual shedding by BVDV PI cattle is thought to be the main reservoir for infection to other cattle in the herd. The presence of BVDV PI cattle in the breeding pasture during gestation also serves to propagate another generation of BVDV PI calves.[8] Thus, identification and elimination of BVD PI cattle is a major CCP in the control or elimination of BVDV in a suspect herd.[23] BVDV eradication programs in Denmark have shown that removal of BVDV PI cattle is a required first step in eradication.[16] Consequently, in the initial year of a BVD PI eradication program in a BVDV-suspect herd, all cattle on the farm should be tested directly or indirectly prior to breeding. The BVD antigen Capture ELISA test[a] can be used to detect BVDV antigen in serum samples. Immunohistochemistry (IHC) examination of skin tissue (ear notch samples) may be used to test cattle of all ages to determine if they are PI. Other tests might include virus isolation (VI) and PCR. Since BVD PI cows consistently transmit BVDV vertically, the dam of a calf that tests negative on an ear notch sample (IHC) will have an extremely high probability of being BVD PI negative.[18]

In a herd with a short, defined breeding period, a complete herd test must be completed before the breeding season starts. This would include testing all calves, all cows (including heifers) that do not have a calf on test day, and all bulls.[23] Calves from pregnant females during the testing period would be tested at birth using IHC. Any dam of a BVD PI test-positive calf should be tested, and all BVD PI test-positive cattle immediately removed from the herd and sold in a terminal market.

To maintain a herd BVD PI test-negative, other risk factors (CCPs) for introduction of BVDV into the herd need to be addressed. All incoming cattle should be isolated and BVD PI test-negative prior to entering the herd. If the ELISA test is utilized, new additions should be over six months of age. All semen and embryos should come from BVDV PI test-negative sources. No milk or colostrum should be used from outside sources unless validated free of BVDV. Contact with other cattle, sheep or wild ruminants should be minimized or prevented.[1] However, since total elimination of contact with other ruminants may not be possible, herd immunity in the case of HACCP plan failure should be increased by immunization with BVDV antigen.

Personnel should be required to wear different clothing and gloves, and wash their hands and boots prior to working with this herd immediately after contact with cattle or sheep from other sources. Research has demonstrated that BVDV virus could survive minutes to hours on fomites like nose tongs, balling guns, gloves or a chute, and could be transferred to cattle when handled in common facilities or medicated with common utensils.[15]

The critical control limit for the number of BVD PI cattle in a herd should be set at zero. The protocol to monitor the level of BVD PI in the herd (a critical control point) might include yearly serum neutralization (SN) tests on a random sample of 10 BVD non-vaccinated progeny at 6-8 months of age.[7,23] Measurement of positive SN titers could indicate endemic BVDV in the herd. If true, the corrective action would be to implement a test protocol for detection of BVD PI cattle in the herd, using BVDV antigen Capture ELISA test and/or IHC; further examine the incoming cattle biosecurity plan, and examine possible contact with other ruminants.[1]

Documentation of the HACCP plan for BVDV requires that all cattle be individually identified and records kept on all testing performed. In BVD high-risk suspect herds, care must be taken to ensure that all cattle or the progeny of all females on the farm are tested before breeding begins. Record reviews of all incoming cattle and all testing should be done yearly. Farm personnel should have periodic updates on the farm's

biosecurity status and educational presentations on the spread of BVDV. Yearly SN testing of a random group of non-BVDV vaccinated calves at 6-8 months of age will verify whether or not the HACCP plan for control of BVDV in this herd is working. Table 1 summarizes the HACCP plan to control BVD in cattle herds.

Protocol for BLV

Bovine leukosis virus (BLV) is common in the beef population in some geographic areas. A national study of BLV in Canada demonstrated an 11% herd prevalence of serum antibody titers to BLV. Limited data in the NAHMS Beef 97 survey demonstrated 10.3% prevalence in US beef cattle.[7] Thirty-eight percent of all beef herds in the United States are thought to have at least one BLV-positive animal.[2] Approximately 1-5% of all BLV-positive cattle will develop clinical signs of infection.[26] These cattle experience reduced production and a lower cull value.[29] BLV can be a significant disease and a hazard to a beef cow/calf herd. Economics of BLV eradication for a US beef producer are determined by herd status and production goals. If a producer is negative on the initial herd test and sells breeding stock, that producer may benefit from yearly testing all cattle, as well as isolation and testing all incoming cattle. If prevalence is high in a commercial herd, the economic benefit of herd BLV eradication may be more difficult to achieve.

BLV-positive cattle are the primary source of infection within a herd. Transmission is by lymphocyte transfer from an infected to a non-infected animal.[21] This may occur via needles, insects, tattooing, dehorning, rectal palpation or any other means of blood transfer.[21] Colostrum and milk from infected cows also can spread BLV.[21] The CCP for BLV is identification and elimination, or at least isolation, of BLV-positive cattle from the herd. If the producer's goal is to eliminate BLV, then the critical control limit of BLV-positive cattle in the herd would be zero.

Initial monitoring with a complete herd test is required to determine the BLV status of the herd. All cattle over six months of age should be tested.[32] The protocol is to test all cattle using a BLV agar gel immuno-diffusion test (AGID).[25] Sensitivity and specificity of the AGID BLV test varies with age, but in cattle over six months of age the sensitivity is 100% and the specificity is 92%.[32] Separate needles must be used for blood collection and vaccination of cattle of unknown status. Biting insects, castration and dehorning tools, and possibly multiple-use obstetrical sleeves are additional means of virus spread.[21]

A second CCP is limitation or prevention of infection by addition of new BLV-positive cattle into the herd. To minimize risk of introduction of BLV into the herd from incoming cattle, all herd additions must be quarantined and test negative for BLV before entering the herd. If the herd goal is to eliminate BLV, then all cattle testing negative to BLV should be isolated from cattle and sheep of unknown or test-positive BLV status. Since no efficacious vaccines are available for BLV, the herd always remains susceptible to infection, and exposure to BLV-positive cattle must be avoided. If the producer's goal is to eliminate BLV, then all cattle testing positive to BLV should be eliminated from the herd.

Yearly BLV AGID testing of the breeding herd is necessary to monitor the BLV status of the herd, with positive cattle either eliminated from the herd or isolated.[11] All cattle must be individually identified, and records of yearly testing retained, to verify the BLV HACCP plan is working. Yearly review of records of incoming cattle and testing needs to be done. Farm per-

Table 1. BVDV PI HACCP plan summary.

Hazard analysis	BVDV PI cattle losses, spread of BVDV to herd, loss of sale value, production losses, loss of genetics
Critical control points	BVDV PI in herd, herd additions of BVD PI, semen from BVD PI, colostrum or milk from BVD PI, embryo from BVD PI, other BVD-positive ruminant contact
Limits	Zero limit for BVDV PI in herd or additions
Monitor CCP	Initial test of herd, test herd additions
Corrective action	Eliminate all BVDV PI-positive cattle, vaccinate the herd
Records	ID all cattle, record of herd additions, record semen and embryo purchases, record of all BVDV PI tests
Verification	Yearly random SN test of 6-8 month old non-vaccinated calves (10 head), yearly record review and personnel education

sonnel should have periodic updates on the farm's biosecurity status and educational presentations on the spread of BLV. Yearly testing for BLV will verify whether the HACCP plan for control of BLV in this herd is working. A summary of the BLV HACCP plan is shown in Table 2.

Protocol for Johne's disease

Johne's disease (*Mycobacterium avium* subspecies *paratuberculosis* [MAP]) infection is a chronic wasting disease that infects cattle as neonates, or possibly *in-utero*.[33] Initial MAP infection may occur in the ileum, and gradually spread to regional lymph nodes and other body organs. After a prolonged incubation period of two to ten years, initial clinical signs include loose consistency of feces and gradual weight loss, but a normal appetite. Eventually, cattle become lethargic and emaciated until the terminal stages of Johne's disease, where they exhibit cachexia and watery diarrhea.[33]

Prevalence of MAP infection in the US beef population is estimated at 7.9%, according to NAHMS Beef 97 data.[13] Economic costs to the cattle industry include loss of genetics, decreased production due to lowered milk production of dams, decreased cattle cull weight, increased culling rates, decreased fertility and increased costs of diagnostic testing.[20,28] These facts make Johne's disease significant on a production unit and a hazard to the cattle industry.

A link between Crohn's disease and Johne's disease has been hypothesized, but there is insufficient scientific evidence to conclusively support this link at this time.[30] This zoonotic concern increases the significance of Johne's disease.

Risk analysis of Johne's disease shows the hazard to a cattle production unit is transmission of disease from a MAP-positive animal to a MAP-negative animal. Most herd infections initially occur with the introduction of a MAP-infected animal.[22] Cattle are most commonly infected as neonatal calves. MAP can be transmitted orally through contact with contaminated feces, semen,[12] colostrum and milk.[22] Consequently, the CCPs for MAP infection should limit introduction of infected cattle into a non-infected herd and, in an infected herd, transmission from a MAP-infected animal to a non-infected animal. To address these CCPs in an infected herd, management to decrease the spread of Johne's disease, coupled with yearly testing and removal of positive cattle, is required.[5]

Guidelines for CCP on beef or dairy farms are addressed in the Voluntary Bovine Johne's Disease Control Program.[5] A handbook from that program, "How to do Risk Assessments and Management Plans for Johne's disease," identifies specific CCP and best management practices for control of Johne's disease. Goals of testing and management protocols should include eliminating or reducing contact of neonatal calves and young stock with colostrum, milk and/or feces from MAP-positive cows. Only cattle from MAP test-negative Johne's status herds should be introduced into the herd. If that is not possible, then dams of all incoming cattle should be culture-negative for MAP. Additionally, all incoming cattle should be isolated for 30 to 60 days and culture MAP-negative. Herd additions should also be serologically tested and/or culture-negative for MAP each six to twelve months.

To ensure that Johne's disease will not be a hazard to the cattle production unit, a zero tolerance must be established in a working HACCP plan for MAP test-positive cattle. To monitor the zero tolerance level of MAP test-positive cattle in a herd, yearly ELISA MAP testing of 30 random cattle over 24 months of age is recommended.[12] Any animal that tests ELISA MAP-posi-

Table 2. BLV HACCP plan summary.

Hazard analysis	BLV cattle losses, decrease production, spread of BLV to herd, loss of sale value, loss of genetics
Critical control points	BLV-positive in the herd, BLV-positive herd additions, vector or fomite transmission, purchased BLV-positive colostrum or milk
Limits	Zero limit for BLV-positive in the herd
Monitor CCP	Initial test of the herd, test herd additions
Corrective action	Eliminate all BLV-positive cattle
Records	All cattle ID, record of herd additions, record of all BLV tests
Verification	Yearly BLV AGID testing of the herd, yearly record review and farm personnel education

tive on these yearly tests should be confirmed with a fecal culture, and if fecal culture-positive they should be eliminated from the herd.[12] Progeny of test-positive cows should be closely monitored, and fecal cultured and/or ELISA tested twice yearly. The dilemma associated with Johne's disease testing is its prolonged incubation and disease course, and very low test sensitivity for disease detection until late in the disease course. Available tests to detect subclinical carriers of MAP may lack the sensitivity needed to effectively remove infected animals in a timely manner.[34] Sensitivity of Johne's disease ELISA tests on cattle not exhibiting clinical signs of disease is approximately 15%.[34] However, the National Research Council concluded, "Available diagnostic tests and information about the biology of Johne's disease and methods to control it are adequate for immediate implementation of control programs."[3] Therefore, the USDA voluntary bovine Johne's disease control program guidelines recommend management protocols to reduce the spread of Johne's disease. Additional recommendations are to test the herd for MAP using the ELISA at years one, two and four of a four-year program, and to do fecal cultures during the third year to validate herd status.[5]

The Johne's disease HACCP plan should be documented. All animals should be identified and test records maintained to include new additions, as well as animals demonstrating clinical signs that were removed from the herd. These records should be reviewed annually. Farm personnel should have periodic updates on the farm's biosecurity status and educational presentations on the spread of Johne's disease.

Conclusions

Initial steps to validate that a farm is free or at low risk for infection by BVDV, BLV and Johne's disease may be applied to a HACCP format. The HACCP process may be used to systematically analyze disease impact, risk factors for the disease, critical control points, set disease prevalence limits, monitor those limits, design corrective actions when the limits are exceeded, document the plan through record systems and validate the process to ensure the plan is working as expected. This systematic approach to disease control will assist practitioners as they work with producers to ensure they are not missing important components of disease control. Through use of HACCP, practitioners can work with producers to evaluate disease risk utilizing this time tested and scientifically validated format, and to educate and address disease problems specific to each production unit. A HACCP plan needs to be modified to fit each producer's individual goals for his production unit, biology of the specific disease of interest, and cost-benefit ratio of production costs to disease control specific to that production unit. This paper illustrates how use of a HACCP system for BVD PI, BLV and Johne's disease can increase productivity and profit through disease control.

Footnote

[a]Bovine Virus Diarrhea (BVDV) Antigen Test Kit For Serum, Syracuse Bioanalytical, Inc.

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Table 3. Johne's Disease HACCP plan summary.

Hazard analysis	Johne's disease cattle losses, decrease production, spread of MAP to a herd, loss of sale value, loss of genetics
Critical control points	MAP test-positive cattle in herd, MAP test-positive herd additions, purchased colostrum or milk from test-positive cattle, purchased semen from a test-positive bull
Limits	Zero limit for MAP test-positive cattle in the herd
Monitor CCP	Yearly random test of 30 three-year or older cattle, using ELISA and confirm positives with fecal culture, test herd additions using ELISA and confirm positives with fecal culture
Corrective action	Eliminate all Johne's disease-positive cattle
Records	ID all cattle, record of herd additions, losses and sales, record of all Johne's disease tests, record of semen purchases
Verification	Yearly record review and farm personnel education

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