

**Voluntary Bovine Johne's Disease
Control Program:
Uniform Methods and Rules, Draft**

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Introduction

This Uniform Methods and Rules (UM&R) provides minimum program standards and procedures of the Cooperative State-Federal Voluntary Bovine Johne's Disease Control Program to control and eradicate Johne's disease in cattle. Content was approved by This UM&R may be amended in the future by replacing pages or by adding new pages.

Part I Definitions

Accredited Veterinarian - a veterinarian approved by the Deputy Administrator of USDA, APHIS, VS to perform functions required by State-Federal-Industry Cooperative programs.

Approved Laboratory - a state, federal or university laboratory that has passed an annual check test for Johne's disease administered by the National Veterinary Services Laboratories. All program testing must be conducted by a laboratory approved for the specific test being used.

Certified Veterinarian - an accredited veterinarian that has taken and passed a training course approved by the designated Johne's state epidemiologist for additional training in Johne's disease epidemiology and herd biosecurity plan development.

Commingling - physical contact or exposure to manure or raw milk of susceptible species. For example, all cattle grazed together or on the same area of a property or farm, at any time during any 12 month period, are considered commingled. Susceptible species include domestic and exotic ruminants such as sheep, goats, cervids and camelids. Exposure to manure via contaminated water or feed sources is also considered commingling.

Designated Johne's disease epidemiologist - an epidemiologist who has demonstrated the knowledge and ability to perform the functions required under the standards of this UM&R and who has been selected for this position by the State animal health official and the APHIS AVIC. The regional epidemiologist and the VS Johne's staff must concur in the selection and appointment of the designated Johne's disease epidemiologist.

ELISA testing - Enzyme Linked Immunosorbant Assay test designed to detect the presence of antibodies for *Mycobacterium avium* ss *paratuberculosis* in serum, blood, and/or milk. Test kits must be approved by USDA.

Herd - a group of cattle managed as a separate and discrete unit not commingled with other groups of susceptible species. This may include two or more groups of animals under common ownership or supervision, geographically separated but which have an interchange or movement of animals without regard to health status.

Herd member - any Johne's susceptible species of animal that is commingled with the herd.

Herd biosecurity plan - A written plan developed by the producer and certified veterinarian that include animal husbandry and hygiene practices specific to that herd which is designed to limit opportunities for exposure to *Mycobacterium avium* ss *paratuberculosis*.

Herd status levels - herds may achieve status Levels of 1, 2, 3, 4, or higher. Each level of increase indicates higher confidence in the Johne's disease free status of the herd.

Official Johne's disease test - An organism detection test approved by the Administrator and conducted in a laboratory approved by the Administrator. The Administrator will approve laboratories to conduct an official Johne's disease test only after determining that the laboratory

meets the check test proficiency requirements prescribed by the National Veterinary Services Laboratories. Approval will continue as long as such check test proficiency requirements are met on an annual basis. Currently the official Johne's disease test is the fecal culture.

Official eartag - an identification eartag approved by APHIS as being tamper-resistant and providing unique identification for each animal. An official eartag may conform to the alphanumeric National Uniform Eartagging System, or it may bear a valid premises identification that is used in conjunction with the producer's livestock production numbering system to provide a unique identification number.

Positive cattle - cattle will be considered positive for Johne's disease when they have been confirmed positive by an official Johne's disease test.

Premises identification number - a unique number assigned by the State animal health official to a livestock production unit that is, in the judgment of the State animal health official and Area Veterinarian in Charge, epidemiologically distinct from other livestock production units. A premises identification number shall consist of the State's two letter postal abbreviation followed by the premises' assigned number.

Program - Voluntary Johne's disease Herd Status Program

State - Any of the 50 States, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the District of Columbia, and any territories and possessions of the United States.

State Johne's Disease Advisory Committee - a committee organized by the chief State animal health official to assist in the oversight and coordination of the State's Johne's Program.

Supplemental test - A Johne's disease test approved by the Deputy Administrator of APHIS, Veterinary Services for use in the Voluntary Johne's disease Herd Status Program and conducted in an approved laboratory. Supplemental tests are other tests that have been developed to aid in determining the presence or absence of blood components associated with field strains of *Mycobacterium avium* ss *paratuberculosis*. Currently the supplemental test is an ELISA test.

Part II. Procedures

A. Administrative Procedures

1. The Cooperative State-Federal Voluntary Bovine Johne's Disease Control Program (VBJDCP) must be supervised by full-time animal health veterinarians employed by the State or Federal Government.
2. Providing Services to Livestock Owners
Program services may be provided without expense to the livestock owner; however, owners are responsible for handling their animals. Program administrators may contract with accredited veterinarians, paraprofessionals, other State and Federal agencies, or the management of privately owned firms, as needed, to assist State and Federal animal health officials in collecting blood, milk, feces, or tissue samples, in identifying animals, and performing other specified activities.
3. Reporting Johne's Disease Activities
The numbers of herds entering and enrolled in the Program must be reported to APHIS on a monthly basis by the State Johne's disease epidemiologist.
4. Exceptions to Deadline(s)
Programs officials must follow deadlines for the herd plan and testing (see parts III & IV) except when the designated Johne's disease epidemiologist determines that there are extenuating circumstances. The extenuating circumstances must make it impossible to meet the deadline established for a particular herd. The designated Johne's disease epidemiologist must immediately set a new deadline in consultation with the herd owner or his or her representative, to accomplish the required testing at the earliest opportunity. The new deadline must be consistent with the current scientific knowledge of Johne's disease control.
5. Administrative Review of a State's Johne's Program Activities and Progress
An administrative review of a State's Johne's disease Program may involve any or all of the following:
 1. VS personnel will conduct ongoing reviews at the local and national levels by receiving and examining routine written monthly, annual, and other statistical and narrative reports that have been prepared and submitted by State and/or Federal animal health officials in each of the States;
 2. The Chief Staff Veterinarian, National Animal Health Programs (NAHPS), VS, will monitor the results of existing State policies and procedures for controlling and eradicating Johne's disease by examining factors such as the prevalence of infection in that State;
 3. Representatives of the Chief Staff Veterinarian, National Animal Health Programs will evaluate the information provided by the various States in special reports regarding the authorities and the policies for implementing the various minimum standards of this UM&R;
 4. Regional directors, regional epidemiologists, and NAHPS personnel will visit the various States to observe program procedures and to make general or specific program evaluations; and,

5. Special evaluation teams comprised of several individuals representing State, Federal, and/or industry and academic interests will make visits to designated States in order to make limited or comprehensive reviews of the Voluntary Bovine Johne's Disease Control Program.

B. Epidemiology Activities

The Johne's Disease Program will furnish epidemiology services to aid veterinarians and herd owners in preventing and controlling Johne's disease, with the goal of eradicating the disease. To accomplish this goal, the following epidemiology related services will be instituted:

1. State and Federal veterinarians and other animal health officials who have responsibilities in the voluntary Johne's Disease Program will attend an APHIS training course or its equivalent on Johne's disease epidemiology within the first year they are assigned to the Program. Those who have been working in the Program but who have not attended a Johne's epidemiology course will receive this training at the earliest possible date. They will attend refresher courses when offered, designated Johne's disease epidemiologist must attend refresher courses at least once every two years.

2. Certified veterinarians performing Official Johne's disease work will be required to participate in a structured program of continuing education on Program elements and epidemiology. At least once during each 3-year period after the initial program they will attend a refresher course on the Program.

3. Appointing Designated Johne's Disease Epidemiologist

Each State will choose one person to act as the designated Johne's Disease Epidemiologist. This person should be selected jointly by the chief State animal health official and the APHIS AVIC and approved by the regional epidemiologist and the Johne's staff of the National Animal Health Programs, VS, APHIS. Only those persons with the prerequisite Johne's epidemiology training, experience, and interest will be appointed to this position. This person must be a full-time State or Federal employee. The designated Johne's Disease Epidemiologist responsibilities include:

a. Test interpretation and classification

i. To determine the final classification of animals that were initially classified as reactors by ELISA testing.

ii. To interpret and classify animals based on the use of supplemental Johne's tests.

b. Providing training for state personnel and certified veterinarians performing official Johne's disease work and develop a mechanism within the state to monitor the involvement of the certified veterinarians within the Program.

c. Reviewing the herd biosecurity plan and sign off on Memorandum of Understanding submitting by herd owners and certified veterinarians.

- d. Periodically auditing the VBJDCP to determine if the Program is adequately controlling Johne's disease in the State.
- e. Assisting State animal health officials, herd owners, and the herd owner's veterinarian, if requested, in developing herd biosecurity plans.
- f. Participating in the Program activities as a member of the State Johne's disease Advisory Committee.

C. State Johne's Advisory Committee

- 1. An Johne's advisory committee must be formed to assist the state in program development, implementation, and review. The committee will provide oversight and assist in coordination of the state Johne's disease program for cattle. This committee should be comprised of, but not limited to:
 - a. Dairy producers - purebred, commercial and commodity groups
 - b. Beef producers - purebred, commercial and commodity groups
 - c. Designated Johne's disease epidemiologist
 - d. University/Extension
 - e. Veterinary practitioner - beef and dairy
 - f. Regulatory veterinary medical officers - state, federal, and/or field services
- 2. The chairperson for this committee should be a representative from either the beef or dairy industry from the producer level.
- 3. The designated Johne's disease epidemiologist must be a member of the committee.

Part III Program Requirements

The State Johne's disease program should be designed to deal with both infected animals and test negative herds.

A. Test negative herds program requirements

Test negative herd programs should include increasing status levels which herd owners can advance their herd by testing and biosecurity measures. Each additional level represents an increasing level of certainty that the herd is free from Johne's but does not guaranty the herd is free of disease. The program should allow the herd to remain at a monitoring level and it should allow the herd to advance to greater surveillance levels. Program elements should include:

1. A Memorandum of Understanding (MOU), which must be signed by the herd owner and certified veterinarian and approved by the State designated Johne's disease epidemiologist. The MOU is an agreement between the herd owner, certified veterinarian, and State animal health department and must be renewed every 10 to 14 months. The MOU must include minimum biosecurity measures and herd addition requirements.
2. Minimum biosecurity measures, which must in place in order to reduce exposure to manure or milk from susceptible species of unknown Johne's disease status. These measures should include but are not limited to:
 - a. Pooled milk from cows of unknown Johne's disease status should not be used to feed baby calves.
 - b. Manure from Embryo Transfer donors or other "visiting" cows (e.g. Transport cows that are kept at program farms for rest or to be milked) which should not be allowed to come into contact with animals of the program herd and this manure should not be disposed of on pastures or in a manner which would contaminate pastures or animal feed.
 - c. Exhibition cows and calves (especially under 6 months old) should be hauled in cleaned and disinfected trailers and avoid commingling. (Animal exhibition, consignment sales and transport are considered situations of low *M. paratuberculosis* infection transmission risk. However, prudent care and diligence about biosecurity is recommended).
 - d. Program herd must not be commingled with or grazed behind susceptible species, (e.g. Sheep, goats, farmed deer, camelids, non-program cattle).
 - e. Feed and water handling to minimize exposure to manure.
 - f. Handling of young livestock to minimize exposure to unknown status animals or manure from older animals.

3. Herd removal provisions; Status herds that test positive by an official Johne's disease test must be removed from the status program (unless pending an appeal).
4. Herd advancement provisions; Herds that test negative will be eligible to proceed to the next status level provided that the designated Johne's epidemiologist determines that the herd meets or exceeds the minimum requirements to advance.
5. Herd Additions;
 - a. Purchased heifers that have not calved and bulls less than 2 years of age may be added to the herd provided that:
 1. the animal was purchased from a herd with a test negative herd status of equal or higher Level, or
 2. the animals were from program herds that are not less than one level below the purchasing herd, and
 3. the animals are not from non-status program herds.
 - b. Purchased first and higher lactation cows or bulls greater than or equal to 2 years of age may be added to the herd provided that:

For status Level 1 - 3 herds:

1. the animal was purchased from a herd with a test negative herd status of equal or higher Level, OR,
2. the animals have been ELISA tested within 30 days prior to entry into program herd with negative results, and
3. Fecal cultures have been collected from each animal and submitted within 30 days of arrival, and
4. Herd additions are tested on the next herd test. The addition's status will remain at its entry level until they have tested negative at the next herd test.

For status Level 4 herds:

1. the animal was purchased from a herd with a test negative herd status of equal or higher Level, OR,
2. The herd of origin is a level 2 or 3 status Level with purchased additions having been ELISA tested with negative results within 30 days prior to entry into program herd, and
3. Fecal cultures have been collected from each animal added and submitted within 30 days of arrival, and

4. Herd additions are tested on the next herd test. The addition's status will remain at its entry level until they have tested negative at the next herd test.

d. Replacement animals raised off the premises must be raised with the proper biosecurity measures in place and raised with animals from equal status Level herds. Replacements raised on premises that do not have a herd biosecurity plan or with animals of lesser status Level should be treated as purchased animals.

e. Program herds may use semen and embryo from other cattle herds provided that semen used is processed according to Certified Semen Services standards and embryos are processed according to International Embryo Transfer Society protocols. Embryo transfer recipient cows must meet herd addition requirements.

6. Animal Identification;

a. All cattle in a Program herd must be permanently and individually identified using an identification method approved by the State Johne's Advisory Committee.

b. All animals in Level 4 herds or higher must be individually identified using a USDA approved official identification system..

7. Testing;

a. All samples collected for the program must be collected by an accredited veterinarian, or state or federal animal health veterinarian.

b. Vaccinated herds will be eligible after vaccination has been discontinued. All testing must be done by an organism detection test until enough non-vaccinated natural additions qualify for ELISA testing.

c. All samples must be submitted to a laboratory approved by the National Veterinary Services Laboratory.

d. Herd owners must test a minimum of 30 randomly selected animals of second lactation (three year old) or higher to remain in the status program. In herds with less than 30 second or higher lactation animals, first lactation animals (two year old) must also be tested. Random sampling should be used to select animals for testing when feasible. Herd owners should be encouraged to test statistical subsets or greater numbers of cattle when possible.

e. To advance from one status level to the next, herds must test a statistical subset outlined in Appendix I and meet the level requirements outlined in Appendix II.

f. The number of animal specified to be tested must be completed within 10 - 14 months of the last status Level testing.

g. Herds not adhering to testing protocol must be removed from the program unless a request for an extension has been received from the herd owner and approved by the designated Johne's epidemiologist.

8. Appealing a positive animal status;

a. When an animal has been found positive by an supplemental testing, any herd status should be classified as "suspended pending confirmation". Owners may elect to leave the program or confirm the test results.

1. Confirmation of an official supplemental test results must be accomplished by conducting an official Johne's disease test.

2. An official Johne's disease test (fecal culture) must be submitted within 45 days of notification of the supplemental test results.

3. If negative, the herd may retain its status Level or advance but that animal must be included in the next round of program testing if that animal is still in the herd.

b. When an animal has been found positive by an official test and the herd owner wishes to appeal the results, the herd status should be changed to "suspended pending appeal". The appeal process may be accomplished by:

1. The owner submitting a written statement to the state designated Johne's disease epidemiologist within 30 days of the positive results requesting an appeal, and

2. Conducting a necropsy of the animal with culture and histopathology of at least the ileum, mesenteric lymph node and ileocecal lymph node, or

3. Conducting a full thickness biopsy of the ileum and biopsy mesenteric or ileocecal lymph node with histopathology and culture of the tissues and culture of a fecal sample taken at the time of biopsy, or

4. Submitting six separate fecal cultures from the animal on samples collected not less than 30 days and not more than 45 days apart. All six cultures must be negative for the animal to be considered a test negative animal.

c. The herd Johne's disease status will be suspended until all testing is completed. Only negative results on all tests will allow the herd to advance or retain it's program level.

B. Handling Positive Cattle

1. Any positive animal that is moved interstate **MUST** be moved in accordance to 9 CFR parts 71 and 80 for interstate movement and in accordance to state regulations.

The following are recommendations for handling positive animals and herds with positive animals in them. When dealing with positive cattle, control measures should be developed to match the goals and resources of the herd owner.

2. Herds with positive animals should be encouraged to do a risk assessment of the herd and design a herd testing protocol that will help identify infected animals to manage the risk of spreading Johne's disease within the herd.
3. Herds with positive animals should be encouraged to develop a herd biosecurity plan with a certified veterinarian.
4. A herd with a positive animal should have husbandry and biosecurity measures in place in order to reduce exposure to manure or milk from susceptible species of unknown Johne's disease status. These measures should include but are not limited to:
 - a. Pooled milk from cows of infected Johne's disease status should not be used to feed baby calves.
 - b. Manure from Embryo Transfer donors or other "visiting" cows (e.g. Transport cows that lay over at program farms for rest or to be milked) should not be allowed to come into contact with the program herd and this manure should not be disposed of on pastures or in a manner which would contaminate pastures or animal feed.
 - c. Exhibition cows and calves (especially under 6 months old) should be hauled in cleaned and disinfected trailers and avoid commingling. (Animal exhibition, consignment sales and transport are considered situations of low *M. paratuberculosis* infection transmission risk. However, prudent care and diligence about biosecurity is recommended).
 - d. A program herd should not be commingled with or grazed behind susceptible species, (e.g. Sheep, goats, farmed deer, camelids, non-program cattle).
 - e. Feed and water handling to minimize exposure to manure.
 - f. Handling of young livestock to minimize exposure to infected animals or manure from older animals.
5. Herds developing biosecurity plans should include the milking herd and replacements. If other susceptible species are located on the premises, they should also be dealt with in the biosecurity plans.

6. Herds removing infected animals from the herd should be encouraged to purchase replacements from status program herd or require testing from the seller.
7. Replacements raised off the premises should be raised with the proper biosecurity measures in place.
8. All animals on the premise should individually identified. Preferably with a unique animal identification system.
9. Animals found positive by a fecal culture or other organism detection test should be removed from the herd by the end of her current lactation. If a calf is born to that animal, the herd owner should label the calf as a suspect animal for Johne's disease. Colostrum from the infected dam should not be used.
10. Animals not currently lactating (dry cows, bulls, heifers, etc.) should be removed as soon as possible.
11. Cattle positive for a fecal culture or other organism based detection test, when removed from the farm, should be sent directly to slaughter.
12. Positive animals should not be commingled with young livestock.
13. All diagnostic samples should be collected by an accredited veterinarian. It is preferred that the accredited veterinarian be a certified veterinarian who can help develop a herd biosecurity plan with the herd owner.

Part V Appendix

Appendix I. Herd Subset Sampling

Sample numbers in the table below have been based on the following assumptions:

The cattle to be tested are in second or higher lactation.

For these calculations, 25% test sensitivity of the ELISA and 40% test sensitivity of the fecal culture were assumed (this were the consensus estimates of the Herd Status Committee of the National Johne's Working Group, United States Animal Health Association for sub-clinically infected cows in first or higher lactation, and no changes were made for older populations sampled).

For these calculation, 100% test specificity of the ELISA and fecal culture was assumed (given follow-up of all ELISA positives with fecal culture)

The confidence of detecting infection (at least 1 test-positive cow), if present at a true prevalence of 2%, is 95%.

Sampling without replacement.

# cows in herd (2nd or higher lactation)	# cattle to sample (2nd or higher lactation)	
	<u>ELISA</u>	<u>Fecal culture</u>
<350	test all	test all
350 - 449	test all	313
450 - 549	test all	324
550 - 649	531	332
650 - 749	540	338
750 - 849	547	342
850 - 949	552	345
>= 950	580	360

In smaller herds, all cattle second or higher lactation must be tested. In herds with less than 30 second and higher lactation animals, first lactation animals must also be tested.

Appendix II. Program Levels for Status Program

Herd Status Levels - herds may achieve status Levels 1, 2, 3, or 4. Each level of increase indicates higher confidence in the Johne's disease free status of the herd. The Level achievement year should also be indicated. The Level achievement year is the year in which a herd met Program standards to be granted a specific status Level. For example, a herd completing Level 2 testing in 1998 which elects to remain at Level 2 would have Level 2 1998 status. The Level achievement year should be noted because continued monitoring increase confidence the herd is not infected.

Standard Track - the standard track is designed to allow entry to the program with a minimal investment of funds and gradually increases the producer's investment in the program. The standard track will require at least three years and four tests to reach Level 4. Additional testing requirements are included with the status levels(time of testing, number of testing, etc.) If an animal is removed from the herd while ELISA results are pending, a fecal culture should be collected and submitted to be held at the laboratory. This will allow, if the owner wishes, an appeal of herd status to be made if the animal test ELISA positive.

Level 1 - Herds have develop a herd biosecurity plan and had negative ELISA test results on 30 second or higher lactation animals. A sample size of thirty was selected to optimize herd sensitivity and herd specificity and maintain a fixed cost for all herds entering the program. Level 1 status is maintained by achieving negative ELISA results on 30 second or higher lactation animals every 10 - 14 months.

Level 2 - Herds have met the requirements for Level 1, and had negative ELISA on a statistical subset of second or higher lactation animals. A statistical subset that is negative by fecal culture will also qualify for advancement. Level 2 testing must be completed within 10-14 months of any Level 1 testing. Level 2 status is maintained by achieving negative ELISA results on 30 second or higher lactation animals every 10 - 14 months.

Level 3 - Herds have met the requirements for Level 2 and had negative fecal culture results on a statistical subset of second and higher lactation herd members. Bulls two years of age and older must be included in this testing. The fecal culture must be collected within 10 - 14 months of any Level 2 testing. Level 3 status is maintained by achieving negative ELISA results on 30 second or higher lactation animals every 10 - 14 months.

Level 4 - met the requirements for Level 3 and have a negative ELISA on a statistical subset of second or higher lactation animals. A statistical subset that is negative by fecal culture will also qualify for advancement. Level 4 testing must be completed within 10 - 14 months of any Level 3 testing. Level 4 status is maintained by achieving negative ELISA results on 30 second or higher lactation animals every 10 - 14 months.

Fast Track - the fast track allows producers to proceed to a higher status level of confidence more quickly than the standard track, and requires greater financial investment at

program entry. The fast track will allow herds to reach Level 4 in two years with three tests.

Level 1 - Skip this level if owner is able to make a declaration that no cows were seen or diagnosed with Johne's disease in past 5 years. The State may require the statement to be cosigned by the herd veterinarian. A signed statement must include:

- A. I am fully aware of the management and disease history of the herd and the past five years.
- B. Johne's disease is not known or suspected to have existed in the herd for the past five years or on the property during the past twelve months.
- C. Cattle are not known to have been introduced from known infected herds during the past five years.

Level 2 - met requirements for Level 1, and negative ELISA on a statistical subset of second or higher lactation animals. A statistical subset that is negative by fecal culture will also qualify for advancement. Level 2 testing must be completed within 10-14 months of any Level 1 testing. Level 2 status is maintained by achieving negative ELISA results on 30 second or higher lactation animals every 10 - 14 months.

Level 3 - met the requirements for Level 2 and have negative fecal culture results on 30 second or higher lactation cows and all bulls 2 years or older. The fecal culture must be collected within 10 -14 months of any Level 2 testing. Level 3 status is maintained by achieving negative ELISA results on 30 second or higher lactation animals every 10 - 14 months.

Level 4 - met the requirements for Level 3 and have a negative ELISA on a statistical subset of second or higher lactation animals. A statistical subset that is negative by fecal culture will also qualify for advancement. Level 4 testing must be completed within 10 - 14 months of any Level 3 testing. Level 4 status is maintained by achieving negative ELISA results on 30 second or higher lactation animals every 10 - 14 months.