# Veterinary Services New Regulatory Direction

**3/1/11**

## BACKGROUND

The Veterinary Services (VS) Office of the Chief Operating Officer is working with the VS Writing, Editing, and Regulatory Coordination (WERC) staff and VS program staff members to streamline the regulatory processes and documents that guide our work. This project includes several subprojects:

- Redesigning disease program regulations to make them more flexible
- Updating VS Memos and VS Notices, and posting them on the Internet
- Standardizing and consolidating terms and definitions used in VS regulations
- Placing lists online rather than in the *Code of Federal Regulations* (CFR)
- Consolidating disease program indemnity rules where possible

The goal of this project is to make the VS regulatory process faster and more flexible. Rules will be made performance-based to increase their flexibility—VS will do more with fewer rules. Specific guidelines for meeting CFR requirement will be contained in program standards, surveillance plans, and other policy documents. By keeping details out of the CFR, VS will be able to change its regulatory and policy documents quickly to incorporate new science and better address the continually evolving animal health and agriculture marketing landscape, rather than having to go through the current lengthy rulemaking process.

The project will also make rulemaking more transparent in accordance with the President's mandate for open government. VS will provide greater public access to materials containing our policies by using the Internet, which will make it easier for the public to see how VS accomplishes its work. VS will increase its engagement of stakeholders in helping to write, review, and amend its rules. The idea is that more public engagement will result in better rulemaking.

Regulatory streamlining is also an important part of the VS 2015 initiative. VS 2015 is about helping VS remain relevant and effective. VS must make good choices regarding how it uses the talent and expertise of its employees to adapt to the changing animal health landscape. The VS 2015 initiative emphasizes flexibility by focusing on disease prevention, preparedness, detection, and early response activities. It also emphasizes transparency by increasing the importance of working with VS' State, industry, and academic partners to evolve guidance for our work. The streamlining project supports this effort by bringing our State, industry, and academic partners into the rulemaking process to develop flexible science-based rules. Such rules will allow VS to focus the talent and expertise of its employees on performance standards that address disease prevention, detection, and response.

A key concern in the streamlining process is regulatory authority. VS must ensure it has the authority to make the necessary program changes to carry out the 2015 vision as well as other changes anticipated in VS programs (such as traceability, bovine TB, and bovine brucellosis). The VS streamlining initiatives will help ensure that the program and regulatory changes carry out the 2015 vision with the necessary regulatory authority.

## CURRENT INITIATIVES

VS is revising several of its programs using a flexible, performance-based, inclusive approach. Regulations associated with these programs are being or will be prepared.

### Traceability

Secretary Vilsack's February 5, 2010, announcement on traceability set a new course for the Department's approach to animal disease traceability that will strengthen VS' ability to successfully respond to animal diseases. VS is drafting a rule implementing a flexible, yet coordinated, approach that embraces the strengths and expertise of States, Tribes, and producers, empowering those entities to find and use the animal disease traceability approaches that work best for them, with support and oversight from VS.

The proposed traceability rule represents VS' first attempt to draft a rule incorporating that kind of flexibility. The rule highlights regulatory goals rather than specifying the ways in which States and Tribes are to achieve those goals, and is being prepared with substantial stakeholder input. In 2010, VS convened a State, Tribal, and Federal Traceability Regulation Working Group to recommend the content of the proposed rule and to establish a process that supports the Secretary's direction to develop a performance-based regulation that is not overly prescriptive. This agriculturally diverse working group prepared a framework and performance standards that include performance measures, timeframes, and consequences for noncompliance. APHIS regulatory staff is preparing the proposed rule. The proposed rule should be published by the third quarter of fiscal year 2011 and the final rule 15 months later.

The traceability rule will ultimately require that:

- Animals moving interstate be officially identified, either with individual identification or group/lot identification, unless otherwise exempt
- All livestock moved interstate be accompanied by an interstate certificate of veterinary inspection, a movement permit, or similar documentation, unless otherwise exempt.

The performance standards supporting the rule are based on actions that animal health officials would take to respond to a disease event. The standards set time parameters for completing such actions. For example, in a disease investigation, animal health officials in the shipping State would need to be able to pinpoint the location from which infected or exposed animals were shipped within a certain timeframe and within a certain percent of the time. These performance standards would apply only to animals that moved interstate.

The cattle sector is a priority in the performance standards because few cattle are identified and traceable. To meet the needs of animal health officials and the cattle industry, VS is considering phasing in the requirements for cattle. Upon the effective date of the rule, dairy, adult breeding, rodeo, and show cattle must be identified when moving interstate. The second phase would be an assessment and consideration of identified performance indicators. Full implementation will include feeder cattle and begin after the performance indicators in the assessment phase are achieved.

**Ruminant Health Programs – Bovine Tuberculosis and Brucellosis**

VS is also emphasizing rulemaking transparency in developing bovine tuberculosis (TB) and bovine brucellosis rules. A combined rule for both programs is being considered as one option. Development of these rules began with soliciting public input through concept papers and listening sessions. The programs have implemented a Federal Order (TB) and an interim rule (brucellosis) to make more immediate regulatory changes.

VS has convened a working group for the rules based on the traceability working group; similarly, it includes State, Tribal, and VS members. This working group's progress will be made widely available to maximize public input for the proposed rules. The TB and brucellosis rules will also be drafted in conjunction with policy and guidance documents, much as the traceability rule. The working group recently outlined key elements for the framework and is working to develop performance standards for those elements.

*Bovine Tuberculosis (TB)*

The goal of the TB program has been to eradicate *Mycobacterium bovis,* the infectious agent that causes TB, from domestic livestock in the United States. The program targets disease control in domestic cattle, bison, and farmed cervids (such as deer and elk) herds. It also mitigates TB transmission among wildlife species (particularly free-ranging white-tailed deer) and between wildlife species and domestic livestock.

In late 2008, VS discontinued revisions of the bovine TB regulations to reevaluate the program, gather input from stakeholders, and develop a new approach for eradicating TB. VS began soliciting public comment on proposed new directions for the TB program through a series of public listening sessions. TB staff based a concept paper for the program, published in the *Federal Register* in October 2009, directly on input from those public meetings. The objectives of the concept paper included:

- Mitigating the introduction of TB into the U.S. national herd from imported animals and wildlife
- Enhancing TB surveillance
- Increasing options for managing TB-affected animals and herds
- Modernizing the regulatory framework to allow VS to focus resources where the disease exists
- Transitioning the TB program from a State classification system to a science-based zoning approach

After reviewing the results of the listening sessions and the comments received on the concept paper, VS determined that the current bovine TB eradication program needed to be updated to match current animal health and producer needs as reflected in the concept paper objectives. VS is working on those changes with the joint TB-brucellosis working group.

*Bovine Brucellosis*

A bovine brucellosis concept paper, published in the *Federal Register* in October 2009, proposed a new direction for the bovine brucellosis program, identified challenges in the current program, and provided an action plan to address these challenges. The action plan proposed in the concept paper included five main components:

- Demonstrating the disease-free status of the United States
- Mitigating disease transmission from wildlife
- Enhancing disease response and control measures
- Modernizing the regulatory framework
- Implementing a risk-based disease management area concept

Public input for changes to the bovine brucellosis program has also been sought through stakeholder meetings. VS staff is working with the TB-Brucellosis Working Group to modernize the regulatory framework.

**Streamlining**

The VS regulatory streamlining project has three phases. The first phase involves reviewing and updating the entire library of VS Memos and Notices, and posting the documents to an internal and to a public Web site. The second phase involves streamlining the VS portion of the CFR. This will be done by moving many of the lists and other appropriate information in 9 CFR to the Internet and amending and condensing the terms and definitions in Title 9. Finally, in the third phase VS management will determine what type of regulatory tools (i.e., VS Memos and Notices, or directives such as program standards) VS will use in carrying out its regulatory mission.

*VS Memos and Notices*

The Memos and Notices phase of the streamlining initiative is well underway. The WERC staff worked with VS information technology staff to create a VS Memos and Notices SharePoint site to post revised documents. Members of the WERC staff began working with VS staff officers in May 2010 to review and update our library of memos and notices to post to the site. So far about 10 percent of the memos and notices have been updated or archived. The WERC staff plans to have all memos updated and posted by the end of 2011.

The SharePoint site is populated with current, archived, and in-review memos and notices:

- *Current* means:
  - The document has been reviewed and the information it contains is still valid.
  - If the document is a memorandum, it has not reached its 3-year review cycle.
  - If the document is a notice, it has not reached its 1-year review cycle.
- *In-Review* means:
  - The document is new or needs to be updated based on changes to 9 CFR. The document remains valid until it has been reviewed, updated, or archived.
  - If the document is a memorandum, it is reaching its 3-year review cycle.
  - If the document is a notice, it is reaching its 1-year review cycle.

- *Archived* means:
  - The document has been rescinded.
  - The document has been superseded.

The memos and notices are being scrutinized by VS program staff officers and WERC staff members not only for out-of-date language and obsolete practices, but also to ensure that they conform to the appropriate portions of the CFR. VS staff will thus find the memos and notices more useful.

Memos and notices will also be made available to the public through the Animal Health Web page. WERC plans to post all VS memos and notices to the Animal Health Web page by April 2011. The documents are being made available to the public to carry out the Administration's commitment to transparency. The public has had little access to VS memos and notices. Being able to read and review the documents will help them understand VS' interpretations of its policies and better prepare them to work with VS in developing new policies to carry out the VS mission.

The memos and notices project will also help streamline 9 CFR. As program and WERC staff members update and eliminate outdated VS memos, associated material that is no longer needed can be removed from 9 CFR, thus increasing efficiency. A newly developed clearance process is making new VS memos and notices available more quickly to provide needed direction to VS staff members.

*Changes to 9 CFR*

The second phase of the regulatory streamlining project, which involves direct changes to 9 CFR, has four subphases:

- Removing lists from 9 CFR and posting them to the Internet
- Standardizing and consolidating the terms and definitions in 9 CFR
- Consolidating all rules dealing with payment of indemnity into a single section
- Examining the remaining 9 CFR content to see what additional material can be extracted and posted online

WERC staff members have been examining streamlining projects at other Federal agencies (such as the Food and Drug Administration, the Environmental Protection Agency, and the Nuclear Regulatory Commission) for guidance.

**Lists in 9 CFR**

The first part of the second phase of the regulatory streamlining project involves consolidating and moving lists from 9 CFR to the Internet.

Currently, 9 CFR contains many lists, such as lists of States and foreign regions that are classified with respect to specific animal diseases, lists of approved tests and treatments, and lists of approved ports of embarkation. Each time VS adds or removes a test or treatment, or classifies or reclassifies a State or a region, the change can only be made through the current rulemaking process. The length of the regulatory process often means the CFR is a step behind the current

science or situation on the ground. To help remedy this, the WERC staff is working with program staff to move such lists out of the regulations to facilitate timely updating as the circumstances warrant.

Under this initiative, VS regulations will specify the criteria for listing or delisting, and the lists themselves will be maintained on the Animal Health Web page. A spreadsheet of all the lists that can be consolidated has been developed, and a workplan specifying the criteria and procedures for listing or delisting should be prepared by April 2011. In the future, when VS needs to add or remove an item from a list, it will notify the public of the action through a notice published in the *Federal Register* and request comment. This notice-based process for amending the lists ensures that the public has an opportunity to participate in the decision.

At least two proposed rules for removing lists from the CFR have already been created, and more are in development. One proposed rule removes certain lists of affected and free regions from 9 CFR Parts 93, 94, and 98. This proposal is with the Deputy Under Secretary for review. The other proposed rule concerns the removal of lists of ports of embarkation and export inspection facilities from the regulations. This proposal has been published in the *Federal Register* and is being converted to a final rule.

Proposals are also being developed for comprehensive rewrites of the swine- and cattle-related (principally the TB and brucellosis initiative referenced earlier) domestic program regulations. The rewrites will include removal of the lists of States and their respective statuses.

**Terms and Definitions in 9 CFR**

Standardizing and consolidating the terms and definitions in 9 CFR is another priority. Terms will be standardized to have only one definition for each term, or as few as possible. All terms and definitions for each subchapter will be consolidated into a specific section of that subchapter that precedes the other parts of the subchapter.

Under this plan, a standard definitions section will be placed as the first part of the subchapter. Terms and definitions listed in this section will apply to the whole subchapter. If there is a word that applies to only a single part in the subchapter, the term and definition will be placed in that part's definition section. If a term or definition applies to multiple parts of the subchapter, the term or definition will be placed in the subchapter's initial definition section.

Standardization of terms is sorely needed. For example, 9 CFR defines the term *administrator* 10 different ways and in 39 separate locations. Terms and definitions alone comprise about 140 pages of material in 9 CFR and are in every section. This plan should cut the number of pages devoted to terms and definitions nearly in half.

WERC staff members have been working on this project for several months and have posted several documents to a SharePoint site for internal review:

- A spreadsheet listing every term and definition currently published or pending publication in 9 CFR. The spreadsheet includes definitions collected from the work in progress for pending proposed and interim rules that will change or add definitions, such as the traceability rule,

the viral hemorrhagic septicemia rule, the chronic wasting disease rule, and the comprehensive bovine spongiform encephalopathy rule.
- Suggestions for decreasing the number of common terms with multiple definitions (those definitions that appear multiple times throughout 9 CFR)
- A workplan for the entire project
- An internal (VS) memo redesigning the way terms and definitions will be drafted and published in future rules

The WERC staff has organized a working group with representation from all subunits of VS to review the workplan and definition proposals, and help develop the proposed rule to consolidate the definitions sections of 9 CFR.

The WERC staff is working with the Terms and Definitions Working Group on a new clearance process that will provide needed direction to VS staff members on how to add, update, or remove a term or definition to or from 9 CFR. The clearance process will help keep the definition sections of the CFR consistent.

**Consolidation of Indemnity Rules**

In the third section of the second phase of the changes to 9 CFR, VS plans to consolidate all of the rules regarding payment of indemnity into a single section of 9 CFR. WERC staff members are identifying and compiling these rules and will be evaluating possible consolidation methods. A workplan is expected to be drafted by April 2011, and a working group with representation from all subunits of VS will be convened shortly thereafter.

**Remaining Content of 9 CFR**

The third phase of the regulatory streamlining project will involve examining the remaining content of 9 CFR to see what additional material can be extracted and posted to the Internet. For example, WERC plans to consolidate and centralize all CFR information on the use of VS seals. WERC anticipates preparing a workplan for this project by May 2011. WERC staff will work with the National Animal and Health Policy and Programs' program staff to centralize all VS seal references and directives into one, new CFR section, coordinating with program staff and Regulatory Analysis and Development staff to determine the most streamlined approach for structuring this new section. Prescriptive details (such as approved VS seals, methods for application, and other directives) that need not be included in the CFR can be placed into a separate guidance document.

WERC staff members also anticipate reviewing VS' current guidance documents (memos, notices, and other directives) to determine what type of guidance document will be most appropriate to direct future VS work. This project is expected to start in the spring of 2011 and continue into 2012.

**Regulatory Streamlining Goals**

Streamlining will bring transparency and flexibility to the regulatory process by using VS infrastructure, such as performance documents and Web-based lists, to support the goals set forth in the CFR. The goal of streamlining is for VS to do its work faster and more efficiently.