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Inside

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What Does It Take To Create a Regulation?

By Jane Johnson, DVM, and Kazuhiro Okumura, LTJG, USPHS

As you know, the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) issues regulations that apply to the products that you produce. You may hear through the grapevine that a regulation has been proposed or is being created, but it may be quite a while before it becomes official and you actually see it in print. That's because there are multiple steps required in issuing or changing a regulation, many of which are required by law. Let's review the process for creating a regulation.

First, when it comes to the Federal Government's regulatory drafting process, the terms "regulation" and "rule" are usually considered interchangeable. This means that when you read or hear about a proposed rule, you are reading or hearing about a proposed regulation. The term "rule" will be used throughout the rest of this article.

The start of a rule can be almost anything that triggers a need. Some common beginnings are new legislation passed in Congress, petitions submitted by citizens, economic or social needs, or an emergency situation, such as a disease outbreak.

After the need for a rule is identified, FSIS' Office of Program and Policy Development (OPPD) forms a docket team. A call memo, which is basically a request for participants, is sent to supervisors in OPPD, as well as Assistant Administrators in other FSIS program areas. Staff members who have significant or direct involvement with the subject of the new rule are assigned by their supervisors to participate on the docket team.

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Depending on the need identified, the docket team begins by drafting an advance notice of proposed rulemaking (ANPR); a notice of proposed rulemaking (NPRM), also known as a proposed rule; or an interim final rule. The ANPR is used when the agency needs additional input from the public before it can develop a proposed rule. An NPRM, as the name implies, is used to notify the public that the agency is considering changing or creating a regulation. The interim final rule is the actual regulation that will become effective on the specified date. It is used in situations where the agency has good cause to skip the NPRM (proposed rule) stage, but still wants to invite some comment from the public.

The initial draft often reflects the input of various subject matter experts. These experts make sure that any available supporting data is included.

The docket team must ensure that all of the proper paperwork is completed, all paperwork includes the required components, all of the appropriate analyses have been completed and are included, and the draft document is reviewed and cleared by all appropriate FSIS managers and any additional subject matter experts deemed necessary to guarantee all of the information provided is accurate and understandable.

The draft rule then has to be reviewed and approved by the FSIS Administrator and then USDA, including the USDA Office of the General Counsel before review and approval outside USDA by the Office of Management and Budget.

After an ANPR, proposed rule, or an interim-final rule has been developed, it is made available for public comment. This is accomplished by publishing it in the *Federal Register*, which is published on a daily basis. It provides official notification of agencies' proposed rulemaking, final rulemaking, public meetings, and other type of actions that require public notification. The *Federal Register* can be accessed on the Internet at *www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR*.

Anyone may submit comments by using the Federal eRulemaking Portal at *www.regulations.gov*, mail, fax, or hand delivery to the agency (the address and fax number are provided with the information published in the *Federal Register*). The typical comment period for most proposed rules is 60 days. However, comment periods may be as short as 30 days, as long as 120 days, and may even be extended beyond the initial comment period if the agency deems it necessary.

After the comment period closes, the docket team will analyze and carefully consider all comments received. For most rules, FSIS will not hold public meetings. However, for certain proposed rules, the agency will decide to hold meetings, which can lengthen the comment period. The docket team will address all issues raised by the comments in the final rule and may include revisions based on the comments received. After the final rule is complete, it is made available to the public. In most instances, a rule does not become effective until at least 30 days after publication.

So there you have it. All of these steps are necessary to make sure the rule accomplishes its objectives and can be applied fairly.

To receive email alerts when new FSIS *Federal Register* publications are issued, sign up at *www.fsis.usda.gov/regulations_&_policies/federal_register_publications_&_related_documents/index.asp*. For policy-related questions, contact FSIS' Policy Development Division at (800) 233-3935 (6:00 a.m.-5:00 p.m. CT, Monday through Friday, except on Federal holidays) or *http://askfsis.custhelp.com* (any time).

FSIS Proposes To Change Procedures for Tested Products

By Jane Johnson, DVM

FSIS inspection program personnel periodically take samples of products to check for adulterants and verify your plant's compliance with the regulations. In *Small Plant News*, Vol. 3, No. 4, we included an article titled "Make 'Test and Hold' an Integral Part of Your Operation," where we explained the benefits of holding your product and not releasing it into commerce until test results are received.

Although FSIS has recommended and requested that you adopt a "test and hold" strategy, the agency has never made it mandatory. On April 11, 2011, FSIS published a Notice of Proposed Rulemaking (NPRM) in the *Federal Register* regarding "its intention to change its procedures and withhold a determination as to whether meat and poultry products are not adulterated, and thus eligible to enter commerce, until all test results that bear on the determination have been received."

This means that any product that has been tested by FSIS must be held until the testing results are known. FSIS inspection program personnel will **not** apply the mark of inspection to product represented by the samples until after the results of product testing have been received. You'll still be allowed to package and label products that are normally packaged and labeled with the printed mark of inspection as part of the production process, but the products won't be allowed to enter into commerce.

This change in procedure should help to substantially reduce serious (Class I or Class II) recalls for meat and poultry products, which will benefit both consumers and you. Consumers will benefit through a reduction in foodborne illness that may result from eating potentially adulterated product. You will benefit from the cost savings attributed to avoiding recalls and the temporary loss in sales that often follows a Class I or Class II recall.

You can read the NPRM, Docket Number FSIS-2005-0044, "Not Applying the Mark of Inspection Pending Certain Test Results," on the Agency's Web site at *www.fsis.usda.gov/OPPDE/rdad/FRPubs/2005-0044.htm.* The comment period ended on July 11, 2011.

Commonly Asked Questions & Answers

Q. *If "retraining employees" is the proposed preventive measure for meeting the corrective action requirement, is a plant required to document the specific retraining event when it occurs?*

A. If the establishment's preventive measure is that the employee "will be retrained," documentation that retraining occurred is required to demonstrate that the training was performed to meet the requirement of 9 *Code of Federal Regulations* (CFR) 416.15(b) and 9 CFR 416.16(a).

Q. *For single-ingredient products or products for which there is a standard of identity and bear Halal, Zabiha Halal, or Kosher on the label, can I take advantage of the generically approved label system or do I need to submit them for a sketch approval?*

A. Yes, in accordance with the generically approved labeling regulations (9 CFR 317.5 and 381.133), you may take advantage of the generically approved labeling system for labels bearing Halal, Zabiha Halal, or Kosher, provided there are no special claims, guarantees, or foreign language (including Arabic script or Hebrew script) on the label.

Q. *Do I need to submit a label for a Halal, Zabiha Halal, or Kosher product that bears a foreign language for sketch approval?*

A. Yes. When any foreign language (such as Arabic or Hebrew) is on a label, sketch approval is required and direct translation of all foreign language must be included on the application. Additionally, when the label states that the food has been "certified" Halal, Zabiha Halal, or Kosher, the name of the organization doing the certification also needs to appear on the label, and "certified" acts as a special claim that requires sketch approval. The label application needs to include documentation that demonstrates that the certifying organization's standards are met. For example, Company AZ submits a label for a Halal product labeled as "IFANCA Certified." FSIS would require Company AZ to submit confirmation from the Islamic Food and Nutrition Council of America (IFANCA) that Company AZ's product meets the IFANCA requirements for certification.