December 7, 2001

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
Room 102
300 12th Street, SW
Washington, D.C. 20250-3700

Re: FSIS's Notice and Request for Comment on its intention to harmonize its procedures with those of the FDA with respect to the target tissue/marker residue policy in testing animal tissues for residues of new animal drugs (Date Issued: August 6, 2001).

Dear Sir/Madam:

The Office of the Chief Counsel for Advocacy of the U.S. Small Business Administration was created in 1976 to represent the views and interests of small businesses in Federal policy making activities.[1] The Chief Counsel participates in rulemakings and other agency actions when he/she deems it necessary to ensure proper representation of small business interests. In addition to these responsibilities, the Chief Counsel monitors agencies' compliance with the Regulatory Flexibility Act (RFA), and works with Federal agencies to ensure that their rulemakings demonstrate an analysis of the impacts that their decisions will have on small businesses.[2]

On August 6, 2001, the Food Safety and Inspection Service (FSIS) issued a notice and request for comment on its intention to harmonize its procedures with those of the Food and Drug Administration (FDA) with respect to the target tissue/marker residue policy in testing animal tissues for residues of new animal drugs.[3] This comment letter is meant to inform FSIS of Advocacy's position on the agency's intended action.

[1] Pub. L. No. 94-305 (1976)(codified as amended at 15 U.S.C. §§ 634a-g, 637).
[2] Pub. L. No. 96-354, 94 Stat. 1164 (1981) (to be codified as amended at 5 U.S.C. §§ 601-612).
[3] 66 Fed. Reg. 40964 (August 6, 2001).

Executive Summary

1. FSIS characterizes the new protocols contained in the notice as being a "change in procedure." Advocacy disagrees. FSIS's action is not a change in procedure, but rather, it is a legislative rulemaking that affects the substantive rights of those entities that must comply with the new protocols. As such, FSIS's action is subject to the Administrative Procedure Act (APA)[4] and it must be published in the *Federal Register* and submitted for public notice and comment.

2. Because the action is subject to the APA, FSIS must comply with the statutory provisions of the RFA. Pursuant to the RFA, FSIS must certify and provide a factual basis that the procedure will not have a significant impact on a substantial number of small entities, or it must prepare an Initial Regulatory Flexibility Analysis (IRFA).

3. Based on Advocacy's calculations, the notice also has the potential to be economically significant under Executive Order (E.O.) 12866; thereby requiring FSIS to prepare a Regulatory Impact Analysis (RIA) and tailor it to size of business.[5]

4. Based on the above reasoning, Advocacy believes that the FSIS should immediately suspend its August 6, 2001, notice and republish it as a proposed rule for notice and comment.

Background

In the notice, FSIS concluded that its prior approach regarding the disposition of carcasses containing residues was not consistent with the FDA's approach. As such, FSIS intends to modify its approach to testing and disposition of carcasses for violative chemical residues so as to be more consistent with FDA's target tissue/marker residue policy. In the notice and request for comment FSIS characterizes the modification as a "procedural change."[6] Under the new procedure, for those new animal drugs for which the FDA has established a marker residue tolerance in a specified target tissue without establishing a tolerance for a residue in muscle residues, FSIS will only test the target tissue that is identified in FDA regulations. If the residues found in the target tissue exceed FDA tolerances, FSIS will condemn the entire carcass. Prior to the intended "procedural change," FSIS condemned only the organ with a violative residue level. FSIS then conducted a laboratory analysis of the muscle tissue to determine whether the muscle portion of the carcass could be salvaged. If no drug residue was detected in the muscle, FSIS released the muscle portion of the carcass for human consumption.

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[4] 5 U.S.C. § 553.
[5] E.O. 12866 § 1(b)(11).
[6] Id. at 40964.

In 1967, the FDA changed its method for establishing tolerance levels for new animal drugs and instituted a marker residue policy. After thirty-five years FSIS now wishes to conform its procedures to those of the FDA. According to industry experts, FSIS' new procedure will have a significant detrimental economic effect on the meat, poultry, milk and other associated industries forcing persons affected by the rule to destroy needlessly entire animal carcasses, portions of which had previously been deemed acceptable by the FSIS. FSIS admitted in the notice that the proposed changes will "affect the industry." Many of the affected businesses are expected to be small entities, explaining Advocacy's interest in the FSIS notice.

Based on its authority under the RFA, this comment letter is meant to inform FSIS of Advocacy's position on the agency's intended action. In short, Advocacy requests that FSIS reconsider the need for promulgation of this rule for the following reasons: (1) Although couched as a "change in procedure," FSIS' rule will affect the substantive rights and obligations of a large number of the regulated entities and is therefore subject to the notice and comment requirements of the APA; (2) The rule will place an unacceptable economic burden on the affected industries, including, but not limited to, increased carcass rejection and increased Hazard Analysis Critical Control Point (HACCP) costs; (3) FSIS has failed to provide adequate scientific evidence and cost analysis in support of its claim that the rule will improve public health. Pursuant to the aforementioned reasons and the anticipated economic burden on affected industries, Advocacy questions whether FSIS's intended action is warranted if the goal is simply to make its testing procedures more consistent with FDA's target tissue/marker residue policy. As there are already numerous regulations governing the testing of meat products, FSIS should be especially sensitive to the cumulative effects of additional regulations such as the one propose here.

The FSIS must comply with the APA in its effort to harmonize its procedures with the FDA.

FSIS's intention to change its procedures for testing for violative chemical residues is a change in agency policy. A number of court decisions make it perfectly clear that agencies may not bypass notice and comment merely by labeling a significant policy change as a policy clarification.[7] The court must look to such factors as the real effect of the rule, the source authority for its promulgation, and the force and effect which attach to the rule itself.[8]

In Brown Express, Inc. v. U.S., the Notice of Elimination issued by the Interstate Commerce Commission (ICC) was deemed not to fall within any of the notice and comment exemptions of the APA.[9] The ICC issued a Notice of Elimination stating that it was no longer necessary to notify competing carriers when another motor carrier filed an application of an Emergency

[7] Nat'l Motor Freight Traffic Ass'n v. United States, 268 F.Supp. 90, 95-97 (D.D.C. 1967), *aff'd,* 393 U.S. 18 (1968).
[8] Id.
[9] 607 F.2d 695 (5th Cir. 1979).

Temporary Authority (ETA). The ICC determined that notice and comment was not required because, among other things, the change only constituted a general statement of agency policy and the change would have little substantive or adverse effect on interested parties.

The court in Brown stated that the Notice of Elimination was not a simple clarification of a pre-existing policy, "Rather, it effects a change in the method used by the Commission in granting substantive rights. As such, it is a new rule . . ." [10] The court also explained that the change was not a general statement of Commission policy because such statements only "[announce] motivating factors the agency will consider, or tentative goals toward which it will aim, in determining the resolution of a substantive question of regulation . . . An announcement stating a change in the method by which an agency will grant substantive rights is not a 'general statement of policy." [11] The Fifth Circuit made the additional point that, "[w]hether something is substantive or procedural hinges on the policies underlying the act to which they relate. . . [and whether the rules] depart from existing practice . . . " [12]

The rationale discussed in Brown, was more recently adopted by the United States Court of Appeals for the District of Columbia Circuit in Community Nutritional Institute v. Frank Young, the Commissioner, Food and Drug Administration [13] A consortium of organizations brought suit against the FDA alleging, *inter alia*, that when the FDA sought to regulate certain unavoidable contaminants in food (particularly aflatoxins in corn) through the use of action levels, it violated the APA because the regulation constituted a legislative rulemaking issued without the requisite notice and comment procedures.[14] In an effort to determine whether the FDA's actions amounted to a legislative action as opposed to an interpretive rule or policy statement, the court looked to two criteria established in American Bus Ass'n v. United States. [15] The two criteria were: (1) If the pronouncement acts prospectively, it is a binding norm ("a statement of policy may not have a present effect, e.g. impose any rights and obligations); and (2) Whether the purported policy statement genuinely leaves the agency and its decisionmakers free to exercise discretion.[16] Based on the application of the American criteria, the court in Community held that the FDA's action levels amounted to legislative rules and were subject to the APA. The court reasoned that "by defining the acceptable level and prohibiting substances," the FDA was clearly reflecting a binding norm. The court also found that the FDA "by virtue of its own conduct has

[10] Id. at 700.
[11] Id. at 701.
[12] Id. at 701-702.
[13] 818 F.2d 943 (D.C. Cir. 1987).
[14] The FDA established action levels informing food producers of allowable levels of unavoidable contaminants such as aflatoxins. Producers that sold products that were contaminated above the action level were subject to enforcement proceedings by the FDA.
[15] 627 F.2d 525 (D.C. Cir. 1980).
[16] Id. at 529.

chosen to limit its discretion and promulgate action levels which it gives a present, binding effect." [17]

The fundamental purpose of notice and comment and informal rulemaking is to allow an agency to gather valuable information from the public and other interested parties regarding the potential impact of the agency's regulatory decisions and actions.[18] Without public input, an agency runs the risk of causing unanticipated economic harm to affected entities—particularly small entities. Without informal rulemaking, the agency removes itself from the requirements of the Regulatory Flexibility Act and other laws designed to encourage agencies to consider the impact of their regulations on small entities. Advocacy is particularly concerned that the actions taken by FSIS will result in an outcome that is repugnant to the legislative intent behind the APA and the RFA. FSIS's "procedural change" has the present effect of departing from existing practice, imposing additional rights and obligations on affected industries and it serves to limit FSIS's inspectors' discretion. If the target tissue tested exceeds FDA tolerances, FSIS will condemn the entire carcass.[19] The impact of the notice will be to require affected industries to comply with **new** residue testing procedures based on **new** target tissue values established by FSIS's sister agency, the FDA. All of these points cut directly against the grain of the court holdings cited in the legal precedent identified above.

This action is clearly legislative in nature and therefore falls under the provisions of the APA. Since the APA applies, FSIS must comply with the provisions of the RFA. Advocacy maintains that the FSIS needs to issue a proposed rulemaking and address several important questions including, but not limited to, the following: What percentage of the industry will be impacted by the policy change? What percentage of those impacted are small businesses? What alternatives exist that are less burdensome? What are the costs and benefits of the proposed change? Is this policy change necessary? Does the scientific evidence warrant such an administrative action? How successful/useful is the current process for testing marker residue, and should it be expanded?

These and other significant questions may never be answered without the benefit of notice and comment rulemaking.

Based on industry comments, any change in chemical residue testing will place significant additional economic burdens on affected industry.

A. FSIS failed to comply with the RFA and thus the small business impacts are disproportionate and unnecessary.

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[17] Community, 818 F.2d at 950.
[18] S. Doc. No. 248, 79th Cong. , 2d Sess. 244 (1946), quoting H.R. Rep. No. 1149, 76th Cong. , 1st Sess. 2 (1939).
[19] 66 Fed. Reg 40964, 40965 (August 6, 2001).

In light of the forgoing legal analysis, Advocacy believes that FSIS's notice is subject to the APA. Therefore, this proposal is subject to the RFA. Under the RFA, Advocacy is charged with monitoring agency compliance with its provisions.

Whenever the RFA applies, a Federal agency must either prepare an initial regulatory flexibility analysis (IRFA) or certify (with a factual basis) that the proposed rule will not have a "significant economic impact on a substantial number of small entities." Since Advocacy has demonstrated that FSIS's notice is subject to the APA, the agency clearly violated the RFA when it failed to prepare an IRFA, or certify that the rulemaking would not have a significant impact on a substantial number of small entities.

Congress established the RFA because Federal agencies tend to promulgate "one-size-fits-all" regulations without considering the adverse consequences for competition, innovation, and productivity. By requiring that each agency review its regulations to ensure that small businesses are not disproportionately or unnecessarily burdened, Congress intended to increase agency awareness and understanding of the impact of regulations on small business, to require that agencies communicate and explain their findings to the public, and to provide regulatory relief to small entities where appropriate. Advocacy believes that the FSIS notice is a textbook example of the situation Congress intended to address when creating the RFA.

An RFA analysis may have revealed that FSIS's notice is unnecessary. Without this regulation, the old procedures would remain in effect and portions of the animal that were not safe would not be released for public consumption. With this regulation, portions of the animal that were not safe would still not be released. The level of protection afforded for public health remains the same. What changes under the new procedure is that meat that is perfectly safe would be discarded at significant cost to industry. FSIS failed to prove that by harmonizing its procedures with those of the FDA, public health would be substantially improved.

Further, an RFA analysis may have shown that the small business impact is disproportionate. While the large business for which we have information would incur a cost of only $100 per employee, a typical small business is one that kills 50,000 head a year or 200 per day (50,000/250 slaughter days a year (excludes weekends)), would incur a cost of $860.[20][21,22,23]

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[20] SBA size standard regulations state that a small meat packing entity would have less than 500 employees. (13 CFR 121.201) Please note that Advocacy is not redefining small business for rulemaking purposes in this case, but is only doing so for the sake of analysis and illustration.

[21] Advocacy believes that it is conservative to assume for IRFA purposes that a beef operation which kills 50,000 head per year is equivalent to a small business. If the number of employees per slaughter remains constant over size of business, a beef operation that kills 225,000 head (450,000x500/1,000) would fall under SBA's definition of small business for this industry (500 employees or fewer). However, Advocacy recognizes that there are economies of scale in this industry and thus uses a much smaller number (50,000) for illustrative purposes.

[22] The large business requires 1,000 employees to kill 450,000 head of cattle per year or an average of .002 employees per slaughter (1,000/450,000). Due to residue testing, this business loses 65-70 whole carcasses per year

Therefore, Advocacy recommends that FSIS prepare an IRFA that discloses information on the small business impact and also considers alternatives. FSIS may certify the proposal, in lieu of preparing an IRFA, if the proposed rule is not expected to have a significant economic impact on a substantial number of small entities, but the FSIS must provide a factual basis for the decision to certify. [24]

Advocacy is providing this information for illustrative purposes. Advocacy acknowledges that FSIS is in a better position to obtain more refined information because it has the resources and expertise in this matter. Ultimately though, the burden is on FSIS to show that the rule is necessary and does not fall disproportionately on small business. Advocacy has great confidence that FSIS will do so.

B. FSIS failed to comply with E.O. 12866 by failing to tailor the requirements of the notice to the size of business.

Advocacy also believes that FSIS did not comply with Executive Order (E.O.) 12866. While Advocacy does not have the authority to monitor compliance with E.O. 12866, Advocacy is concerned that FSIS did not comply with it because, as with the RFA, FSIS failed to tailor the regulation to small businesses.[25]

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and estimates that if the new policy is implemented, it will lose another 200 carcasses annually for an estimated loss of between $500 and $600 per carcass. That is a five fold increase! Hence, the total annual cost of this regulation for this business would be $100,000 (200 x $500) or $100 per employee (100,000/1,000). This large business already spends $750,000 a year for the additional testing; thus, this business would not incur an additional cost for testing under this rule.

[23] To estimate the small business impact, Advocacy developed an estimate of the number of employees and the compliance costs, based on information on a large business (see footnote 3). To maintain its 450,000-head operation, this business requires 1,000 employees or .002 employees per slaughter (1,000/450,000). Therefore, one that kills 50,000 head annually would have 100 employees (.002 x 50,000).

To estimate the cost, Advocacy used information from the company described above. That company is expected to lose an additional 200 carcasses or .044% of its total production under this rule. We assume this will not change for small business because it is clear from the Agency's notice that the FSIS intends for every slaughtering facility to use the same test procedures that the business described above is already using. Indeed, on a percentage basis, a small business may lose more carcasses than a large business because smaller facilities in this industry tend to buy lesser quality cattle than the large facilities. Therefore, this small business, which kills 50,000 head per year, would be expected to lose an additional 22 head annually (.044% of 50,000) under this rule. At $500 a head, the incremental cost would be $11,000 (22 x $500).

In addition, this small business would incur a cost for increased testing. The 1,000-employee business described above spends $750,000 annually for the increased testing or $750 per employee. Assuming that cost per employee is constant across size of business, an operation with 50,000 head killed per year would incur a cost of $75,000 annually (750x100). However, there are scale economies in this industry and Advocacy may be underestimating the impact. Thus, this small business (100 employees) would incur a total cost of $86,000 annually or $860 per employee.

[24] See 5 U.S.C. § 605(b).

[25] E.O. 12866, § 1(b)(11).

To comply with E.O. 12866, agencies must prepare a Regulatory Impact Analysis (RIA) for each regulation that the Office of Information and Regulatory Affairs, or the agency designates as "economically significant." Section 3(f)(1) of the Order defines an "economically significant" rule as one likely to "have an annual effect on the economy of $100 million or more, or adversely affects in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities." This definition is functionally equivalent to the definition of a "major" rule as that term is used in the Congressional Review Act.

Advocacy believes that it is likely that this rule would cost at least $100 million or more per year. If one applies the large company's data on the increased rate of loss of carcasses (see above) to a national scale, certain conclusions can be objectively reached. Nationally about 35,631,000 cattle were slaughtered in the U.S. in 2000. Applying the aforementioned company's condemned carcass figure to the national data results in an increase in condemned carcasses nationally from 4,988 to 19,240 carcasses annually or a difference of approximately 14,000 carcasses per year. The total incremental loss in annual sales nationally would range between $7 million and $8 million annually (14,000 x $500 to $600).

In addition, industry will incur additional costs to accommodate the increased testing to comply with the new FSIS procedures. The aforementioned company estimates that it spent $750,000 in capital improvements to accommodate enhanced testing by FSIS.[26] Advocacy recognizes that small entities would probably not incur compliance costs as high as the company discussed, but any significant increase in capital costs to a small entity can prove fatal. For example, with 672 slaughter plants, each killing fewer than 50,000 head annually and incurring annual costs of $75,000 per plant, the total annual compliance costs would be approximately $50 million.[27] Further, the potential for an unfair competitive advantage for large industry exists. Large plants are likely to be in a better position to afford the additional HAACP measures necessary to comply with the FSIS notice. Small entities are not as flexible and are therefore at a distinct disadvantage.

The $7-8 million loss to industry annually from the increase in lost carcasses combined with the $50 million increase for compliance costs will result in a total annual cost of approximately $60 million per year.

One should appreciate that the above analysis does not contain information on the poultry, hog or veal packing industry. Advocacy was unable to obtain figures regarding the anticipated

[26] Based on information provided by an industry source Advocacy was told that the rate of residue testing at the company is currently higher than at other cattle packing facilities.

[27] There are currently 738 cattle slaughtering plants in the U.S. All but 66 (672 plants) kill fewer than 50,000 head annually which equates to 200 head per day. Based on information form an industry contact, plants killing 200 head per day are likely to be small entities (less than 500 employees) based on SBA size standards.

regulatory impact on these industries, but the concerns raised as to the beef industry likely apply in the veal and hog industry as well. As Advocacy only considered the potential impact of the rulemaking on the beef industry, it is reasonable to assume that rule's total cost on the meat packing industry as a whole will exceed $100 million a year.

Again, Advocacy believes that FSIS is in a better position to obtain the necessary information to determine the true economic impact of this notice. One way that FSIS can obtain the information is to open the notice up for informal rulemaking and allow the public to comment on it. Because the information was not contained in the FSIS notice, Advocacy was left to derive the information from alternative means. Advocacy is aware that its economic projections do not exceed the $100 million a year threshold required by E.O. 12866. Nonetheless, it is reasonable to assume that E.O.12866 would apply because the notice will also impact the poultry, hog, and veal industries. When these industries are combined, FSIS's actions will likely result in an economic impact of greater than $100 million annually.

Finally, industry has suggested to the FSIS that it consider harmonizing its policies with the policies established by the Codex Alimentarius Commission (CODEX). CODEX is the international food standard-setting organization. Based on industry comments, the meat industry in the U.S. imports and uses products that are deemed satisfactory by CODEX standards. This reality requires that there be reciprocal standards in place here in U.S. and abroad. FSIS's notice would qualify as significant under E.O. 12866 also because is it may serve to restrict international trade (see section 3(f)(3)).

Because there may be a violation of E.O. 12866, Advocacy will forward a copy of this letter to the Director of the Office of Information and Regulatory Affairs at the Office of Management and Budget for their consideration.

C. FSIS's suggestion that establishments should consider incorporating controls into their HACCP plans to avoid exceeding residue tolerances will only serve to further disadvantage small entities.

FSIS also suggests in the notice that establishments should consider incorporating controls into their HACCP plans to avoid exceeding residue tolerances. Based on studies obtained by Advocacy, it is apparent that small businesses subject to HACCP regulations suffer disproportionately high economic impacts when compared to large entities.[28] FSIS's new

[28] The Office of Advocacy commissioned a study on the impact of HACCP and other regulations on small businesses. The study, *Impacts of Federal Regulations, Paperwork, and Tax Requirements on Small Business* (February 1999), concluded that small businesses subject to HACCP regulations suffered a disproportionately high economic impact when compared to their large counterparts. In the category of poultry slaughterers, for instance, the regulations cost 2.95% of their annual revenue.

regulatory action amounts to a heaping on of regulations that will be particularly felt by small businesses. FSIS has an obligation to minimize such impacts based on the RFA and other statutes.

FSIS published a document dated December 2000, entitled, Results of a FSIS Survey of the National Residue Program: Uniform Application in Cull Cow Plants. The survey was conducted in 30 of the top 40 establishments. The report concluded that the testing of cull cows for residues with respect to uniformity of application of current regulations, policies and procedures, was complex. FSIS also noted that it was not able to predict the applicability of the survey to smaller establishments. The survey contained input as to general plant conditions and procedures, staffing requirements, training needs and suggestions concerning incorporation of the residue program into HAACP.[29] Advocacy suggests that FSIS complete its investigation into the areas identified by the survey rather than taking the draconian steps contained in the notice. Ideally, this will be facilitated by FSIS formalizing the rulemaking process pursuant to the APA.

D. FSIS's action should do more to ensure that the economic burden of reducing the risk to the public from chemical residues in meat and poultry is spread equitably.

Advocacy is concerned that the regulatory action will place a disproportionate burden on the meat packing industry and does nothing to induce the producers of the animals to reduce or cease the use of drugs that create the residue concern. For example, the Packer's and Stockyard Act of 1921[30] requires packers to pay the producer of the cattle within twenty-four hours of the receipt of the cattle. Therefore, packers are faced with the prospect of paying for cattle before they can ascertain whether the cattle will test positive for violative chemical residue. This results in a situation where the producers are left holding cattle that are of no value under the new regulation. Under current FSIS testing procedures, the packers could minimize their losses if a determination is made that the muscle tissue could be salvaged. Advocacy asks the FSIS to submit this rulemaking to the notice and comment period provided for by the APA so that a more equitable solution can be reached. Reasonable alternatives to the notice exist and have been embraced by industry, such as the use of a broad-spectrum test and the publication of the names of sellers who are responsible for repeated sale of product with violative levels of chemical

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Of course, that amount would increase dramatically if presented as a percentage of profits instead of revenue. Also, poultry slaughterers pay 15.31 times the amount to comply with the regulations in relation to their large counterparts. The significant impacts and disproportionately high costs for small firms remained even though some regulatory flexibility measures were included in the regulations. The report also details information for cattle/hog slaughterers and raw ground processing plants. Please note the attached chart that was taken and reproduced from the report. Copies of the report are available on our web site: www.sba.gov/advo.

[29] September 4, 2001, comment letter from the National Meat Association.

[30] 7 U.S.C. § 181 (1999).

residues. Advocacy notes that in a companion *Federal Register* notice FSIS agreed to post on its website the names and addresses of the sellers of livestock and poultry, who the FDA has determined are responsible for the repeated sale of livestock and poultry that contain violative levels of chemical residues.[31] Advocacy commends FSIS for this action and suggests that this is the type of solution that will serve to spread the burden of reducing the risk to the public from chemical residues in meat and poultry more equitably.

Advocacy questions whether a sufficient scientific basis exists to justify FSIS's desire to harmonize its procedures with the FDA in testing animal tissues for chemical residues.

Industry suggests that FSIS determine whether the analytical relationship for measuring depletion of animal drug residues in target tissue utilized by the FDA in approving new animal drugs corresponds to the actual level of the residual drug residue found in the carcasses of animals at slaughter.[32] This suggestion seems reasonable to Advocacy, especially because it is likely to affect smaller farms as they have traditionally derived income from the sale of market slaughter animals.

Industry opines that the FDA, in approving new animal drugs, does testing under highly controlled conditions. Those studies are designed to determine the depletion profile of a particular marker residue in the target tissues by employing a methodology selected by the drug manufacturer. Under such controlled conditions, the FDA can be expected to know the relationship between the concentration of the marker residue in the target tissue and the concentration of the total residues (parent and metabolites) in the edible tissues. Contrary to the FDA drug approval process, FSIS is testing the kidneys and livers in slaughter plants with a broad-spectrum residue detection plate test. This is not a determinant method used by the FDA to ascertain the residue depletion profile of a new animal drug. It is also not a methodology specific for any given drug marker residue or its metabolites. This raises a concern that the FSIS will not be pursuing the same methodology that underlies the new animal drug approval process employed by the FDA. This disparity can result in a variant in that the residual levels of animal drugs in target tissues may not accurately reflect the actual residue profile in the carcass tissue of the same animal at slaughter. This concern may be compounded by the fact that drug residues generally deplete more slowly from target tissues that FSIS is selecting than from muscle tissue. Industry suggests that FSIS should evaluate the use of a broad-spectrum test compared to the determinant methodologies used in the drug approval process.

[31] 66 Fed. Reg. 40965 (August 6, 2001).
[32] September 5, 2001, comment letter to the FSIS from the National Milk Producers Federation.

Conclusion

The Office of Advocacy urges FSIS to suspend immediately its August 6, 2001, notice that seeks to harmonize its procedures with those of the FDA with respect to target tissue/marker residue policy in testing animal tissues for residues of new animal drugs until the public has a meaningful opportunity to comment. To do otherwise might cause the agency to run afoul of the APA and established case law resulting in a significant economic impact on the affected industries. Please do not hesitate to contact our office if you have any questions, 202-205-6533.

Sincerely,

Susan Walthall
Acting Chief Counsel for Advocacy

Linwood L. Rayford, III
Assistant Chief Counsel for Advocacy

Austin Perez
Assistant Advocate

cc: Dr. John Graham
Administrator, Office of Information
and Regulatory Affairs, Office of
Management and Budget