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Subject: Regulation Nomination

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May 20, 2004

Ms. Lorraine Hunt
Office of Information and Regulatory Affairs
Office of Management and Budget
NEOB
Room 10202
725 17th Street, NW
Washington, DC 20503

Dear Ms. Hunt;

Please find attached, both following this letter and as a file, Comment and Nomination as solicited in the Draft 2004 Report to Congress on the Costs and Benefits of Federal Regulations (69 FR 7987). On behalf of Viet My Corporation, I am nominating the Listeria Rule of the U.S. Department of Agriculture, Food Safety and Inspection Service (68 FR 34207, 9 CFR 430 et seq.) for review, amendment, and/or rescission.

Please do not hesitate to contact me should you have any questions.

Thank you.

Sincerely,

William A. Russell, Jr.
President

Cc: Col. Thomas Harrison
Viet My Corporation

- Nomination of Rules Pursuant to OMB.doc

Comment and Nomination
Draft 2004 Report to Congress on the Costs and Benefits of Federal Regulations
69 FR 7987

May 20, 2004

Pursuant to the Draft 2004 Report to Congress on the Costs and Benefits of Federal Regulations (69 FR 7987) of the Office of Management and Budget, Executive Office of the President, William A. Russell, Jr. submits this Comment and Nomination of Viet My Corporation. Viet My, a Virginia corporation, wishes to comment with regard to Chapter I of the Draft 2004 Report: The Costs and Benefits of Federal Regulations. Viet My further wishes to nominate for review, amendment and/or rescission the so-called *Listeria* Rule of the United States Department of Agriculture, Food Safety and Inspection Service (68 FR 34207, 9 CFR 430 *et seq.*), as per the solicitation of Chapter II of the Report.

Viet My is a Virginia corporation engaged in the processing of foods under the regulatory jurisdiction of the USDA/FSIS. In business for over 31 years, Viet My with eight employees is by USDA definition a very small processor. It is adversely impacted by the cost burdens inherent to the regulations.

At the outset, we would like to state our belief that the justifications for the new rule, both in economic content and governmental policy, lack the rigorous analytical examination that such an undertaking should exhibit, particularly given the potentially overwhelming adverse impact on small business. Indeed, it avoids that analytical rigor partly by declaring the adverse impact on small and very small business to be so small as to be nonexistent.

Chapter I - Comment.

At page 19 of the Draft 2004 Report (Table 4. Summary of Agency Estimates for Final Rules October 1, 2002 to September 30, 2003.), OMB presents a summary of the USDA projected costs and benefits of the new rule. The Report reiterates USDA projected industry costs of $16.6 million per year and benefits in a range of $44 million to $154 million per year, both annualized at a 7% discount rate over ten years. Viet My strongly believes that both figures are based upon faulty assumptions and/or methodology. We believe that the costs are badly understated and that the benefits at both ends of the range have been inflated by faulty methodology based partly on out-of-date epidemiological data and partly on misuse of the data.

The projected cost of compliance per each of the 10,000 plants involved of only approximately $1,600 per year is so low as to appear ludicrous upon its' face. FSIS ignores the actual costs of expert consultant advice on compliance for small and very small processors who, by economic fact of life, will not have such personnel on payroll. The costs of reconfiguration of operations and new equipment are vastly understated.

Our client experience indicates a cost per small and very small processor of approximately $11,500 for each year of the ten-year period used in the study. We have used cost estimates of new equipment and/or plant reconfiguration plus interest over the ten years of $50,000 per plant and a very reasonable cost of outside expert technical assistance for compliance and periodic testing of $6,500 per year for ten years. We believe that the total cost per plant is $115,000. This may very well be a low figure for many smaller plants. The costs are over **7** times those projected by FSIS and for many very small processors may dictate the economic decision to cease business. And those are likely to be average costs for all plants, not taking into account the likely higher costs of compliance for small and very small processors. It may well be that the costs per plant approach closer to $200,000 rather than $115,000 over the ten years of the study. FSIS figures led OMB to estimate a regulatory cost to industry of $16,600,000 per year or $166,000,000 over ten years (see OMB Draft 2004 Report to Congress on the Costs and Benefits of Federal Regulations, noticed at 69 FR 7987). We believe that the true costs are closer to $115,000,000 per year and over $**1.15 billion** over the ten years.

FSIS has consistently grossly underestimated the costs of its regulatory burdens imposed upon meat processors. It partially justified the flawed HACCP system imposed on small and very small processors as only imposing a cost of approximately one cent per pound of meat processed. Yet the American Association of Meat Processors in 1998 estimated the real costs at between eight and twelve cents per pound based upon the actual experience of the industry. Again, in the rulemaking referenced by this Comment and Nomination, FSIS estimates costs over seven times less than those estimated by experienced processors. Margins of error of these magnitudes cry out for a thorough government examination of Regulatory Flexibility Act compliance by FSIS. It also points up the need for increased funding for added personnel at both OMB/OIRA and the Office of Advocacy at the Small Business Administration.

A review of the benefits data used in this rulemaking leads to the further conclusion that the FSIS has adopted a solution in search of a problem in seeming contradiction of the statutory requirements of the Regulatory Flexibility Act (RFA). Clearly, FSIS premised its public benefits on stated estimates on annual rates of 2,500 cases and 500 deaths from *listeriosis* induced by *L. monocytogenes*. The bottom line figures were not even best available figures - for ALL annual cases and deaths - at the time of the rulemaking. Both the cases and the death numbers are based upon Center for Disease Control and Prevention (CDC) estimates on data through 1997. Subsequent CDC data, available prior to the adoption of the rule, showed a 38% decrease in incidence and mortality from 1996 to 2002. It is quite interesting that this evidences significant reductions in *listeriosis* incidence being achieved under the previous FSIS regulatory regime - which might well have achieved the stated timetable of the Healthy People 2010 goals for overall reduction without the adoption of any new rule. Even more interesting is the way in which FSIS and other federal agencies have used those figures with regard to the industries under their jurisdiction. The basic question of just what caused which portion of the cases and

or deaths was never addressed. That question is central to the faulty and unsubstantiated benefits under the RFA analysis.

Listeriosis is the infectious disease resulting solely from exposure to *L. monocytogenes*, a bacterium that is the sole etiologic agent of this disease. This rule is aimed at decreasing, if not eliminating, the incidence of *listeriosis* resulting from *L. monocytogenes* exposed processed food in plants under FSIS jurisdiction. *L. monocytogenes* bacterium can come from a variety of non-FSIS processed foods and other sources, including pets, individuals in the home, restaurants, contaminated fresh vegetables, processed foods under FDA jurisdiction, and the environment in general. Although these may be the contamination origination, FSIS has made no real effort to distinguish or quantify the cases and/or deaths from improper handling or packaging in FSIS inspected plants and those from other sources. Even if one accepted the numbers of annual cases at 2,500 and deaths at 500, **it is unlikely that more than 10% -at most - are attributable to foods processed in plants under FSIS jurisdiction.** However, based upon the FDA/CFSAN joint FDA/FSIS Questions and Answers in the *Listeria monocytogenes* Risk Assessment, published October 21, 2003 (www.foodsafety.gov/~dms/lmn2quhtml), it is likely that with the overall approximate 40% reductions in cases and deaths, there is a total annually of less than 1,500 cases and 300 deaths. Therefore, areas under FSIS jurisdiction would probably account for less than 150 cases and 30 deaths annually, and that very likely considerably exceeds the real incidence. The corresponding benefits produced under the *Listeria* Rule RFA should quite properly be significantly reduced.

Chapter II - Nomination

In Chapter II of its' Report, OMB solicits the nomination of "promising regulatory reforms" relevant to the manufacturing sector of the economy." In particular, commenters are requested to suggest specific reforms to regulations, guidance documents or paperwork requirements that would improve manufacturing regulation by reducing unnecessary costs, increasing effectiveness, enhancing competitiveness, reducing uncertainty and increasing flexibility." If ever a regulatory rule met that test, surely it is the so-called *Listeria* Rule (68 FR 34207, 9 CFR 430 *et seq.*). We hereby nominate for rescission the Rule and associated subparts, related directives, and subsequently issued or proposed guidance. (See especially FSIS Directives 5000.1, 5400.5, 8080.1, 10,200.1, and 10,240.4).

We believe that the following observations, considerations requested in the Report, make clear that this Rule should be seriously considered for rescission or major amendment.

1. Contrary to the figures reported in the rulemaking and in the OMB review, the costs far exceed any benefits under an adjusted and more rigorous analysis. Indeed, it is our position that even if you accepted fully the low end range of the FSIS estimated benefits, $44 million per year, costs would still exceed benefits by some $71 million per year and $710 million over the ten years. In fact, it is our

belief that the benefits figures are so faulty - a point also raised by OMB and the Small Business Administration during the several attempts at the rulemaking - that costs may exceed benefits by up to $1 billion during the ten year period.

2. USDA has the statutory authority to review the rule for the purposes of amendment and/or rescission.

3. The present rule will place domestic food processors at an international competitive disadvantage because of increased cost burdens apparent under a more vigorous and realistic cost/benefit analysis. In docket 99N-1076 (64 FR 24661 Risk Assessment of the Public Health Impact of Foodborne *Listeria Monocytogenes*), the Food and Drug Administration noted that "[o]ther countries, including certain major trading partners of the United States, take a slightly different approach to *L. monocytogenes* contamination." This difference and its' impact on small and very small processors should have been pursued more vigorously in the rulemaking. Amendment and/or rescission need not impose any burdens on fair or open trade.

4. The *Listeria* Rule has already been found by OMB to be an "economically significant" regulatory action.

Of particular note is the intricate level of bureaucracy put in place by FSIS to enforce the rule. For instance, FSIS Directive 10,240.4, Verification Procedures for the *Listeria monocytogenes* Regulation and Microbial Sampling of Ready-to-Eat (RTE) Products for the FSIS Verification Testing Program issued for the benefit of FSIS program personnel. It begins with two levels of staff, Consumer Safety Inspectors (CSIs) and Consumer Safety Officers (CSOs) where there had only been one level under both HACCP and pre-HACCP systems. The document, issued October 2003, includes three pages of flow diagrams to track how the information is supposed to go from CSI to CSO through Technical Service Center (TSC) to District Office (DO). This document was partially augmented with regard to HACCP compliance by FSIS Notice 54-03, Review of Establishment Data by Inspection Program Personnel, issued December 2003, which apparently replaces the CSO with an Enforcement Investigation Analysis Officer (EIAO), although that is admittedly not clear to this commenter.

What is apparent from a review of FSIS employee directive and general notices is that an entirely new level of bureaucracy was added to the previous system while removing a great deal of the authority and responsibility of front-line Consumer Safety Inspectors. Whereas previous systems had allowed them to provide easily accessible advice and technical assistance, such service is not now within their purview. In actual operational experience to date, it has become evident that there is no single point of contact within FSIS for processor inquiries as to best practices and that repeated attempts at asking the same question of multiple parties can result in entirely different answers. Plant

management cannot get day-to-day assistance without hiring and having constantly available outside technical expertise. Even in a situation where he has sought agency advice on compliance, the processor remains subject to a Noncompliance Report.

This rule imposes a significant burden on small business. We believe that for many small and very small processors it may represent the final burden that causes them to cease business. It will certainly adversely impact hiring by small and very small processors who may be forced to forgo expansion opportunities or to reduce present levels of employment.

We believe that the best solution is a return to a pre-HACCP regulatory regime. FSIS inspectors should inspect the operations of the plants rather than paperwork compliance. Uniform guidebooks for plant safety and hygiene compliance should be issued. And, in particular, plant operators should have access a single point of written or oral contact for compliance advice. This would be far more likely to result in safe products reaching the consuming public that the current HACCP/*Listeria* Rule exercise of posting paperwork for inspection. The net result would hopefully be a return to days when the industry viewed the efforts of FSIS as a model of government/industry cooperation for the public benefit.

Recommendations:

1. As a preferred alternative, Viet My suggests that the *Listeria* Rule and its associated directives and guidance be rescinded and a new rulemaking be opened to consider less burdensome alternatives to both the rule and the HACCP system with a return to the pre-HACCP USDA regulatory regime.

2. As the second alternative, we suggest the amendment and/or rescission of the *Listeria* Rule as it applies to small and very small processors. We suggest replacement with a pre-HACCP regulatory environment.

3. As the least favorable alternative, we suggest the amendment and/or rescission of the *Listeria* Rule as it applies to very small processors only. Again, we suggest replacement with a pre-HACCP regulatory environment.

Although our preferred alternative would scrap the *Listeria* Rule/HACCP system for all processors, we note that the rule imposes a proportionally greater regulatory burden upon small and very small processors. As the SBA noted in its' 2001 Annual Report of the Chief Counsel for Advocacy on Implementation of the Regulatory Flexibility Act, "because a large company is able to spread the compliance costs over larger output, it can maintain a competitive advantage over a small company subject to the same regulation." Not only is the net effect of the *Listeria* Rule the imposition of a relatively large cost burden on the small and very small processor, its' ultimate effect is to reduce competition

within this sector of the economy through that relatively higher cost burden, thereby reducing consumer choice and increasing consumer prices.

In closing, we would like to suggest that the failure to adequately address a realistic figure for the instance of *listeriosis,* both cases and deaths, and to trace and pinpoint actual sources, may be tragically avoiding the real action that may have greater consumer benefit through safe consumption of food. If the majority of *listeriosis* cases are caused by non-food processor sources, larger reductions in *listeriosis* cases and deaths may best be achieved by increased efforts at consumer education. Combined with our proposed return to a pre-HACCP regulatory regime, the consumer education approach should have a significantly greater impact to the public benefit while reducing the heavy cost burden to small business.

Submitted on behalf of Viet My Corporation by:
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