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April 16, 2010

Mr. Tom Vilsack  
U.S. Secretary of Agriculture  
U.S.D.A.  
1400 Independence Ave, SW  
Washington, DC 20250

RECEIVED  
APR 30 2010

Dear Mr. Vilsack:

We are a very small meat processing company that has been in business since January 7<sup>th</sup>, 1980, 30 years. During the past 30 years, we have seen many changes in our industry. As a result of these many changes, we have ALWAYS complied with all of the regulations that are in place to insure that we are putting out the best quality and most wholesome food products for our customers.

To say that we have deep concerns regarding the March 19<sup>th</sup>, 2010 FSIS Draft Guidance: HACCP SYSTEMS VALIDATION would be an understatement.

We feel that this new ruling would make it very difficult, if not impossible, for small plants such as ours, to continue to operate in a profit capacity, to continue to stay in business and support our payroll and our everyday operating expenses.

Any processor or meat locker that holds the licensing of "Department of Agriculture and Land Stewardship Meat & Poultry Inspection" is being targeted by special interest groups and lobbyists. This is just another example of Big Business wanting Small Business out of the picture and the government ALLOWING it to happen.

This WILL NOT affect grocery stores as they hold different licensing and are NOT subject to inspection by the USDA on a daily basis. They can sell meat and poultry products with far less accountability to the consumers overall. In fact, the USDA has an office in our plant and our products and processes are inspected daily. In addition to our daily USDA inspections, we are also required to send samples for lysteria and e-coli testing on a monthly and quarterly basis.

Current costs for our laboratory testing for lysteria is \$26.25 per sample and e-coli testing is \$37.00 per sample. Even if these costs didn't increase in the future, testing 50-75 times per month (more based on the proposed validation scenario) for the different sample tests that these changes are going to require, would cost our business \$3,162.50 to \$4,743.75 per month minimum! That would be approximately \$37,950.00 to \$56,925.00 per year! We offer over 1,000 product items to our customers and the proposed validation would require the testing of each individual product. Obviously, this is something that would put us out of business. Simply put, we could NOT afford to do this repetitive testing and stay in business and neither can any other small business meat processor or meat locker.

We have 8 full time and 1 part time employee and ALL of them depend FULLY on the income derived from working at B&R Quality Meats to support their families and their households. Our employees range from single mothers, semi-retired seniors and a single dad. Some have been employed here more than 15 years and we can honestly say that they enjoy their jobs and the working conditions here.

Their continued livelihood is very important to us as the owners of this business. We currently provide health insurance for our employees and we are proud when we are able to realize a small profit sharing at the end of the year. We aren't always able to do that and we certainly wouldn't be able to continue in this capacity if these changes are implemented. We wouldn't even be in business! Nobody here thinks that they are going to get rich out of coming to work everyday and doing a good job. Instead, we all feel that we are doing a very worthwhile job in an industry that we are proud to represent.

We certainly understand that there must be some government guidelines and regulations in place to make sure that businesses operate safely and appropriate to their industries. We feel that the government is trying too hard to correct problems that just don't exist and can be remedied simply by "SAFE HANDLING INSTRUCTIONS".

Currently, we utilize ALL of the necessary government required handling and cooking instruction labeling, applied to every box or package of product that we process and that leaves our building. You simply cannot FORCE the end user to read the instructions or even follow the methods of handling and preparation, once it is purchased and in their home or business.

Let's just say for the sake of the argument here that the government has complete control over how we run our business, which it does. What if we have a product returned due to the consumer becoming ill after consumption of the product due to not following the labeling instructions for handling and/or preparation? Is the government going to assume the liability for the lawsuit that would probably follow? Is the government going to accept full liability for our products since we follow ALL of the rules and regulations regarding testing, labeling and licensing? No, this customer is going to come after us and could probably win a lawsuit even though the reason they became ill was because they did not follow the labeling instructions. How can this happen?

Our question has always been, "How can a plant or a manufacturer be held responsible for mistakes that are made by the consumer if ALL of the government requirements for labeling and handling have been met?" This labeling is required by law. Proper cooking will, in all likelihood, eliminate most food borne illnesses, as studies have shown. But again, you cannot FORCE anyone to perform as the labeling on any product suggests.

We also feel that if new requirements are put in to place to validate what is already a process that is taken care of w/ legitimate and accurate testing and inspection by regulatory agencies, it will drive all of the small processors out of business, create even more unemployment and cost literally millions of dollars to achieve basically the same end result that is currently in place.

**We also note that the special interest groups and lobbyists will have their pockets full by the time this all falls out, unlike our then unemployed employees! And what about those full pockets? We all know that when special interest groups and lobbyists get involved, someone is making money. It will NOT be the meat processors.**

**Not only will this jeopardize our ability to stay in business, it will do nothing but force us to raise prices and this cost will then be passed on to the consumer. How can raising costs to the consumer possibly be beneficial when the safe handling and cooking methods are in the consumers hands anyway? Now we are just going to charge them more money to continue to handle meats and poultry items in the same way that they always have. How does this make sense to ANYONE?**

**What can WE do to save our 30 year old PROFITABLE business and the jobs that our employees ~~DEPEND ON?~~ We are told that this validation process is already a done deal...that what we have to say or how we feel will not affect this change from happening. It's too bad that our small voice doesn't matter to the big business of GOVERNMENT anymore!**

**Dennis Brennan  
Owner**



**Mark Ratkovich  
Owner**



IOWA DEPARTMENT OF AGRICULTURE AND LAND STEWARDSHIP

Bill Northey, Secretary of Agriculture

April 12, 2010

RECEIVED  
APR 30 2010

Tom Vilsack, U.S. Secretary of Agriculture  
U.S. Department of Agriculture  
1400 Independence Ave., S.W.  
Washington, DC 20250

Dear Secretary Vilsack:

I am writing to share with you concerns I have been hearing from Iowa meat processors about the Draft Guidance: HACCP Systems Validations that was released by the USDA Food Safety and Inspection Service on March 19, 2010.

As you are well aware, the Iowa Department of Agriculture and Land Stewardship is responsible for implementing Iowa's cooperating agreements with USDA/FSIS to provide meat and poultry inspection that is "at least equal to" the federal requirements. The major difference is that state inspected products are not allowed interstate commerce.

I share the concerns of these Iowa processors that the proposed reinterpretation of the requirements will add substantial new cost that will have a disparate impact on the small and very small meat plants located in and serve our rural communities. These plants typically slaughter more than one species of livestock and often produce a wide variety of products under several different HACCP systems. Often large plants have fewer HACCP plans than small and very small plants because they produce large volumes of fewer products.

It is also unclear to me the food safety benefits that would result from the substantial new costs for these plants. HACCP was designed to prevent, reduce or eliminate food safety hazards at Critical Control Points and requires processors to document their food safety procedures. These processes have already proven that the implementation of HACCP is effective in making our meat supply the safest in the world.

In addition to these costly new requirements, FSIS has also indicated that they will require that all pre-requisite programs, such as plant sanitation, cooler temperature monitoring and pest control programs to be validated under the same protocols outlined in the draft guidance. These programs are numerous and validating these will also add substantial new costs.

The manner in which this major regulatory re-interpretation was undertaken is also a cause of concern. Since the draft guidance is considered a re-interpretation and not a new rule, it does not follow the same rule making process and allow for the same scrutiny as typical regulatory changes. In particular, there is no opportunity to have this new interpretation reviewed by the Small Business Administration to determine the financial impact on small businesses.

In conclusion, I would just add that small and very small meat plants are a vital part of many of our rural communities and our rural economy. I have serious concerns that this re-interpretation will impact their ability to stay in business and continue serving as a vital link between farmers

and consumers. I commend your efforts through the "Know your Farmer, Know your Food" initiative to support small, local food producers, but I worry that these proposed guidelines could significantly setback the goals of that initiative.

Thank you for your consideration. Please feel free to contact me if you have any questions.

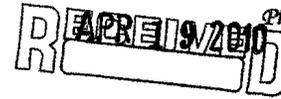
Sincerely,

A handwritten signature in cursive script that reads "Bill Northey".

Bill Northey  
Iowa Secretary of Agriculture



1105 8<sup>th</sup> Street North  
Northwood, IA 50459  
Establishment # 20239



Phone: 641-324-1466  
Fax: 641-324-2125

**Date:** 4/15/2010

**Address**

Docket Clerk, FSIS  
Room 2-2127  
5601 Sunnyside Avenue  
Beltsville, MD 20705

Email: DraftValidationGuideComments@fsis.usda.gov

**Re: Comments - Draft Guidance on HACCP System Validation**

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Dear Mr. Almanza:

Northwood Foods, Inc. respectfully submits these comments regarding the Draft Guidance on HACCP System Validation that were publically released on March 19, 2010.

As a supplier/provider of boneless and semi-boneless raw, not ground pork products to the meat industry, our concern regarding process validation in inspected establishments HACCP programs has prompted Northwood Foods, Inc. to comment regarding our concern. Through communication with our trade organizations and meat processing customers it has become apparent that initiating systems validation in these establishments would considerably affect our company as well. It is our belief that this will cause many federal and state inspected processing plants we supply to be forced out of business, or their operations significantly reduced. The loss of income resulting from this will be devastating to Northwood Foods, Inc. because approximately 50% of our business is with very small and small establishments. In addition, we still struggle to recover due to the impact of the economic recession in the USA and worldwide, as do many companies. Our exports have been severely reduced within the past 12-18 months; thus, our company economics have been directly affected, which in turn has affected our employees. If the new guidance becomes regulation, we will suffer, as will many other companies, yet another economic hit by the increased costs associated with compliance. This action, along with tightening supplies of raw materials by the slaughterhouse/packer due to consolidation, ultimately affects small processors such as Northwood Foods, Inc. and places us at further economic disadvantage. Please keep in mind, small processors such as Northwood Foods, Inc. help to support the economic stability of employees, companies, and communities in the United States. Economic success in the United States is dependent the successes of companies of all sizes. Limiting small companies, limits success in the United States.

We respectfully request that the Draft Guidance on HACCP System Validation be revised to clearly state that no in-plant microbial testing is required when an establishment is following the long-standing, safe processes of HACCP that has been supported with scientific data and documents encompassing similar process situations.



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Establishment # 20239

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Northwood Foods, Inc. appreciates the chance to comment on the Draft Guidance on HACCP System Validation. Thank you for your time and consideration regarding the proposed guidance material.

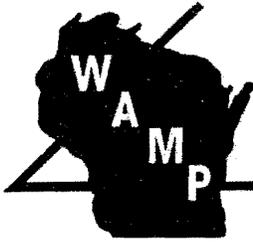
Sincerely,

A handwritten signature in black ink that reads "Brian Burkard". The signature is written in a cursive, flowing style.

Brian Burkard  
Owner / President  
Northwood Foods, Inc.  
[brian@northwoodfoods.net](mailto:brian@northwoodfoods.net)

cc: U.S. Senator Chuck Grassley  
U.S. Senator Tom Harkin  
U.S. Representative Tom Latham

RECEIVED  
APR 23 2010



**WISCONSIN ASSOCIATION OF MEAT PROCESSORS INC.**

Phone (608)-994-2559 • Box 331 • Bloomington, WI 53804

April 9, 2010

Docket Clerk, FSIS  
Room 2-2127  
5601 Sunnyside Avenue  
Beltsville, MD 20705

Re: Draft Guidance on HACCP Systems Validation

Dear Mr. Almanza:

The Wisconsin Association of Meat Processors (WAMP) is an organization of small and very small meat producers in the state of Wisconsin. With a current membership of 124 processors from Wisconsin, in addition to 30 associate members who are in the meat industry, but are not processors, we have worked since 1939 for the advancement of the meat industry. As an organization, WAMP deeply appreciates the need for effective food safety programs, and believes effective food safety regulations are best drawn up through cooperation between regulatory bodies and industry groups. This letter represents the position of the WAMP membership on the Draft Guidance issued by the USDA FSIS on HACCP Systems Validation.

It is the position of WAMP that the rule proposed by the FSIS in the Draft Guidance on HACCP Systems validation does not implement measures that are likely to result in safer food. Therefore, WAMP is opposed to the proposed rule, and believes that in the present food safety environment, there are many advantages to continuing to uphold the currently accepted validation method as the rule.

HACCP is designed to work by controlling the process of food production to prevent chemical, physical or biological hazards, such as harmful pathogens, from contaminating meat and poultry products. Through scientific study and years of data collected from in-plant environments, the processes used in our HACCP plans have been extensively validated as effective means to produce safe food. More microbiological testing conducted by the processor will not further validate the effectiveness of the processes used; it will only establish what has already been proven, and add unnecessary costs to the meat production process. Scientific study is the most effective and safe method of validating a process. In-plant validation should be focused on validating that the processor has followed the procedures described to be effective in the study. This approach to in-plant validation is the best way to promote the production of safe food products, as it allows processors to focus on meeting

established performance parameters that result in the production of safe food rather than testing to establish standards every time they perform a process.

Furthermore, in-plant microbiological testing is already implemented as part of the ongoing validation through certain verification activities. The frequency of testing has been chosen by considering years of in-plant experience. From this experience the individual processor has determined what the frequency of testing should be to further validate their HACCP plan. If the FSIS requires further testing, it will completely disregard the years of data compiled by each individual processor, and repudiate the long held stance by the FSIS that in-plant microbiological testing should be conducted on a schedule that the plant determines to be effective. It is self-evident that testing beyond what is effective will not produce safer food, it will only increase costs.

We have studied the costs involved with meeting the suggested rule, and have determined for a typical member processor, the costs could exceed \$100,000 of additional testing per year. This amount of money is an outrageous amount of money to spend on a requirement that will not produce safer food. We wish to make it clear that WAMP's members are not opposed to spending money, time and effort on our food safety measures; it is our duty to our customers to take every reasonable effort in producing the safest food possible. However, we are vehemently opposed to spending money that does not achieve results.

An extra \$100,000 of testing costs would mean that many of our members would seriously consider if they should remain in the meat processing business. This impractical regulatory requirement would close family businesses that have been open for more than 50 years, in some cases. For those plants that are able to stay in business, they would be forced to raise prices, making them less able to compete with large chains. Small businesses such as those of WAMP's membership are the backbone of America's economy, and these needless regulations will make it exponentially harder for them to support our nation's economy in these times of real economic duress.

Additionally, vague, constantly changing and unproductive rules such as the proposed validation rule have the additional effect of motivating processors to consider dropping regular inspection and pursue retail or custom exemptions. As an organization, we feel this step is counterproductive to producing the safest food possible, as regular agency oversight is a key part of maintaining food safety. We believe the FSIS is creating incentives for processors that they may not want to create in the formulation of the validation rule. These broader consequences should be considered by the FSIS in its policy determination process.

Finally, it is vital to consider that the member processors of WAMP and the FSIS are both ultimately responsible to the same person: the food consumer. It is the consumer's best interest both groups must ultimately always bear in mind when making decisions. The consumer will suffer only negative consequences from these regulations: the consumer will not receive safer food, the consumer will pay more for his food, and the consumer will have fewer choices where they can buy their food. The consumer is just as hard-squeezed by the economic situation as businesses are, and their needs must be considered as this rule is finalized.

After careful consideration of the current food safety situation and future needs, WAMP respectfully requests that the FSIS continue to use the current, long-standing interpretation of validation requirements when it formulates the final requirement on HACCP Systems Validation. Without precise evidence that a new food safety issue exists that would require further data collection, increased microbial testing is extremely unlikely to improve the safety of meat products produced in the United States. While we have highlighted the many drawbacks to increased testing previously in this letter, there are many advantages to keeping the current interpretation.

The current validation interpretation has stood since the implementation of HACCP, and has helped processors successfully adapt their production methods to new food safety threats, such as the emergence of *E. coli* O157:H7, BSE, and the need for increased *listeria* testing. There is no reason to believe that the current validation interpretation will not continue to be adaptable to new food safety issues. Processors have learned how to validate that their manufacturing processes and meats products using this interpretation, and have become experts at using this method to ensure that they are making safe food. Forcing them to change how they validate will cause them to lose their expert knowledge and become food safety beginners once again. Finally, the currently used validation method is an extremely customizable and cost-effective program that allows even the smallest of processors to follow a HACCP plan that lets them maintain an inspected meat business that provides safe, affordable food to consumers. Given the extreme harm that will come to small and very small processors from this major reinterpretation of the validation requirement, with such negligible food safety gains, we strongly believe and request that the FSIS should continue to use the current validation interpretation.

In summary, WAMP, on behalf of its membership, is opposed to the proposed rule on HACCP Systems Validation. The additional testing requirements that would be mandated by the rule are extremely costly and do not make safer food. Through an open dialogue with industry groups, a new rule should be formulated that is a cost-effective means of ensuring safe food is produced for the consumer. We look forward to reaching an equitable solution to the validation issue, and continuing to work with the FSIS on other food safety issues

Sincerely,



Bob Andorfer  
Excalibur Seasonings  
Green Bay, WI



Matt Bayer  
Country Fresh Meats  
Weston, WI 54476



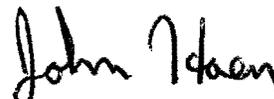
Peter Drone  
WAMP, Executive  
Secretary  
Bloomington, WI



Rod Aspenson  
Westby Locker and Meats  
Westby, WI



David Downs  
Mar/Co Sales, Inc.  
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John Haen  
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Haen Meat Packing  
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*Brian Halopka*

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*Rita M. Leahy*

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*Louis Muench*

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Louie's Finer Meats, Inc.  
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*Kelly J. Nolechek*

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*Jim Peterson*

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*Rick Reams*

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*Jeffery J. Sindelar*

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*Tom Tasse*

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Hewitt Meats  
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*Mike Vold*

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*James J. VanEss*

James VanEss  
Newton Meats Inc.  
Newton, WI

*Dave Van Hemelryk*

Dave Van Hemelryk  
Maplewood Meats  
Green Bay, WI

*Randy Von Ruden*

Randy Von Ruden  
Von Ruden's Meat  
Processing  
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*Scott Vorpapel*

Scott Vorpapel  
Lake Geneva Country  
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Lake Geneva, WI

**cc:**

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