

Form Letter 1

April 20, 2010

RECEIVED
APR 20 2010

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

Re: Comments - Draft Guidance on HACCP System Validation

Dear Mr. Almanza:

As a customer of quality meat products, I respectfully submit these comments regarding the Draft Guidance on HACCP System Validation that were publicly released on March 19, 2010. My concerns regarding process validation in inspected establishments with HACCP programs have prompted me to comment.

Through communication with our current butcher at Paris Frozen Foods, Inc. in Hillsboro, IL it has become apparent that initiating systems validation in establishments such as theirs would considerably affect my ability to buy the products I have become accustomed to putting on my table. It is my belief that these proposed mandates will cause many of the small federal and state-inspected processing plants that we rely on to be put out of business. When they pass the increased costs onto us, the per pound increase to their products will, in essence, make their very high-quality product unaffordable.

My family enjoys the ability of buying quarters or sides of beef from Paris Frozen Foods, or a half or whole hog when we want. But, if we want only a package or two of quality, locally grown beef and pork, their retail meat case is always an option. A particularly nice feature is the variety of in-house specialty products they produce - especially their famous Big Porkies. This is enjoyed not only at family barbeques, but at fundraisers throughout the county. Without this facility and their capability to produce their signature products this will no longer be available to me, my family or others in the greater Montgomery County community.

Paris Frozen Foods, Inc. is a clean, safe, state-inspected plant that has served us proudly for more than 50 years. We know they have food safety as one of their top priorities. Surely there is a better way to make sure that those plants that are not presently following the letter of the law do so without shutting the doors of so many facilities that are.

I appreciate the chance to comment on the Draft Guidance on HACCP System Validation. Thank you for your time and consideration.

Sincerely,

Mr. + Mrs. Blake Malloy

17264 IL Route 185
Coffeen, IL 62017

Cc: Senator Richard J. Durbin
Senator Roland Burris
Congressman John Shimkus
Congressman Phil Hare

Form Letter 2

April 14, 2010

RECEIVED
APR 26 2010

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

Re: Comments - Draft Guidance on HACCP System Validation

Dear Mr. Almanza:

As a livestock producer/farmer who depends on the meat industry, I respectfully submit these comments regarding the Draft Guidance on HACCP System Validation that were publicly released on March 19, 2010. My concerns regarding process validation in inspected establishments with HACCP programs have prompted me to comment.

Through communication with our current butcher and other concerned meat processors it has become apparent that initiating systems validation in these establishments would considerably affect our business as well. It is our belief that this will cause many of the small federal and state inspected processing plants that we rely on to be forced out of business, or pass the increased cost onto us in such a manner that ultimately it would put our livestock business into financial jeopardy as well.

The loss of income resulting from this will be devastating to us because our business depends on very small and small custom meat processing establishments. Our local plant, Paris Frozen Foods, Inc. serves us by processing our livestock for our home use and custom resale. We can sell that portion of our livestock we do not use to our friends and family, since it is fully inspected in a clean, quality plant.

Paris Frozen Foods also uses local livestock as the basis for a splendid retail meat market, which serves both the local the surrounding communities. Without their plant, the local market for our product will be nil. While other markets, farther away, will still exist, transportation costs, along with time considerations, will also be a factor in our continued livestock production.

We appreciate the chance to comment on the Draft Guidance on HACCP System Validation. Thank you for your time and consideration.

Sincerely,



Cc: Senator Richard J. Durbin
Senator Roland Burris
Congressman Phil Hare

Form Letter 3

RECEIVED
MAY 04 2010

Flandreau Locker
Dave Flatten
114 2nd Ave. W
Flandreau, SD 57028

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

Re: Draft Guidance on HACCP Systems Validation

Dear Mr. Almanza:

I am a member of the South Dakota Association of Meat Processors (SDAMP), an organization of small and very small meat producers in the state of South Dakota. With a current membership of 100 processors from South Dakota, we have worked many years for the advancement of the meat industry. I deeply appreciate the need for effective food safety programs, and believe effective food safety regulations are best drawn up through the cooperation between regulatory bodies and industry groups. This letter represents my position on the Draft Guidance issued by the USDA FSIS on HACCP Systems Validation.

It is my position 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, I am opposed to the proposed rule, and believe that in the present food safety environment; there are many advantages to continuing to uphold the current 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.

I have studied the costs involved with meeting the suggested rule, and have determined for a typical processor, the costs could exceed \$100,000 per year of additional testing. This amount of money is an outrageous amount of money to spend on a requirement that will not produce safer food. I wish to make it clear that I am not opposed to spending money, time and effort on our food safety measures; it my duty to my customers to take every reasonable effort in producing the safest food possible. However, I am vehemently opposed to spending money that does not achieve results. Furthermore, I won't have to worry about my customers because there is no way I will be able to financially do what FSIS is asking.

An extra \$100,000 of testing costs would mean that I and many other processors would seriously consider if we should remain in the meat processing business and a lot of us would not even have to consider it because there would be no other option but to close. 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 mine, is the back bone of America's economy, and these needless regulations will make it exponentially harder for me 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 additional effect of motivating processors to consider dropping regular inspection and pursue retail or custom exemptions. I feel this step is counterproductive to producing the safest food possible, as regular agency oversight is a key part of maintain food safety. I believe 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 is it vital to consider that processors 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 because this regulation will close many of our plants. 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, I respectfully request 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 safety of meat products produced in the United States.

While I 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 0157: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 meat 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 requirements, with such negligible food safety gains, I strongly believe and request that the FSIS should continue to use the current validation interpretation.

In summary, I am 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. I look forward to reaching an equitable solution to the validation issue, and continuing to work with the FSIS on other food safety issues.

Sincerely,

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

Dave Flatten
Member South Dakota Association of Meat Processors

Form Letter 4

Tom Tasse
Hewitt's Meat Processing
8300 Co. Road V
Marshfield, WI 54449

RECEIVED
APR 23 2018

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

Re: Draft Guidance on HACCP Systems Validation

Dear Mr. Almanza:

My name is Tom Tasse, and I am the owner of Hewitt's Meat Processing, a small meat packing establishment located in Marshfield, Wisconsin. I am writing you to ask you to reconsider the proposed USDA FSIS rule on HACCP Systems Validation.

The current proposed rule does not put in place any new food safety measures that will result in safer production processes, but only adds additional cost to the operations of all meat packers. I understand the need for strict food safety rules, and take every effort I can to ensure I make safe food, but this costly interpretation of validation does not help manufacture safe food. There are other ways to validate a HACCP plan without large-scale, expensive microbial testing.

As a member of the Wisconsin Association of Meat Processors, I fully support my organization's view on this subject, along with their proposed alternative rule. At our recent annual convention, the members of the organization have placed our thoughts into one letter and have proposed an alternative rule on HACCP Systems Validation. As an organization, we have hundreds of years of combined experience in the meat industry. We have researched, written and implemented HACCP plans for our organizations, and are a valuable source of "on the ground" knowledge about food safety. Ignoring our experience and knowledge in formulating this rule would be a mistake. I ask you to please carefully read this letter and consider our viewpoint.

Thank you for allowing me the opportunity to comment on this important issue. I sincerely hope you decide to reformulate the proposed rule on HACCP Systems Validation, and work closely with the industry to make a rule that is a cost-effective means of delivering safe food to consumers.

Sincerely yours,

Tom Tasse



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 Producers (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,

The Wisconsin Association of Meat Processors
2010 Annual Convention
Madison, WI



**Wurst & Meat House
Restaurant
Gifts Plus...**

APR 19 2010

1106 Texas Palmyra Hwy., Honesdale, PA 18431

April 14, 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

Dear Mr. Almanza:

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

Food safety has been a top priority for us not only since the implementation of HACCP, but long before HACCP was implemented. The overall purpose of HACCP was prevention of harmful pathogens that could potentially be associated with meat products. It seems as though the Agency is continually reverting to excessive end product microbiological testing of meat products to control pathogens instead of relying on the established HACCP food safety systems. HACCP is controlling the process rather than attempting to test safety into the system. There are several well-recognized, long-standing processes and supporting documents which, when followed, result in the production of safe meat products.

The microbiological testing that may be potentially required by this validation initiative would be extremely costly to our business and a huge financial burden. No in-plant microbial data should be required to validate our processes and food safety systems utilized. No establishment, especially small and very small, should be forced to expend thousands of dollars to validate what has been so widely accepted over the years.

If this validation initiative goes through as it is currently presented, it will definitely make us reevaluate our future in the inspected meat industry and/or our survival as a business. This initiative may systematically cause the remaining inspected (state and federal) independent processors that make a wide variety of meat products out of business.

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. We appreciate the chance to comment on the Draft Guidance on HACCP System Validation. Thank you for your time and consideration.

Sincerely,

Mark Eifert
President
The Alpine Inc.

Form Letter 6

Clair D. Thompson & Sons Inc
400 Allegheny Street
Jersey Shore, PA 17740



April 12, 2010

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

Dear Mr. Almanza:

Clair D. Thompsons & Sons Inc respectfully submits these comments regarding the Draft Guidance on HACCP System Validation that were publically released on March 19, 2010.

*Food Safety has been top priority for Clair D. Thompsons & Sons Inc not only since the implementation of HACCP, but long before HACCP was implemented. Clair D. Thompson Inc is a small family operated business in which our continued goal is to produce safe, high quality meat products for our consumers. Clair D. Thompson & Sons Inc has been operating under HACCP for 10 years and has reassessed annually to address emerging food safety related concerns.

Clair D. Thompson & Sons is struggling to determine the existence of a clear food safety problem which this validation initiative will resolve. Clair D. Thompson & Sons Inc is troubled that the USDA's Food Safety and Inspection Service believes so strongly that the current HACCP system is so badly broken to such an extent that this type of focus on validation must occur, especially given the fact that Clair D. Thompson & Sons Inc has been operating under HACCP for 10 years. This initiative would push us back to the beginning without any clear or present need. Furthermore, if Clair D. Thompson & Sons Inc collects all of this expected data, it is unknown what value any of this data would provide to make our meat products safer.

The overall purpose of HACCP was prevention of harmful pathogens that could potentially be associated with meat products. It seems as though the Agency is continually reverting to excessive end product microbiological testing of meat products to control pathogens instead of relying on the established HACCP food system systems. HACCP is controlling the process rather than attempting to test safety into the system. These are several well-recognized, long standing processes and supporting documents which, when followed, result in the production of safe meat products. These processes are found within:

- . FSIS regulations
- . FSIS Federal Register documents (e.g., FSIS Appendix A, FSIS Appendix B, etc.)
- . Peer-reviewed scientific documents

Page Two...Comments – Draft Guidance on HACCP System Validation

Clair D. Thompson & Sons Inc operates under a variety of HACCP plans. Within this establishments we have the following HACCP plans:

RAW, NOT GROUND PRODUCTS RAW, GROUND PRODUCTS
HEAT TREATED BUT NOT FULLY COOKED, NOT SHELF STABLE PRODUCTS (bacon)
HEAT TREATED BUT NOT FULLY COOKED, NOT SHELF STABLE PRODUCTS
FULLY COOKED, NOT SHELF STABLE PRODUCTS

With the exception of each of the slaughter HACCP plans, we produce a wide variety of fresh and processed meat products under the HACCP plans. The Agency should recognize this fact, since its inspection personnel are in the establishment daily. In regards to this issue, we produce the following number of products within each HACCP plan:

Since these new validation guidelines and scenarios are written so vaguely, it is difficult to determine what exactly will be accepted and what exactly will be expected from this establishment and each inspected establishment that makes up the meat industry. Historically, guidelines are interpreted by each person differently. This could cause a huge problem for this establishment, as well as the inspection personnel assigned to this establishment.

The microbiological testing that may be potentially required by validation initiative would be extremely costly to Clair D. Thompson & Sons Inc. This establishment has calculated some of the estimated costs Associated with this initiative. The initial validation will cost this establishment approximately 200,000.00 Annually. This is a huge financial burden for Clair D. Thompson & Sons Inc. No in-plant microbial data should be required to validate our processes and food safety systems in place at Clair D. Thompson & Sons Inc. No establishment, especially small and very small, should be forced to expend thousands of dollars to validate what has been so widely accepted for many years.

If the validation goes through as it is currently presented, it will definitely make us reevaluate our future in the inspected meat industry and/or survival as a business. This initiative may systematically cause the remaining inspected (state and federal) independent processors that make a wide variety of meat products out of business.

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.

Clair D. Thompson & Sons Inc appreciates the chance to comment on the Draft Guidance on HACCP System Validation. Thank you for your time and consideration.

Sincerely,



Cc: Pa Beef Council
Lycoming County Farm Bureau
Senator John N. Wozniak
Senator Gene Yaw
Senator Garth Evert

Rhodes, Suzette

From: Yelena Ogneva-Himmelberger [YOgneva@clarku.edu]
Sent: Wednesday, May 12, 2010 4:54 PM
To: Draft Validation Guide Comments
Subject: Comments - Draft Guidance on HACCP System Validation

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

Re: Comments – Draft Guidance on HACCP System Validation

Dear Mr. Almanza:

I respectfully submit these comments regarding the Draft Guidance on HACCP System Validation that were publically released on March 19, 2010.

As a consumer of livestock products who depends upon local, small independent meat processors, my concern regarding the process validation in inspected establishments HACCP programs has prompted me to submit these comments. I am not an industry big-wig; I am only one person who is concerned with the damage that I foresee these new validation requirements causing my local, independent meat processors. When HACCP was implemented, the meat industry saw a decrease in establishments. This initiative and new interpretation has the potential to decimate the remaining very small to small establishments, upon which so many Americans, including myself, depend. There is nothing wrong with the current HACCP system, whereas independent, small processors are concerned – nor is there any reason to believe the extraneous requirements would produce a safer end product. It has been estimated that the potential cost to validate a processors entire food safety system could easily run upward of \$500,000 initially and over \$100,000 for ongoing validation. No food safety problem has been identified to require this shift in agency interpretation of validation; I don't understand why this is necessary when there is a system in place that is working. All I see this shift in interpretation accomplishing is:

- Devastating the remaining small meat processors (hinders commerce)
- Large decrease in the variety of products available
- Discouraging the introduction of new products, therefore reducing the number of employees (increased unemployment)
- Increasing the cost of production, therefore increasing what I have to pay

None of these sound like they would be for the good of the American consumer.

I know, believe in and trust my local meat processors; therefore, I 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.

I appreciate the chance to comment on the Draft Guidance on HACCP System Validation. Thank you for your time and consideration.

Sincerely,

Yelena Ogneva-Himmelberger, Ph.D.
4 Valley Forge Circle
West Bosyton, MA 01583

Rhodes, Suzette

From: sara@toshiro.net
Sent: Sunday, May 30, 2010 3:36 PM
To: Draft Validation Guide Comments
Subject: Message from Internet User - Small slaughterhouses

Locally-raised, pasture-fed, and humanely-slaughtered meats are healthy, promote small business and encourage innovation in the marketplace. Please look for ways promote food safety that wont kill this growing and valuable market segment.

Please do not put small-scale producers out of business. Onerous regulations and reporting requirements will cause loss of jobs and loss of consumer choice without commensurate increases in safety.

APR 21 2011

Al Pinter
Pinter's Packing Plant
193 S. Front St.
Dorchester, WI 54425
715-654-5444

The Honorable David Obey
2314 Rayburn Building
Washington, D.C. 20515

Dear Congressman Obey:

My name is Al Pinter. I am the owner of Pinter's Packing Plant, a meat processing plant which is located in Dorchester, in your district. I am writing you today to ask for your help in lobbying the Department of Agriculture's Food Safety and Inspection Service (FSIS) to reconsider proposed meat inspection rules which, if passed will hinder my ability to stay in the inspected meat business.

The FSIS is the agency that sets the rules all processors of inspected meat in America must follow. The FSIS mandates that every processor institutes a plan to produce meat free from harmful contamination called a Hazard Analysis and Critical Control Points (HACCP) plan. The HACCP plan lays out step by step the process in which food is made to ensure that no possible contaminants can get into the food we manufacture. To write a HACCP plan, seven steps are followed, to guarantee no aspect of production is overlooked. The steps we follow in our HACCP plans are backed by scientific study conducted by university Animal Science Departments, trade associations, and regulatory bodies. These scientific studies validate that our HACCP plans produce food that is safe for the general public to eat.

Currently, to ensure that the conditions in our businesses are the same as those in the scientific studies, we keep extremely detailed records of our actions during food manufacturing operations, and conduct microbial testing on our finished products to make sure we have produced food safe to eat. This is called the "validation" step of HACCP, as it validates that we have followed procedures that will result in safe food products for our consumers. The FSIS wishes to change the requirements on how we validate the safety of our food products. Under the proposed rule on HACCP System Validation, the FSIS will require meat processors, such as myself, to conduct microbial testing at the start of a process, and at the end to show changes in the meat product.

While this may sound like a good idea to ensure safe food is produced, it is not. Adding a testing requirement to the beginning of the production process will not make for safer food products. Rather, it is through testing meat at the end of food production and following documented scientific procedures that we make food that is safe for our customers to eat. I am willing to follow the procedures necessary to produce safe food; the safety of my customers is my highest priority. However, the additional testing proposed by the FSIS just won't help produce safer food. The only thing it will do is increase how much it costs me to stay in business. I have calculated this unnecessary testing will likely cost me around \$100,000 per year. I cannot afford

to bear this extra cost for something that does not produce safer food. I would either have to pass these costs along to my customers or go out of business.

You are well aware that in the current economic situation, there are many people in the Seventh District without jobs, and many consumers I speak with in my store around Dorchester are feeling the pinch in their pocket from this down-turned economy. This proposed rule by the FSIS is an example of an out-of-touch federal agency making rules that cost outrageous amounts of money and accomplish nothing. It will hurt small businesses such as mine, and others in the Seventh District, and consumers will pay more for their meat products from fewer businesses. No one wins if the FSIS passes this revised rule.

Congressman Obey, I would like you to please contact the FSIS and ask them to work with industry groups to rework the proposed rule on HACCP Systems Validation. I know you work hard to represent the interests of the Seventh District, and it would mean a great deal to me, my employees, and my customers if you could speak with FSIS about this matter. For your reference, I am enclosing a letter that my trade association, the Wisconsin Association of Meat Producers, is sending to the FSIS on behalf of all meat processors in the State of Wisconsin. This letter is more detailed about the problems with the proposed rule, and talks about the changes we would like to see made.

Please contact me if you have any questions about this issue.

Thank you for your time and assistance,

Al Pinter

Al Pinter
Pinter's Packing Plant
Dorchester, WI

I employ 10 people.

*With all the new and old regulations
I am better off not to work*

To whom it may concern Al

7th DISTRICT, WISCONSIN

DAVID R. OBEY

CHAIRMAN
APPROPRIATIONS COMMITTEE

CHAIRMAN
SUBCOMMITTEE ON
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Tom Vilsack, Secretary
U.S. Department of Agriculture
14th Street and Independence Ave., S.W.
Washington, D.C. 20250

April 27, 2010

Dear Secretary Vilsack:

I am contacting you on behalf of the Wisconsin Association of Meat Processors and a number of small meat processors in my congressional district who have contacted me to express their concern with the Food Safety and Inspection Service's draft guidance on HACCP systems validation. Please find, enclosed, copies of these communications.

The primary concern appears to be that this guidance will require costly microbial testing at the beginning and end of processing. As these letters note:

"While this might sound like a good idea to ensure safe food is produced, it is not. Adding a testing requirement to the beginning of the production process will not make for safer food products. Rather it is through testing meat at the end of food production and following documented scientific procedures that we make food that is safe for our customers to eat."

According to Wisconsin's meat processors:

"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 In-plant validation should be focused on validating that the processor has followed the procedures described to be effective ..."

Further, according to the Wisconsin Department of Agriculture, Trade and Consumer Protection:

"as written [the draft guidance] 'raises the bar' for state-inspected plants. If the standards for interstate shipment are viewed as higher than for regular state inspection ... [and] that is the perception, then the guidance would make it even harder for interstate meat shipment programs to get started. In short, the guidance, as applied to small plants, is a costly answer in search of a problem. Many processors would not be able to absorb the

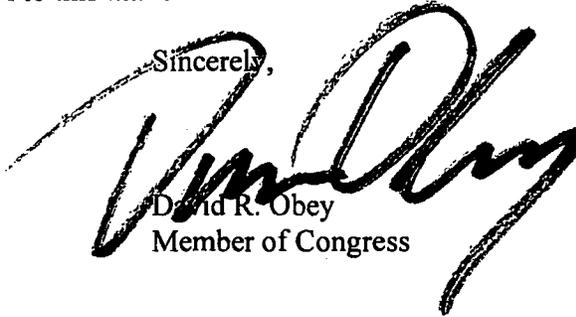
costs.”

As you know, for some time Wisconsin has been seeking to allow state-inspected meat in interstate commerce as long as state inspections meet or exceed federal standards, and Congress has endorsed that. As such, further regulatory roadblocks are troubling. Further, I understand there is great concern that the proposed guidance run counter to the Administration’s efforts to promote locally-grown foods and small-scale production and could force some small firms out of business.

With this in mind, I would urge you to review these concerns and the proposed guidance to ensure that it does not undermine the economic security of these businesses and their ability to sell their products in interstate commerce, as you seek to ensure the safety of the food products they process.

I appreciate your attention to this matter.

Sincerely,

A large, stylized handwritten signature in black ink, appearing to read 'David R. Obey', is written over the typed name and title.

David R. Obey
Member of Congress

Rhodes, Suzette

From: sarahbdonovan@gmail.com
Sent: Thursday, May 27, 2010 9:47 AM
To: Draft Validation Guide Comments
Subject: Message from Internet User - Hazard Analysis and Critical Control Point HACCP

I understand the intent of HACCP is to prevent contamination of meat by harmful pathogens. On March 19, 2010, the FSIS published a draft guidance document on HACCP system validation, outlining new rules which would institute regular, year-round testing of all meats, whether or not problems have been identified.

The proposal recommends testing for testing's sake, and it will cost small plants tens of thousands of dollars, perhaps even hundreds of thousands, every year. The financial burden appears great enough that this will destroy much of the remaining community-based meat processing industry, which is enjoying a renaissance and creating jobs. These jobs are essential to our local economies and the recovery of our nation as a whole.

Small, local meat processors have always supported food safety. At one local plant I patronize in Virginia, they have had a functioning HACCP plan since 1999, and it works. They undergo extensive E. coli testing every year, and have never had a positive result.

The purpose of HACCP is to employ well-recognized, established processes and process-control parameters to produce safe meat products-processes and parameters recognized and published by you, the USDA.

Now the USDA wants to test the system and require excessive end-product microbiological testing, rather than allowing local slaughterhouses to depend on these well-recognized procedures. Perhaps a large plant slaughtering 5,000 animals per day can afford its own lab and microbiology staff, and can pass the cost along to the consumer, but most small plants can't. And perhaps large plants should open labs-those are the plants where a massive beef recall can involve millions of pounds.

In my opinion, the USDA needs to recognize that "one size fits all" inspection no longer fits current industry practice and consumer demand. These new HACCP requirements are going to cause a train wreck in a portion of the industry that is growing for the first time in years. Someone needs to take a clear-eyed look at this situation and find a way to split the agribusiness mega-plants from the community-based localized plants within the regulatory structure.

This does NOT mean that small plants are not serious about food safety. It is because consumers such as myself are serious about food safety that we are going to small scale slaughterhouses, and we need to keep local infrastructure alive in this country. We need an inspection system that recognizes that the small plants do not put either the food economy or millions of people at risk in case of a food safety event.

Please do not cut off my access to locally-raised and processed, pasture-fed, and humanely-slaughtered meats.