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APR 30 2010  
April 1, 2010

**TO:** Individuals Wishing to Comment on the Draft Compliance Guide on HACCP Systems Validation  
**RE:** Talking Points on the Draft Compliance Guide on HACCP Systems Validation

Depending on how the draft compliance guide on HACCP systems validation is interpreted by the establishment owner and inspection personnel of the Food Safety and Inspection Service (FSIS), this guidance information could potentially be devastating for the affected group of inspected (state and federal) independent very small and small processors.

It is **STRONGLY** advised that individuals take the time to review the information provided and **COMMENT** appropriately. The following are some talking points that individuals could focus on:

- Currently, the Agency has not provided a clear and supportable case of the existence of a food safety problem which this validation initiative will resolve. The meat industry has been under HACCP for nearly 10 years and this initiative pushes the industry back to the beginning without any clear and present need
- The overall purpose of HACCP was prevention of harmful pathogens that could potentially be associated with meat products and 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
- The Agency is encouraging the enumeration of indicator organisms along with additional side-by-side pathogen positive/negative detection testing in which a supportable scientific correlation does not exist between indicator organisms and pathogens of concern.
- It is not appropriate for the Agency to ignore safe harbors that include widely acceptable documents (e.g., regulations, Federal Register documents, scientific literature, etc.)
- In-plant microbial sampling is going to be very costly with the end result being of very little benefit to the industry or the Agency since the guidance material does not demonstrate true scientific validation
- The financial burden may cause many more very small and small independent processors to go out of business, significantly decrease the variety of products offer, and/or the consumer will end up paying the cost of this validation initiative as processors raise their prices to cover the costly microbiological testing of their products
- Years ago, the regulations established that validation could be achieved where processes are well-documented in the scientific literature and no in-plant microbial data should be required to validate processes and food safety systems
- Due to the fact that the industry lack other scientific validation literature and past experience in regards to other FSIS guidance documents, FSIS inspection personnel will utilize this guidance material as Agency minimum expectations for validation and guidance material will inadvertently be mandated as regulation

FSIS Administrator Al Almanza asks for comments on this draft validation compliance guide. Submit your comments to the email address [DraftValidationGuideComments@fsis.usda.gov](mailto:DraftValidationGuideComments@fsis.usda.gov) or to the Docket Clerk, USDA, FSIS, Room 2-2127, 5601 Sunnyside Avenue, Beltsville, MD 20705. Comments should be submitted by April 19, 2010. After April 19<sup>th</sup>, FSIS will begin its review on the comments it receives and its process of deciding how it will proceed with respect to the validation of HACCP systems.

# Graziano Brothers, Inc.

Wholesale & Retail Italian Foods

1601 South Union St.  
Des Moines, Iowa 50315

515-244-7103 Phone  
515-243-2228 Fax  
gbros@qwestoffice.net



APR 30 2010

April 9, 2010

Mr. Tom Vilsack  
U.S. Department of Agriculture  
1400 Independence Avenue, S.W.  
Washington, DC 20250

**Re: FSIS Draft Compliance Guide on HACCP Systems Validation**

Dear Mr. Vilsack:

Graziano Brothers Inc., respectfully submits serious concern regarding FSIS's (Food Safety and Inspection Service) recent Draft Compliance Guide for all HACCP approved plants throughout the nation. The compliance, once mandated, will require ALL processing plants (federal and state inspected) to be validated plants. In short, they are requiring the absolute impossible from processors, especially the small and very small plants.

As an Iowa native, I am sure you are aware of the small meat industries throughout the state. They are your local meat lockers, custom-plants, and processing plants such as ours. I hope you are aware of our product, Graziano's famous Fresh Italian Sausage. We are a proud to service the Des Moines area and surrounding communities within our state for 98 years. We also boast that our sausage reaches most states in the United States once shipped by customers to their families who "can't live without our product". This says quite a bit about an Iowa-made product. But that can easily change.....

Enclosed you will find a copy of my petition sent to Mr. Almanza from the Department of FSIS. He has invited comments regarding this issue until April 19th, 2010. **TIME IS OF ESSENCE!** Please review the letter along with a fact sheet provided by the American Association of Meat Processors. Hopefully this will provide some enlightenment on our predicament as well as others small plants within the state of Iowa.

**WE ARE IN DANGER OF CLOSING OUR BUSINESS** due to the exorbitant and unjustified expense this will require. The proposed requirement will not produce any safer product than what is already provided. It is requiring an extra and expensive measure without providing justification for such stringent changes.

Please help us in our plight. If for any reason, to sustain the livelihood of small businesses, like ours, in the state of Iowa. Many ancillary businesses and workers are at stake as well.

Respectfully submitted,

Frances Graziano, President  
Graziano Brothers, Inc.

May 20, 2010

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

Dear Mr. Almanza:

I am writing in regard to the Draft Guidance on HACCP System Validation that was publicly released on March 18, 2010. I believe the proposed mandates would put many small federal and state-inspected processing plants out of business because they would have to pass the increased costs on to the consumer, making their products unaffordable.

My family and I have especially enjoyed the Shisk-Kebabs and Big Porkies that Paris Frozen Foods of Hillsboro, IL, carry. We know that they are conscientious people who make food safety a top priority. Please find a better way of dealing with plants who are not in compliance without penalizing the many places that are.

Thank you for considering this.

Sincerely yours,  
Cindy Huber

cc: Senator Richard Durbin  
Senator Roland Burris  
Congressman John Shimkus  
Congressman Phil Hare

Dear FSIS,

On the proposed changes on validation of HACCP plans and additional testing. It would cause a severe hardship for us. We are a very small plant.

It would put us at a serious disadvantage with the big plants. They can spread the cost over thousands of animals where we might only have tens or at most hundreds of animals. I feel we spend more time per animal than the bigger plants and therefore can be more careful about keeping them clean and sanitary. I feel testing is important but what we are doing <sup>already</sup> is sufficient.

The reason we built

a plant is because we  
have had a hog farm  
since the 1970's and we  
got crowded out <sup>(by the big guys)</sup> in the  
late 1990's. I told my  
son we need to direct market  
meat instead of hogs. It  
has been working well for  
us for almost 5 years now.  
Our whole family, myself my son  
and 3 daughters are employed  
here as well as 3 of our  
neighbors. We sell our meat  
to the surrounding community.

These new rules would  
start pushing us back into  
a situation like we were  
in in the late 90's.

I feel we can produce  
a good safe product without  
more testing.

Yours Truly

Jonas L. Miller

MIKON J. MILLER

DOUGHTY FARM MEATS  
5362 S.R. 557  
MILLERSBURG OHIO 44654  
330-674-6257

RECEIVED  
APR 28 2010

Docket Clerk.  
USDA. FSIS.  
Room 2-2127.  
5601 Sunnyside Dr.  
Beltsville MD. 20705.

to whom it may concern;

I read in the local paper today about proposed inspection rules since major concerns in meat industry.

Why do we need rules changed on meat lockers that are on the small scale.

There is a lot more concerns on other companies that are on bigger scale.

Why not go after the large scale meat processors that at times put out contaminated meat. But you let these big companies go and let do as they want until there is a breakout of sick people. Has there been a small locker sent out contaminated meat?

The reason you let the large Co's go is because they are so big for inspectors to rule and try and control.

all you are trying to do is close the small independent lockers so we have to go to grocery stores to buy. And you don't have to inspect the small Co's so you can cut the number of inspectors on the payroll.

I would like to see you people get your minds together and try to cooperate and let the small lockers alone, so they can have a decent business and employ people instead of closing and have more people unemployed than what we have now.

And also if they have to get there business in order to pass inspection the way you want it also has to be passed on down the line, so our meat will cost us more. Please keep your hands out of the locker business.

Concerned person?

Osborne, Bartola  
Atlantic Town

Box 171.

50022

RECEIVED  
MAY 04 2010

Dear USDA officials:

As a livestock producer who depends on the meat industry, I am concerned about the draft validation compliance guide because it will hurt small meat processors. The new validation systems would raise costs significantly for processors, driving them out of business or passing new cost onto farmers and consumers. These changes would severely impact our farm and make the growth of local and regional food systems harder.

We enjoy fresh and great tasting meat from meat markets. We see no need for this validation, unless your goal is to end family farms and just have <sup>cooperative</sup> ~~cooperation~~ farming.

Sincerely,

David & Madonna Sellner