

**Rhodes, Suzette**

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**From:** Kathy Tibbits [ktibbits@lrec.org]  
**Sent:** Sunday, April 11, 2010 9:30 PM  
**To:** Draft Validation Guide Comments  
**Subject:** HACCP Microbial Testing Costs

Date April 10, 2010

**Fluffy's Compleat Boutique**

P.O. Box 1116

Stilwell, OK 74960

918 797 5016

**Address**

Docket Clerk, FSIS

Room 2-2127

5601 Sunnyside Avenue

Beltsville, MD 20705

Email: [DraftValidationGuideComments@fsis.usda.gov](mailto:DraftValidationGuideComments@fsis.usda.gov)

**Re: Comments - Draft Guidance on HACCP System Validation**

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Dear Mr. Almanza:

Fluffy's Compleat Boutique, a Producer in Oklahoma Food Cooperative comments on HACCP System Validation:

A better solution would be a SCALEABLE one that does not create a threshold barrier for small businesses.

One way to achieve this is to limit the validation process by its cost, to some small percentage of the operation's gross revenue or net profits— perhaps an added regulatory burden of 5% would be bearable. ( I leave it up to you to decide how much of a "proof tax" can be assessed without affecting processors. )

Otherwise, the unintended consequence would be a different kind of risk—the risk that too few processors exist in order to meet local food safety risk diversification. Because if the processors can't afford the verification, they will go out of business and local food systems will break down.

In-plant microbial testing is a noble idea, but be practical. It can only be mandated to the extent it is affordable.

Kathy Tibbits

Fluffy's Compleat Boutique

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- Kathy Tibbits, Attorney at Law
- OBA#10233
- P.O. Box 1116
- Stilwell, OK 74960
- 918/696-3175 landline
- 918/797-5016 anywhere
- Licensed, U.S. Supreme Court
- [The Blog](#)
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**Rhodes, Suzette**

**From:** Martin Luther [martin571@embarqmail.com]  
**Sent:** Monday, April 05, 2010 10:55 AM  
**To:** Draft Validation Guide Comments  
**Subject:** HACCP system validation

Est. 13214

04-05-10

Dear Mr. Almanza:

We are a very small meat processing plant. Here are my comments representing Luther's Smokehouse regarding the Draft Guidance on HACCP System Validation - March 19, 2010;

Food safety has been the most important for us for over 30 years (in the same business and location) long before HACCP was implemented. The overall purpose of HACCP was prevention of harmful pathogens that could potentially be associated with meat products. We've been using the HACCP process with excellent results in the safe production of our meat products.

The proposed In-plant microbial testing for our products would mean the end of our business while the end result would be of very little benefit to the industry or USDA since the guidance material does not demonstrate true scientific validation.

If this validation initiative goes through as it is currently presented, not only us, but many other small meat processors will be forced 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. Thank you for the opportunity to comment.

Sincerely,

Martin Luther, President

Luther's Smokehouse, Inc.

102-6th LeRoy Ks.66857

email - [martin@jerkysa.com](mailto:martin@jerkysa.com)

cc: Senator Pat Roberts

Senator Sam Brownback

SBA

Farm Bureau

Kansas beef council

Kansas pork council



I do not need a reply to my message, I just hope that my opinion reaches the relevant parties within the USDA.

Sincerely,  
Patrick Vinograd

Rhodes, Suzette

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From: DERAMUSINC@aol.com  
Sent: Thursday, April 01, 2010 10:30 AM  
To: Draft Validation Guide Comments  
Subject: THIS WOULD PUT OUR LITTLE SMALL PLANT OUT OF BUSINESS.

THERE IS NOT WAY IN THIS ECONOMY THAT OUR LITTLE PLANT COULD AFFORD TO HAVE ALL THE TEST DONE . THE PEOPLE SMART ENOUGH TO DO ALL THE TESTING AND DATA FOR FACTS ON FOOD PROCESSING HAVE COLECTED DATA OVER THE YEARS AND SHOWN HOW PROCUCTS AND HEAT TREATMENT AND REFRIDGERATION CONTROLLS HARMFULL BACTERIA . THE MEAT INDUSTRY AND THE GOVERNMENT HAS SPENT UNTOLD AMOUNTS OF MONIES TO DO THESE TEST FOR FOOD SAFTY AND TO NOT USE THEM WOULD BE SUCH A SHAME . WE HAVE BEEN DOING BUSINESS FOR OVER 80 YEARS . WITH NO RECALLS , NO POSITIVE TEST FOR LISTERIA OR ANY OTHER PATHOGEN . A SMALL FAMILY OWNED BUSINESS THAT IS STRUGGLING TO HOLD ON IN A TROUBLED ECONOMY . TO GET THIS MESS OVER HACCP IS JUST REDICULUS . FOOD SAFTY IS CONTOLED IN THE MEAT PLANTS .TO A HIGHER LEVEL THAN EVER BEFORE. THE GROCERY STORES AND RESTURANTS . ARE DOING SO MUCH BETTER TO KEEP PATHOGENS FROM GETTING OUT OF COUNTROLL . WE SHOULD NOT BE PUNISHED FOR OUR HARD WORK. BY PUTTING IMPOSIBLE REQUIREMENTS ON US BY OUR GOVERNMENT . TO PUT US OUT OF BUSINESS. CROOKS WILL BE CROOKS AND THEY WILL GET CAUGHT . THERE ARE SORRY PEOPLE IN EVERYTHING EVEN THE GOVERNMENT AND CHURCH. BUT THERE ARE SO MANY GOOD PEOPLE IN THIS WORLD WHO DESERVE TO HAVE FOOD THAT TASTE GOOD AND IS GOOD FOR YOU. WITH OUT ALL THE SILLY GOVERNMENT EXTRA COST . THESE TEST AND RESULTS FOR GOOD SSOP HAS BEEN DONE. AND PROVEN THAT THEY WORK. WE DON'T NEED MORE TESTING TO SHOW THAT THEY WORK OVER AND OVER AGAIN. AT A COST OF THE UNKNOWN.

Please wake up and save what jobs and business that are doing all they can to stay in business. Believe me we are not getting rich putting out good products . Most of us are just getting by if that . or trying to hold on for a better time. Thank You !

Herb Murray  
The DeRamus Family Inc.

**Rhodes, Suzette**

**From:** Woods Smoked Meats [wsmeats@yahoo.com]  
**Sent:** Thursday, April 15, 2010 9:34 PM  
**To:** Draft Validation Guide Comments  
**Subject:** Draft Guidance on HACCP Validation

Dear Mr. Almanza:

Woods Smoked Meats, Inc. of Bowling Green, MO submits these comments regarding the Draft Guidance on HACCP System Validation that were publicly released on March 19, 2010.

Food safety and quality has been our companies goal since 1947, the year Woods Meats was founded by my father. We have operated before there was any meat inspection, operated under State Inspection. Federally inspected since 1972. Woods has been HACCP certified since 1999, having been reassessed annually and passing two FSA reviews with only very minor problems. Also I have a degree in Food Science and Nutrition with a minor in Microbiology from the University of Missouri. Believe me sir, food safety is a very high priority here.

For the life of me, I cannot figure out the food safety problem the USDA claims that exists in small and very small plants. There is nothing wrong with the HACCP system that is in place in our business. The new validation initiative will not fix something that is not broken, but has been working for eleven years. If USDA feels the HACCP system is so badly screwed up, they should step back and reevaluate their own procedures. Don't make the small and very small plants go to unneeded expense and headache to try to solve a problem that is definitely not there.

The main problem with the USDA is they cannot, or refuse to control the potential pathogens that are on boxed beef shipped from the big packers. E-Coli control is a huge problem that HACCP has been unable to eliminate because there is no Kill step. As long as cattle have access to water right up to being harvested, their bellies are full and ripe for carcass contamination. Killing 400 head per hour doesn't help solve the problem either. So the small plants downstream, the further processors and grinders, have had to find a solution to a problem that was shipped to them as USDA Inspected and Passed Beef. Let the little guys fix it, the USDA has more control over them, they don't have the money and the clout to tell the USDA what to do.

HACCP's purpose was the prevention of harmful pathogens on meat and meat products, but with the current regs and processes in place for large plants, zero tolerance is a target goal that is unachievable. USDA is intent on testing and testing end products for microbials, but until you eliminate pathogens at the source, all the test results are meaningless.

At Woods Smoked Meats we have an established HACCP Food Safety system in place. We use several well recognized processes and have the supporting documentation, which when followed result in the production of safe meat products. Remember, my name goes on almost every package that goes out the door, so it better be safe and wholesome. My forty years in business here will prove me out.

Woods Smoked Meats operates under FSIS regulations, and uses FSIS Federal Register documents and peer reviewed scientific materials. We operate under 6 HACCP plans and have for eleven years.

Pork Slaughter Beef and Buffalo Slaughter

Raw - Not Ground Product

Raw--Ground Product

Fully Cooked Not shelf Stable

Heat Treated Not fully cooked

Heat Treated Shelf Stable

With the exception of the slaughter plans, we produce a wide variety of fresh and processed products under the other HACCP plans. We further process beef, pork, chicken, turkey, duck, pheasant, Buffalo, venison, Elk, wild boar, antelope and caribou. We manufacture approximately 150 to 175 different products for wholesale

and retail. All these categories of products have lab tested for E-Coli, Sallmonella, Listeria, some tested for pH, water activity, yeasts, coliforms and staph. All tested to our HACCP mandated schedule. We have run environmental tests for listeria on a regular basis. In all these tests has one come back positive in eleven years. Do we have a problem?, I do not believe so.

The new validation guidelines are written so vaguely that everything is a gray area. It is impossible to determine what past testing and past procedures will be accepted. So if none of the past years of HACCP testing and recording is now not recognized, what was the point of spending all that money and time on HACCP in the first place? Why does the USDA even have an inspector here all those years if his efforts are not acknowledged? Having to go through the new validation process would make everything the inspector has done and the plant has done for food safety basically null and void. Now that's Government waste at its finest.

With the incredible amount of microbial testing that would be required by the validation system, the cost would put Woods Smoked Meats out of business. The initial validation cost for our plant based on 160 to 175 product would be around \$300,000 the first year and \$80 to \$90,000 in years to follow. There is no way my business could afford costs like that. Nor could any other small meat plant stand charges even half that amount. This is absolutely ludicrous and out of the question. This whole scheme smacks of a USDA plan to put more small meat plants out of business and to perpetuate big government. Lets save those high paying USDA jobs, and generate some more worthless paperwork.

There should be no inplant microbial data required to validate our food safety processes. We already have eleven years worth on file. In fact, for USDA to adopt the HACCP System Validation makes no sense what so ever. If this does pass, in its present form or any part of it you will see a mass exodus of small meat plants from the business world.

Business people in rural and small town America will try for a while, but will eventually throw in the towel, because they just can't afford to stay in business to meet the USDA over the top demands. People will lose jobs, thousands of quality speciality products will be removed from the market place. Speciality sausage makers will cease to exist and artisans of sausage making will vanish from the American business landscape. It's a pretty sad situation when the US Government runs tax paying people out of business, because the USDA thinks we have a food safety problem. Sir, the USDA is THE PROBLEM.

I would request that the Draft Guidelines on HACCP System Balidation be dropped in its entirety, and for sure the inplant microbial validation testing be eliminated. As demanding and time consuming as HACCP is, it has served food safety processes in our plant very well.

Woods Smoked Meats would like to thank you for the chance to comment on this very important and business threatening issue.

Sincerely,

Edward Woods    President    Woods Smoked Meats



Please let me know who I can contact to express my concerns and make my voice of opposition heard regarding regulation which endangers local and small farming initiatives.

May 16, 2010

USDA  
1400 Independence Ave., S.W.  
Washington, D.C. 20250

Dear Kathleen Merrigan:

I am writing to appeal for a reasoned approach to a problem recently brought to my attention by a small farm family in Minnesota. Attached is the e-mail request I received, although I deleted the name of the farm family because I wouldn't want to put any unfavorable attention on them; obviously they have enough issues to cope with.

I received the appeal for help because I am active in my community around support for local food growers, processors and eaters. I have the honor of being a founding member of our town's natural food co-op, I work ten hours a week on an area farm and encourage other townies to do so too, I am the mother of three boys teaching the values of hard work, good food, community optimism.

In our part of the country, a number of farmers have worked hard to develop a sustainable food system, with an emphasis on quality land use to supply area businesses and even some schools with locally grown, pesticide-free fruits and vegetables, antibiotic-free meat and dairy products. With minimal effort, area residents can obtain 50% or more of their dietary needs from local farmers. We host community gardens, community supported agriculture share programs, donate hundreds of pounds of quality produce to the food shelf, organize potlucks featuring seasonal food. We take our farming livelihoods seriously. This seriousness is revered by the consumers, we expect nothing less than the highest quality from our farmers. And, they have delivered, over and over again, year after year.

Let me tell you who we don't revere: corporate agricultural concerns who don't know us or our families, who may or may not have the delivery of highest quality food products as their first and foremost business priority. If one of our farmers delivers questionable food, there are few secrets in a small, talkative town.

Burdensome regulations have their place, and I believe it is the job of the federal government to decide these things. But, I question this new decision as necessary for our small processors. Has anyone talked to them, the smaller processors? In your attempt to save us from "the bad food guys", please remain mindful that many of us, out here in the trenches of food sanity, have developed and followed safe food practices that reflect farm sensibility, not corporate sensibility.

Lastly, I am distressed that one of my family's food suppliers is worrying about a fight with the government, instead of her real business of feeding me and my neighbors.

Sincerely,



Angel Dobrow  
1301 Washington Street  
Northfield, MN 55057

**Russell, Linda**

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**From:** Jeffers, Mary Katherine  
**Sent:** Friday, May 07, 2010 1:33 PM  
**To:** Russell, Linda  
**Subject:** FW: usda testing/Question from Ask the Expert-- Other - 1272324204186  
**Attachments:** TEXT.htm

Please draft a response.  
Thanks,

Mary Katherine Jeffers  
Issues Analyst  
USDA/Food Safety and Inspection Service  
Office of Public Affairs and Consumer Education  
Executive Correspondence & Issues Management Staff  
1400 Independence Ave SW, Room 1166  
Washington D.C. 20250  
Phone 202-690-3626

-----Original Message-----

**From:** Carson, Bryce  
**Sent:** Thursday, May 06, 2010 3:20 PM  
**To:** Jeffers, Mary Katherine  
**Subject:** FW: usda testing/Question from Ask the Expert-- Other - 1272324204186

Another one:

Bryce Carson, Issues Analyst  
U.S. Department of Agriculture  
Food Safety and Inspection Service  
Office of Public Affairs and Consumer Education  
Executive Correspondence & Issues Management Staff  
1400 Independence Avenue, S.W., Room 1164-S  
Washington, DC 20250  
(202) 720-7894  
[bryce.carson@fsis.usda.gov](mailto:bryce.carson@fsis.usda.gov)

-----Original Message-----

**From:** FSIS Webmaster  
**Sent:** Tuesday, May 04, 2010 12:02 PM  
**To:** Carson, Bryce  
**Cc:** [experts@usda.gov](mailto:experts@usda.gov)  
**Subject:** FW:usda testing/Question from Ask the Expert-- Other - 1272324204186

**Rhodes, Suzette**

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**From:** Heather Hampton+Knodle [progress2050@royell.org]  
**Sent:** Monday, May 24, 2010 10:54 AM  
**To:** Draft Validation Guide Comments  
**Subject:** EDC - Comments on HACCP Draft Validation Guidance  
**Attachments:** FSIS Comments 4 2010.doc

May 18, 2010

Mr. Alfred Almanza, Administrator  
Food Safety and Inspection Service  
U.S. Department of Agriculture  
Washington, DC 20250-3700

RE: HACCP Validation

Dear Mr. Almanza:

This attempt at tighter validation controls on the HACCP process might result in unintended consequences for rural development with little or no perceivable gain in food safety.

Our interest is rural economic development. At a time when our county has 15.1% unemployment (preceded by almost 10 years of 2% higher unemployment than our state), this proposal threatens one of the few small businesses that provides health insurance to its employees.

Our conversations with the local business owner, lead us to be concerned that the proposal will have a disproportionate impact on small business.

In this case, the plant has been in the business of custom meat processing since 1959. It has provided health insurance to employees since 1983. Based on 2009 numbers of 20 retail products and total processing numbers of 410 cattle, 290 hogs, 20 sheep and 10 goats, the plant owner estimates \$65,000 additional cost to comply with the proposed regulation. This estimate does not include labor costs to prepare the samples for laboratories or to record paperwork that would otherwise be spent in work that generates income for the employees.

In order to comply, they will have to borrow a minimum of \$50,000. The plant owner has stated he would have to tell sheep and goats to go elsewhere because the cost of ongoing compliance estimated at \$2800 per year per specie, would outweigh any income from processing those animals. He also stated he could not afford to innovate in the areas of trying different seasonings for ready-to-eat products because the costs could not be recovered.

The bottom line is that this plant does not have the volume of sales to be able to bear the costs of testing as it has been proposed in the draft guidance.

Given this example as our local frame of reference, we respectfully ask that you

consider some suggestions related to the administration of this regulation.

**Set frequency proportionate to market share.**

Frequency of Tests – Require tests based on the number of animals slaughtered. One base test per specie, then an additional test at a benchmark point such as the 100<sup>th</sup> animal of that specie processed in the facility. If time of year is critical based on data of past recalls, then provide a requirement for 1 test prior to peak seasons (ex. June before the July 4<sup>th</sup> holiday; November before Thanksgiving and Christmas holidays) or “x” number of animals, whichever is reached first in the calendar year.

Streamline retail product testing based on size of plant and volume of retail sales. The proposed guidance references HACCP categories, which is useful, but it is still unclear as to whether tests will be required on every product every month where a plant produces sausage links and sausage patties or a sausage with different seasonings. Again, testing prior to peak seasons might be an approach to working with smaller plants while meeting the larger mission of food safety.

**Set testing standards proportionate to recalls.**

To our knowledge, most recalls have pertained to products produced in plants that process several hundred head of animals a day.

An approach requiring a set number of tests per species in a given time period penalizes all meat processors, rather than recognizing that increased testing should be required in locations where increased risk of recalls is projected based on past history.

Consider more frequent tests on ready-to-eat (RTE) products where recalls have been more prevalent such as head cheese and specific sausage products.

We thank you for considering our comments.

Sincerely,

Heather Hampton+Knodle  
MCEDC Direct Line 217.851.4332  
Home Office 217.538.2171  
Executive Director  
Montgomery County Economic Development Corporation  
Hillsboro, Illinois  
[www.montgomerycountyillinois.org](http://www.montgomerycountyillinois.org)

**Rhodes, Suzette**

**From:** Mark H. Anbinder [mha@14850.com]  
**Sent:** Saturday, April 17, 2010 3:22 PM  
**To:** Draft Validation Guide Comments  
**Cc:** mario@gardengatedelivery.com; first.lady@whitehouse.gov  
**Subject:** Tightening regulations on small meat processors

Good afternoon! I'm writing to express my concern about the USDA's apparent plan to tighten regulatory control on small meat processors. I'm very concerned about the undue impact this will have on family farmers and other small producers, who are filling the small but growing demand for fresh, LOCAL meats in communities that have grown tired of factory food and are seeking local alternatives.

In and around Central New York, increasing regulation and the costs associated with meeting regulatory requirements have driven quite a few smaller meat processors out of the business already. My friends and neighbors who produce fresh, flavorful beef, chicken, duck, goat, lamb, pork, and more tell me that there are fewer and fewer places they can go to have their animals safely and humanely slaughtered and butchered for sale, and I worry that this problem will get considerably worse if the USDA makes it even harder for these small businesses to meet its standards.

Food safety is of course of vital importance, and I don't believe our standards should be loosened. But we mustn't pretend that small businesses who process meat are the same as, or should be treated the same as, the enormous factories that process mass-market meat for our supermarkets. It's those huge factory processors that carry the biggest risks of contamination and other issues, not the local processors. Forcing small processors to sharply increase their testing risks placing an undue burden on local processors, whose overhead is already tough to spread across the amount of business they do.

The local food movement can and must play an increasing role not just in our country's varied food economy, but in the way we as individual consumers feed our families. The First Lady's vital push for fresher food and better education for our children about healthy eating comes at exactly the right time, as farmers markets appear, thrive, and grow around the country; as consumers think more and more about the source of the food they're eating; and as television viewers tune in to watch Jamie Oliver's efforts to help bring healthful food to our schools. We as a country must do everything we can to advance, not hinder, these aims.

I urge the USDA to take every possible step to make it easier, not harder, for the small, community-focused businesses that do meat processing for our small farms to stay in business and to make a living for their own families. We need more, not fewer, of these processors, and adding to their regulatory burden could only have the opposite effect.

Thank you so much for your attention.

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Mark H. Anbinder, Vice President |  
Public Communications Inc. |  
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[mha@14850.com](mailto:mha@14850.com)  
<http://www.14850.com/>  
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