

Rhodes, Suzette

From: Rand Thomas [rand_thomas@harbro.net]
Sent: Saturday, April 03, 2010 3:30 PM
To: Draft Validation Guide Comments
Cc: 'Jay Wenterh'
Subject: Comments: HACCP System Validation

April 3, 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Re: Comments - Draft Guidance on HACCP System Validation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:

Harbro Packaging Company is a supplier of packaging materials and other products to small to medium-sized **meat** processing companies throughout the country. Through communication with our trade organizations and meat processing customers we are concerned that **initiating** systems validation for small to medium sized establishments will have a profound negative impact on the industry and our company as **well**.

It is our belief that this will cause many of the federal and state inspected processing plants we service to **dramatically** reduce their operations -- or even go out of business! The loss of income resulting from this could be devastating to Harbro **Packaging** Company and other industry suppliers, as a significant percentage our business originates from small establishments.

As a supplier to the meat industry, the integrity and safety of meat products is of major importance to us. Yet, it **appears** the proposed systems validation requirements will not significantly increase the safety of meat products above and beyond the **current** scientifically derived regulations, hazard control processes, and inspection systems that these plants currently operate under.

We strongly encourage you to reconsider the proposed systems validation requirements. The added costs will **almost** certainly lead to loss of income and jobs among the industry and the hundreds of suppliers that serve it—with no apparent benefit to the safety of our **food chain**.

The proposed regulations will have far-reaching impact. Now is not the time to impose yet another unnecessary **burden** on the small businesses that make up the back bone of our nation's economy!

We appreciate the opportunity to comment on the Draft Guidance on HACCP System Validation.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

Rand Thomas
Vice President

Rhodes, Suzette

From: Jeana Park [mihwap@gmail.com]
Sent: Sunday, May 23, 2010 8:50 AM
To: Draft Validation Guide Comments
Subject: Fwd: [FWD: Meat Processing Crisis: Comments Due!]

We raise several pigs and goats for ourselves and to sell at farmer's market. We slaughter our animals several times a year at a local USDA certified slaughterhouse. If any such regulation passes, it would put us in jeopardy. Make regulations that fit smaller plants. NOT ONE SIZE FITS ALL!

Yong Yuk
Et Cetera Farm
936 County Route 21
Ghent, NY 12075

> ----- Original Message -----

> Subject: Meat Processing Crisis: Comments Due!
> From: Krys Cail <KLC32@cornell.edu>
> Date: Tue, May 18, 2010 7:30 pm
> To: New York Farmers Market Federation Listserv
> <nyfarmersmarket-l@list.cornell.edu>
>

> I would like to take this opportunity to remind you of proposed meat processing regulations that might have an effect on the vendors in your market who sell meats. While these proposed regulations are aimed at slaughterhouses and meat packing facilities, not farmers, they may, if made law, drive both small meat processors and the small farmers who use them out of business. This is a serious threat, and we should all inform ourselves and submit comments before the extended comment due-date, May 19. If you have been meaning to do this, the time is now.

>
> The Advocacy Committee of the Board of Director of the Farmers Market Federation has considered this issue only briefly, as the time is short. We do not have a consensus position at this time, but we would like to encourage everyone to send in their comments on the proposed regulations. That can be done by sending email to: draftvalidationguidecomments@fsis.usda.gov

>
> Here is a link to a quote from a local beef and pork producer, by way of a local foods delivery service, that sums up the issue succinctly:
<http://maildart.awpry.com/t/r/e/bjjjth/jueujdh/>

>
> Here is an article in Salon:
http://www.salon.com/food/feature/2010/04/26/usda_testing_end_local_meat/

>
> Here is an advocacy call, with resources, from Beginningfarmers.org :
<http://beginningfarmers.org/act-to-support-local-meat-comments-on-haacp-system-validation/>

>
> Below I have reproduced a piece from a Virginia meat processor

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> Thanks,
>
> Krys Cail

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> Notes From a Slaughterhouse: Proposed USDA Rules Could Crimp Local Meat
> By Samuel Fromartz

>
> The following post was submitted by Joe Cloud, partner in T&E Meats, a small-scale locally focused slaughterhouse in Harrisonburg, Va. I wrote about T&E in the WaPo and invited Joe to post his thoughts on this blog. - SF

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> By Joe Cloud

> This is usually the slowest time of the year for butchering, but T&E Meats is booked months in advance, like the other small meat processing plants in Virginia. We're working at almost full capacity to bring locally grown, pasture-raised, and humanely slaughtered quality meats to market.

> But, right now, our future is looking tenuous due to newly proposed regulations from the USDA.

> Picture an hourglass and you'll understand the local, sustainable meat crisis: there are plenty of willing consumers looking for humanely raised, quality local meats, and there are more and more farmers looking to "meat" that consumer demand (sorry - couldn't help myself!), but the real bottle neck is processing capacity. Small, community-based meat processing plants have become an endangered species in America, done in by an ocean of super-cheap industrial meat and the challenges and costs of meeting one-size-fits-all regulations.

> Although species go extinct on earth on a regular basis, every so often there is a major event that comes along and wipes out 40% or 50%. The same happens in the small business world. A few businesses fold every year due to retirement, poor management, and changes in the market, and that is quite normal. But then every so often a catastrophic event comes along that causes a wholesale wipeout.

> In the small meat businesses in America, catastrophic events result from changes high up in the regulatory food chain that make it very difficult for small plants to adapt. The most recent extinction event occurred at the turn of the millennium when Small and Very Small USDA-inspected slaughter and processing plants were required to adopt the HACCP (Hazard Analysis and Critical Control Point Plan) system. It has been estimated that over 20%, perhaps more, of existing small plants went out of business when HACCP was first instituted. Now, proposed changes to HACCP threaten to take down many of the remaining local plants, making the availability of healthy, local meats a rare commodity.

> This is ironic given the USDA's new emphasis on promoting local food production. The department's Know Your Farmer Know Your Food Program web site says it wants to "foster the viability and growth of small and mid-size farms and ranches, and we want to create new opportunities for farmers and ranchers by promoting locally produced foods." But the newly proposed regulations from the Food Safety and Inspection Service (FSIS), the inspection arm of the USDA, will reduce local opportunities for ranchers, never mind create new ones.

>
> The intent of HACCP is to prevent contamination of meat by harmful pathogens. It does so by instituting well-recognized, established processes and controls set by the USDA itself. At T&E, we have had a HACCP Plan in place since 1999, and it works. We undergo extensive E.Coli testing every year, and have never had a positive sample.

> But on March 19, the FSIS published a Draft Guidance on HACCP System Validation, outlining new rules which would institute much more intensive testing of all meats, whether or not a problem has been identified. These requirements will cost small plants tens of thousands of dollars, perhaps even hundreds of thousands, every year -- a financial burden appears great enough to force many to shutter.

>
> Now, the reason these rules are being proposed is clear: millions of pounds of recalled hamburger, e. coli food poisoning incidents and distrust by consumers and foreign trading partners of U.S. produced meat. But these problems have arisen at plants that handle thousands of animals a day in extremely fast-moving production lines.

- > Small plants operate quite differently. At T&E, for example we process around 20 animals a day. I know which farmer delivered each animal, often because that same farmer wants his butchered animal back so he can sell it. We're not mixing thousands of animals of unknown provenance into piles of hamburger meat and then sending it all around the country.
- > 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. And perhaps they should, given the recalls arising from these large-scale facilities. But most small plants can't handle it.
- > The USDA needs to recognize that "One Size Fits All" inspection no longer works. The risks arising from mega agribusiness plants are far different from community-based plants and they should be regulated appropriately. This does not mean lowering the hurdles for small processors. Rather it means tailoring regulations to the scale and risks of an operation. That way we can provide what the consumer wants - safe AND local food, not just the shrink-wrapped anonymous meat in the supermarket.
- > The USDA is accepting comments on this matter until June 19th, 2010. The original deadline was April 19. You can learn more at the Association of American Meat Processors web site, or the Niche Meat Processors Assistance Network.
- > Please submit a comment if you care about community-based meat processing and humanely produced meats. Your comments really do matter. Submit your comments to the email address DraftValidationGuideComments@fsis.usda.gov or to the Docket Clerk, USDA, FSIS, Room 2-2127, 5601 Sunnyside Avenue, Beltsville, MD 20705.
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Rhodes, Suzette

From: danarcadiameats@netins.net
Sent: Thursday, April 01, 2010 10:22 AM
To: Draft Validation Guide Comments
Subject: Message from Internet User - Validation Comments

To whom it may concern in FSIS,

I am writing you to express my concern to the new interpretation of validation of CCP's in HACCP plans.

As I read, listen, and try to understand why such extensive validation testing would be needed, I remember that you are sitting behind a desk and not running a business. However you do not realized the impact you will have on many processors, producers, distributors and end consumers. The increased operating cost you would impose on businesses will force many to close, which will mean job losses and economic hardship for many.

If this draft is passed through and implemented family owned and loved business like ours will end as we know it today. It is very disheartening to know what little care you have for small and medium sized business owners that rely on their uniqueness to survive in today's market. The Extreme cost of lab work to validate each and every ccp is unacceptable by any size business. The economic impact this will place on the end consumer will be great, as those businesses that are left will be forced to drive their prices skyrocketing and probably to the point where sooner than later they'll lose their business because they priced themselves out of business. The businesses left will probably be big business. This seems to be the way that government would like it anyways, as it is easier to regulate few than many.

We completely understand food safety and believe in it as we sell to our families, relatives, friends and neighbors. We also believe that food standards have tripled over the last decade which is great. However with this new interpretation of this regulation is going above and beyond the call for food safety. All small plants already implement HACCP, GMP, SSOP's, SOP's, SPS's ect ect ect. From what we also understand the regulation is being re-interpreted because you believe that the current system is broken in plants. If you truly look the current system is broken only in big plants because they do not have hands on control of all steps in the HACCP plan. That is why you do not find near the NR's in small to very small processing plants. However you would want us to believe that because in most small to very small plants there are not any findings so something has to be wrong. The reason there is less finding is because we care more, as the big plants are about how much they can pass through for a profit vs. truly caring about the end consumer. It's just a job to most big plants vs. in a small to very small plant it's our lively hood, our life. You put everything you have into your job there are no hours, no set paycheck. You make the extra effort to take care of everything, in which in return you offer better food safety, quality and standard. We know what happens in our plant from the first step to the final step on how product is handled because we are hands on in every step of the process. Please remember we are the owners, HACCP coordinators, reviewers, quality control and clean up.

If this reinterpretation of this regulation is implement into federal, state, small and very small plants the economic impact will be enormous. The trickle down effect will definitely be passed on to the end consumer and supply companies. The cost of raw meat and cooked product will jump so high that no one will be able to afford to buy meat or cooked products unless under retail exempt status. We hope you can see the affect this will have on businesses and consumers. This reinterpretation if implemented will destroy the know your farmer know your food initiative, along with all size processors from small, very small, medium and big.

I also understand there are many grey area's as in any reinterpretation of any regulation and there will be changes along the way, however to what extent and what cost to businesses and consumers. There is already scientific evidence out there to validate the

processes in each plant. Currently implement HACCP and testing to validate the processes we follow. All HACCP pathogen testing done has proven that all products tested are safe with no findings. If findings are found or NR's are written correction action forms and steps are taken correct any issues that arise. HACCP plans have also been validated since the beginning of HACCP with supporting documentation and scientific evidence which has been going on for over a decade. This has also been reconfirmed with routine check ups by certified on-site inspection staff and routine pathogen testing. If this program is not sufficient enough now, will there ever be anything that is sufficient enough? We understand that HACCP is an always a change in progress and between new scientific evidence and findings the plan must be reviewed and altered. To what cost do we slow down or stop and at what cost will it take you to realize we have too much regulation and government. Common sense tells us that if we do not make a quality product that safe for the end consumer we will not survive as no one will purchase your product. How many job losses and business losses will it take for you to realize that it was small business and hard work that made this country the way it is along with its economic power?

Now about the economic impact of this reinterpretation of this regulation will impact the whole United States from processors, producers, distributors and end consumers. Could you imagine that with the current estimated cost of hundreds of thousands of dollars to processors in lab tests to validate their product what prices will need to be charged to make up for the increased operating cost. Imagine products cost will double to triple for the end consumer, restaurants, anywhere food is needed, like the schools. Since the huge operating cost for processors will increase they will be forced to close doors. Now that only leaves the big processors that will regulate the market, in which they already do. Prices of meat will be driven high, so anyone that uses meat in their business will need to charge more in return they will probably price themselves out of business. Also farmer prices will more than likely plummet because there will be only a few processors left to bring their livestock to in which will cause a high supply and low demand because of meat prices. As the livestock price plummets, the end cost to the consumers and distributors skyrocket and businesses will close. Many farmers will quit raising livestock because they will not be able to afford to, especially the small farmers and all that will be left will be the big farmers, even if they can survive the crash. Prices will eventually come back up but no one on the small scale will ever be able to afford to get back in. Which leads back to one of my first points that it seems like the government is not about the small businesses but only big business. Remember that it is a scientific fact that you cannot test safety in food products. If you implement this reinterpretation of this regulation I want to say, wait sorry, I mean we, our family want to personally extend a big thank you for helping to push us out by over regulation and high operating cost of our business and our livelihood for the last 3 generations. That means our family has been in this type of occupation for over 50 some years and with a reinterpretation by an individual, can take that all away with a signature and without any disregard to us and to the economic impact you will create. So on behalf of my family, our employees, our customers we thank you for working on taking away a business so dearly loved and built by hard work and sweat with a swoop of a signature.

Sincerely,

A very small family owned and operated business.

Steve and Linda Julin 2nd generation, Dan and Abbie Julin 3rd generation, Cole Julin 3rd generation, and hopefully grandchildren 4th generation.

Rhodes, Suzette

From: Jess Aulwes [Jess@edgewoodlocker.com]
Sent: Thursday, April 01, 2010 3:52 PM
To: Draft Validation Guide Comments
Subject: Comment

Edgewood Locker, Inc.

609 W. Union St. ~ P.O. Box 245 ~ Edgewood, IA 52042
Phone (563) 928-6814 ~ Fax (563) 928-6925

April 1, 2010

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

Dear Mr. Almanza:

This letter is written on behalf of the Edgewood Locker in Edgewood, Iowa and all of the small meat processors, in regards to **March 19, 2010 USDA:FSIS Draft Guidance: HACCP Systems Validation document.**

At the Edgewood Locker food safety is the number one priority. The facility and staff are USDA inspected and operate under an approved HACCP plan, as required by the Meat and Poultry Inspection Regulations. Validation is a requirement of an approved HACCP plan (CFR 417.4) and has been since 1996, when HACCP was implemented. After numerous correspondence from several of our associations, USDA, FSIS released on March 19, 2010 the "USDA: FSIS Draft Guidance: HACCP System Validation" document which laid out the proposed changes to our validation process.

Until this time, well-recognized processes, which are being used by hundreds of plants and have been for numerous years, have been recognized by FSIS as needing no validation. Though not technically regulation, FSIS has included in *Federal Register* Notices "FSIS will consider such process schedules validated, since they will consist of processing methods already accepted by the Agency as effective" 64 *Fed Reg.* 741, col.1 (January 6, 1999).

USDA, FSIS is now proposing that establishments be required to perform *Initial Validation* (CRF 417.4). "Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended." Large processors have been operating under HACCP since 1996 and small and very plants since 2000. We have established over the last 10 years that our HACCP plan is "functioning as intended."

The proposed verification standards would require validation of all prerequisite programs as well as validation of critical control points. The guidelines set-forth by USDA, FSIS, would mandate microbiological testing in-plant as the only acceptable form of HACCP validation. USDA, FSIS has proposed that 13 consecutive sets of tests be performed for each established critical control point, and prerequisite program the establishment uses as support for why the establishment considers a food safety hazard to be not reasonably likely to occur. The testing they suggest would require that testing be performed for each different kind of product a plant produces, which for Edgewood Locker would be nearly 100 different products. Each test would require a two pound sample of product be taken before the CCP is met and following the CCP (et. two pounds of raw uncooked hot dogs and two pounds of fully cooked hot dogs must both be tested). These samples would need to be taken 13 times for each product. Some HACCP plans have more critical control points and would require more samples to be sent in for testing. We have estimated that in order to comply with the new rules the Edgewood Locker would be required to test well over 4000 pounds of product. The cost involved in the samples alone is astounding. This does not even take into consideration the cost of overnight shipping these samples to a lab or the cost associated in actually running the microbiological tests. Some of the tests that would be required can run as much as \$300 each, as in the case of *Clostridium Botulinum*. We have roughly estimated that implementing this program would cost the Edgewood Locker a minimum of \$350,000.

The cost of operation under these provisions would greatly impact all small meat processors. Many would be forced out of business. If the impact did not cause a business to close completely, it would potential force them to operate as custom exempt facilities instead of operating under inspection. This would affect both USDA and state inspected facilities. If a facility was able to continue operation under inspection the increase in cost to the consumer would also be greatly increased.

The reinterpretation of CFR 417.4 severely impact everyone. The Edgewood Locker is a major employer in the community. The proposed rule change could potential cause us to layoff a number of employees. We provide a significant positive economic impact in our community and all of Northeast Iowa. If we are no longer able to operate as a USDA facility we will no longer be able to process for a number of wholesale customers and would potentially put several small family owned companies out of business.

We are concerned about recent actions by the United States Department of Agricultural, Food Safety Inspection Staff that would affect the economic viability of this industry. It is not feasible for the Edgewood Locker or any small processor to logistically perform the tasks that USDA, FSIS is proposing. The cost is too great.

Sincerely,

Jessica L. Aulwes
HACCP Manager
Edgewood Locker, Inc.

Rhodes, Suzette

From: ionimeatproc@iowatelecom.net
Sent: Thursday, April 01, 2010 6:00 PM
To: Draft Validation Guide Comments
Subject: Validation of HACPP Plans

To Whom it May Concern,

My name is Michelle Weiss. I am from North East Iowa. Born and raised. I am 44 years old. My husband, Robin, is 45. We have been together for 28 years. We have raised 3 terrific children. In September of 2000, we took a plunge and bought the locker in Ionia, Iowa. We took everything out of our 401K and prayed that we had made the right decision. It has been, to say the least, an interesting ride. It was quite an eye opener. Working 70 to 80 hours a week, not having a weekend off, dealing with employees, the public, and, of course, the state. At our locker, we employ 5 people besides ourselves. Craig is a young man, just 19, who works two jobs. His mother married a man and moved out of state when he was 14. She left him with an older sister. Craig is just trying to survive. And, I'm sure, trying to get over the fact that his mom didn't love him enough to take him with her. Dale is 45, he's a farmer. A small farmer. He can't compete with the corporate farms. He needed extra income so he cuts meat at our locker. Farming, if your small, doesn't pay all the bills. Bronlyn is a 57 year old woman who has worked in a bank for 30 years. They are trying to help their daughter pay off student loans. So, she helps part time in the office. They didn't help their other children because their other childrens loans didn't have an interest rate of 8-10%. Patrick is 26 and the father of two small children. He has full custody of them. He is working a \$7.50 an hour job wrapping meat so he can put food on his table. Then there's Clayton. He is also 45. Doesn't have a pot to pea in or a window to throw it out of, but that, as he will tell you, is because of his own doings. Clay got involved in drugs at an early age. Spent time in the slammer. This is a life you and I know nothing about. He came here a couple of years ago and begged me for a job. He had been out of prison for 3 years and no one would hire him because he was an ex-con. I hired him. He has missed one day of work in almost two years and he has never been late.

At our locker, we all know the absolute most important thing is food safety. We strive to be the safest, cleanest and most accommodating locker around. We have to be, because this is our lively hood. It takes all of us to make this work.

Why did I tell you all of this? Because I wanted you to know a little bit about the people who will be without jobs after these validation requirements are implemented.

You see, we need the local bars' business, we cannot go retail exempt. We simply will not be able to afford the costs involved in the validation process.

Thank you for your time.

Sincerely,
Michelle Weiss

Ionia Meat Processing, Inc.
204 East Union
Ionia, Iowa 50645