

- Your partner in implementing Biotechnology

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IRRADIATION

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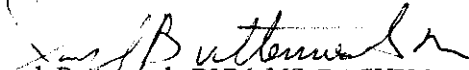
FSIS Docket Clerk
Room 102
Cotton Annex Building
300 12th Street, SW
Washington DC 20250-3700

REFERENCE Docket No. 00-047N

FSIS AGENCY'S FUTURE

1. You need to put more of your resources to make HACCP work. This means you must empower your customer, the processor. You should do this before you go on to something else such as the HACCP FARM-TO-TABLE continuum or merging programs with other governmental agencies.
2. The USDA/FSIS should not get involved with an on the farm program. You can encourage the processors to go to the farm with a program that pays the producer for delivering a better product.
3. Stop micromanaging. HACCP was supposed to reduce this. You need to do what other federal agencies have done. Reduce manpower in Washington DC and at the management level.
4. You need to assure imports meet the standards that you impose on our domestic products. You say you do, but we all know this is not true.

Sincerely:


Joseph Butterweck, DVM, MS, DACVPM
Director, Environmental Medicine Programs

ATTACHMENTS:

1. Discussion of FSIS HACCP program
2. Thirteen suggestion for implementing HACCP

Pathogens do not read regulations. Regulators will always regulate and write more regulations. Washington DC will always try to run the food safety programs. There lies the problem. It is a regulator culture issue. Not much chance of making real improvements in food safety. Unless you make HACCP work.

Today another meeting. There have been many in the past and there will be more in the future. The cost is tremendous. The results will always be the same. No productive changes, just a paper change. You talk about alliances with FDA, CDC and others. Maybe even merging programs and giving authority to one new agency. None of these in the past or future will significantly improve food safety. You must bring the field decision makers at the farm level into the process. You must pay them just like you are being paid.

The major reason you are gathered here today is the concern about O157:H7. It defies regulators. Now you are talking about farm food safety. Good idea, but how will you implement it? You do not have the authority to go on the farm and you should not. You talk about promoting on the farm better sanitation by cleaning the water troughs. That does not need a Washington or State level regulatory initiative. My Grandfather knew and did thus like most ranchers' do today.

Let the private sector with no government involvement deal with farm food safety. Presently, no one pays the producer significant incentives to produce a safer product. Until that happens, you will not see much progress. The buyer and processor of the raw cattle product must pay. No more regulators or government encouraged programs by joint industry and governmental-university funded education. They are too costly, take too long to make a dent and are out dated by the time they get implemented.

What does the meat industry do today? They are so over regulated that wait to see what the air is like from Washington. They act only because of a regulation, not because it makes good food safety sense. Until Washington really empowers the producer and processor, there will be no significant improvements in improving food safety. Those segments of the food industry that are not over regulated do much better in providing a safe product. They do it without micro managed governmental food safety.

Do not misunderstand me; I'm not against government involvement. However, when the problems get worse and the regulations fill the bookshelves, more decades pass, more meetings are convened; it is time to take a fresh look.

This was attempted with HACCP. In theory, it would give the industry the empowerment to make the necessary changes quickly. Innovation systems and technology like food irradiation could be implemented at the local level. But it has not worked. Why, because the reason I discussed above. The regulatory had to get back in and they started to over regulate again. The HACCP paradigm shift never happened.

What is the proper path to take? Reduce the food safety bureaucracy. Eliminate positions in Washington. Forget about creating alliances and reorganizations. Put your resources in HACCP, the way it was supposed to have been done. Also encourage the buyer and processor of the raw product to pay for safer product, not just talk about it or wait until for another program from Washington. Sure, the food safety agencies will lose power. That is part of HACCP. Empower your local inspectors and the processors. If you fail to do this, you will have more meetings to discuss what you should have done. Isn't this what you're the tone of the meeting is today?

Now, start thinking and discussing methods to reduce the regulations and how to pass their current tasks to the private sector. Then do it. Of course, this will result in loss of authority by the bureaucracy. All the other options have been tried with little success.

I'm also attaching an: answers to "13 common asked questions about HACCP". It was presented at the American Biological Safety Association meeting October 2000. It also applies to the food safety, medical devices and other applications to implement a complete HACCP program.

Joseph Butterweck, DVM, DACVPM

HACCP is high technology to prevent illness and injury. It must be implemented and managed appropriately to achieve the desired outcome. It is the leader in safety risk management. It is a tool that must be used only when indicated.

ANSWERS TO 13 COMMON ASKED QUESTIONS

1. HACCP is a **paradigm shift** in the way we inspect. It will gradually replace many traditional inspections systems.
2. It is **science based**. Thus it is defensible. It puts industry in charge of introducing new technology into their business with minimal regulatory interference and delays.
3. ISO standards and HACCP are not the same and should not be commingled. Quality is needed for a good HACCP plan. It is possible to have good quality and an unsafe system.
4. HACCP doesn't have a **higher source of authority**. It is self generating and should promote harmony. The team is the final decision maker.
5. HACCP **reduces paper work**. Too many CCP's are worse than not enough.
6. **Biological hazards** are the most challenging safety problems. HACCP was primarily developed for reducing risks from pathogens. **HACCP focus on biological safety**.
7. A **HACCP plan** is more than just using HACCP principles. HACCP principles alone are not workable.
8. HACCP is a continual process that must be re-evaluated frequently. **Customer input** is imperative. You must also diligently review your suppliers (sources) HACCP plan.
9. It **takes more than a year** for a company team to develop and implement a HACCP plan. Attempting to cover up a deficient HACCP plan with a voluminous paper plan results in a non workable plan.
10. Industry leaders have found HACCP can dramatically reduces costs. It is necessary for your HACCP team to have full support from the companies executives
11. **Private industry must lead**. Academia and regulators can only provide the spark.
12. Implementing HACCP requires a team approach and lots of **experience and continuous scenario training**.
13. The **California 3 "C's "** HACCP system addresses current problems of HACCP implementation. Paper work reduction, scenario training and positive outcome are it's priorities.

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