COMMENTS ON RECALL POLICIES AND PROCEDURES

October 16, 1998

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

RE: **Docket Number 98-029N**

S.T.O.P.; Safe Tables Our Priority appreciates this opportunity to comment on recall policies and procedures at the Department of Agriculture. S.T.O.P. is a nonprofit, grassroots organization consisting of victims of foodborne illness, family, friends and concerned individuals who recognize the threat pathogens pose in the U.S. food supply. S.T.O.P.'s mission is to prevent unnecessary illness and loss of life from pathogenic foodborne illness. Improving food recall policies is a top priority for this organization.

In the past year, FSIS has made some significant improvements in recall policies and procedures. First, the agency took unusual, but appropriate action in the case of the Hudson Foods recall by continuing to investigate the scope when it learned that plant was a high capacity establishment, by withdrawing inspection when the plant didn't cooperate, and by expanding the recall as information widening the potential spread of contamination was available. FSIS has appropriately reinforced this approach in the recent case of the Bauer Meat Company.

Second, we applaud the agency for publicly recognizing the need for expanded recall authority and for requesting legislation for mandatory recall and civil fines and penalties. S.T.O.P. will continue to support this effort.

Third, we thank FSIS for holding a public meeting on recall September 24, 1997. The meeting was timely and the agency's constituents had a strong interest in the information presented.

Fourth, we commend the agency for incorporating several proposed improvements suggested at the public meeting. These adopted suggestions include updating the recall list on the website to include the exact name of the pathogenic adulterant and placing all recall press releases on the agency web site.

Fifth, we applaud the establishment of the Recall Notification Report and its posting on the agency web site. While we continue to urge issuance of press releases for all pathogen related recalls, we are encouraged by the interim step of posting recall information in an easily accessible format.

While S.T.O.P. applauds FSIS for making these improvements in its recall policies and procedures, there is ample room for further improvements. We strongly urge the agency to require brand labeling and origin labeling on all consumer food packages

under its jurisdiction. We continue our support for thorough trace back in every recall related to human pathogens. We endorse the suggestion to deploy compliance officers to plants when a potential recall problem arises. Our support for mandatory recall authority, authority to assess fines and civil penalties, and authority to require safe food practices on the farm has not wavered.

S.T.O.P. is deeply concerned about several recommendations made in the working group report. There is no question that the federal government should have an active role in recalls. We vehemently oppose recommendations to transfer government responsibilities to the regulated, recalling entity. The recalling establishment should not determine the scope of recalls and write recall press releases.

I. Process

S.T.O.P. has concerns about the manner in which the committee was formed and the process for handling the report. Generally, the agency forms advisory committees with a design to ensure balanced representation in an effort to elicit well-rounded advise. As far as we can tell, only one out of twelve working group members has public health credentials. It is our understanding that none of the committee members are epidemiologists.

It appears that the group may have been formed with the intent of providing an internal review for the agency, yet the committee's report was released publicly. We question the effectiveness of a review process that led to the public release of a controversial document that does not reflect the official views of the agency. We also are concerned that stake holders were requested to provide comment on this un-official document. This process has denied stake holders from learning the agency's official current thinking on recall. It has also placed stake holders in the awkward position of investing resources in preparing comments on a report that does not necessarily reflect the views of the regulatory agency.

Finally, we are concerned that FSIS representatives met with Senators Kerrey and Harkin on July 27 regarding the report. We do not understand why FSIS representatives met with members of Congress to discuss recommendations in a report that does not officially reflect the views of the agency. The August 6 issue of FSIS' "Thursday Report" stated, "Both offices were generally supportive and understood the differences between these changes to voluntary recall provisions and the mandatory recall provisions requested in the legislation they have introduced." It is not clear whether the offices understood that the report was not an agency endorsed document.

II. Purpose

The working group states that the purpose of recall "is to effect the removal from commerce of meat, poultry, or egg products that there is reason to believe are adulterated or misbranded. (page 4)" While we agree that removing tainted product

from the market place is a critical component of recall, we would characterize this action as the function of recall. Since the 1993 west coast *E. coli* O157:H7 outbreak, FSIS has repeatedly assured the public that protecting public health is the agency's primary purpose.

Recall is not designed to solve contamination issues. Fortunately, the FSIS inspection laws demand government scrutiny of every meat and poultry carcass that enters interstate commerce. However, mistakes are inevitable. Even with strict monitoring and prevention methods, some contaminated product does reach the market place. Therefore, recall is a corrective action.

Foodborne contamination frequently causes illness and death. The Council for Agricultural Science and Technology estimates that there are between 6.5 and 33 million illnesses and 9,000 deaths due to foodborne illness in the U.S. each year. Foodborne pathogens pose very serious risks to consumers. Our members have suffered heart attacks, blindness, seizures, paralysis, liver failure, brain damage, kidney failure, and death due to foodborne illness.

Product retrieval is yet another food safety component that prevents illnesses and deaths. If pathogens are found in food, that food needs to be recalled as quickly as possible to avoid harm. The longer tainted product is in commerce, the higher the probability that it will cause harm.

S.T.O.P. is very disappointed that the agency's over arching dedication to public health appears to have been forgotten or misplaced by the working group. The organization firmly believes recall of contaminated product is a public health function. The primary purpose of removing tainted products from the market is to prevent illness and death. The secondary purpose is enforcing food safety laws: prevent contaminated product from reaching consumers. The agency may not have explicit recall authority, but as the working group noted, it is charged with removing adulterated products from commerce.

Recall requests are an emergency enforcement measure taken when product does not meet the standards of the food safety laws. The design of the agency's food inspection system should have no bearing on the agency's request to remove confirmed or suspected tainted product from the market place. Inspection and recall are separate functions. Inspection involves oversight to prevent contaminated product from entering commerce. Recall is the emergency action taken to remove tainted product from commerce.

By its definition, recall results from an inspection and food handling mistake: tainted product was produced and incorrectly passed the inspection system. Once a mistake has been made that puts the public at risk, no margin for additional error should be allowed. FSIS should not rely on faith and corporate goodwill when public health is at risk. The agency should to the best of its ability under present authority make sure recalls are implemented correctly as soon as they are determined.

III. The Agency's Role

Taxpayers expect the government to take immediate action to protect public health. The food inspection program is financed by the public's taxes for their protection. At a minimum, consumers expect a government food safety agency to identify product contamination, to remove contaminated product from commerce, and to notify the public of contamination and recall.

The 1998 Hudson Foods recall emphasized USDA's lack of recall authority. The significant attention this authority gap garnered demonstrates the public's attitude towards recall: it is a government function. S.T.O.P. received numerous phone calls on its victims hotline from consumers who were angry that federal food safety agencies did not possess recall authority. Most taxpayers assumed that federal food safety agencies already had recall authority.

S.T.O.P. adamantly and vociferously opposes all recommendations made by the working group that would reduce FSIS' role in recalls. The move to HACCP should not be used as an excuse to diminish enforcement of food safety laws. We agree that the food industry should bear responsibility for the safety of foods that they produce, but industry's adoption of greater safety responsibility does not release the government from enforcement responsibilities. We are frankly shocked that a government committee charged with reviewing food inspection recall procedures would conclude that the same government agency requesting authority to recall should diminish its role in recalls from ensuring that they are handled properly to verifying that they are handled properly.

Consumers want a neutral, third party to inspect food and enforce food safety laws. Like other businesses, food establishments have an interest in making profits. And like other businesses, some will cheat to increase revenue. Evidence of food companies risking public health to make a profit urged the adoption of new meat inspection laws in 1906, and the creation of those laws is justified every day. The FSIS first "Quarterly Regulatory and Enforcement Report" provided numerous instances in its criminal actions section of intentional efforts to mislead the public or risk public health for profit. Because the temptation to cheat is great and the consequences to public health are serious, it is vital that FSIS take a proactive rather than a passive, verifying role in potential recall situations.

The public expects those who violate the law or harm public health to be held accountable. Any law is meaningless if it isn't enforced. Lack of accountability provides a disincentive for the food industry to comply with the law. It makes better business sense to avoid taking extra precautions if the chances of linking contamination to an establishment are minimal.

Only a small fraction of foodborne illness is traced to its source. Time after time recalled food cannot be identified by consumers or FSIS. The source of contamination frequently isn't found. For example, the source of raw materials that went into the Jack in the Box ground beef that caused over 700 illnesses and four deaths was never determined. There were approximately twelve suppliers identified in the Hudson Foods recall, but the likely source of contaminated raw materials was not identified.

Consumer confidence in food safety is down. A Kimberly-Clark September 9, 1998 press release announcing the results of consumer food safety confidence polling stated, "people are clearly concerned about the safety of the food they eat." In a

September 1, 1998 Burger King press release, the company noted that it took a full eight months after the Hudson Foods recall for its sales to recover after Hudson was identified as a supplier to the restaurant chain.

The persistent lack of accountability for food safety violations exacerbates consumers' distrust of food safety enforcement and the food industry. Placing responsibility for determining the scope of a recall and notifying the public of a recall in the hands of the recalling establishment will decimate consumer confidence in the government's food safety agencies, and rightly so. The entity with strong financial interest in limiting the amount of product recalled and diminishing concern about the safety of the firm's products cannot be trusted with these tasks. Profit, not public health, is the primary concern of the food industry.

While we admire the working group's optimism, we simply do not agree with the group's assumption that the entire food industry will take full responsibility for food safety under HACCP. Nor do we believe that the industry's fear of bad publicity or accountability would prevent some establishments from risking public health for profit.

A. Recall Committee

S.T.O.P. strongly supports the working group's recommendation to include a compliance officer in the recall committee, and dispatching him or her to the plant as soon as there is the possibility of a recall. Sending a committee member trained in records review to the establishment as soon as possible is a good way to assure that a subsequent recall is the right scope, and that establishments who have violated the law will be held accountable. The incentive to adhere to food safety laws is diminished if violators are not held accountable.

The Hudson Foods recall provides at least one example that the recalling entity cannot be relied upon to determine the scope of a recall. According to the transcript of the September 1997 National Advisory Committee for Meat and Poultry Inspection, FSIS Administrator Billy stated, "what needs to be clear here is that the company provided us the figure of 20,000 pounds as representing the product associated with the two codes as a result. After we started to get information from other sources that those codes added up to much more product, it was then that we sent one of our compliance officers to look at records. (page 399 of FSIS transcript)"

Putting a compliance officer on premises to check records will increase the probability that the appropriate scope of a recall will be determined from the onset, and therefore prevent illnesses and deaths. The compliance officer record review should take place simultaneously with the establishment's review. Time should not be lost waiting for the establishment to present their information before verifying it.

S.T.O.P. also agrees with the working group's recommendation to include CDC in the recall committee when human pathogens are involved in a recall. We applaud FSIS' decision to hire additional staff with public health and human medical credentials to guide agency action with regard to human health concerns.

The organization encourages inclusion of both epidemiologists and compliance officers in the recall committee. The combined skills of these experts would better ensure the accuracy and efficacy of the committee's work.

S.T.O.P. supports the working group's recommendation that FSIS develop SOPs for recall. It is our understanding that FSIS has developed a recall manual, which may have addressed this recommendation. The SOPs or manual should include or be accompanied by a list of "case histories" that establish recall policy precedents. This compilation could guide and expedite future, difficult recall decisions and provide precedence to defend or promote a decision.

The organization urges the agency to maintain a single, central location for compiling information about recalls. Recall files are information resources that should be maintained in a manner that provides easy access to important facts in each case. It is our understanding that institutional memory plays a significant role in FSIS recall decision making. Such a file should prevent loss of institutional memory when recall committee members retire.

The present classifications of recalls should be more clearly defined. For instance, all human pathogen related recalls should be classified Class 1. The classification should be specified for human pathogen in a raw or ready to eat product. There should be no opportunity for an establishment to negotiate a recall classification in exchange for deciding to initiate a recall. Once the definitions are clear and opportunities for negotiating classifications are removed, the director of EDR should be authorized to independently decide whether to request a recall.

In the spirit of the President's Food Safety Council's effort to harmonize government food safety policies, S.T.O.P. further encourages all food safety agencies to better define recall classifications and, where feasible, share the same definitions across food safety agencies. The legal restrictions on the agencies' recall classifications should be addressed. Each agency should recognize the same hazard and risk posed in the food product under their jurisdiction with the same response. For instance, both FSIS and FDA should recognize E. coli O157:H7 as an adulterant in raw and cooked products and have the same approach for recalling E. coli O157:H7 contaminated product, whether it is apple juice or ground beef.

B. Communicating with Establishments About Recall

FSIS does not have mandatory recall authority. If a company disagrees with the government's request for a recall, it can refuse to recall its products. The fact that the company is the ultimate decision maker in the event of a recall relieves the government of any responsibility to provide additional opportunities for an establishment to argue against a recall.

Every moment that contaminated product is in commerce extends an opportunity for illness and death. While the agency has the responsibility to treat regulated parties fairly, the agency should not extend special courtesies in recall cases where public health is at risk. Establishments responsible for placing the public health at risk have demonstrated that they could not prevent contaminated product from reaching consumers. They have betrayed the public's trust and they should not be allowed an egregious opportunity to inflict further damage on the consuming public.

The recall committee should take the establishment's reputation into consideration when making decisions related to recall. For instance, the agency should take a stricter approach when the establishment involved with the recall has poor compliance records or microbial testing results. Information relevant for quickly

assessing whether an establishment tends to act in good faith, to consistently produce product of a higher quality than its peers, and to comply with the law should be easily accessible to the committee.

S.T.O.P. urges the agency to require that establishments notify FSIS each time it conducts a recall, particularly in cases where human pathogens have adulterated ready to eat foods. There is precedent for this recommendation. Currently, FSIS requires establishments and laboratories that detect E. coli O157:H7 in ground beef to notify the agency. Certainly pathogens such as Listeria or Campylobacter in ready to eat product pose similar public health risk and meet the same adulteration definition as E. coli O157:H7 in raw or cooked product.

FSIS should be notified in order to assure that the proper steps are taken with regard to recall scope, implementation, and public notification. In addition, FSIS would need to be notified to investigate whether the source of the contamination in the recalled product was distributed to additional establishments, and to ensure that corrective action is taken to address the contamination source. If our legal argument for notification is deemed invalid, S.T.O.P. suggests that in addition to recall authority, the agency seek authority to demand notification of all potential product adulteration from establishments and laboratories.

S.T.O.P. agrees with the working group that protocol for contacting FSIS about a potential recall problem should be well defined and documented. Easy access to this information will facilitate FSIS notification of potential problems and industry initiated recalls. We urge the agency to create a 24 hour, toll free recall information hotline that would dispense the latest information on recalls to callers. FSIS recall contacts for the industry should be included in the proposed hotline menu options.

We also support the recommendation that establishments identify their recall contact (name and 24 hour phone contact information) and that this information be published in the Meat and Poultry Inspection Directory. If the working group's recommendation doesn't call for requiring contact information, we do.

We agree that establishments should be notified as soon as there is any hint of a potential recall problem. Early notification increases the likelihood that a necessary recall will take place as quickly as possible. Good corporate citizens will respond immediately to notification by gathering information needed to determine whether there is a problem and, if a problem is confirmed, by taking corrective action as soon as possible to protect public health. We note that in the case of the 1997 Hudson Foods recall, the first hint of illnesses linked to Hudson ground beef occurred in mid-July. The recall was not announced until August 12. There was ample opportunity for a more responsible company to have taken action much earlier to prevent illnesses.

C. Data Needed for Recalls

It is our understanding that to request a recall, FSIS requires data that would meet legal scrutiny. The nation's food inspection laws provide some basis for facilitating collection of recall information, but in some cases do not provide enough authority. In another instance of legal restraints obscuring the public's interest in recall, important public notification information is withheld if it is key to a criminal investigation.

S.T.O.P. recommends that the agency seek any additional authority required to improve quick, efficient compilation of relevant recall information. For instance, we encourage providing food safety agencies the authority to commandeer independent laboratory information stored off establishment premises. Any documentation relevant to determining the facts and the scope of a potential recall should be available to the agency in the interest of protecting public health and enforcing food safety laws.

Although the records necessary to effect a recall should be maintained in accordance with a valid HACCP plan, we recognize that adoption of the HACCP regulation does not guarantee consistent compliance with the rule. Therefore, S.T.O.P. supports the working group's recommendation to embark on rule making that would require comprehensive record keeping necessary in the event of a recall, including supplier records, production records, production codes, SOPs, and distribution records. Consistent with the government's farm to table HACCP approach, we recommend that these records reach from farm to retail.

In instances where recalled product was purchased by consumers using debit or credit cards, the records should extend to the consumer. At the March 1998 Public Voice conference on food policy, Carolyn Bernardi noted that Sutton Place Gourmet called its customers to inform them that products sold at the store were contaminated with Cyclospora. The store urged customers to return or discard the contaminated products. S.T.O.P. applauds this practice.

S.T.O.P. endorses the agency's decision to compile quarterly reports of its enforcement activities, phone logs of consumer complaints, and databases of microbial testing results. We encourage FSIS to continue compiling this very useful information. It not only makes the agency accountable to the public, it also provides useful records for the recall committee. We recommend that all of the food safety agencies follow the lead of FSIS by providing similar accountability materials to the public. Investors use annual reports to evaluate performances of companies, taxpayers can use these reports to evaluate the performance of the nation's food safety agencies.

In addition to record keeping rule making, S.T.O.P. strongly encourages FSIS to require brand and origin labeling on all consumer packaging. Labeling is the single best step FSIS can take to improve recalls. Although mandatory recall authority is needed, this drawback would be less disastrous if FSIS could skip over the step of convincing the establishment to recall product and instead directly inform all distribution points and consumers to remove the clearly labeled and identifiable product from commerce. Labeling provides the most effective means to quickly identify recalled product and swiftly remove it from commerce without waiting to convince an establishment that refuses to recall.

Evidence located right on the food package is just as valuable and valid in a court of law as evidence buried in files of records, but it is more readily accessible. Labeling will assure that poor record keeping and uncooperative behavior don't prevent a recall from being as effective as it can be.

Labeling greatly increases the effectiveness of a recall and provides the best opportunity for FSIS to meet its farm to table food safety goal. Through labeling, every subsequent step in the production chain from contamination source to

consumers would have the greatest opportunity to remove recalled product from their inventory or pantries. For the first time it would be the exception rather than the rule for consumers to be unable to determine whether they have recalled product in their pantries.

Brand and origin labeling is possible and it is necessary. We have already remarked on the lack of accountability within the present food safety system. Tracing contamination to the source is the exception not the rule. Instances where recalled product can be identified by consumers to facilitate its removal from the market are rare.

In fact, the current policy of restricting the issuance of press releases to instances where the recalled product can be identified by consumers provides a disincentive for consumer product labeling. This disincentive must be removed to improve the effectiveness of recalls and thereby improve public health protection.

At least one company, Coleman Natural Meats, currently tracks its production from the individual animal to the consumer package through the use of bar codes. The United Kingdom recently established a cattle tracing system that tracks the history of every bovine within the country. The 1997 Food Code urges retailers to observe origin labels on molluscan shellfish. The identification of the harvester, date of harvest, and location of harvest are required.

Requiring brand and origin labeling will provide another incentive not only for greater food safety law compliance but also for adoption of voluntary measures that surpass present food safety laws. Accountability increases the likelihood that establishments will take precautions to avoid recalls.

We have evidence that poor product is willfully dumped into the large, un-branded food products market where the source is unlikely to be identified in case of recall or illness. The attached IBP memorandum obtained by an anonymous source documents the purposeful diversion of risky product from name brand products. In the memo, the foodborne risk associated with temperature abused carcasses is acknowledged. The company recommends that carcasses which are not placed into the cooler within two hours "be designated for outside (non-IBP) carcass sale." This memorandum confirms that companies divert risky product from items that will bear their brand name. Product that doesn't meet company set standards or supplier contract standards can be diverted to other buyers who won't place a brand name or other origination information on the product.

Clearly, the current practice of allowing unlabeled meat on the market does nothing to instill one of the main objectives of HACCP regulation: placing the responsibility of food safety on the industry. Without accountability, the industry can easily evade responsibility for food products served to millions of Americans. The opportunity for food companies to engage in this type of evasive behavior should have passed long ago.

Origin labeling is needed not only to build accountability and additional precautions into the food system, but also to facilitate trace back to the source in every instance of recall and illness. As was mentioned earlier, tracing contamination to the source is rare. Between 1982 and 1996, 139 outbreaks linked to ground beef were reported to CDC. For fourteen years, there were an average of approximately 10 ground beef

outbreaks per year. Only one outbreak has ever been linked to the farm or ranch. The chance that contaminated product would be linked to the farm or ranch is 1 in 901,000. There are approximately 1,900 ground beef processing plants and 100,000 ground beef grinders at the retail level in the U.S. Assuming that one outbreak is traced to each processing level each year, the chance that contaminated product would be linked to a specific ground beef processing plant is 1 in 1,900 and is 1 in 100,000 at the retail grinding level. The odds are stacked against consumers.

The likelihood of finding and correcting contamination is very slim. Even with required record keeping the opportunity for mistakes is great. To best increase the chances of determining the source of contamination, every food product should be marked with codes representing each step of its life from farm to final distribution point.

Facilitating trace back to the source of contamination will greatly improve the odds of removing all contaminated product from the market and best protecting public health. For example, if the source of contaminated raw materials to a grinder could be determined along with the exact raw materials from that source, it could also be determined whether the lot or carcass of contaminated raw material was sent to others. If the source of contamination was chronic, it would be more likely to be identified and addressed. For instance, a contaminated conveyor belt would be identified as the source and replaced to prevent further contamination and threat to public health.

We predict that the agency will conserve resources if brand and origin labels are required. Swifter trace backs and facilitated recalls take less time to complete and therefore require fewer resources. Tax payers deserve an improved food safety system that costs less.

It is S.T.O.P.'s understanding that consumer product complaints to FSIS are handled through a triage system. We have not reviewed the system, but intend to. S.T.O.P. would support a system that effectively identifies and sorts unfounded complaints from legitimate concerns so that resources are directed to investigating all legitimate concerns. If consumer complaints are not part of records compliance officers can check, they should be.

S.T.O.P. maintains its own consumer hotline and understands that some members of the public have concerns that cannot be investigated based on available information. However, we are concerned that some legitimate concerns could be ignored or improperly prioritized. We strongly urge the federal government to investigate all legitimate consumer concerns. Further, we recommend that the agency create a consumer feedback loop so that those who interact with the agency can evaluate its response.

We applaud FSIS' decision to post consumer complaint contact information on its website. We recommend that the agency establish a toll free, 24 hour recall information hotline to disseminate the latest recall information to the public. We also recommend placing the consumer complaint information on the menu of this proposed hotline.

S.T.O.P. would like to see reporting of foodborne illness standardized and required in every state, in conjunction with the requirement that reported illness information be

shared immediately with CDC and food safety agencies. This would provide means to assess epidemiologic information and find illness patterns. In the absence of this ideal, we encourage the agency and state public health departments to continue their present cooperative measure in the effort to disseminate relevant and timely information.

The working group's recommendation to have state health departments compile foodborne illness attack rates and odds ratios concerns S.T.O.P. This request implies that there is a particular threshold for illness that dictates particular responses. If this is true, we find it reprehensible. A threshold for investigation should not exist in a prevention based system. The risk of one severe illness or death should be enough to warrant action. Every person counts. Our members vehemently oppose creation of any decision making standard that lowers the criteria of response to include expendable human beings.

It is S.T.O.P.'s understanding that recently implemented laboratory accreditation systems will ensure that samples are handled in a consistent manner to guarantee consistent, dependable results. While we understand that the agency is inclined to only rely on its own laboratories' analysis to ensure results that would be recognized as valid in a court of law, we encourage the agency to accept results from accredited laboratories.

All reports of pathogen adulteration findings in food products should trigger establishment and appropriate public health agency(ies) notification of a potential recall problem. The earlier the alert, the better establishments can prepare in case the concern is justified.

S.T.O.P. supports the working group recommendation to prepare a more thorough checklist that will better reflect FSIS' information needs.

E. Effect of Pathogens on the Recall Process

S.T.O.P. strongly disagrees with the working group's conclusion that pathogen contamination should not affect the agency's recall principles or approach to Class I recalls. The purpose of the food safety agencies is protecting public health. Recall is many times one of the last opportunities to protect public health by removing contaminated or suspected contaminated product from commerce. Tainted product doesn't belong in commerce. It violates the food safety laws. It is a mistake that passed inspection. Recall corrects the mistake.

Human pathogens are appropriately delegated Class I recall status. However, S.T.O.P. argues that the presence of pathogens does necessitate an alteration in the present Class I recall procedure.

The working group recognizes the difficulty of determining the extent of contamination, tracing contaminated product forward, and identifying contaminated product in the market place. We find it remarkable that the working group identifies these difficulties without making an effort to work around them. Consumer notification coupled with available recall information to provide an incentive to adhere to precautions isn't the best outcome of a recall process, but it is the best outcome in circumstances where determining contamination scope, trace back, and / or product identification falls short.

Pathogen contamination poses a very real and serious risk to the public. If the public is notified of the risks and hazards posed in the market place, they have an opportunity to address these risks and hazards. Currently, FSIS issues press releases regarding Class I product recalls when the product can be identified by the consumer. This policy ignores the opportunity to reduce illnesses and deaths through risk communication and consumer education.

S.T.O.P. strongly recommends that the agency improve public health by issuing a press release any time a pathogen contaminated product is detected in the marketplace. Press releases issued in cases of pathogen contaminated, anonymous product should:

- notify the public that they have been exposed to a foodborne pathogen;
- provide as much information as possible to assist consumers in determining their risk of exposure (information that meets this criteria includes listing the states where product was distributed, the type of retail establishments affected, and the names of the retail outlets);
- warn the public about possible secondary exposure and list appropriate precautions to prevent secondary infection; and
- inform the public about illness symptoms and incubation periods.

To increase the chances of reducing foodborne illness and death, FSIS should provide the information needed to convince likely illness victims to seek medical attention, notify the public of appropriate precautions to avoid infection, and strengthen the education message by coupling it with an incentive to change behavior.

As noted in section D, S.T.O.P. supports allowing a pathogen finding from an accredited outside laboratory to serve as the basis of a recall request. The credibility of non-accredited laboratory findings or analysis from another source will probably need to be determined on a case by case basis. We expect that in these cases testing methods, protocol and other assessments will be made, and that in some cases further testing, plant sanitation records, HACCP records, or other investigative findings will be necessary to establish the need for a recall.

Again, we recommend that notification of a possible problem be made to the establishment and relevant public health authorities as soon as possible. In the case of the 1997 Hudson Foods recall, testing of product opened by a subsequently ill consumer tested positive in July. Hudson Foods was notified of the results at that time but chose not to voluntarily recall. When the agency obtained an intact sample positive test result nearly two weeks later, the recall was announced. We concur with the working group's recommendation that FSIS update the recall directive to reflect the agency's policy on external laboratory findings.

F. Trace Back

S.T.O.P. vehemently opposes limiting the depth of trace back for the following reasons: consumers expect food safety agencies to hold establishments accountable for violating food safety standards, the source of contamination must be found to determine whether other tainted product is in commerce, and if the source continues to pose a threat to consumers, it must be found to correct the contamination problem. The vast majority of S.T.O.P.'s victim members do not know the source of

their foodborne illness. Trace back is a top priority for those who have suffered from gaps in FSIS' food safety system. Victims are appalled to learn that FSIS employees appear to place little priority upon learning from their own mistakes and the mistakes of the industries they monitor which have led to the victims' illnesses and deaths.

S.T.O.P. finds the working group's logic for limiting trace backs deeply flawed. The group argues that with HACCP in place, source product will not be adulterated and adulterated product won't be produced. If it is produced it, "will be detected by the establishment and will not affect the establishment's products. If they are not, the establishment has a significant problem that requires FSIS' attention as well as the attention of the establishment. Thus, placing emphasis on trace backs will divert FSIS' attention from were it belongs in a HACCP system. (page 35)"

Although we support HACCP, we do not perceive it as a panacea. If FSIS employees really believe that HACCP will prevent all contamination unless there is significant problem, the agency has a significant problem. The agency's own quarterly reports indicate that approximately 10% of HACCP plants are not in compliance. HACCP isn't working approximately 10% of the time.

S.T.O.P. participated in developing the generic HACCP models for FSIS. It was clear from the discussions among the working groups that developed those models that those who envisioned supplier testing of raw materials as part of HACCP were in the minority.

FSIS recognizes that this is the case. Currently, the agency tries to encourage supplier testing through a boneless beef supplier active testing exemption to the E. coli O157:H7 random testing program.

Every FSIS employee who served on the working group should know by now that the agency has no rules regarding the content of HACCP plans. No particular procedure should be assumed to be present in any HACCP plan.

Trace back is a corrective action. It is part of enforcement. HACCP is an inspection program that is separate from recall. By the time recall comes into play, the tainted product has already passed inspection. The fact that tainted product passed inspection is a significant problem. Recall informs FSIS in the most alarming way that a HACCP plan didn't work. In the instances of recall, FSIS should be diverted from HACCP. Recall is a wake up call.

The working group also argues that it doesn't have the resources to conduct trace back in every instance. If the agency doesn't have sufficient revenue to do its job, it should document its budget short fall and ask Congress for a supplement. Appropriate funding should be included in the next budget submitted to Congress. In addition, the agency should cut the expenses related to trace back by requiring origin and brand labels on all consumer food products.

We entirely disagree with the group's statement, "trace back one level makes sense because it balances the need to find the source of the problem against the resource requirements of doing so. (page 36)" We are deeply concerned that any FSIS employees have the attitude that an incomplete trace back is justified to save money. Resource concerns are relative. When tight budgets are a problem, tasks are

prioritized. Trace back to the source of contamination that slipped through inspection to end up in the market place should be a top priority.

It appears that those who share the attitude reflected in the working group document have little commitment to holding those responsible for contamination accountable for posing public health risks or harming consumers. This is a serious cause for concern.

In section C, S.T.O.P. proposes origin and brand labeling to facilitate more effective, and cost efficient trace backs. If tight resources are such a great concern, the agency should require origin and brand labeling as soon as possible so it can afford to do its job.

S.T.O.P. recommends that the agency include in its record keeping rule making, the requirement that all source product in a final product be documented. This suggestion has two benefits. First, record keeping will facilitate trace back. Second, it is likely to urge establishments to avoid mixing product from many sources together to reduce record keeping tasks. It is widely recognized that limiting the sources of a pooled product decrease its likelihood of being contaminated.

In cases where contamination could be traced to the farm, the agency would lack the authority to require corrective action. This should change. Increasingly, correlations have been drawn between animal husbandry practices and contamination. For example, it is widely recognized that stressed animals are more likely to shed pathogens. A Cornell University study indicates that a certain diet may prevent E. coli O157:H7 infection in the animal. Dale Hancock has compiled evidence to show a correlation between infrequently cleaned feed and water troughs and contamination. FSIS should have the authority to require animal husbandry practices that reduce or eliminate pathogenic contamination of animals. Prevention of initial animal contamination is a substantial preventive measure, and one that is in accordance with FSIS' farm to table approach.

S.T.O.P. disagrees with the working group's recommendation to restrict the use of an interdisciplinary team. Interdisciplinary teams offer the best chance of conducting an effective trace back. Consumers pay for the food safety system, they value determining the cause of food safety mistakes, they want accountability, and they want justice. Those paying for the system expect to have the best system. The President, Congress, and FSIS repeatedly tell the public that they have the best food safety system in the world. Therefore, the public should receive the best food safety system, which includes interdisciplinary trace back teams.

G. Retail Recalls

According to the working group report, "the adulteration and misbranding provisions of the FMIA and PPIA apply to these [retail produced] products. Thus, FSIS has jurisdiction over products produced in exempt retail processing operations. (page 39)" The report states that all FSIS retail recalls have involved E. coli O157:H7 contamination. It is our understanding that this is the case because FSIS tests retail ground beef in accordance with its E. coli O157:H7 sampling program and because the other likely retail product to be recalled by FSIS is ready to eat foods, which are almost always sampled and held before distribution until results are returned.

S.T.O.P. is deeply concerned with FSIS' approach to retail recalls. If the agency has jurisdiction at this level, it should take appropriate action. Deferring to the state or locality invites an opportunity for error that can cost illnesses and lives. This is evident from the description of the manner in which three out of five recalls were handled by states and localities: a general alert was issued reminding consumers to cook ground beef or there was no action whatsoever. In three out of five instances where FSIS deferred to the state, the state response was unacceptable.

Every time there is an E. coli O157:H7 ground beef retail recall there should be issuance of a press release notifying the public that there is a recall and urging appropriate precautions. Notifying the public is a method to encourage removal of product from the marketplace, clearly a recognized goal of recall.

In addition to always notifying the state agency responsible for food inspection, S.T.O.P. urges FSIS to always notify state public health agencies at the same time that it notifies an establishment of a potential positive E. coli O157:H7 test, or any other potential recall problem. Early alert to a suspected problem increases the chances of preventing and identifying illnesses.

IV. Public Notification

The public wants more information. Public notification furthers the goals of improving public health, removing contaminated product from commerce, and providing enforcement information to the public. S.T.O.P. absolutely opposes the working group's recommendation to transfer responsibility for public notification of recall to the recalling establishment. The recall establishment is the most likely entity with the greatest interest in diminishing the impact of public notification about a recall. The establishment simply cannot be trusted to adequately notify the public of a recall and present the facts in an unbiased manner.

S.T.O.P. members are offended by the recommendation to make the recalling entity responsible for notifying the public of recalls. This is particularly shocking because the recommendation is contained in a report that was initiated after the largest and most notorious food recall in the nation's history.

The same recall surprised the public by alerting it to an alarming lack of enforcement authority and an inappropriate need to negotiate recalls with the regulated industry. The Secretary of Agriculture told the public in a televised press conference on August 20, 1997, "most folks would be shocked to know that industry -- and not the federal food safety experts -- ultimately made the decision as to whether or not food is recalled when the public's safety is compromised."

The press who knew about it took particular interest in the fact that the agency had a practice of allowing the recalling establishment to review agency press releases. An August 21, 1997 Wall Street Journal article began with this statement, "Last week, when the Agriculture Department announced what was to become the largest beef recall ever, who was it that cleared the press release? The answer: Hudson Foods Inc., the company responsible for producing the bacterial-tainted ground beef that health officials have linked to an outbreak of 16 food-poisoning cases in Colorado."

Around the time that this article was published, the Secretary of Agriculture issued a memorandum to all sub cabinet officials and agency administrators informing them the industry would no longer be allowed to review agency press releases.

There is something very seriously wrong within a government department that on the one hand makes a very visible effort to assure the public that it wants mandatory recall authority and that it has changed its procedures so that the recalling entity no longer reviews the press releases regarding its recall, and on the other hand produces a document within a year of these actions that recommends giving sole authorship of the recall press release to the recalling establishment. There appears to be a disturbing breech between the philosophy advocated by the Secretary and the philosophies of the working group. This leads one to question whether there are other important issues on which FSIS staff oppose the edict of the Secretary of Agriculture.

Just as the public responsible for financing the food safety system expects a neutral, third party to inspect food, they also expect to receive unbiased, accurate information about recalls from a neutral, third party. The press release information is very important. It can prevent consumers from eating contaminated product and thereby avoid illness and death. This function is too important to risk by placing it in the hands of the very entity with the greatest interest in downplaying the information contained in the press release.

The public deserves accurate and truthful recall information that will encourage proper precautions, and they deserve this information from the start. There is no good reason to risk the public health in a misguided effort to transfer federal responsibilities to the regulated entity. Appropriate recall information can save lives, misleading information can result in illness and death.

There is very good evidence to support the need for an unbiased party to present recall information to the public. Food industry attorney Phil Olsson noted in an April 27, 1998 Food Drug Law Institute conference on product recalls that companies have a vested interest in distributing as few press releases as possible. He also noted that establishments should regard writing a recall press release as an opportunity to put their spin on the issue. Olsson made a point of telling attendees that FSIS no longer allowed establishments to review the agency's recall press releases.

Information in recall press releases should urge consumers to remove recalled product from their pantries. In the case of the recent recall of Salmonella tainted, ready to eat Zartic beef patties, the company's CEO is credited with giving the following advice in an October 13, 1998 Atlanta Journal-Constitution article: "properly re-heating the Zartic products should eliminate any possible danger." He then assures the public that "the vast majority of the products we are recalling are perfectly good." These statements do not encourage consumers to return or discard an adulterated, recalled food. In fact, they encourage eating the recalled food. This is particularly egregious because the products in question tend to be heated in microwaves, which unevenly heat food. Therefore, the cooking process is often inadequate to kill the pathogen and there is a greater likelihood that people eating these patties will get sick.

It is clear that consumers can anticipate further downplayed risk and negligent statements if establishments are given the responsibility of informing consumers

about their own recalls. A June 29, 1998 Costco press release about a recall of E. coli O157:H7 contaminated meat reads as if it were crafted to specifically contradict the agency's findings justifying the recall: "Costco has an extensive testing program to help minimize any possible risk from E. coli 0157:H7 in beef sold at our warehouse stores. Our internal tests and those of independent certified laboratories detected no contamination in this meat..." USDA tested Costco beef taken from the same batch eaten by an illness victim and found traces of E. coli 0157:H7. A woman was hospitalized after consuming contaminated Costco beef.

One who read the Costco press release would be unlikely to conclude that eating the product could lead to hospitalization. Under the "consumer remedy" section of the press release Costco stated, "Consumers can ensure the safety of ground beef by cooking it to an internal temperature of 160 degrees Fahrenheit." There was no mention of the fact that handling the raw product could lead to illness or death.

It is more difficult to correct news that to present news. Setting the facts straight once incorrect or misleading information is released requires greater effort than the initial notification effort. In light of the evidence that the recalling entity is very likely to issue misleading or incorrect information, it is also very likely that the federal government will not only have recklessly placed the public health at risk by relying on the recalling establishment to issue press releases, but also will have wasted more resources by requiring a greater effort to notify the public than what would have been required if the agency made initial contact with the press.

It is our understanding that FSIS is not authorized to penalize establishments that mislead or mis-characterize important information regarding recalls in press releases. Even if FSIS did have authority to penalize establishments for negligence, it would be difficult to prove. It is far better for FSIS to maintain authority for writing press releases than risk having to prove fraud or negligence.

Besides, press offices are regularly flooded with corporate press releases. A federal food safety agency issued press release regarding recall is far more likely to attract attention than a food establishment or trade associated press release. As in the case of the consumer, the media is far more likely to find the government more credible than the food industry when presenting information about food recalls.

A. Communication to the Public

S.T.O.P. strongly supports the issuance of press releases in the case of every human pathogen related recall. Proactive public notification can save lives by giving people information they need to assess symptoms, seek medical attention, and take appropriate precautions.

The New York Times recently reported that 16% of Americans lack health insurance. This is a very large segment of the population approximately 43.4 million people. People without health insurance have a very strong financial disincentive to seek medical attention. These facts place greater emphasis on the need for proactive public notification of recall information that will provide a sufficient incentive for likely foodborne illness victims to seek medical attention. Nearly one out of five in the recall press story audience will require a very compelling reason to seek medical treatment.

The working group notes that FDA follows a policy where the recalling company writes its own press release and is responsible for distributing it to local press. The fact that another federal food safety agency has established a bad precedent should not be grounds for weakening FSIS' recall policies and procedures. In this instance, FDA should follow FSIS' lead.

We support the working group's recommendation that the recall press release be issued the same day as the recall decision. Reports and press releases should be updated as soon as relevant information is made available. It is better to update a press release than to wait until information becomes available before issuing a press release. We urge the agency to release information related to human pathogen recalls as soon as possible. In cases where there are uncertainties about important information, the documents should be released with uncertainties clearly noted.

S.T.O.P. also agrees that the press release should contain as much information as possible about the amount and distribution of the recalled product, the location of the establishment, and the identity of the parent company. At a minimum, all press releases and notification reports related to human pathogen recalls should include:

- information that alerts the public to the recall,
- facts that help people identify the recalled product as best as they can,
- information that assists the public in determining the risks that the recalled product poses or posed to them and others,
- a strong warning that the recalled product should not be consumed,
- a recommendation that the recalled product be returned or discarded immediately,
- information that will help people determine whether they should seek medical attention, and
- a list of appropriate precautions that will reduce the chances of contracting illness.

We agree that proper handling information should appear in the press release. However, this information should never be presented in a manner that would suggest that the procedures are a remedy -- that contaminated product be cooked and eaten. We recommend that the press release and / or notification report include the following handling information statement: "Most foodborne illnesses are not linked to outbreaks. Food handlers should always follow safe handling procedures to reduce the probability of contracting illness. These precautions include..." Procedures addressing cross contamination and secondary infection should be included.

We agree with the working group that in cases where product has reached sub-consignees and the recalling establishment and its consignees can document precisely where the recall product has gone, that a press release is not needed. However we add the stipulation that all product be accounted for and returned within 24 hours. As the case of Malt-O-Meal's Salmonella contaminated cereal recall demonstrated, as long as contaminated product is around there is a risk that it could re-enter commerce.

S.T.O.P. applauds the agency's decision to at least notify the public of recalls that are not coupled with press releases. We support the development of the Recall Notification Reports and their posting on the world wide web. We appreciate that all recalls should have a report and that all reports will be posted on the website and

summarized in the quarterly enforcement report. We also support the issuance of these reports in the Constituent Update or Constituent Alert. We agree that the FSIS Constituent Report should include a listing of the week's recalls and their notification reports.

We recommend adding the following information to the recall report:

- Any information that will help the consumer identify the recalled product.
- The fate of the product, such as "cooked at John Doe's Poultry Processing Inc. and incorporated into Ma's Chicken Noodle Soup and Ma's Hearty Stew."
- Whether it is known that the recalled product has been linked to illnesses and the number of illnesses, hospitalizations, or deaths
- Illness symptoms, such as "most cases are characterized by severe abdominal cramping, many are accompanied by diarrhea and / or bloody stools, most cases are not accompanied by fever."
- Illness incubation period, such as "in most cases illness onset follows 2-3 weeks after exposure, the earliest known incident of onset is 6 days after exposure and the latest known instance of onset is 124 days after exposure."
- Whether the pathogen can be passed person to person.
- A strong recommendation that the recalled product be returned to the retailer or discarded.

Consumers should be urged to take precautions when discarding or returning recalled product that is contaminated with a pathogen that has a low infectious dose. Consumers should know that handling infectious products may lead to illness. For example, if the recall involved E. coli O157:H7 grocery store prepared and purchased ground beef, the agency should tell consumers to avoid touching the package by handling it with a plastic bag enclosed hand and bagging the package with that leak proof plastic bag. Any drippings from the recalled product should be immediately removed with a disposable tissue and the area disinfected.

- The address should be included in the corporate contact listing.
- The corporate contact listing should follow the government contact listing.

Again, the organization suggests that the agency improve recall communication with the public by establishing a toll free, 24 hour recall information hotline to disseminate information to the public as it becomes available. Even if the industry is offering a similar toll free, 24 hour recall information hotline, many consumers will want to get recall information from a neutral, third party.

To improve the dissemination of recall information to the public, FSIS should actively encourage publications to regularly list recalls. We assume that the agency media office already has or is attempting to foster good relationships with consumer, health and food reporters who are most likely to cover recall stories. If not, it should.

We also recommend that federal food safety agencies pool resources to disseminate information. For example, FSIS recall information could be included in FDA Consumer, which regularly lists FDA recall information. FSIS could also work with

FDA and the Consumer Product Safety Commission press staff to disseminate recall information to interested press. These cooperative efforts would be a small step in improving food safety agency coordination and resource allocation.

B. Communication Between Recalling Entities and Their Consignees

The working group notes that communication between the recalling establishment and consignees and sub-consignees is frequently hampered by poor record keeping and difficulty identifying product. In the case of the 1997 Beef America tainted beef chubs recall, the Food Marketing Institute was enlisted to inform its members of the recall. The fact that the agency had to resort to asking a food trade association to contact its members about a recall indicates that there is a serious problem with the present recall system. Sadly, consumers were not similarly notified of the recall through a press release. To address both the distribution records and the product identification problems, S.T.O.P. again recommends that FSIS require brand and origin labeling on individual, consumer packages. S.T.O.P. also supports the working group's record keeping recommendations.

S.T.O.P. supports the working groups recommendation that FSIS create a model letter that can be easily adapted by agencies to notify consignees and sub-consignees of a recall. This letter should be readily available in an electronic format to increase the chances that it will be quickly used to form a final document to be sent to consignees and sub-consignees. Use of electronic documents removes the time consuming step of typing information into a computer.

In cases where the recalling establishment does not have easy access to the machinery needed to ensure quick delivery of information, such as computers and fax machines, FSIS should assist the agency in contacting its consignees and sub-consignees as quickly as possible. We predict that these instances will be rare, and therefore will not place a great burden on FSIS' resources. The need to act quickly should outweigh resource conservation demands.

C. Interagency Communication

S.T.O.P. supports the ERD's current practice of faxing the Recall Notification Report to state departments of health and state epidemiologists as soon as a recall decision is made. We recommend extending this practice to instances when the potential recall problem is first identified.

The organization also applauds FSIS' effort to expedite recall communication with state agencies through FDA's computer network system. In addition, we support the recommendation that FSIS commit resources to develop and maintain good communication with other federal recall agencies. We applaud all of FSIS' efforts to develop relationships with state and federal public health agencies and groups such as FORCG.

We agree that FSIS should be apprised of food recalls outside its jurisdiction. There should be a designated person responsible for collecting and disseminating a monthly list of all federal food recalls, and this list should be published in an appropriate government document, such as FDA Consumer or the FSIS Constituent Update.

D. Intraagency Communication

S.T.O.P. supports the recommendation that the Recall Notification Report be used to notify all FSIS deputy administrators, all FSIS District Officers, and all parts of the Office of the Administrator. Intraagency communication is a necessary prerequisite for a unified food safety program.

V. Aftermath of Recalls

S.T.O.P. supports the working groups recommendation that the recall committee regularly evaluate its performance. Regular reviews provide an opportunity to identify flaws and propose improvements to the program. In the end, regular evaluations will contribute to a better recall program.

We encourage the agency to develop a feedback mechanism for gathering the assessments of consumers who alerted the agency of a potential recall problem and of consumers who suffered from recalled food contamination. Illness victims and those who alerted the agency to a problem are the best candidates to provide constructive comments. They have a strong interest in sharing their comments, and they provide the perspective of the very people FSIS is striving to serve.

In the course of a recall, S.T.O.P. urges FSIS to ensure that recalled product is handled properly. The recall represents at least two errors: food was adulterated and adulterated food passed inspection. Once contaminated product is retrieved from the market place there should be no opportunity for its return to commerce.

As long as a criminal investigation of a recall is ongoing, the recall should be open. The Recall Notification Report should note that this is the case. Once the investigation is concluded and the findings are made available to the public, the Recall Notification Report should be updated to include the findings.

A. Recovery of Recalled Product

Improved record keeping and brand and origin labeling would improve product recovery. Both record keeping and labeling would enhance recalled product identification, including identification and determination of the product's fate at the consignee and sub-consignee level. As previously mentioned, S.T.O.P. supports both measures.

S.T.O.P. also supports development of more rapid pathogen tests and quantitative pathogen tests. More rapid pathogen tests would enhance problem discovery. Quantitative pathogen tests would facilitate the development of pathogen adulteration standards in raw product.

B. Disposition of Recalled Product

S.T.O.P. disagrees with the working group recommendation to give the recalling establishment the responsibility for determining the disposition of recalled products. The working group's logic for proposing the change in disposition responsibility is

flawed. Simply because HACCP is the rule and plants are supposed to take responsibility to ensure that products it produces are adulterated, does not guarantee that products will be safe. In every recall instance a mistake has been made. There should be no further opportunity for error, particularly when the product to be processed is adulterated. We support the current requirement that FSIS be notified when recalled product is returned to an establishment and that FSIS be provided an opportunity to re-inspect product before it is reprocessed.

S.T.O.P. also disagrees with the working group's recommendation that the Secretary of Agriculture issue a statement ensuring the public that reprocessed E. coli O157:H7 product is safe. First, this statement sends the message to consumers that they can safely cook recalled E. coli O157:H7 contaminated product and consume it. In light of the fact that raw, E. coli O157:H7 product poses a danger through mere contact, the government should not spread a message implying that the public can safely store, handle, or cook E. coli O157:H7 contaminated product.

Second, there is a small risk that reprocessed product will not be treated properly or will be re-contaminated. There is always an opportunity for food contamination. The Secretary would by lying if he told the public that any food product is safe. As the food industry repeatedly reminds consumer advocates, there is no such thing as guaranteed safe food. The Malt-O-Meal recalled cereal incident demonstrated that recalled food can be accidentally returned to commerce.

S.T.O.P. recommends that FSIS specially certify reprocessing facilities and maintain a list of approved establishments. The reprocessors should take extra precautions such as running a special line specifically for known adulterated food. This specially designated area would have extra barriers to cross contamination.

The 1996 European Communities (Zoonoses) Regulations notes the required use of specially designated slaughtering facilities when poultry flocks test positive for Salmonella enteritidis or Salmonella typhimurium:

"no birds leave the house concerned until the Minister has authorized the slaughter and destruction of the carcasses of such birds under the supervision of an official veterinarian or alternatively such birds are slaughtered in a slaughterhouse designated by the Minister... all the birds in the house shall be slaughtered in accordance with point 31 (c) of Chapter VI of Annex I to Council Directive 71/118/EEC, the official veterinarian of the slaughterhouse being informed of the decision to slaughter, in accordance with point 25 (a) of Chapter VI of Annex I of that Directive or be slaughtered and destroyed so as to reduce as much as possible the risk of spreading salmonella."

C. Review of Process Control Systems at Recalling Establishments

S.T.O.P. agrees with the working group that issuance of contaminated product should trigger review of the responsible establishment's HACCP plan. If errors are found, FSIS should ensure rather than simply verify that corrective action in addition to recall is taken. The incident should be investigated to determine whether the establishment violated food safety laws. If the establishment has violated food safety laws, punitive measures should be taken.

The agency should also review of the establishment's recall response. The effectiveness of the establishment's recall written plan should be assessed.

D. Review of Policy and Regulatory Significance of Recalls

S.T.O.P. agrees with the working group that the agency should review whether a recall is the result of an isolated HACCP plan failure or whether it signals a potential, industry-wide problem. We also agree that there should be regular evaluation of the agency's recall efforts.

However, S.T.O.P. also recommends that the agency seek external evaluations, particularly from state health departments, CDC, consumers who have registered product complaints that led to recall, and victims of recalled product contamination. A feedback mechanism to regularly solicit evaluations of those made ill by recalled product would be most useful. We anticipate that this group would consistently invest the necessary thought and effort into providing constructive evaluation of agency performance.

E. Indemnification

S.T.O.P. concurs with the working group's recommendation that FSIS not indemnify firms affected by poorly justified recalls. However, our reasoning differs significantly from the working group's. First, FSIS shouldn't indemnify establishments because the means to avoid mistakes are not always available. In some cases it will be prudent to quickly make a recall request decision without needed information.

Secondly, FSIS must act in the interest of the greatest good. While no one wants to needlessly cause financial loss to anyone, the risk of causing temporary financial harm should not outweigh the benefit of public health protection.

Third, and most important, the decision to recall remains ultimately the industry's decision. Should an establishment make the wrong judgment in light of subsequent evidence, they are ultimately responsible.

However, S.T.O.P. recommends that FSIS assist in absolving establishments that chose to initiate a recall in response to an FSIS request that was based on incomplete or incorrect information. In these instances, the agency should issue a public statement explaining the circumstances of the recall and note that the recall was initiated due to incomplete or incorrect information. This statement could be used by the company to reassure clients and customers that there was an error. In these instances, Recall Notification Reports should be corrected, distributed to the usual channels, and posted on the agency's website. Finally, if the agency establishes the proposed toll free, 24 hour recall hotline, the message should provide information that would present the corrected facts in the case of an unnecessary recall.

It is S.T.O.P.'s understanding that instances in which a decision based on incomplete information leads to an unnecessary recall are extremely rare. In fact, we are not aware of any.

VI. Conclusion

S.T.O.P. appreciates the agency's willingness to re-evaluate and improve its recall policies. While the agency has recently made many positive improvements, there is plenty of room for additional improvements. Thank you for providing S.T.O.P. with the opportunity to formally comment on the working group's report. We look forward to continuing to work with the agency on this important issue.

Respectfully submitted by,

Heather Klinkhamer
Program Director