

**Written Testimony of Jim Lugg
Former Executive Vice President, Food Safety and Quality,
Fresh Express and
Consultant, Chiquita Brands**

**before
House Energy and Commerce Subcommittee on Health
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Thank you Mr. Chairman and Members.

My name is Jim Lugg and I am former Executive Vice President of Food Safety and Quality for Fresh Express and Consultant for Chiquita Brands.

All food manufacturers are committed to having a food safety strategy in place. A solid food safety strategy minimizes food contamination and resulting public health issues.

Even though a solid food safety strategy is in place, experience has taught us that regular reviews and a thorough analysis of each and every step of the production, harvesting, and processing is necessary to understand where contamination could come from and address methods to eliminate the source.

At Fresh Express we have focused intensely on choosing production locations that allow us to easily see where contamination could have occurred. Rules are in place to

abandon a lot, or at least abandon the portion of the field suspected of having been compromised.

We produce nearly one hundred percent of our crops out of doors and we know there are serious risks from creatures in the environment, workers, and certainly irrigation water. Each of those risks must be identified, quantified, and a strategy must be in place to manage the risk. We also package produce in a facility subject to FDA's Good Manufacturing Practice regulations, which we stringently enforce in our operations.

I am convinced that any responsible food manufacturer is constantly conducting risk evaluations, addressing any possible source of contamination. This relentless process of risk evaluation leads to developing process adjustments or new preventive controls to manage the risks.

There are certain fundamental processes that all food manufacturers follow, but fresh produce is different from frozen or canned products. This means that each type of product has unique sorts of risks and this is why it is so vital that producers and processors carefully analyze their own unique risks and develop plans to address them.

At Fresh Express we rely on regular and frequent measurement of all the risks we have identified in our business. For example, before a field of lettuce is harvested someone has to walk the perimeter to look for animal incursion, sanitizer chemicals in plant wash water must be constantly measured, and harvesting equipment must be

inspected before use. All of these steps require that a written record must be kept telling us who did the inspection and at what time of day and on which day. Records are invaluable, but someone in our food safety group must review them before product gets into commerce and look for risks that we might not have previously identified.

I have just made a point of how critical monitoring, inspections, and testing are; however, I assure you they are steps that only tell us how effective our preventive process controls are. They do not tell us if we have contaminated product.

We urge Congress to require all food manufacturers to conduct a thorough risk evaluation that documents each and every risk. A part of that analysis must be a description of the preventive controls that are in place and regularly monitored to document and verify that the controls are effective. At Fresh Express we have company documents for Good Agricultural, Harvesting, and Processing practices. The documents are regularly reviewed and updated based on the latest information available to us.

At Fresh Express we believe FDA's role should be to review these plans and, where appropriate, to work with food manufacturers to improve those plans. We do not believe FDA approving those plans would gain anything. During the spinach crisis in 2006 we voluntarily provided FDA with the food safety documents developed by our company, even though we were not implicated in the outbreak.

A critical part of any risk evaluation is frequent review and that should be an absolute requirement along with review findings. Corrective actions taken following the reviews are every bit as important as the reviews themselves and must be documented. This should be a standard requirement for all food manufacturers because it would continuously increase the level of food safety.

FDA inspections could then be conducted frequently enough to verify that companies are evaluating foodborne hazards and implementing preventive controls according to their plan. Equally important would be to inspect the records documenting the changes made following the evaluation.

This approach is vital to a successful food safety result because it is a process that goes on daily. Another approach that some have suggested is more testing. The challenge with testing is where to take the sample. An acre of spinach has 3,000,000 plants. Even if we take sixty plants selected randomly, the odds of finding a human pathogen are not good. This is but one illustration of why we believe so strongly in developing processes through the supply chain that alert us to problems before product gets into commerce.

In summary, a vital role for FDA is to insist on complete and thorough food safety plans from all manufacturers that ensure regular risk evaluation is done. Just as important as the risk evaluation are the corrective action plans. Both the risk evaluation and the corrective action plan must be documented and confirmed by an audit of the

process. Such audits may be done by company auditors or by competent third parties, but they should not be mandated. Rather, audits should be used as a self-improvement tool for preventive control programs and their implementation. We must all work together to maximize the safety of food in the United States. However, ultimately safe food is industry's responsibility. Congress should explicitly recognize this by requiring that companies assess hazards and implement appropriate controls that are then verified by regulatory agencies.