AFLATOXIN: STRATEGIES FOR THE FUTURE

IOWA AFLATOXIN TASK FORCE

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Acknowledgements

The Iowa Corn Growers Association formed a task force in August of 1988 to deal with the problem of aflatoxin in the corn crop. The task force included representatives from the Iowa Department of Agriculture and Land Stewardship, Iowa Farm Bureau Federation, Iowa Grain and Feed Association, the Iowa Institute of Cooperation, and Iowa State University specialists in Veterinary Medicine, Plant Pathology, Economics, Agricultural Engineering, Statistics, and Veterinary Diagnostics.

This task force reviewed the results of a monitoring program, gathered and disseminated appropriate information about aflatoxin, and advised regulatory agencies and the Iowa Legislature on what was happening with aflatoxin and how to handle the situation.

This task force has developed an outline for the needs of the nation regarding aflatoxin in future years. In the event that weather conditions are such that aflatoxin may exist, appropriate organizations will begin to take actions.

This report does not imply that Iowa has higher levels of aflatoxin than any other state. However, this report does indicate that Iowa is prepared to deal responsibly with aflatoxin in the future.

This plan is an effort of all parties involved. We acknowledge the contributions made to this report, but this report should not be interpreted as a statement of policy of the individual organizations.
The Objective Of This Report:

To propose a general strategy and specific actions to protect the human and livestock health from the effects of aflatoxin contamination while minimizing the economic impact and market disruption.
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A. AFLATOXIN IN CORN: SAMPLING AND TESTING ISSUES AND ALTERNATIVE STRATEGIES FOR TESTING

I. Sampling and Testing Issues

A. Introduction: The 1988 Problem

Aflatoxin is a mycotoxin or a naturally occurring contaminant that may be produced by the fungus *Aspergillus Flavus* on corn. *Aspergillus flavus* can become established on ears of plants in the field or on corn after harvest. While the presence of *Aspergillus flavus* on corn or in feed products does not always mean that harmful levels of aflatoxin exist, it does mean that the potential for aflatoxin production is present. The widespread drought and accompanying hot weather during the summer of 1988 led to an elevated level of *Aspergillus flavus* on corn in the field and of aflatoxin in harvested grain. Aflatoxin was identified in the U.S. Corn Belt, an area where it does not normally occur. Although higher levels of aflatoxin are often present in corn produced outside the Corn Belt (Southern and Border States), a relatively small portion of the total crop is affected. Thus, 1989 presented special problems in marketing because aflatoxin occurred in the areas of greatest corn production.

Accurate sampling, grading and testing are essential to maintain a low cost bulk grain marketing system where each producer’s grain may be commingled and moved into market channels. The sampling, grading and testing are also critical factors in determining the capability of the grain system to function within its current regulatory framework. When a significant portion of the crop contains aflatoxin, failure to have practical and accurate sampling and testing creates several serious marketing problems.

The ability of the market to value the product according to end use, the ability of regulators to establish and enforce reasonable action levels for grain containing aflatoxin, and the ability of grain handlers and merchants to control internal financial risk, all depend on reliable measurements of aflatoxin levels in bulk lots. Experience from the 1988 corn crop indicates that current sampling technologies fall short when applied to aflatoxin.
B. Sampling Grain at the First Handler Level

One of the most serious problems was reliable sampling of inbound deliveries and outbound shipments at the country elevator. The current sampling and testing practices are well adapted to the task of moving bulk grain under normal circumstances. Grade factors have allowed the system to value bulk product accurately on a lot by lot basis with appropriate protection and minimal risk for buyers and sellers. This is not the case when aflatoxin levels must be determined.

The nature of aflatoxin is so radically different from typical grade and quality factors that accepted sampling, grading and testing practices may not be adequate to move grain through the system. Furthermore, aflatoxin sampling techniques compatible with the present bulk commodity handling practices may not be feasible.

Several characteristics of aflatoxin corn create severe problems for buyers, sellers, and regulators. These are:

1. The concentration of aflatoxin occurs in individual kernels of corn. A representative sample is needed to conduct accurate tests and make a correct inference about the bulk lots. However, a relatively small number of contaminated kernels may raise the level of the entire lot.

   For example, 6,000 kernels with a 0.1% (by weight) concentration of aflatoxin in a hopper car lot of 3,400 bushels (about 300 million kernels) would result in an aflatoxin level of 20 parts per billion (ppb) for the lot. Individual kernel concentrations of up to 0.5% have been reported in research studies. Concentration of such amounts in relatively few kernels reduces the accuracy of small samples to much lower levels than would exist if the aflatoxin were spread evenly through each of the 300 million kernels.

2. A second problem exists because the infected kernels themselves may not be evenly distributed through the bulk lot. In fact, they are not likely to be. Thus, a great deal of sample variation may occur due to the dispersion pattern of the affected kernels within the lot being sampled. This may be improved by sampling from multiple locations in the lot, but there is still inadequate assurance that a representative sample will be taken.

3. A third and even more intractable problem arises from differences in the aflatoxin levels in the individual kernels. Some infected kernels may contain many times the level in others. Thus, even if a representative number of affected kernels were to be selected in a sample, the ppb levels from sample to sample would vary a great deal depending upon whether or not a heavily contaminated or a modestly contaminated kernel was selected.
4. Finally, aflatoxin is measured in exceedingly small quantities compared to typical grade and quality characteristics. Gross defects such as broken corn, foreign material or even moisture content are not present in such minute quantities. Sampling practices compatible with measuring gross defects are ill suited to the fine measurements used for aflatoxin.

The problem can be illustrated by considering the example described above where 6,000 kernels, each with 0.1% contamination by weight, are in a carload of grain (about 300,000,000 kernels). Even if it is assumed that the infected kernels are evenly distributed through the load, typical sampling practices would not be reliable. The typical 2,000 gram inspection sample contains about 6,000 kernels. The odds are only about 11% that a sample would contain one or more infected kernels. But, assuming for simplicity that the kernels all weighed the same, a sample containing even one infected kernel would have 167 ppb aflatoxin, well above the actual concentration of 20 ppb for the entire lot.

The combined effects of the potentially small number of kernels contaminated, the potentially uneven distribution of infected kernels in a bulk lot, the variation in ppb levels within contaminated kernels and the precise measurements make existing sampling practices questionable. While quantitative test measurements on a given small sample can be accurate to about 1-5 ppb, such results are misleading unless the sample is representative. Sampling error may negate any relationship to the true level of aflatoxin in the bulk lot. Given current sampling technology and the large number of bulk lots delivered by producers in the harvest season, it may be extremely cumbersome and expensive to overcome these sampling problems at the first handler level.

The inability to sample and test with an acceptable degree of accuracy created a number of problems in marketing the 1988 crop. In some elevators, blacklight positive samples were further tested using precise quantitative techniques yielding either specific levels of aflatoxin in ppb or presence of a threshold reading. In other cases, grain with blacklight positive was rejected without further testing. Blacklight screening or quantitative testing was not conducted at some elevators.

In the cases where testing was done, the lack of sample reliability was a frustrating experience. In some cases, samples that tested less than 20 ppb were commingled with negative blacklight grain only to test above 20 ppb when loaded out. In other cases, inbound loads were rejected because test results showed greater than 20 ppb, but the same corn was accepted at a competing elevator where a new sample and test indicated lower ppb. In still other cases, FDA samples indicated that a whole elevator contained more than 20 ppb. Subsequently the storage bins were emptied and tested with all results at less than 20 ppb. The sampling difficulties were compounded by the FDA policy of considering any lot testing over 20 ppb as adulterated, and thus subject to seizures, even if the test result was unreliable.
II. Alternative Strategies For Sampling And Testing Of Corn

The primary goal of aflatoxin monitoring programs must be the protection of human and livestock health. Strategies to achieve this goal should be selected so that unnecessary cost and economic disruption are not created in the market channels. Three alternative strategies for sampling and testing may be pursued to accomplish the desired results. The cost and economic disruption are different for each strategy. The heaviest burden of cost and disruption falls on different firms and institutions under each strategy.

A. Inbound Oriented Testing Program

The first strategy is one of rigorous screening and testing of all inbound loads at the first handler level. To be effective, this would necessarily involve screening more samples from each load or lot delivered to first handlers. More samples with more grain in them would probably need to be tested in order to improve sampling reliability. This kind of program would be a radical departure from the standard grain industry procedures. Moreover, it remains to be seen whether or not precise enough sampling can be accomplished.

Advantages of this program (assuming that a procedure could be developed to sample with enough precision) are: (1) grain with a heavy aflatoxin content can be identified before it enters the channel. (2) Warehouse handlers, exporters and processors would run a lower risk of unknowingly purchasing corn with aflatoxin. (3) Grain purchased with aflatoxin content above action levels would not be inadvertently commingled with grain below the action threshold. (4) Producers’ indemnification programs could be more accurately handled. (5) Handlers would know the aflatoxin content of their inventory within narrower tolerances.

The strategy has a number of disadvantages over other possible approaches. These are: (1) All grain delivered would have to be rigorously sampled, screened with a blacklight and tested using quantitative methods at the first point of sale. Current capacity to handle harvest-time deliveries at the country elevator would probably be taxed to the breaking point. During harvest periods there is already congestion. Added sampling time would worsen the problem. (2) Reduced capacity to handle harvest-time delivery at elevators would induce farmers to place a larger fraction of the crop in on-farm storage. The marginal bushels would tend to be stored in less adequate facilities or would tend to be managed less intensively than would be the case in elevators. Both situations have the potential to increase the aggregate amount of aflatoxin and other mold damage in the crop. (3) The cost of sampling and testing rigorously at the first point of sale would be very large. All inbound grain would necessarily be subjected to the more complex and costly sampling and screening even though a significant fraction (well over half) would
be destined for feed uses that could accept grain with more aflatoxin. (4) There is more variation in lot sizes and delivery vehicles at the first handler level (ranging from 100 bushel lots in wagons to 1,000 bushel semitrailer-loads). This would make rigorous sampling more difficult. (5) More rigorous and complicated sampling would have to take place at a much larger number of sites. There are in excess of 4,000-4,500 licensed elevators and warehouses receiving grain under a federal license and/or a Uniform Grain Storage Agreement. Many of these licensed firms receive grain in multiple locations. Each location would have to be capable of implementing the appropriate sampling and testing procedures. (6) If supervised blending were to be required at all these sites, the available FDA personnel would be taxed and the intensity of supervision diluted. (7) Standardization of testing procedures would be needed. (8) This strategy does not prevent future contamination resulting from aflatoxin growth in stored grain.

If sufficiently reliable sampling techniques were to be developed, this strategy could function. If not, it is of dubious efficacy. Even with reliable sampling, there would be major disruption at the first-handler level. The largest cost burden would fall on producers and first-handlers. The least burden would fall on final processors, feed millers and exporters. The ability to pass the added cost to consumers would be limited with most being absorbed at the producer and first-handler level.

B. Final-Use Oriented Testing Strategy

In a final-user oriented strategy, the major regulatory emphasis in sampling and testing could be placed at the level where corn kernels have been ground or otherwise refined. This would not eliminate the need for testing whole kernel corn received at the processor level. Nor would it eliminate the need for screening at the first-handler level. It would place major emphasis on these test results from intermediate products. However, analysis of grain processed for direct human consumption would be concentrated at the grain processing plant. In the case of feed, it would be at the feed manufacturing plant or mill where the grain is ground and processed. In the case of export grain, it would be the river terminal or perhaps the export receiving and loading elevators, although exporters would not have the advantage of a ground or semi-processed product.

When the corn is ground (or converted to some partially processed intermediate product) any aflatoxin content would be more evenly distributed and the entire lot would be more homogeneous. This would eliminate some of the sampling problems encountered in bulk lots of whole kernels as a result of variation in aflatoxin levels in individual kernels. Statistical reliability and precision would be increased by eliminating the problems of kernel concentration.

A final-handler emphasis may provide an incentive for a separate market for aflatoxin free grain. Much of the grain now entering the channel for human consumption as snack foods and cereals is already produced under contract with processors. Contract grain would not enter the commercial channel and could be intensively monitored. However, grain processed for corn sweeteners is not currently produced under contract.
Food processors will probably require that grain be tested more rigorously, cleaned more thoroughly and more carefully commingled at the first-handler level. First-handler elevators could choose not to access these markets if they do not wish to rigorously test and segregate. This grain would likely trade at a premium compared to other grain as a result.

Grain destined for alcohol production could contain higher aflatoxin content but would have to be segregated from food grade inventories. While this would be somewhat cumbersome, overall disruption is likely to be less than what might exist if the entire crop is segregated at the first-handler level.

In the case of feed, the manufacturers are in a better position to identify the ultimate end-use for the product by species and age of animals likely to consume the feed. This allows truly representative samples and more reliable test results with ground mixed corn than whole kernel corn where there may be wide variation in the amounts of aflatoxin concentrated in individual kernels. If blending is necessary to reach acceptable levels of aflatoxin, blending intermediate products are likely to result in more reliable and precise levels.

The case of export grain is more uncertain under this strategy. The whole kernel sampling problem would remain. However, as demonstrated in 1988 and 1989, different export customers demand or accept different aflatoxin levels. If blending must occur to accomplish these targets, a high degree of emphasis on sampling and testing is already required. There is some evidence that exporters are already accomplishing the task of blending to target levels within tolerances acceptable to foreign customers.

The advantages to the final-handler system include the following: (1) Processors, manufacturers and exporters generally have better sampling and testing capabilities than first handlers. Facilities are usually more elaborate and staffed with better trained personnel. Nearly all processors and large feed manufacturers have well-equipped laboratory facilities available on site. (2) Concentration of sampling and testing into fewer and more centralized locations reduces the number of points that regulatory authorities must supervise. This is true for evaluation of final products as well as for prescribed practices such as supervised blending. (3) This strategy tends to direct corn with varying aflatoxin contents to the most appropriate end uses. (4) A separate low aflatoxin market, with separate handling and a premium price for the small portion of the crop to be used directly as food, would avoid the need to maintain human consumption standards for the major portion of the crop to be used as animal feed. Overall handling costs may be lower by avoiding attempts to apply food grade standards to all products moving through a low cost bulk handling system that relies on commingling into larger lots. (5) If improved sampling techniques that provide greater precision are not developed, then this level would be the last point where aflatoxin could be prevented from entering the human food or animal feed product. (6) Overall system-wide costs may be reduced by concentrating on the most intensive testing efforts into fewer locations where the precision sampling
and testing can be performed more economically. (7) Concentration of regulatory effort at the processor level may improve chances that final food and animal feed products are within standards.

The final-use oriented strategy also has a number of disadvantages. (1) Increased emphasis on sampling and testing at the processor level and decreased testing at lower levels in the channel may be more risky. The processor or feed manufacturer assumes greater responsibility as the final barrier preventing aflatoxin from reaching the consumer. Failure to identify aflatoxin contamination at this point could be serious. (2) In years when there is a large fraction of the crop affected with high levels of aflatoxin (i.e. 50% or more) there may be difficulty in identifying aflatoxin-free supplies for food processing. Because high aflatoxin levels in corn are likely to be drought associated, animal feed demand may be sufficient to consume most of the affected crop. It is, however, important that adequate preharvest forecasts help direct aflatoxin free supplies to the right uses. Producers holding aflatoxin free inventories or producers in areas where the weather stress did not occur, need to be made aware of the need as early as possible. (3) This strategy does not discourage commingling in years when adequate aflatoxin-free corn may be in short supply. (4) The processor and feed manufacturing firm would bear the majority of the cost of monitoring. These costs may be passed forward to final users, back to producers and prior handlers, or some combination of both. (5) While the export level in the market channel may be able to sample bulk lots with greater precision, many of the sampling precision problems associated with whole kernels would still remain.

**C. Layered Testing Strategy**

A third strategy closely resembles the one which is now in place. It involves sampling and testing at each level in the channel using the same sampling practices used for grading and inspection purposes. Grain would be sampled, screened with a blacklight, and positive blacklight samples would then be quantitatively tested for aflatoxin. All corn that moves interstate would be treated as potentially food grade with an FDA action level of 20 ppb as the standard. Exceptions would be made on a temporary basis to allow larger ppb in grain shipped provided appropriate documentation stating final use as animal feed is attached.

This system of sampling and testing has a number of advantages: (1) The grain is tested numerous times in channel. (2) Use of the 20 ppb action level allows corn in interstate commerce to move freely to any end-use market including food processing. (3) Sampling and testing before the sale offers a limited amount of protection to buyers and sellers despite the possibility of gross sampling error at any level in the channel. (4) Corn lots containing extremely high levels of aflatoxin are likely to be identified early in the marketing process before they are commingled.

Among the disadvantages to this strategy are the following: (1) Inaccuracies and lack of precision in sampling can create quite different test results in a given lot of grain between origin and destination. (2) Tests yielding precise measurements in ppb based on non-representative samples create a false sense of security on the part of buyers, sellers and
the general public. (3) Sampling disparities (and the resultant differences in aflatoxin levels from quantitative tests) encourage sellers to deliver rejected loads to other buyers because there is a high probability that subsequent samples and tests will be different. (4) Failure to precisely determine aflatoxin levels creates a great deal of uncertainty and, in some cases, a cynical attitude among farmers and grain handlers about the problem of aflatoxin. This is particularly true because condemnation can be based on test results from unreliable samples, causing the farmer or warehousemen to perceive the system as capricious and unpredictable.

D. Summary Comparison

The three strategies are shown in summary form in the table. Comparison of the systems has been made on several factors.
<table>
<thead>
<tr>
<th></th>
<th>Layered Testing</th>
<th>Final Use Oriented</th>
<th>Inbound (1st Handler)</th>
<th>Comparison Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure</td>
<td>Poor</td>
<td>Good</td>
<td>Cost</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Intermediate Reliability</td>
<td>Lowest: least skills concentrated</td>
<td>Highest: most numerous testing</td>
<td></td>
</tr>
<tr>
<td>Close to 1st handler</td>
<td></td>
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</table>

**Alphazone Jobs.**
- Early identification of heavy testing.
- Reliability of sampling, testing.
- Cost: Total System wise testing.

**Local Elevators.**
- Supervised blending at all levels.
- Supervised blending possible.
- Separating at transfer points. Analysis at elevators, option.
- Separating at 1st handler level.
- Exhaustive sampling. Screen at 1st handler level, receipt level (block/shift).
- Segregation, allocation of supplies at 1st point of sale.
- Exclusively sampling. Receiving at 1st handler level.

**Handling Points.**
- Less emphasis on subsequent.
- Reliable certification of alphazone in inventory, shipments.
- Exhaustive monitoring of intermediate and final products.
- Supervised blending at various points. Division to feed users.
- Paperback, expeditor level.

**Comparision of ALTERNATIVE SAMPLING AND TESTING STRATEGIES**
## COMPARISON OF ALTERNATIVE SAMPLING AND TESTING STRATEGIES FOR AFLATOXIN IN CORN

<table>
<thead>
<tr>
<th>COMPARISON FACTOR</th>
<th>INBOUND (1st HANDLER) ORIENTED SYSTEM</th>
<th>FINAL-USE ORIENTED SYSTEM</th>
<th>LAYERED TESTING SYSTEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blending supervision.</td>
<td>Most difficult; numerous sites, systems with varying degrees of sophistication.</td>
<td>Simplest; ground products, tests of large lots, skills of lab personnel are good.</td>
<td>Intermediate; erratic needs throughout the market chain. Depends on sampling reliability.</td>
</tr>
<tr>
<td>Consumer perception of comfort.</td>
<td>Best; farthest away from retail level.</td>
<td>Least; distrust of large firms may be a factor.</td>
<td>Unclear; consumers could be confused.</td>
</tr>
</tbody>
</table>
B. AFLATOXIN MONITORING AND REGULATORY POLICY OPTIONS

I. PROBLEM

The widespread drought and hot weather during the summer of 1988 led to a higher than usual prevalence of aflatoxin in the U.S. crop. This is the third time in the last 11 years that significant aflatoxin occurred in the Corn Belt, the other years being 1977 and 1983.

The human and animal health concerns associated with aflatoxin testing require that a uniform national program exist to deal with aflatoxin outbreaks. This program should be a combination of routine annual activities and contingency plans for conditions known, or highly likely, to cause aflatoxin contamination. The State of Iowa must be prepared to support and conform with the national program, as needed.

II. PRIMARY GOAL

To protect human and animal health from the effects of aflatoxin contamination.

III. OBJECTIVES

An effective national program should:

1. Provide pre-harvest warning of possible aflatoxin prevalence.

2. Contain appropriate national industry and regulatory actions to minimize the impact of aflatoxin on food and feed industries.

3. Enable grain producers, handlers and users in individual states to economically and equitably meet national regulations on aflatoxin in grain and foodstuffs.

4. Minimize the economic impact and market disruptions of aflatoxin contamination to grain producers, handlers and users.
IV. OVERALL STRATEGY

A general strategy is required to provide structure and rationale for individual elements. The strategy should be designed to minimize cost and market disruptions, while still meeting the primary goal.

Current Situation
The Food and Drug Administration uses informal action levels to establish the need for regulatory intervention, but it does so with few resources and little discernable planning or organization. Action levels have been held inappropriate by a recent court decision; FDA is currently in the rulemaking process with respect to redefining its activities. Individual states are left to themselves to develop monitoring programs. There is no uniform aflatoxin test procedure for first-level purchasers or official inspections. The industry regulates with whatever test result the buyer will accept as the governing standard.

Assuming that direct governmental monitoring at all market points is politically and economically infeasible, there are three general strategy options, as discussed previously.

1. The first-handler strategy: Exercise rigorous quantitative testing at the first-handler level to prevent aflatoxin from entering the market chain.

2. The final-handler strategy: Focus intense efforts at food processor and exporters to remove aflatoxin just before it enters the human food chain.

3. The layered-testing strategy: Test at market points filtering off contaminated grain at transfer points. The food processor, exporter or feeder would be left to deal with as little contamination as possible.

There are several specific issues that a comprehensive marketing and regulatory plan must address, regardless of which strategy is adopted. These issues are divided into two categories: 1) Those for which solutions are relatively independent of which strategy option is selected and, 2) Those for which solutions depend on the choice of strategy option. In summary form, the issues are:

1. Strategy independent
   • Preharvest weather monitoring
   • Physical sample monitoring at harvest
   • Contaminated grain alternatives
2. Strategy dependent
   - Action by grain receivers
   - Official USDA-FGIS procedures
   - Food safety and retail product monitoring
   - Food and Drug Administration policy
   - National Grain Warehouse policy
   - Relationship of aflatoxin to income-support and other federal programs

Conclusion
The layered-testing strategy will provide the greatest amount of protection to human and livestock health, because the testing inadequacies are accommodated without placing either full responsibility or excessive cost burden on any one market participant.
V. STRATEGY INDEPENDENT ISSUES

A. Pre-harvest Weather Monitoring And Early Warning

Issue: The need for and structure of an advance warning program, to alert the market to impending conditions of aflatoxin development.

Current situation: Each state handles this in its own way. Early warning is usually left to press reports of general consensus or opinions in the industry.

Conclusion: The State Crop Reporting Services should provide information to the USDA concerning temperatures and moisture-status during critical periods. Aflatoxin prevalence is primarily influenced by conditions at silking and during the late-filling stages. A set of criteria will be needed for the USDA-National Agricultural Statistics Service to establish regions of high, medium, and low likelihood of aflatoxin contamination. Research data appears to be adequate for developing these criteria. If aflatoxin appears to be a problem, state officials would provide information relating to affected areas in their respective states. In Iowa, a task force would be activated to assist in interpreting national data and in developing any special plans for Iowa action. Special emphasis could be placed on targeting geographical areas for specific marketing strategies.

B. Physical Sample Monitoring

Issue: The need for, and structure of, an organized sample testing program that would confirm or deny advance warning data. The extreme variability of aflatoxin within and across fields presents the major complication for this effort.

Current situation: Each state conducts whatever monitoring program it deems appropriate. A failure to monitor leaves the public to derive its own estimates from whatever information is available. A monitoring program differs from a survey. A survey implies a statistically accurate report whereas a monitoring program simply indicates whether or not aflatoxin is present.

Conclusion: Given the variability of aflatoxin and problems associated with sampling, a survey would not accurately estimate the amount of aflatoxin in the crop. However, a monitoring program would provide adequate warning of a potential problem.

The task force recommends that an organized national monitoring program be conducted. The USDA-National Agricultural Statistics Service (NASS) could modify its already existing, at-harvest crop sampling program to include screening for aflatoxin. This program, designed to give state-by-state estimates of average yield and quality, is also used to estimate averages for the corn quality factors protein, oil, starch, test weight, and
breakage susceptibility. The aflatoxin screening could be done as a means to substantiate advance warning data.

NASS procedures will have to be modified to collect larger samples and to dry the samples immediately so that further Aspergillus Flavus growth and toxin production cannot occur before analysis. The VICAM fluorometric method, or other rapid quantitative methods, could be used. This testing will add to the cost of the NASS survey. However, NASS action would relieve regulatory pressure on state officials and would utilize predeveloped statistical plans to obtain a third party assessment of the situation.

C. Contaminated Grain Alternatives

Issue: The appropriate means to utilize, or dilute contaminated grain.

Current situation: In 1988, the drought assistance bill required that highly contaminated grain be destroyed and made inaccessible to livestock and wildlife. Neither the EPA nor the FDA has clear guidelines on disposal of contaminated grain. The FDA did allow blending of contaminated grain under its direct supervision. The option was not widely used because of the interagency reporting of high levels of aflatoxin and the possibility of a blending program triggering an inspection by another regulatory agency.

Conclusion: The FDA should simplify procedures to allow for utilization of grain, or diluting grain so that it can be used in a safe and beneficial manner. Economic considerations and responsibility for dilution should be considered.

Blending of corn does not necessarily mean blending with other corn, in the case of livestock feed. When corn is ground and diluted with feedstuffs other than corn, more even distribution and lower concentrations would be achieved. Supervised blending is not needed as long as mixes are tested, and blending is done within limits outlined below.

FDA should consider aflatoxin as a naturally-occurring contaminant, rather than an introduced adulterant. If an effective testing program is in place, the blending of lots would not pose a threat so long as tolerance levels accurately reflect public or animal health thresholds. Blending limits should be established based on final use. This means that a maximum blending level should be established so that corn containing aflatoxin above the 20 ppb action level could be diluted with aflatoxin free corn to achieve an aflatoxin level below 20 ppb. For each tolerance level, (e.g. 20 ppb for general use, 100 ppb for swine, etc.) an upper limit should be set for any fraction of the blend. As an example, 75 ppb might be set as the upper limit for any fraction of a blend entering general commerce. Any lot testing over 75 ppb has relatively little chance of ever testing below 20, regardless of how many times it is sampled. The upper limit should also be based on some estimate of the kernel to kernel aflatoxin variation, and therefore, the chance that a sample of the blend will test over 20 ppb. The establishment of precise upper limits may require some research by FDA.
One possible strategy for use of very highly contaminated grain might be to allow public entities with coal burning or fluidized bed burning facilities to burn the contaminated grain provided this meets emission standards. Research in burning biomass has been conducted at Iowa State University and has shown that it is feasible. Destruction of grain should only be allowed if all other options are deemed infeasible.
VI. STRATEGY-DEPENDENT ISSUES

The recommended actions described for these issues support the layered-testing strategy. Other policies may be more appropriate for the other strategies, but the issues are valid for all.

A. Action By Grain Receivers

Issue: First-receivers (country elevators) are a critical step in the defense system against aflatoxin and, as such, are exposed to both monetary loss and regulatory action. While some contaminated corn can be isolated for feed on farms, a significant share will be offered for sale and storage at country elevators. A consistent, workable procedure is needed to guide country elevator receiving and shipping operations.

Current situation: Country elevators devise their own grain receiving procedures based on aflatoxin meetings and literature provided by private and public bodies. Aflatoxin testing ranges from quantitative analysis on large samples to no testing at all. The quantitative analysis is divided between in-house procedures and certified laboratory analysis outside the house. All receiving strategies are developed with the goal of all grain testing below 20 ppb when resold, using whatever methods are acceptable to or required by the buyer.

Conclusion: The following actions are recommended in identified risk areas as a reasonable standard operating practice for country elevators, and represent only a medium risk dispersal approach.

1. All grain received at the scale should be probed to wagon or truck box depth, using recommended Federal Grain Inspection Service sampling procedures, on a load-by-load basis. A 10 lb. sample is recommended. Typical probes collect about 1 lb. per insertion.

2. All samples should be scanned using an approved ultra-violet (black light) lamp.

3. As a guideline, if five or more glowing (greenish/gold) particles of any size are found in a 5 lb. sample, the following options should be followed regarding the handling of the immediate load in question:

   a. If elevator space will permit, segregate the load into an Identity-Preserved (IP) status bin, preferably not commingled with other IP questionable loads, while quantitative tests are run. If IP loads are commingled, rigorous testing will be needed to establish the level of the mix.
b. If space does not permit IP storage, hold the individual load until tests are completed by appropriate quantitative methods.

c. When testing is done using a method which is based upon a "yes" or "no" answer below 20 ppb, accept all grain into general inventory that is a negative test. Loads testing above 20 ppb must be placed into designated storage or rejected. At some point a quantitative analysis will be needed to establish use and to relate to blending limitations.

d. If testing methodology yields a precise quantitative analysis of aflatoxin, accept all grain testing 20 ppb or less and run into general inventory. Loads testing above 20 ppb must be placed into designated storage or rejected. Identity preserved storage can be done in the bracketed parameters as set forth in the Iowa/FDA Aflatoxin Agreement. All aflatoxin levels between 21 ppb and 100 ppb, binned IP; all aflatoxins between 101 ppb and 200 ppb, bin IP; and all remaining loads between 201 ppb and 300 ppb, in a final IP bin. If limited blending is allowed, then the IP storage could be arranged to fit blending parameters.

e. If IP space is not available and/or the producer does not want to wait for a test procedure, then reject the load if five or more greenish-gold particles are detected by black light in a five pound sample.

Current grain sampling and testing procedures are the total key to inventory protection from aflatoxin contamination. Each lot then should be black-lighted for greenish-gold glowing kernels or particles. Aflatoxin concentrations normally occur in grain particles with a much higher incidence of contamination than in whole grain.

Cleaning is a preferred method of preparing corn for long-term storage and this should be done if practical. Even though cleaning will probably reduce aflatoxin levels, it should never be assumed that cleaning will remove aflatoxin below actionable 20 ppb levels. The cleaning process is simply one of the more acceptable insurance condition-actions that can be taken with grain in any circumstance.

Corn should be dried as soon as possible after the decision is made to receive it into the elevator. Information on storage guidelines is available from Iowa State University Extension Service.

Corn screenings should always be analyzed for aflatoxin, and should always be suspect if they are produced in an area of moderate or high aflatoxin risk. Screenings can be marketed using the same guidelines for aflatoxin levels as corn.

 Receivers following these practices will be assumed to have made the best possible efforts to remove aflatoxin from market channels.
It is recommended that when these practices are followed consistently by a grain handler, the State of Iowa and/or FDA should take this into consideration when legal liability is considered, in contrast to a handler who receives grain with no surveillance program. Receivers’ responsibility to protect against aflatoxin is equally great in high-risk and low-risk growing seasons, and responsible actions should always be taken to detect aflatoxin in grain coming from long-term storage, regardless of crop year.

The decision to use or not use aflatoxin detection procedures should be an individual handler’s decision.

B. Official Testing Procedures

**Issue:** The development of an official testing method and dispute resolution procedure should be considered.

**Current situation:** Federal Grain Inspection Service (FGIS) provides aflatoxin tests at its field offices, under the provisions of the Agricultural Marketing Act. FGIS cannot license its interior agencies to perform aflatoxin tests so long as aflatoxin is covered by the Agricultural Marketing Act and not the U.S. Grades and Standards Act. The Food and Drug Administration regulates aflatoxin in interstate and foreign commerce. The information generated from FGIS inspections is shared with the FDA.

**Conclusion:** Aflatoxin should be sampled and tested when conditions warrant. By monitoring the weather, an early warning system can alert the trade and the growers to sample and test for aflatoxin.

Standardized aflatoxin tests should be done by the FGIS, but making aflatoxin an Official Criterion under the U.S. Grades and Standards Act shifts the responsibility for dealing with contaminants from the FDA to the FGIS. It should be the responsibility of the FDA to ensure that contaminants are not entering interstate commerce.

Many countries have different limits for aflatoxin. By following the foreign country’s standards on a contractual basis, the customer remains confident of the aflatoxin level. In many cases, the foreign country’s standards are lower than FDA’s 20 ppb action level.

There are agreements between FGIS and the FDA covering data-sharing between agencies. Information is shared whenever FGIS personnel perform the complete aflatoxin test, sampling and analysis. Data from submitted samples are not shared with FDA. These agreements to share information need to be carefully evaluated in the light of the increased flow of information if aflatoxin were put under the U.S. Grades and Standards Act instead of the Agricultural Marketing Act authority.
FGIS should, however, develop a practical standard sampling and testing procedure to determine aflatoxin in an official test conducted by the Federal Grain Inspection Service under its AMA authority. Grain elevators, handlers and private laboratories offering aflatoxin tests should follow these standard testing procedures when testing for aflatoxin. The task force believes that market pressures will dictate that the standard procedures are followed without formally including aflatoxin in the Standards.

C. Food Safety

**Issue:** Monitoring of food products derived from aflatoxin-susceptible grains.

**Current situation:** Each state differs in food monitoring programs. The Iowa Department of Agriculture monitors milk from dairy producers and tests the milk for aflatoxin content. If aflatoxin levels are found to exceed the .5 parts per billion level set by FDA for direct human consumption, the milk is rejected and destroyed. Retail corn products are not monitored, nor are wholesale corn products, such as corn sweeteners.

**Conclusion:** Consistent with the layered defense strategy, the Iowa Department of Agriculture and Land Stewardship should implement an action plan to sample and test food products at the processor and consumer level.

As noted in Section I of this document, substantial difficulty exists in all efforts to sample and test corn at the producer and first-handler level. Although the detection of aflatoxin contamination and rejection of the corn at the earliest level of the food chain provides the consuming public with the greatest degree of safety, this approach is suspect due to a high probability of sampling error. Though important, first-handler testing will not afford the degree of protection that consumers enjoy, for instance, in producer-level milk testing where representative sampling poses no significant problem.

Furthermore, the FDA’s responsibility in food safety is nationwide and only a limited degree of protection is extended to Iowa consumers. The Iowa Department of Agriculture and Land Stewardship can augment the FDA effort by analyzing samples drawn at the processor and consumer level. As these consumer products are likely in interstate commerce and subsequently in FDA jurisdiction, the department should forward laboratory analyses to FDA for their information and follow-up.

D. Food and Drug Administration Policies

**Issue:** The regulatory responsibility for aflatoxin rests with Food and Drug Administration (FDA). In addition to having the direct authority to establish limits and monitor grain shipments in interstate commerce, FDA interacts with FGIS inspections and warehouse examinations. According to a Memorandum of Understanding, FGIS' official aflatoxin results are forwarded to FDA if in excess of 20 ppb. Expanded availability of official aflatoxin testing will give FDA greater access to information about suspect grain.
Current situation: The FDA has traditionally used an action level of 20 ppb to determine when regulatory action--seizure, salvage, etc.--is taken. Action levels are not established through rule-making and are only guidelines that do not preclude regulatory action at other levels, higher or lower. Courts have held the concept of action levels to be inappropriate in their current form. FDA is currently revising its interpretation and phraseology relative to action levels, and is asking for comment as to whether formal rules should be established.

In years of high aflatoxin risk, FDA has relaxed action levels for grain to be used for livestock feed. In 1988, a progressive scale of 100, 200, and 300 ppb was established, for various species of livestock. Special documentation and supervised blending was required to utilize the feeding limits. The fluctuating limits did cause international customer concerns. The action level is slated to return to 20 ppb for all uses on October 1, 1989. In practice, nearly all shipments, regardless of use, have been marketed as 20 ppb or less. The financial loss from loss of interchangeability and market vulnerability is too great to do anything else. Handlers are in a grey area, legally, relative to blending to meet 20 ppb, given that the exact aflatoxin level of any blending components is never known.

Expanded official inspection for aflatoxin could give FDA much greater access to information. Potential use of this information to identify elevators with aflatoxin will cause anxiety in the trade, if policy is not well defined.

Aflatoxin is considered a quality deficiency in warehouse examinations. FDA may refer evidence to warehouse examination officials for follow up. Warehouses in most states can be licensed as either federal or state warehouses. There appears to be little uniformity across jurisdictions in how aflatoxin referrals are handled, and to be no standard procedures for obtaining or evaluating evidence for referrals.

Conclusion: The Iowa task force believes FDA policies and action levels should not change from year-to-year in response to the presence or absence of aflatoxin, but should be based on best known scientific evidence. Utilization guidelines based on research information should be established as an element of national policy. Available research data should be carefully evaluated to determine if the 1988 temporary limits are indeed the limits of choice. Workability of requirements to utilize higher limits should be improved. Altering (raising) limits in time of crisis gives domestic and international customers the impression that when problems arise, the U.S. will simply widen its tolerances and place the burden for control on the customer. That is the opposite of the necessary message and is inconsistent with the stated national policy of marketing high-quality grain, as established by Congress in a 1986 amendment to the U.S. Grain Standards Act.
When the FDA becomes aware, either by its own sampling or from data provided to it, of grain with aflatoxin in excess of general commerce limits (20 ppb at this time), specific policies should be developed to describe reasonable disposition of this grain. Limited blending or diversion to approved feed markets should be options to forced destruction or return to originating shipper. Refer to Section V., Subsection D. of this report for a discussion of recommended alternatives.

E. National Grain Warehouse Policy

Issue: Whether or not existing grain warehouse regulations and examination procedures are adequate to ensure the integrity of warehouse receipts without undue inconvenience to elevator operations:

Current situation: Warehouse law was designed to secure depositors’ warehouse receipts, not enforce food safety regulations. Aflatoxin has presented great quandaries for officials, particularly in states where the warehouse agency and the FDA-designated food testing agency are within the same department.

Sampling and analysis variability compound the warehouse examination problem, assuming exhaustive examinations for aflatoxin are deemed necessary. Warehoused grain is stored in lots of up to several million bushels. Sampling options are probing and/or completely emptying the structure for mechanical diverter sampling. Proper procedure for either option is not well defined, nor is the expected uncertainty in the results well known.

Conclusion: Grain warehouse policies with respect to aflatoxin should be uniform in all jurisdictions, state and federal. Adherence to the recommended grain receiving procedures will greatly reduce a warehouseman’s risk exposure. Nonetheless, all warehouse examining bodies, state and federal, should use consistent policies and procedures.

Only FDA inspections using established sampling procedures and official FGIS testing using established sampling procedures should trigger a warehouse examination. Information shared on a private lab analysis or an inbound test should not trigger aflatoxin examinations. This is consistent with the FGIS sharing information to the FDA.

Aflatoxin tests should not be included in routine quantity examinations. In a year of high probability of aflatoxin, state and federal warehouse officials should monitor the problem. If aflatoxin is found, through referrals or other agency information, then the state and federal warehouse officials should test for aflatoxin in areas of high risk. All factors, such as method of sampling, level of aflatoxin, amount of grain, etc., should be carefully considered before warehouse examinations occur. If state and federal warehouse inspectors test for aflatoxin, a standard procedure for sampling and testing needs to be developed.
If corn is above the 20 ppb guideline, it should be eligible to be receipted for storage provided recording and receipting corresponds to the guidelines developed by FDA for livestock feed at the levels of 20 - 100 ppb for breeding animals and poultry, 101 - 200 ppb for hogs, and 201 - 300 ppb for feedlot cattle. Corn that is designated for livestock use should remain segregated from other warehouse inventory. If limited blending is permitted, then segregation could be done to meet whatever limits FDA sets.

Corn that contains more than 20 ppb aflatoxin, either from accepting into a warehouse or finding aflatoxin through inspection, should be appropriately valued. The state and federal warehouse officials need to work with elevators on a case-by-case basis to determine the value of the corn.

FDA operations should be related directly to warehouse policy because the impetus for many exhaustive examinations in Iowa was referral from the FDA. FDA should use documented and established procedures for obtaining any samples to be used for regulatory follow-up or referral.

F. Government Programs

Issue: There is an economic loss associated with corn that contains aflatoxin. This economic loss could be an incentive to avoid current regulations.

Current situation: The Drought Relief Act of 1988 provided financial relief for grain producers hurt by drought. Aflatoxin grain was considered as lost production and producers were compensated if they received no economic value from the grain, destroyed the grain, and made it inaccessible to livestock or wildlife.

The Agricultural Stabilization and Conservation Service (ASCS) first required that all corn going under the commodity loan program must be tested for aflatoxin. Later the ASCS modified its position to say that any corn known to contain aflatoxin cannot be placed under the commodity loan program. If corn is placed under loan and later is found to contain aflatoxin, the loan will be called immediately and the producer must pay off the loan rather than have the option to forfeit the grain.

The Federal Crop Insurance Corporation will insure against financial loss from aflatoxin up until the time of harvest. However, Federal Crop Insurance Corporation will not pay if the aflatoxin was created in storage rather than in the field.

Conclusion: An important facet of the layered defense strategy is the removal of incentives for avoiding aflatoxin detection. The federal government should pay indemnity to those who have aflatoxin contaminated grain that cannot be marketed for human or livestock consumption. Indemnification should be directed toward individuals that have no control over the growth of aflatoxin. This will remove the incentive for high levels of aflatoxin to be blended into the system and provide some economic compensation for
loss to the agricultural production sector. More flexible blending provisions may reduce the need for such indemnification.

The Federal Crop Insurance Corporation should continue to consider loss from aflatoxin in insurance claims.

An important corollary to the incentive issue is the need to impress on all sellers, including growers, that they have a responsibility for the safety of products offered for sale into the food chain.
VII. SUMMARY OF ISSUES

These regulatory recommendations support the layered defense strategy. Others are applicable regardless of strategy. The Iowa Aflatoxin Task Force also has a list of research needs to address testing and other questions regarding aflatoxin. The industry can only be expected to do the best job technologically possible. Regulatory enforcement should therefore allow for appeal procedures and should limit the liability of growers and handlers.

The Iowa Aflatoxin Task Force recommends that:

- Weather data be used as an early-warning of aflatoxin.
- USDA-NASS analyze a national sample set for aflatoxin.
- IDALS test food products for aflatoxin.
- FDA consider aflatoxin a naturally-occurring contaminant and allow limited blending within the established tolerances for the market being served.
- Grain receivers follow a set of recommended practices for testing and segregation.
- Standardized sampling and testing procedures be developed for FGIS inspections.
- FDA maintain usage guidelines as consistent policy from year to year.
- National policies be set for warehousemen’s responsibilities relative to aflatoxin.
- Procedures be defined for the FDA, FGIS, warehouse officials and others to make referrals to other regulatory agencies and each other.
- Government programs be implemented to remove the incentive for evading aflatoxin detection and to provide economic compensation if the corn cannot be marketed for human or animal consumption.
C. RESEARCH NEEDS -- AFLATOXIN

There are several areas of research that need to be looked at regarding aflatoxin. If we can answer these questions, consumer confidence would remain high and we would reduce the financial risk and the need for regulatory enforcement. These questions include:

1. Methodology of accurate sampling must be developed. What is the variability of sampling with \( X \) contaminated kernels with \( Y \) level in these kernels in \( Z \) bushels of grain? How many samples must be taken? Is giving a range better than an absolute value?

2. Further modeling of climatic conditions for aflatoxin potential needs to be done. What is the specific ecology of aflatoxin production relative to heat, humidity, moisture, soil conditions, fertility, insect prevalence, and other factors?

3. Can accurate screening panels for several mycotoxins be developed? Can quick, rapid, quantifiable tests be developed that can be run by layman at shipment or receiving site, once assured of an accurate sample?

4. With a given condition of grain and a given level of aflatoxin, what are reasonable expectations for aflatoxin removal with careful cleaning?

5. What happens to kernel integrity that permits invasion of Aspergillus flavus organism and toxin production? What damage to kernel permits this invasion? What is the specific ecology of toxin resistance and development?

6. What are the best harvest recommendations based on sampled aflatoxin levels, climatic conditions, storage and drying facilities, and potential use for livestock versus sale? What effect does feeding various livestock species have on this?

7. What are effective methods of detoxification of corn given various levels? What are the equipment and chemical needs, handling and safety considerations, timing, various considerations of effectiveness and economic feasibility?

8. What are effective methods of preventing the growth of aflatoxin and other mycotoxins in the field and in storage. The use of grain preservatives and management practices should be looked at for effectiveness and economic feasibility. Will drought resistant varieties and other genetic traits help prevent the growth of aflatoxin and other mycotoxins in the field?