Association of Food and Drug Officials

2550 Kingston Road, Suite 311 York, PA 17402
Telephone (717)757-2888 • Fax (717)755-8089
E-Mail: afdo@afdo.org • Internet: www.afdo.org

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Food and Drug Administration
5630 Fishers Lane
Room 1061
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Docket No. 98N-0359, Program Priorities in the Center for Food Safety and Applied Nutrition.

For over 105 years, the Association of Food and Drug Officials (AFDO) have endeavored to create uniformity among government regulatory agencies at all levels. By building consensus with program managers at the state and local levels, AFDO is able to establish united positions on national food safety matters that affect us all. It is in this spirit of uniformity that AFDO is pleased to offer comments on program priorities in the Center for Food Safety and Applied Nutrition.

As the primary representative of State regulatory officials, AFDO wishes to point out that the activities of FDA and the States are very much intertwined in protecting public health by ensuring a safe food supply. As such, many of the recommendations included herein are made for the purpose of ensuring that (a) the States are adequately supported in their efforts to protect our food supply; (b) gaps and overlaps between State and FDA regulatory systems are eliminated; (c) adequate FDA oversight of and training support for the food safety activities at the State (and local) level are provided to assure consumers that State inspections are of high quality; and (d) information flows freely and smoothly between FDA and the States.

It is understood that FDA has the primary responsibility in areas such as food safety-related research and in the approval of new food additives and technologies. These should continue to be "A" list types of activities for FDA. At the same time, AFDO believes that FDA realizes the important role the States (and locals) play in protecting the food supply - not only from undesirable microbiological, physical, and chemical hazards, but also in reviewing the ingredients going into the manufacture of foods to ensure safety; the conditions under which they are stored, shipped, displayed, and otherwise handled; reviewing product labeling for truthfulness and compliance with regulations; and in the approval of source water used in the manufacture of nearly all foods, among many other important activities. AFDO wishes to emphasize that these are activities that FDA cannot manage alone.

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Bearing these thoughts in mind, and using CFSAN's 2001 Program Priorities as a template, the AFDO Board of Directors (hereafter referred to as AFDO) would like to offer the following comments with respect to CFSAN's 2002 Program Priorities:

Strategy 1.1 – Domestic Inspections

For the purpose of determining which establishments should be inspected at least annually, FDA should consider operator performance in addition to the potential food safety risk posed by a food or food process. Since the objective is to allocate limited inspection resources toward food businesses that present the greatest potential risk to the safety of the food supply, "high risk food" should not be the only factor used to determine the inspection frequency of an establishment. An establishment may have a spotless inspection history (and there are many that do) irrespective of what type of food they process; or, they may manufacture a food that is a "medium risk" but have a terrible inspection history. We believe that an operator's inspection history should be factored into determining routine inspection frequency.

FDA should develop a MATRIX, which includes the regulatory history, and current inspection status, IN ADDITION to the inherent risks of the foods they process. We (and FDA) are aware that at least one state uses such a matrix to (a) ensure that establishments that process high AND medium risk foods are inspected frequently; and (b) that establishments with a poor compliance history are reinspected on a frequency comparable to the types of regulatory problems previously encountered.

- FDA should also work with the States to establish an equivalency status through standardization, at least with the States that have the resources. This would eventually allow FDA to concentrate more on imports where the potential for unsafe food is ever increasing.

- To facilitate uniformity with respect to food product recalls, FDA should work closely with FSIS to develop uniform recall policies/procedures, and to finalize food recall classification criteria.

- The redefinition of potentially hazardous foods should be moved to the "A" list. It probably has been a "B" list objective because it is a 2-year project, but it is a very important food safety issue with regard to retail preparation, holding and handling of ethnic potentially hazardous foods.

Strategy 1.2 – Imports

FDA should add a section to the "A" list dealing with "domestic" imports (i.e. imported foods already in U.S. commercial channels). For the past several years FDA has categorized "warehouse inspections" as a low priority (unless the firm has a history of non-compliance). However, it has been many years since FDA included examination of imported foods as a formal part of the State Food Inspection Contracts. Since FDA has the resources to examine less than one percent of import entries, it is incumbent upon FDA to do all it can to ensure that foods in domestic commerce are safe, unadulterated, and not misbranded. The primary location to identify such foods is at the wholesale warehouse level.

Since the States have tremendous human resources to conduct inspections of such establishments, AFDO suggests that FDA modify the Food Inspection Contracts to include reviews of various imported foods observed during routine inspections of food warehouses. Further, FDA should no longer consider warehouses to be of low priority. From what the States routinely observe during inspections, more problems are often encountered in these facilities than during inspections of food processors. Examination of the regulatory actions several states have taken in this area should be enough proof that many imported foods that present health hazards are indeed making their way into domestic commerce.

Strategy 1.3 – Seafood

FDA should continue to press forward with respect to Vibrio issues. Ideas for consideration should include:

- Conducting aggressive surveillance sampling to look at the multiplication of V. parahaemolyticus during harvest, handling, transportation and at retail during warmer months to fully identify when the shellfish become unsafe to eat.
- Continuing to push for more stringent control strategies for V. vulnificus (a copy of AFDO's recently adopted resolution five is included as a reference).
- Looking at imported sources of fresh shellfish (e.g., South East Asia and South America) for V. vulnificus and V. cholera.
- Development of regulations or policies to hold imported shellfish to the same standards as are required of domestic shellfish including harvest area standards, bacteriological and marine biotoxin standards, labeling and traceability.

For the past few years, FDA has sent "untitled letters" and warning letters to seafood establishments that violate the seafood HACCP regulations. AFDO believes it is time for FDA to "get tough" with those establishments that have not yet gotten the message. FDA should include an objective under this strategy that focuses on the development of more rigorous enforcement actions for non-compliant seafood operations.

Strategy 1.4 – Fruits and Vegetables

- Whether as an addition to the "A" List or "B" List, FDA should become more proactive on food safety issues when dealing with other federal agencies which "invade" FDA food safety territory. FDA should not "speak softly" when agencies such as the Agricultural Marketing Service are charged with sampling raw produce for a multitude of organisms linked to food borne illness, unless the objectives and impacts of these sampling initiatives are clearly defined, bounded, and communicated to all affected agencies; coordinated and integrated with FDA efforts; and personnel performing sampling are properly trained and equipped. If the objectives are not clear, if the operational impacts associated with pathogen-positive results are not fully identified and communicated, or if samples are taken improperly or documented incompletely, the result may be that neither the states nor the FDA will be able to do a traceback on any positive analytical results, and the positive results themselves may be suspect. It is imperative that FDA is an active participant in the design and coordination in any such collateral sampling initiatives.

- AFDO recommends that the development of training modules for juice HACCP and a video on safe juice processing be split, with the training modules being on the "A" List and the video remaining on the "B" List. The rationale is based on the fact that the new regulations become effective January 22, 2002. Industry and regulators need those training modules as soon as is possible.

Strategy 1.5 – Egg Safety

Within the "A" list regarding regulatory activities at the farm level, FDA must seriously consider the impact on state regulatory programs, which at the present time frequently do not have the capacity or expertise to monitor the implementation and operation of preventive farm level food safety systems. AFDO has consulted with members from several states who have been involved in environmental monitoring as follow-up to Salmonella enteritidis outbreaks, and the resources and training required are enormous. Therefore, FDA must identify a continuous source of funds to pay for these services and the requisite training before implementing any farm level program. This is another excellent example of why FDA needs a line item within the budget process for "state program funding."

Strategy 1.6 – Listeria

FDA should seriously consider contracting with the States to collect appropriate samples of foods for Listeria monocytogenes testing (as well as other pathogens). Many states already have ongoing programs that involve sampling for certain foods at wholesale, processing, and retail. Additionally, FDA could derive significant benefit from the utilization of already existing State databases with respect to Listeria monocytogenes contamination of foods.

Strategy 1.9 – Food Code

Since FDA has an ongoing contract with the Association of Food and Drug Officials for gathering information to track the Food Code adoption by the states, locals, and tribal governments, this should be moved to the "A" list.

FDA should also develop an objective that addresses the need for continued guidance and interpretation to state programs that are in the process of adopting and implementing the Food Code. Such guidance and interpretation is absolutely necessary if uniform application of Food Code requirements is ever to be achieved. Such an objective should also address necessary funding to fully staff the Retail Food and Interstate Travel Team so that training, guidance, and interpretations can be handled in a uniform and timely manner.

Strategy 1.12 – Outbreak Response

The interstate Outbreak Response document has been created by the National Food Safety System's Outbreak Response and Coordination Work Group and forwarded to FDA for finalization. The finalization and implementation of this document should therefore be moved from the "B" list to the "A" list.

Strategy 2.2 – Nutrition, Health Claims and Labeling

FDA should assess problems related to potentially hazardous foods and develop new labeling requirements that uniformly identify at what temperature a food must be held to maintain its safety. In addition, FDA should develop science-based consumer "use-by" dates to alert the consumer when to not buy or use a food due to the risk of pathogen growth, toxin formation or loss of nutritional value due to spoilage.

Strategy 2.3 – Dietary Supplements.

AFDO recognizes that the issue of dietary supplements containing ephedrine alkaloids continues to be a sensitive political issue. However, we believe that objective 2.c. must be moved to the forefront and considered a high priority. Public health, not politics, needs to be the primary policy driver on this issue.

- Under item 2, add objective "e": Provide training and guidance to state regulatory officials on the regulation of claims (health, structure/function, unapproved drug) on supplements.

- AFDO recommends that FDA expend the resources now for item (2)(d), the completion of the Dietary Supplement Labeling Guide.

- AFDO also recommends that item (2)(b) from the "B" list - development of an enforcement strategy for the definition of "represented as a conventional food," be moved to the "A" List.

- As a recommendation for the "B" list, FDA should consider the development of regulations to require manufacturers to label dietary supplements with adequate directions for use for any structure/function claim made on the label, in labeling or in advertising. Basically, if advertising or labeling states that "X" is good for stimulating the immune system, the label should advise the consumer how much of the product should be taken to get the claimed effect of "X."

Strategy 3.2 – Science Base

- Item 4 from the "B" list should be moved to the "A" list. Along the lines of method validation, we encourage FDA to become a close partner in the development of the "National Method Validation System" as identified in resolutions eight and nine (copies attached), which were adopted by AFDO during the recent 105th educational conference in Atlanta, GA. Additionally, attention must be given to enhancing the "research infrastructure" of CFSAN since sound science is the underpinnings of most, if not all, food safety regulations.

- AFDO also recommends that FDA should inspect, sample and evaluate the safety of foods being distributed in interstate commerce by both private and commercial carriers to determine the extent and priority of food safety concerns and provide a basis for the regulation of the transportation of food. FDA should attempt to coordinate this project with USDA/FSIS. However, this coordination should not unduly affect the time line necessary to accomplish this goal. Dateline NBC plans to run a story soon that will focus on the lack of federal (and state) regulations for addressing time/temperature abuse of foods in the transportation channels.

Strategy 3.5 – Regulatory Processes

During the past few years it has come to AFDO's attention that FDA (CFSAN) lacks coordination with the States regarding regulatory actions which FDA is contemplating. As a result, several situations have arisen whereby FDA has taken regulatory action against a firm where State regulatory action has already been initiated. Since none of us can afford to expend valuable resources in a duplicative manner, AFDO recommends adding to the "A" list the development of a mechanism to ensure there are no unplanned duplications with ongoing State enforcement actions. AFDO stands ready as a potential conduit for discussion of how such a system might work.

AFDO wishes to thank FDA for allowing us to share our thoughts on CFSAN's program priorities for 2002.

Sincerely,

Doug Saunders

Doug Saunders
President
Association of Food and Drug Officials

Attachments

cc: AFDO Board of Directors

ASSOCIATION OF FOOD AND DRUG OFFICIALS

2001

RESOLUTION NUMBER FIVE

Submitted by: Seafood Committee

Date: June 17, 2001

Concerning: Interstate Shellfish Sanitation Conference (ISSC) and FDA actions to address Vibrio vulnificus foodborne illnesses.

Whereas, virtually all foodborne *Vibrio vulnificus* infections where the food has been traced to its source have been associated with the consumption of raw oysters harvested from the Gulf of Mexico during the months of May through September, and

Whereas, *Vibrio vulnificus* is a significant public health problem that has caused life-threatening infections in at-risk individuals (e.g., those with liver disease, chronic alcohol abuse, cancer and diabetes), and

Whereas, *Vibrio vulnificus* infections in at-risk individuals result in a greater than 50 percent mortality rate, even with treatment, and survivors are often left permanently disabled with amputations frequently necessary, and

Whereas, as many as 30 million people in the United States population may be at-risk for *Vibrio vulnificus* infections if they consume contaminated raw oysters, and

Whereas, there is no practical way for at-risk individuals to know whether an oyster about to be consumed is contaminated, and

Whereas, educational measures, including consumer education programs, oyster container advisories and point-of-sale warnings, have been employed by the shellfish industry, FDA, the states and others to reduce the consumption by at-risk individuals of contaminated raw oysters, and

Whereas, time-temperature control measures have been employed by the shellfish industry to prevent further growth of *Vibrio vulnificus* in oysters after harvest, and

Whereas, despite these measures, at-risk individuals continue to consume contaminated oysters and become ill and die as a result, and

Whereas, failure to prevent these continuing illnesses and deaths is of increasing concern to the shellfish industry, public, consumer groups and public health agencies, and

Whereas, there are effective public health control measures available to significantly reduce *Vibrio vulnificus* levels in contaminated raw oysters, therefore be it

Resolved, that the AFDO President communicate AFDO's support of the following to ISSC and FDA:

- the institution of appropriate harvest restrictions, post-harvest treatments or other effective public health control measures as soon as possible to protect at-risk individuals from further consumption of *Vibrio vulnificus* contaminated raw oysters; and

- the use in all states of current and future *Vibrio vulnificus* educational measures as beneficial adjuncts to the public health control measures; and that

- ISSC and FDA support the implementation of these public health control and educational measures as soon as possible.

ASSOCIATION OF FOOD AND DRUG OFFICIALS

2001

RESOLUTION NUMBER EIGHT

Submitted by: Laboratory, Science and Technology Committee

Date: June 17, 2001

Concerning: National Method Validation Pilot Project

Whereas, the vision/resolution for a National Method Validation System will create a significant challenge for implementation among the nation's food testing laboratories, AOAC International and other associations involved in method validation, and

Whereas, the scope of changes necessary to achieve this National Method Validation System will require significant financial and resource investments over a period of time, and

Whereas, to sustain this level of commitment from all stakeholders, a demonstration of this system's capabilities will be necessary, and

Whereas, a successful pilot of this system would provide the necessary information to make the strategic decisions regarding long-term support of this endeavor, therefore, be it

Resolved, that AFDO strongly supports and encourages federal, state, and local food safety agencies and associated industries/organizations to work cooperatively with AOAC to develop and implement a pilot that models infrastructure changes in AOAC that support the National Method Validation Vision/Resolution developed at the 2001 AFDO Pre-Conference Workshop.

ASSOCIATION OF FOOD AND DRUG OFFICIALS

2001

RESOLUTION NUMBER NINE

Submitted by: **Laboratory, Science and Technology Committee**

Date: **June 17, 2001**

Concerning: National Method Validation System Vision/Resolution

Whereas, the attendees of the AFDO 2001 Rapid Validation of Methods: A National Laboratory Challenge Workshop overwhelmingly adopted the National Method Validation System Vision/Resolution (as attached), therefore be it

Resolved, in the interest of promoting a more uniform, effective and efficient National Food Safety System, AFDO supports moving the nation's food safety laboratories toward the use of AOAC as the primary repository/clearing house for validated methods and be it further

Resolved, that AFDO encourages Federal Agencies associated with food safety to support and participate in the development, communication and maintenance of this national system; and that Federal, State, Local government and Industrial food safety laboratories, businesses and organizations, to move methods into this system that are formatted to ISO Standards and have appropriate method validation documentation for category assignment and be it further

Resolved, that AFDO supports and encourages the participation of food safety laboratories, businesses, and organizations in validation and collaborative efforts to ensure that new and revised methods are quickly adopted into the system.

NATIONAL METHOD VALIDATION SYSTEM VISION/RESOLUTION

In the interest of promoting a more uniform, effective and efficient National Food Safety System, we support moving the nation's food safety laboratories toward the use of AOAC as the primary repository/clearing house for validated methods;

wherein, methods are assigned and organized into categories of method validation, which are based on clearly defined criteria that communicate and demonstrate methods in terms of intended use.

This support is contingent upon:

- These category assignments are based on review by appropriate and internationally recognized scientists.

- AOAC, in this capacity, will make this body of methods available on an Internet based, searchable and downloadable system that includes the ability for input and feedback about the method.

- As the system evolves, methods will be formatted to ISO standards that ensure uniform understanding of the method and compatibility with ISO accreditation requirements.

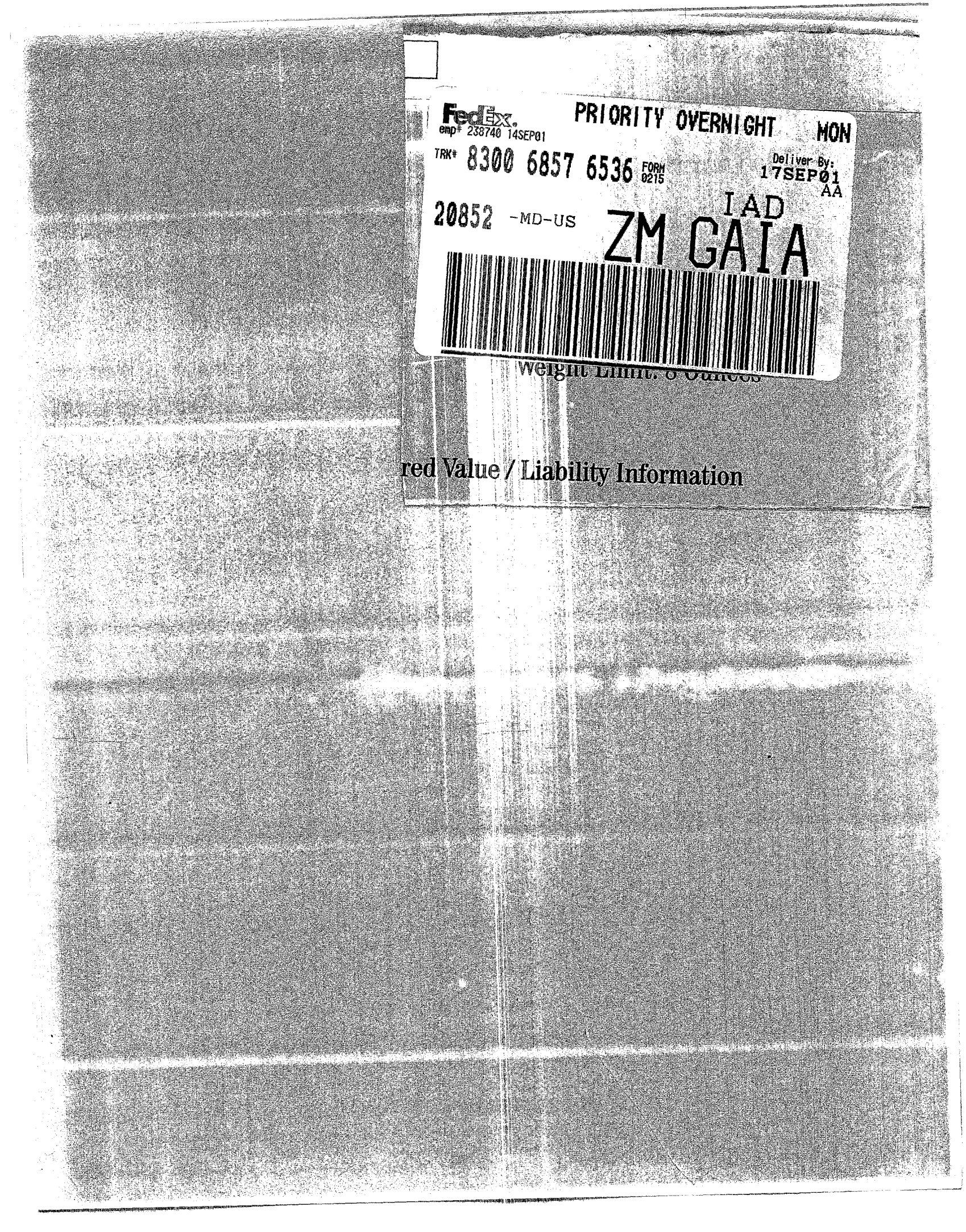
- AOAC will, in this capacity, act as the source for communication of method naming/identification, nomenclature and reporting specifications to organizations that establish and coordinate national data standards for the electronic transmission of laboratory data.

- AOAC will interface with appropriate accreditation bodies to ensure that method validation criteria meet internationally accepted standards and requirements.

- The necessary strategic investments and application of resources will be made into the AOAC infrastructure from Federal/State agencies and industry to facilitate this transition to a true National Method Validation System.

We also encourage Federal Agencies associated with food safety to support and participate in the development, communication and maintenance of this national system; and that Federal, State, Local government and Industrial food safety laboratories, businesses and organizations, will move methods into this system that are formatted to ISO Standards and have appropriate method validation documentation for category assignment.

And finally, we support that food safety laboratories, businesses, and organization will participate in validation and collaborative efforts to ensure that new methods are quickly adopted into the system.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