



The Scientific Association Dedicated to Analytical Excellence®

An Approach for Collaboration among AOAC, FDA, and the Seafood Industry on the Prevention of Contaminated Seafood from Entering the Food Supply

August 10, 2007: Revision #3

Issues:

Seafood imported into the United States may be contaminated with antibiotics, pesticides, and other contaminants. Federal and state governments do not have the necessary resources to adequately monitor imported seafood. For the industry, reliable screening tools are essential to help avoid the loss of seafood and revenue.

Program Mission:

To help **prevent** contaminated seafood from entering the food supply.

Goals:

- 1) To develop a science-based solution through collaboration between government and industry;
- 2) To encourage the development, evaluation, validation of rapid, realistic, reliable, and affordable detection systems and confirmatory methodologies that meet or exceed the consensus performance requirements as established and articulated by the government, industry, and other relevant stakeholders worldwide for monitoring contaminants in seafood;
- 3) To develop a proficiency testing program to assess user competence in the use of these assays; and
- 4) To reach consensus between government and industry stakeholders on the statistical basis for sampling schemes and homogeneity of samples.

About AOAC INTERNATIONAL:

AOAC INTERNATIONAL is a globally recognized, 501(c)3, independent, not-for-profit association founded in 1884 to facilitate the resolution of trade disputes, by bringing together government and industry stakeholders to reach consensus on method performance requirements and then to ensure that the methods are fit-for-purpose. AOAC provides a science-based solution and its methods give defensibility, credibility, and confidence in decision-making. In addition, AOAC provides other quality measurement tools including proficiency testing and training.

Approach:

Validated rapid screening technologies, and possible confirmation technologies, that meet agreed upon performance criteria, will help the industry police itself for the contamination of imported seafood. With such tests, importers can require their sources upstream in the supply chain, at the farm level, and packaging facilities worldwide to screen their products and verify their acceptability before shipment. Importers can then be confident in decision-making and ensure that contaminated seafood is not sold to distributors, retailers, and restaurants.

AOAC can assist exporters in establishing a quality system. An AOAC A2LA accredited laboratory proficiency testing program can be used to ensure competence in the use of these assays. Such technologies and quality systems would not only benefit the government and industry by providing a level of confidence, but ultimately, the public, by providing wholesome seafood.

The top areas where contamination issues have been identified:

- (a) Antibiotic residues (e.g. chloroamphenicol, nitrofurans)
- (b) Pesticide residues (e.g. fungicides)
- (c) Toxins
- (d) *Vibrio vulnificus* and *parahaemolyticus*

Another high priority area that has been identified but is not a contamination issue is fish substitution. As such, rapid screening technologies in this area will be very important.

Short-Term:

In the short-term and as a high priority, AOAC will focus on evaluating rapid, realistic, and affordable detection systems and confirmatory methodologies for antibiotic residues to determine if the methods meet or exceed the consensus performance requirements as established and articulated by the government, industry, and other relevant stakeholders worldwide for monitoring contaminants in seafood. In addition, AOAC will develop the technical requirements and feasibility of a laboratory proficiency testing program.

1) Background Work by AOAC Volunteer Experts

AOAC proposes to engage a subgroup of experts from its Chemical Residues and Contaminants Community. Members of this community represent some of the world's leading experts in residue analysis. This subgroup would convene at the AOAC Annual Meeting the week of September 16, 2007 since many of them will already be attending the Meeting. With the input of seafood importers, AOAC will invite other scientists to participate in this technical meeting.

This subgroup would gather background information on current antibiotic residue methods for seafood. The information to be collected would include the performance of the methods and their applicability, gaps in methodologies, and technical challenges in improving methodologies. This background information would be extremely useful in planning and preparing for the broad stakeholders meeting and Expert Review Panel.

2) Stakeholders Gathering

AOAC proposes to hold a 1-day stakeholders meeting. With the input of the seafood importers, AOAC will identify key scientists from China, India, Thailand, Ecuador, and possibly other countries

that export seafood. For those that cannot afford to attend the meeting, this program would support their travel.

AOAC would identify key test kit and other manufacturers of instrumentation to participate in the meeting. Based on a recent conference call with test kit manufacturers, Charm Sciences, r-Biopharm, Neogen, and others are supportive of the program and would be willing to participate.

AOAC would also engage its own Chemical Residues and Contaminants Community and Marine and Freshwater Toxins Community since members of these communities represent some of the world's leading experts in residue analysis.

Involving stakeholders from many sectors, including government agencies, industry, trade associations, academia, and international organizations not only takes advantage of their collective wisdom, but also creates buy-in and acceptance of decisions made by the group. AOAC works very closely with trade associations to ensure industry's participation in methods selection and validation. That buy-in and acceptance of decisions is done by consensus.

The purpose of the meeting would be to clearly define and reach consensus on the fitness for purpose statement (matrices, analytes, instrumentation, intended use, and analytical range) and performance requirements for antibiotic residue methods. This meeting will lead to development and evaluation of rapid screening test methodologies and confirmatory technologies that meet both the industry and government needs.

3) Issue Call for Methods

On the basis of the performance requirements for antibiotic residue in seafood as articulated by the stakeholders, AOAC will issue a call for methods that includes validation data to its seafood stakeholders, communities, membership, test kit manufacturers, and global sections. AOAC will also utilize its website and publications to solicit appropriate methods. AOAC will collect these methods for review by an Expert Review Panel.

4) Expert Review Panel

AOAC will hold an Expert Review Panel (ERP), led by AOAC's Chief Scientific Officer, to conduct a science-based peer review and a gap analysis of rapid screening and confirmatory methods for antibiotic residue methods in seafood to assess their fitness-for-purpose against the performance requirements developed by the stakeholders. In addition, these experts will establish the technical requirements for a proficiency testing program for antibiotic residues in seafood.

Expert Review Panel members are chosen based on their professional credentials as world-wide scientific and technical expertise.

Timeframe:

<i>Tasks:</i>	<i>Dates To Be Completed By</i>
Initiate Program upon Receipt of Funds	August 30, 2007
Preliminary background work by AOAC Volunteer Experts	Wk of September 16, 2007
Global Stakeholders and Experts Identified	September 2007
Stakeholders Meeting Conducted (1 day)	September 2007

Calls for Methods Issued	October 2007
Expert Review Panel Conducted (1 day)	October 2007
Finalize Fitness-For-Purpose Report Prepared	
Final Technical Requirements for Proficiency Testing Prepared	
Final ERP Report Prepared	November 30, 2007
High Level Mtg between FDA & Seafood Industry to Present Reports	December 2007

Deliverables:

AOAC INTERNATIONAL will deliver the items below no later than November 30, 2007.

AOAC will develop a focused list of appropriate stakeholders gleaned from the networks of the core stakeholders supporting this project.

AOAC will issue invitations to persons to attend a broad stakeholders’ meeting.

AOAC will secure the participation of AOAC’s relevant volunteer scientific experts in this broad stakeholders’ meeting.

AOAC will stage and lead the broad stakeholders meeting and carefully document the proceedings.

AOAC will develop fitness-for-purpose statements for a minimum of five antibiotic residues in relevant matrices, based on the discussions of the stakeholders.

AOAC will prepare a scientific report on these fitness-for-purpose statements to be delivered to all stakeholders. This report will be vetted by all stakeholders and consensus will be reached.

AOAC will conduct a survey to identify and collect extant screening and confirmatory methods related to said analytes and matrices.

AOAC will convene an expert review panel (led by AOAC’s chief scientific officer) to assess all collected methods against the fitness-for-purpose statements. All collected methods will be categorized as “fit for purpose,” “fit for purpose with development or optimization,” or “not fit for purpose.”

AOAC will ask the expert review panel to develop the technical requirements for a proficiency testing program.

AOAC will, based on a gap analysis, prepare a methods needs report and distribute this to all stakeholders.

AOAC will prepare a comprehensive report on this project and distribute it to all stakeholders.

AOAC will convene a follow-up meeting with the group of core stakeholders to determine next steps, costs, and timelines.

Financial Support:

AOAC provides science-based solutions to those companies (importers, suppliers, retailers, manufactures, distributors, restaurants, and test kit companies) who are AOAC Organizational

Affiliates. To join as an AOAC Organizational Affiliate, the cost is \$10,000. This charge is an annual charge.

In order for AOAC to initiate the next step of a seafood stakeholders meeting as outlined above, AOAC will need to raise \$120,000. As such, AOAC suggests that each Organizational Affiliate interested in participating in the seafood program contribute, at a minimum, an additional \$10,000.

The financial support received to initiate the short-term phase will be used for the following:

- To support AOAC staff salaries and benefits for two FTEs to coordinate the technical and logistical aspects of stakeholders meeting, expert review panel, and draft the reports;
- To support travel (hotel, air, food, and lodging) for 15 people from other countries (China, India, Thailand, and possibly other countries) and other critical experts including statisticians needing support to participate in both the stakeholders meeting and expert review panels;
- To support meeting space, audio visual equipment, and food needed for the meetings;
- To support supplies including binders and badges for participants;
- To support conference calls with experts;
- AOAC charges a 6% fee on all projects; and
- AOAC includes a 35% overhead.

NOTE: The duration needed to complete all the tasks and deliverables are 90 days from the start of the program, which will begin immediately after the necessary \$120,000 is received. AOAC would like to secure the funds by **August 30, 2007**.

NOTE: AOAC INTERNATIONAL is a 501(c)(3) qualified not-for-profit organization. Please consult your tax advisor on the deductibility of your contribution to AOAC.

Funds received above \$120,000 will be used towards the mid-term part of the project. AOAC will provide a cost estimate for the mid-term (validation) aspect of the program once the assays are selected and the fitness-for-purpose statement are finalized. Prior to initiating the mid-term phase, AOAC will also ask those test kit companies whose assays were selected by the Expert Review Panel to financially support the program.

Mid-Term:

In the mid-term, AOAC will focus on validating the rapid, realistic, and affordable detection systems and confirmatory methodologies for antibiotic residues that were identified by the Expert Review Panel as being fit-for-purpose. AOAC estimates the duration to be 6-8 months.

Also, in the mid-term, AOAC will pilot the proficiency testing program. AOAC estimates the duration to be 6 -8 months.

Long-Term:

In the longer-term, AOAC will then initiate work on pesticide residues (e.g. fungicides), toxins, and *Vibrio vulnificus* and *parahaemolyticus*, species of fish identification, allergens, and follow a similar process and approach as outlined above.

If sufficient funds are available, AOAC can initiate work in one of these other longer-term areas.

AOAC INTERNATIONAL's Current Customers and Customers within the Past 5 Years and Associated Projects:

U.S. Department of Homeland Security

- ❖ Stakeholder Consensus, Validation, and Evaluation of Hand-held Assays for *Bacillus anthracis*
- ❖ Stakeholder Consensus, Sampling Standard for Suspicious Powders
- ❖ Stakeholder Consensus, Validation protocol for Ricin
- ❖ Stakeholder Consensus, on Developing an Enduring National Capacity for Development, Validation and Evaluation of Threat Detection Technologies and Defining a Public Health Actionable Assay

U.S. Food and Drug Administration

- ❖ Recommendation for Best Practices in Microbiological Methods Validation
- ❖ Stakeholder Consensus, Validation and Evaluation of Detection Systems for *E. sakazakii* in Infant Formula (Wyeth Nutritionals, Nestle, Mead Johnson, and Ross Products)
- ❖ Validation and Evaluation of FDA's Method for Ephedrine Alkaloids and Aristolochic acid
- ❖ Validation and Evaluation of FDA's Method for *Clostridium botulinum*

U.S. Department of Defense and U.S. National Guard

- ❖ Validation and Evaluation of Triple Signature PCR Method for *Bacillus anthracis*

U.S. National Institutes of Health-Office of Dietary Supplements

- ❖ Stakeholder Consensus, Expert Review Panels, Validation, and Evaluation of 15 Methods for Dietary Supplements (beta-carotene, ginkgo, saw palmetto, and others)
- ❖ Single Laboratory and Collaborative Study Training Course for Dietary Supplements

U.S. Environmental Protection Agency

- ❖ Expert Review Panel and modification of AOAC *Official Methods*SM Sporidical Activity Test, **966.06**
- ❖ Validation and Evaluation of a Quantitative Test for Sporidical Activity

U.S. Department of Agriculture-Food Safety and Inspection Services

- ❖ Electronic Compilation of Analytical Methods (e-CAM)
- ❖ Laboratory Auditing Program
- ❖ Laboratory Proficiency Testing Program: *Salmonella in Egg*

Coca Cola and Pepsi Cola

- ❖ Stakeholder Consensus and Expert Review Panel on Pesticide Residue Methods for Soft Drinks.