PRIVATE LABORATORIES FDA, IMPORTS AND THE FUTURE

Presented by: Martin Mitchell

ASTA 2008 Regulatory and Legislative Workshop

Washington, D.C.

Date: September 24, 2008

Certified Laboratories, Inc.

Full Service Laboratory – Est. 1926

- Issues
  - Detention Without Physical Examination
  - Congressional Investigation
- Proposals
  - ACIL White Paper
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NEWS RELEASE

Committee on Energy and Commerce
Rep. John D. Dingell, Chairman

Dingell, Stupak Move to Expose Purveyors of Adulterated Food

ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

May 1, 2008

O & I INVESTIGATION

- Ongoing investigation into the safety of our nation's food supply
- Ten private laboratories that play a critical role in the nation's food safety system
- Laboratories asked to identify the importers of adulterated food in an effort to determine whether this food is making it into the country's food supply

O & I INVESTIGATION (Cont'd)

- "The fact that the FDA tolerates this imminent threat to the public health is outrageous. We will probably never know how many people have suffered illness or worse because some importers have chosen to profit from selling tainted food. While our bill will ensure that this despicable practice stops, selling contaminated food is illegal and FDA ought to be in all these private labs now demanding the information necessary to protect the public health."

O & I INVESTIGATION (Cont'd)

In order to assist the Committee in its investigation of the safety of the Nation's food supply, we request that you provide the Committee with the following information:

For each of the previous six years, 2002 through 2007; please provide the number of samples of food products you tested that were under Import Alert

O & I INVESTIGATION (Cont'd)

- The number of violative test results you found.
- For each violative test result, please provide a list of each that includes the name of the importer, whether FDA was notified of the violative result, and whether that product was eventually released into commerce.

LABORATORIES INVOLVED

- ABC Research Corp.
- Michelson Laboratories, Inc.
- Certified Laboratories, Inc.
- Imperial Private Laboratories, Inc.
- Central Analytical Laboratories, Inc.
- Northland Laboratories
- Strasburger & Siegel, Inc.
- Microbac Laboratories, Inc.
- The National Food Laboratory, Inc.
- Analytical Food Laboratories, Inc.

Sincerely,

John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigations

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American Council of Independent Laboratories (ACIL): Import Safety

Enhancing the Existing Public-Private Laboratory Partnership will Build Confidence, Quality & Safety Into Food Imports for Decades to come

ACIL'S PROPOSALS TO IMPROVE IMPORTED FOOD SAFETY

PROPOSAL 1: FDA'S ADOPTION OF ISO/IEC ACCREDITATION STANDARDS

- FDA to adopt and specify ISO/IEC 17025 accreditation as a mandatory basis for qualifying private laboratories and independent sample collectors collecting and/or submitting analytical data to FDA.
- The agency must be willing to assist and cooperate with independent accrediting organizations and to specify the requirements so that accreditation to ISO 17025 will meet the agency's requirements regarding accredited laboratories' technical, administrative capabilities and their ethics policies and training.

PROPOSAL 2: THE NEED FOR CLEARLY ARTICULATED LABORATORY STANDARDS AND QUALIFICATIONS

- FDA should mandate that all analytical work performed by an accredited private laboratory under a uniform and standardized third party verification program for imported food safety, be submitted to FDA for its review directly by the private laboratory.
- FDA to establish and enforce a system of nationally uniform private laboratory data submission requirements and FDA laboratory analytical review procedures.

PROPOSAL 3: NEED FOR ADDITIONAL FDA RESOURCES AND LEVERAGING OF ACCREDITED PRIVATE LABORATORY SERVICES

- FDA's inspection resources must primarily be focused on shipments where it is more likely to find violations that relate to safety risks.
- A further expansion in the use of accredited private laboratories would form a basis for creating incentives among the U.S. importer community to develop best practices.

PROPOSAL 3: NEED FOR ADDITIONAL FDA RESOURCES AND LEVERAGING OF ACCREDITED PRIVATE LABORATORY SERVICES

(Cont'd)

- Those companies (foreign or domestic) falling into a confirmed high-risk population would bear the burdens and costs of demonstrating the safety of their imported products and FDA would be able to oversee an inspection and sampling program.

PROPOSAL 4: NEED TO EXPAND FDA'S USE OF ACCREDITED PRIVATE LABORATORY SERVICES TO IMPLEMENT RISK-BASED IMPORT STRATGIES

(Cont'd)

Periodic third party sampling and testing of *low-risk products* from manufacturers and shippers with *positive* compliance histories would further expand FDA's ability to focus its inspection and detection resources where enforcement is more urgently needed to protect the public health and the U.S. food supply.

PROPOSAL 5: REQUIRING IMPORTERS TO HIRE INDEPENDENT THRID PARTY SAMPLERS FOR PRODUCTS ON FDA IMPORT ALERT

PROPOSAL 6: INCLUDING ACCREDITED INDEPENDENT LABORATORIES TO PARTICIPATE IN THE FOOD EMERGENCY REPONSE NETWORK (FERN) AND eLEXNET

PROPOSAL 7: PRIVATE LABORATORIES SHOULD BE A COMPONENT OF ANY FOREIGN MANUFACTURER OR PROCESSOR CERTIFICATION PROGRAM

PROPOSAL 8: FDA SHOULD ACCEPT PRE-SHIPMENT ANALYTICAL WORK BY ACCREDITED INDEPENDENT PRIVATE LABORATORIES

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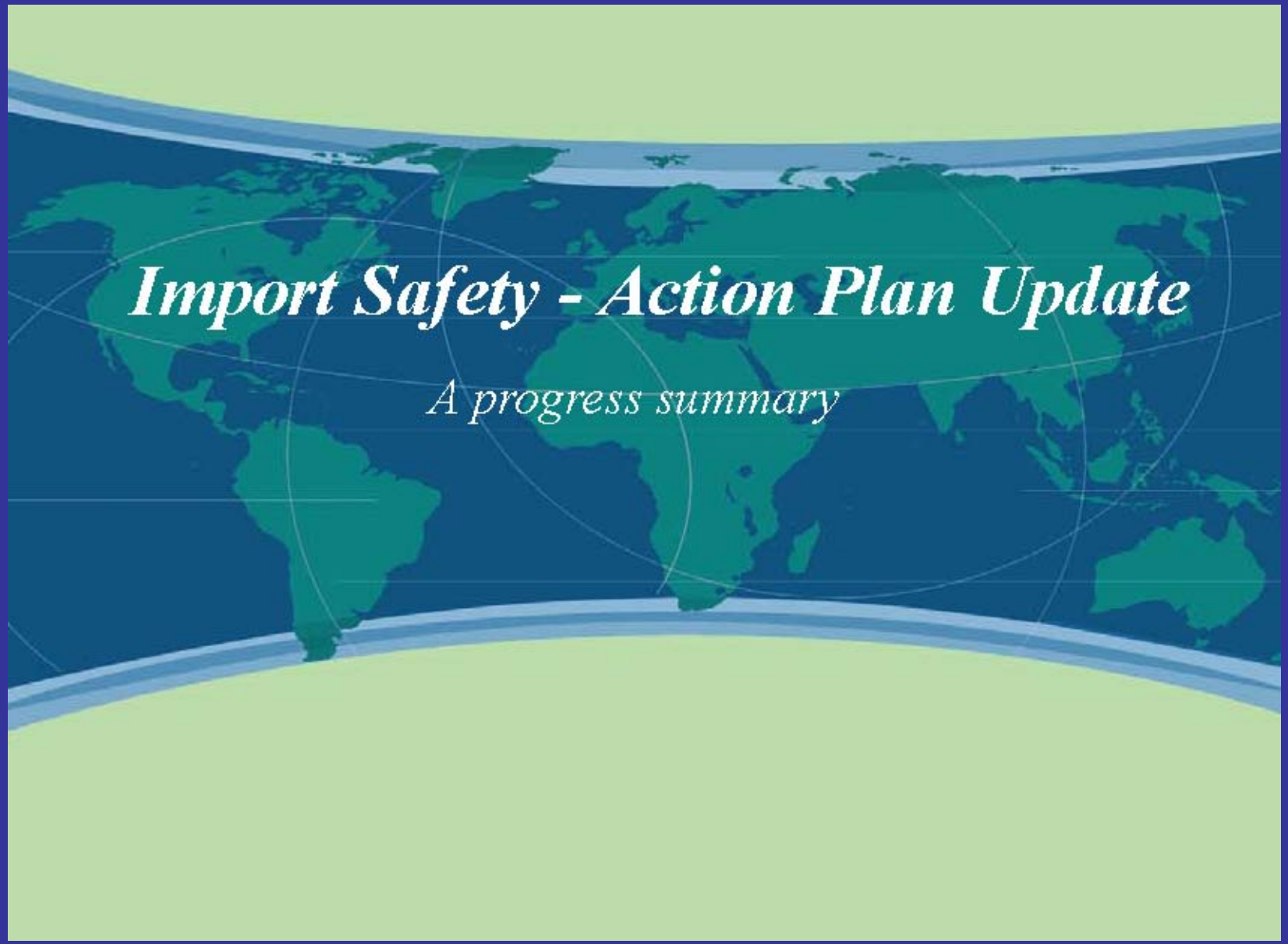
Import Safety - Action Plan Update
A progress summary

A REPORT TO THE PRESIDENT INTERAGENCY WORKING GROUP ON IMPORT SAFETY JULY 2008

PRIVATE SECTOR ENGAGEMENT HIGHLIGHTS

(Cont'd)

- Expanding the use of private sector standards programs;
- Developing voluntary certification programs and giving priority to certified entities;
- Developing and incentivizing good importer practices;

PRIVATE SECTOR ENGAGEMENT HIGHLIGHTS

(Cont'd)

- Creating best practices for the use of technologies to expedite the notification of consumers of product recalls; and
- Identifying best practices for development and use of track-and-trace technologies.

EXAMPLE OF PRIVATE SECTOR EFFORTS

In February 2008, Wal-Mart announced that certain suppliers must be certified by the Global Food Safety Initiative. Certification requires that all goods must be audited by licensed food safety auditors. Wal-Mart requires full certification by July 2009.

EXAMPLE OF PRIVATE SECTOR EFFORTS

The spice Board of India created a certification process assuring that spices exported from India have met a high standard.

Baltimore-based McCormick customers requested McCormick impose a requirement for traceability on all India spice imports.

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Key Provisions in Selected Food Safety Legislation

	FDA Globalization Act of 2008 (Dingell Discussion Draft)	Safe Food Enforcement, Assessment, Standards, and Targeting Act (The Safe FEAST Act) (H.R. 5904 - Costa/Putnam Bill)	FDA Food Safety Modernization Act (S. 3385- Durbin Bill)	Current Law -Federal Food, Drug, and Cosmetic Act (FFDCA)
Laboratory Testing	Food facilities that are not certified would be required, before every shipment of food, to conduct laboratory testing in an FDA-accredited laboratory and to have the results sent to the FDA. FDA would accredit laboratories, and collect an accreditation fee to defray costs of the accreditation process. FDA would monitor accredited labs through annual on-site audits.	A mechanism would be established for FDA to maintain a registry of laboratories recognized by other government agencies and qualified nongovernmental organizations as capable of analyzing food products. FDA itself would not be authorized to accredit laboratories. University and food company laboratories could be used (even if not recognized) so long as the qualifications of the laboratory are made known to FDA, a validated test method is used, and the results are provided to FDA.	Food testing is to be conducted either by Federal laboratories or non-Federal laboratories that have been accredited by an accreditation body that is listed on a registry established by the FDA and publicly available.	NONE

FOOD AND DRUG ADMINISTRATION GLOBALIZATION ACT OF 2008

The Discussion Draft builds on H.R. 3610 (Rep. Dingell), H.R. 3624 (Rep. Pallone), H.R. 3115 (Rep. Stupak), and H.R. 3484 (Rep. DeGette) and the findings from investigations conducted by the Subcommittee on Oversight and Investigations of the Committee of Energy and Commerce.

FOOD AND DRUG ADMINISTRATION GLOBALIZATION ACT OF 2008 (cont'd)

- Allow FDA to accredit third-party laboratories to perform testing to ensure food facilities' process controls are working and performance standards are being met
- Accredited laboratories would be required to send any test results to FDA

Casey-Grassley EAT SAFE Act of 2007

Ending Agricultural Threats: Safeguarding America's Food for Everyone

Import Inspection and Testing

- Requires private laboratories conducting tests on FDA-regulated products on behalf of importers to apply for and be certified by FDA
- Directs FDA to develop a determination, certification, and audit process for these private laboratories, and authorizes FDA to collect user fees to cover certification costs
- Imposes civil penalties for laboratories and/or importers who knowingly or conspire to falsify laboratory sampling results
- Establishes civil penalties for importers who circumvent the USDA import reinspection system

FDA Food Safety Modernization Act S. 3385-DURBIN BILL

RECOGNITION OF LABORATORY ACCREDITATION FOR ANALYSES OF FOODS

- Not later than 2 years after the date of enactment of the FDA Food Safety Modernization Act.
- Provide for the recognition of accreditation bodies that accredit laboratories, including laboratories run and operated by a State or locality, with a demonstrated capability to conduct analytical testing of food products
- Establish a publicly available registry of accreditation bodies,

FDA Food Safety Modernization Act

MODEL ACCREDITATION STANDARDS

- The Secretary shall develop model standards that an accreditation body shall require laboratories to meet in order to be included in the registry
- Shall look to existing standards for guidance.

FDA Food Safety Modernization Act (cont'd)

MODEL ACCREDITATION STANDARDS

The model standards shall include methods to ensure that;

- Appropriate sampling and analytical procedures are followed and reports of analyses are certified as true and accurate.
- Internal quality systems are established and maintained

FDA Food Safety Modernization Act (cont'd)

MODEL ACCREDITATION STANDARDS

- Procedures exist to evaluate and respond promptly to complaints regarding analyses and other activities for which the laboratory is recognized
- Individuals who conduct the analyses are qualified by training and experience to do so
- Any other criteria determined appropriate by the Secretary.

FDA Food Safety Modernization Act (cont'd)

To assure compliance with the requirements of this section, the Secretary shall

- Periodically, or at least every 5 years, reevaluate accreditation bodies
- Promptly revoke the recognition of any accreditation body found not to be in compliance with the requirements of this section.

FDA Food Safety Modernization Act (cont'd)

Food testing shall be conducted by either Federal laboratories or non-Federal laboratories that have been accredited by an accreditation body on the registry whenever such testing is either conducted by or on behalf of an owner or consignee

- In support of admission of an article of food under section 801(a)
- Due to a specific testing requirement in this Act or implementing regulations

FDA Food Safety Modernization Act (cont'd)

- Under an Import Alert that requires successful consecutive tests (DWPE)
- Is so required by the Secretary as the Secretary deems appropriate.

The results of any such sampling or testing shall be sent directly to the Food and Drug Administration.

ANY QUESTIONS?

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