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Docket No. FDA-2008-N-0183

**Third-Party Certification Programs for Foods and Feeds
Notice, 73 Fed. Reg. 64, 17989 (Apr. 2, 2008)**

THE AMERISCI GROUP (or “AMERISCI”) is pleased to submit the following comments to the Food and Drug Administration (“FDA” or the “Agency”) in response to its Notice in the April 2, 2008 Federal Register, 73 Fed. Reg. 64, 17989, requesting public input into FDA's emerging policies and positions on Third-Party Certification for Foods and Feeds. We appreciate FDA's intention to expand the role of third-party certification in helping to ensure the safety and quality of the U.S. food supply, and we thank the FDA for this opportunity to provide our input into its deliberations on how best to structure this role.

A. General Comments of AMERISCI in Support of FDA Work and Its Unique Perspective on FDA and Other Related Initiatives

AMERISCI, a private U.S. company that provides third party certification services, applauds FDA's current effort to create a direct, recognized, and sanctioned role for independent third-party certifiers and auditors in assuring the safety of the U.S. food supply. We have previously expressed support for these efforts in connection with recommendations of the Agency's Food Protection Plan, as well as the President's Interagency Working Group on Import Safety, to improve food safety by relying on third party certification and auditing programs. AMERISCI is familiar with ongoing legislative efforts in both the U.S. and the People's Republic of China (hereinafter, “China” or the “PRC”) with respect to food safety, as well as with the recent issues concerning food safety and cooperation between these two countries, and has addressed the FDA questions from this background.

AMERISCI believes third party certification is essential to ensuring the safety of the U.S. food supply. Given the variety and volume of food products, it is doubtful whether government programs alone — no matter how well funded, designed, and implemented — can ever “guarantee” the safety of all food and feeds that enter the U.S. market. Accordingly, to complement and strengthen government efforts and provide the level of confidence in food safety expected by consumers and required by private sector commercial entities, we agree it is necessary to consider the ability of independent third-party food safety certifying and auditing programs and entities to provide an additional level of safety.

We look forward to working with the Agency as it integrates independent third-party certification programs into its food safety regulatory framework. As part of this cooperation, we submit these comments in response to FDA's request for input on the issues surrounding third party certification programs. Our comments below first provide background information on AMERISCI and other general commentary relevant to the FDA requests, and then specific responses to the Agency's questions and requests for information.

1. The Unique Expertise of AMERISCI

THE AMERISCI GROUP, is a U.S. company based in Richmond, Virginia, with offices and laboratories in New York City, Boston, and Los Angeles and an office in Shanghai, China. The company specializes in two principal areas. We provide comprehensive analytical testing services to the food, consumer product, and environmental sectors in the United States and in other countries,¹ and we offer compliance-oriented third-party auditing, certification, and consulting services to assist manufacturers of foods and consumer products in satisfying applicable government regulations and contractual specifications bearing on product safety and quality.

2. AMERISCI Efforts To Provide Its Expertise to the U.S. Government

AMERISCI has been actively involved in recent legislative activity regarding food and product safety, closely following and attending Congressional hearings on these issues. AMERISCI's CEO Tomi Hong submitted testimony on the lead Senate bill concerning product safety and testified about consumer food and product safety issues before the President's Interagency Working Group on Import Safety. Congressional initiatives have important implications for third party certification, and AMERISCI's comments below are consistent with the positions it has taken before the U.S. Congress.

3. AMERISCI Experience in China and Recognition of the Important Relationship of Chinese Food Safety Policies to FDA Regulation

While AMERISCI provides services to clients in several countries, it has recently developed a strong presence in *China*, where its top management has been actively engaged with the Chinese government and food industry in food safety initiatives. These activities are aimed at strengthening controls at the production level and significantly enhancing oversight of supply chain management throughout the "life cycle" of foods and consumer products. For example, AMERISCI has conferred with China's Administration of Quality Supervision, Inspection and Quarantine ("AQSIQ") in connection with its development and implementation of long-term

¹ In connection with food and consumer product testing, AMERISCI uses a proprietary system for tracing contamination through the chain of custody back to the primary source. AMERISCI programs have been accredited by the American Association for Laboratory Accreditation (A2LA), the National Voluntary Laboratory Accreditation Program (NVLAP), and the American Industrial Hygiene Association (AIHA). It is ISO/IEC 17025 certified and adheres to all FDA, USDA, and CPSC testing guidelines.

solutions to these food safety issues. AMERISCI also provides testing services in China, and has the ability to provide primary source data on its testing through a secure server that could be accessed by government agencies in both the U.S. and China. The Company is familiar with the recent issues concerning the safety of foods and food products originating in China and has closely followed the emerging cooperation between the U.S. and Chinese governments with respect to food and consumer product safety.

We believe AMERISCI's familiarity with China and its initiatives can directly benefit FDA, whose lead many other countries follow. Given China's emerging position as a major food supplier in the global economy, we believe it is important that FDA, in developing programs and initiatives, take the implications of those initiatives for China into account as they are developed. AMERISCI has seen through its firsthand experience in China, that U.S. global leadership in food safety has had profound and direct effects in China, influencing their economy and legislation. Accordingly, our perspective and experience in China informs these comments.²

B. Specific Responses and Comments to FDA's Request for Information

The following are our comments and responses to some of the Agency's specific questions and requests. Questions are grouped and listed under the respective request number given in the Federal Register Notice, 73 Fed. Reg. 64, 17989.

1. Nature of Existing Third-Party Certification Programs for Foods

a. FDA Question/Request:

What domestic and foreign third-party certification programs for suppliers are currently in use by U.S. companies? We would like more information regarding these and other certification programs, the standards on which they are based, and who is currently using these third-party programs.

AMERISCI Response/Comment:

In addition to our own services, we are aware of *numerous other third-party programs and consulting arrangements* that provide various testing and certification regimes aimed at ensuring that foods are "safe". These programs and activities *range in size and scope from very large and well designed programs, to much smaller, firm-specific quality control programs*. The larger programs often provide for comprehensive food safety controls from primary production (farm level, raw materials, *etc.*), through processing and distribution to the retail marketplace.

² AMERISCI is familiar with and has been following the food safety initiatives of the Chinese Congress, as well as China's AQSIQ and CNCA, AQSIQ's Commodity Inspection and Quarantine Bureaus (CIQs), the Ministry of Agriculture (MoA), Ministry of Health (MoH), the State Food and Drug Administration (SFDA), the Ministry of Commerce (MoC), the Center for Disease Control (China CDC), State Environmental Protection Administration (SEPA), provincial and municipal governments, and the U.S. FDA. Its suggestions reference, and have taken into consideration, each government's regulations, guidelines, and policies governing the roles, responsibilities, and limitations of third-party auditors.

Intermediate size programs may employ consulting firms specializing in food safety to identify and remedy process control deficiencies for either individual establishments or for multiple establishments across several firms. The smaller programs usually provide the individual buyer-seller with some minimum level of assurance that a specific product satisfies some measure of safety, *e.g.*, a national regulatory numerical standard for a chemical contaminant, a process control standard such as HACCP, or a particular contract specification bearing on safety.

The programs also *vary in the nature of the food safety standards on which their guarantees of safety are based*. Some programs use national regulatory standards developed by the competent authorities of the country in which the finished food products are imported/marketed, *e.g.*, the Grocery Manufacturer's Association's (or "GMA") food safety program, referred to as the GMA-SAFE Program, is based on compliance with FDA standards. Many, if not most, other programs use "private standards" developed by importers or retailers. These "*private standards*" *may be based on a national regulatory standard, but usually they are much more stringent than science-based national standards*. Still other auditing and certification programs use a myriad of contractual standards agreed to by buyer and seller. These contractual specifications may or may not be based on *bone fide*, science based standards.

i. Two Model Third Party Certification Programs

While we are not able to describe the features and characteristics of all third-party certification programs, we will mention two specifically, which we believe have particular merit with regard to ensuring the safety of products imported into the United States.

First, the GMA-SAFE Program, is currently one of the more established and recognized programs in the United States. We will defer to GMA to describe its program in detail, and a complete description is provided on the GMA web site at <http://www.gma-safe.org>. Briefly however, the GMA-SAFE Program provides for comprehensive third-party auditing and certification of food producers and their products to ensure that the producer is operating in accordance with all applicable FDA regulations and guidelines and that raw food materials and finished products comply with FDA standards for safety and quality. The Program incorporates auditor training and credentialing to ensure competence and independence.³

The second program bearing mention with respect to the U.S.-China food trade was established in late 2007 between the Oregon Department of Agriculture and the Zhuhai (China) Certification

³ AMERISCI supports many of the ideas advanced in the recent GMA proposal that are aimed at enhancing the safety of foods imported into the United States. GMA's "Four Pillars" program for food safety echoes the FDA position that there should be a significantly increased role for third-party entities in helping to ensure the safety of foods imported into the United States. Specifically, AMERISCI supports GMA's proposal to the extent it suggests: (1) that all importers be required to adopt a foreign supplier quality assurance program and verify their products meet U.S. FDA standards, (2) that importers and other companies help FDA qualify them as lower risk companies by sharing test results with FDA in a confidential manner and those certified or qualified companies then could receive expedited treatment at ports of entry into the U.S., (3) increased cooperation with foreign countries on food safety initiatives, and (4) increased funding for FDA.

and Inspection Group, an entity associated with AQSIQ.⁴ While not strictly a private sector, third-party entity, given the association with the Oregon state government and the Chinese government, the new facility plans to provide service directly to food producers and processors on a for-profit basis. The cooperative effort aims to set up a food product testing and certification center in the Zhuhai Special Economic Zone in South China and to test China-produced foods destined for export to the United States for compliance with applicable FDA requirements. Since Zhuhai is located along South China's major shipping routes near Hong Kong and Macao, the testing and certification facility should be convenient to many Chinese food producers exporting abroad. This type of end product testing is one component of an overall and comprehensive supply chain management strategy, and such testing can complement the type of comprehensive safety and quality supply chain management services provided by AMERISCI and other third-party auditors. Such testing and certification activity should complement the HHS-AQSIQ government-to-government MOA signed last year.

ii. *Retailer Imposed Third Party Certification Requirements*

In various parts of the world, but particularly within the European Union, *some retail supermarket chains and other retail establishments have implemented mandatory testing and certification requirements for their suppliers as conditions of doing business.* This practice has resulted in a proliferation of private standards and many auditing and certification programs intended to ensure “compliance” with these private standards. In general, these private standards, which suppliers must satisfy if they wish to gain and maintain market access to the retail chains, are much more prescriptive and stringent than corresponding national regulatory standards. Also, given the transnational nature of many of these retail chains, for example, France's Carrefour, the private standards are being “enforced” not only within the home country of the parent firm, but in other countries in which the firm has retail establishments. Consequently, private standards are more and more becoming *de facto* international standards.

We have provided below an illustrative, but non-exhaustive, list of retail firms that either mandate auditing or certification to “compliance” with private standards for products they sell, or which conduct such auditing and certification. While these firms may not be directly involved in auditing and certification for foreign-produced foods destined for the United States, *their approaches and requirements influence the safety protocols operated by at least some suppliers of U.S. imported food. This influence over producers to abide by various private standards is sufficient to have direct impact on FDA's ultimate success in using third-party auditors as a means of ensuring compliance with FDA regulations.*

Selected Private Standard-setting and Auditing Entities:

- Assured Food Standards
<http://www.redtractor.org.uk>

⁴ This program was created through an agreement between Oregon and a regional division of the Chinese AQSIQ, entitled, “Memorandum of Understanding Between Oregon Department of Agriculture and Zhuhai Peace Logistics and China Certification and Inspection Group Zhuhai Co., Ltd.” USDA's Foreign Agricultural Service has provided a description of this program, which is available at <http://www.fas.usda.gov/gainfiles/200801/146293500.pdf>.

- British Retail Consortium Global Standard – Food
http://www.brc.org.uk/standards/default.asp?mainsection_id=2&subsection_id=2
- Carrefour Filière Qualité
<http://www.carrefour.fr/etmoi/fqc/>
- EurepGAP
<http://www.eurepgap.org/Languages/English/about.html>
- Global Food Safety Initiative
<http://www.ciesnet.com/2-wwedo/2.2-programmes/2.2.foodsafety.gfsi.asp>
- International Food Standard
<http://www.food-care.info/>
- ISO 22000 - Food safety management systems and ISO 22005 - Traceability in the feed and food chain
<http://www.iso.org>
- QS Qualität Sicherheit
<http://www.q-s.info/index.php?id=92&L=1>
- Safe Quality Food (SQF) 1000 and 2000
<http://www.sqfi.com>
- Tesco Nature's Choice
<http://www.tescocorporate.com>

b. FDA Question/Request:

We would also like to know how national government bodies interface with or recognize these certification programs.

AMERISCI Response/Comment:

Until recently, neither the Chinese nor U.S. government, due primarily in the U.S. to funding constraints, had indicated the intent to interface on an on-going basis with third party certification programs or companies. In the U.S., government interface with these programs has occurred on limited occasions. We are aware that the U.S. Department of Agriculture has relied upon and accredited third party certifying and auditing bodies for assistance with their National Organic Program, run under their Agricultural Marketing Service (“AMS”). Also, under the current system, FDA has been able occasionally to utilize the services of third parties to assist it with conducting background studies and other testing services. However, FDA does not have a framework in place to interface with, or directly regulate, certifying and auditing companies and programs.

In view of the globalization of the economy and food supply specifically, coupled with the scope and complexity of safety efforts, there have been several proposals to change this situation, such that national governments could work directly with third party certification programs. FDA's recent efforts to improve the safety of foods imported into the U.S., including its formal agreement with China, as well as legislation introduced by the Chinese Congress and the U.S. Congress, provide the framework for the two countries to interface with third party certification programs directly. The Memorandum of Agreement (or "MOA"), signed by the Department of Health and Human Services and the Chinese AQSIQ at the end of 2007, obligates China to put into place a strong registration and certification system for certain "designated covered products" exported from China to the United States, that is, certain categories of foods and pet foods, among others, which fall under the jurisdiction FDA.⁵

To implement that obligation and to improve food safety more broadly, the Chinese Congress recently introduced legislation that addresses safety issues related to food production, processing, testing, recalls, and public notification. This legislation would require certification by the Chinese food safety agency that food products being exported from China meet the safety and other requirements of the country to which those products are being sent.⁶

Due to the magnitude of the food trade between the two countries, and the breadth, complexity, and disparate nature of their food industries, AMERISCI believes it will be important for the private sector to assist the Chinese government in handling testing, auditing, and certification for these numerous products. AMERISCI believes the Chinese government should be encouraged to consider, as the U.S. Congress is, requiring certification for food producing facilities and retailers, in addition to requiring certification for the exported food products, since certification of these companies and their food safety practices is more feasible than certification of the food products themselves. Such certification of facilities and retailers would significantly protect the food supply chain and thus the end products exported to the United States.

For their part, U.S. Congressional leaders in the Senate and House of Representative have introduced several bills to promote the use of third party certification programs for food producing companies, including those in foreign countries like the PRC. Two leading and

⁵ This MOA, signed December 11, 2007, and entitled, *Agreement between the Department of Health and Human Services [HHS] of the United States of America and the General Administration of Quality Supervision, Inspection and Quarantine [AQSIQ] of the People's Republic of China on the Safety of Food and Feed*, is aimed at ensuring that only safe food and animal feeds are traded between the two countries. The MOA also establishes a formal government-to-government cooperative relationship between AQSIQ (including the Certification and Accreditation Administration, CNCA) and HHS (including FDA) that will promote continuing discussions at both policy and technical levels to prevent future food safety problems, or mitigate their effects.

⁶ Along the lines of FDA efforts in the U.S., the proposed law would (1) create a national food safety risk monitoring system to monitor and assess food borne diseases, food contamination, and harmful substances in food products; (2) establish and enforce national and local food safety standards; and (3) permit independent entities to perform food testing after being selected by the inspection and supervision agency under China's State Council, which will also establish qualifications for the testing entities, as well as the conditions and scope of the required food testing. AMERISCI believes these are important steps that the Chinese Government is taking to formulate a comprehensive food safety regime to address both domestic and international concerns about the quality and safety of China's food products.

comprehensive proposals are pending before the House Committee on Energy and Commerce, including the Discussion Draft of the Food and Drug Administration Globalization Act of 2008 (the “FDA Globalization Act”), introduced by Chairman Dingell, Health Subcommittee Chair Pallone, and Oversight and Investigations Subcommittee Chair Stupak, and the Safe Food Enforcement, Assessment, Standards and Targeting Act of 2008 (the “Safe FEAST Act”), introduced by Representatives Costa and Putnam. These bills have many important features that would strengthen FDA efforts, including some of those suggested by FDA that our comments discuss, including incentives for participation in certification programs, increased funding, incentives for foreign firms exporting products to the U.S., and requirements for companies to institute food safety plans, among other provisions.

c. FDA Question/Request:

[W]e would like information on the standards and procedures used to ensure that the third parties used are independent (i.e., without conflicts of interest), the standards used to accredit third parties, who accredits these third parties, and how and by whom these third parties are audited and evaluated for performance.

AMERISCI Response/Comment:

The independence of accrediting third parties is a critical issue. Individual auditing and certification firms often have their own internal controls to ensure their independence and freedom from conflicts of interest. We believe, however, that as FDA proceeds to develop guidelines or regulations pertaining to third-party auditing and certification, it will be necessary for the Agency to consider the need for establishing, by regulation, one or more oversight or accreditation entities, that would ensure all auditors and certification bodies providing services intended to demonstrate the safety of foods produced in, or imported into, the United States are unbiased and working under clearly defined guidelines. If the FDA had significant additional funding, it could potentially be responsible for accrediting these auditing and certifying entities. *See infra* Section B.2.b. for additional discussion of the FDA ability to accredit these entities itself.

Both the FDA Globalization Act and the Safe FEAST Act would require FDA, or the oversight and accreditation entities that it would designate, to accredit auditing and certifying entities, thereby ensuring their independence and adequacy to perform audits and certifications. Section 107 of the FDA Globalization Act” would require the FDA to accredit these entities itself, but would also provide for laboratory accreditation fees to cover the expense of such a program. Another option that could be developed if laboratory accreditation fees were unavailable, would be for the FDA to accredit third party entities who could then certify and audit food processors and producers, to ensure their independence and adequacy. *See* Section 11 of the Safe FEAST Act.

2. Consistency of Third-Party Certification Programs with FDA Requirements for Food Safety and Quality

a. FDA Question/Request:

Do the current third-party certification programs ensure compliance with FDA requirements? FDA solicits comment on whether the requirements for certification used by these programs encompass FDA requirements. If not, what modifications need to be made for the U.S. marketplace?

AMERISCI Response/Comment:

There is a clear trend within at least the retail sector of the agri-food industry to establish and “enforce” safety standards that are different from, and usually much more stringent than, national food safety standards. These private standards are described above. The diversity of these standards contributes to an often indecipherable matrix of foods and food safety attributes that makes it unclear as to what exactly is being certified and whether that certification actually helps to ensure compliance with FDA requirements.

Only a few of the “major” third-party *auditing and inspection programs* in place around the world are intended specifically to ensure compliance with FDA requirements. We mentioned two such programs above. There are, however, many *U.S.-based companies and consulting firms* that do provide auditing, inspection, and certification services intended to ensure compliance with particular FDA regulations. Many of these firms are very reputable and extraordinarily thorough in their work, such that an audit and certification provided by one such firm can provide FDA and American consumers with reasonable assurances that a U.S. or foreign-produced food complies with FDA requirements. Some of these firms, however, are less reputable and the rigor of their audits is usually not sufficient to ensure compliance with applicable FDA regulations. In the absence of FDA regulation or guidance on the exact criteria for conducting audits and certification to demonstrate compliance with FDA requirements, there will remain a disparate array of programs of variable quality and reliability.

To help bring all auditing and certification bodies up to a single, highly protective and readily understood standard of performance, we believe it will be necessary for FDA, at a minimum, to develop a series of commodity-specific guidelines against which all auditing and certification programs and companies must conduct their programs. For example, the Agency may wish to produce a series of guidelines akin to its HACCP-related “Hazard Analysis Guides” (for seafood and juices) such that the major categories of foods — seafood, dairy, canned and packaged foods, fresh and processed fruits and vegetables, grains, supplements, etc. — have a clearly defined set of food safety attributes that must be considered and addressed during any audit and certification process. The Agency could provide “checklists” of essential food safety attributes that would have to be assured by food safety certification programs and companies for as many foods/food categories as practical, perhaps initially for broad categories of foods, followed subsequently as they can be developed, by checklists for selected, specific food types.

Without such simplified checklists of “must have” commodity-specific food safety attributes, auditors and certifiers, as well as foreign producers, are forced to speculate as to which parts of Title 21 (and/or Titles 40, 7, and 9) of the CFR apply to their products and whether all applicable regulations and guidelines must be addressed systematically as part of their audit and certification. In our opinion, simplified and practically achievable lists of commodity-specific food safety attributes prepared by FDA, albeit not comprehensive lists of all applicable regulations, would greatly assist in assuring needed consistency in third-party auditing.

In this context, we also suggest that the international food safety standards and guidelines developed by Codex Alimentarius (Codex) might play a greater role than they have heretofore in helping ensure the safety of imported foods. Indeed, Codex standards and guidelines could help FDA create these “simplified lists” that would serve to standardize and harmonize the criteria against which imported foods and manufacturers of imported foods are audited and certified.

FDA, and more broadly, the United States, has invested extraordinary resources in Codex, particularly since the World Trade Organization’s Agreement on the Application of Sanitary and Phytosanitary Measures (the “WTO SPS Agreement”) recognized Codex as the principal and only international food safety standard setting body for foods moving in international commerce. The Agency has spent millions of dollars to help ensure that consensus international standards developed by Codex are protective of U.S. public health. FDA experts have devoted countless hours to help ensure that FDA “influences” the development of Codex standards and guidelines. Yet, Codex standards are rarely utilized by FDA in any of the Agency's inspection and enforcement programs for imported foods. In the development of a third-party audit and certification program, FDA could recover some of its substantial investment in Codex.

Specifically, the concept of equivalence, as put forth in Article 4 of the WTO SPS agreement and as articulated in guidelines developed by the Codex Committee of Food Import and Export Inspection and Certification Systems (CCFICS), could serve a useful purpose in third-party audit and certification programs. Put simply, are Codex standards, which are numerical standards, Codes of Hygienic Practice, and Guidelines, equivalent to corresponding FDA standards, and would certification to “compliance” with Codex standards provide FDA with reasonable assurance of safety? Does “compliance” with Codex standards ensure that a food satisfies the U.S. “appropriate level of protection” (ALOP), which in international contexts, the United States has generally stated to be what is phrased in the Federal Food, Drug and Cosmetic Act as “a reasonable certainty of no harm?”

We understand fully the complexities surrounding Codex, equivalence, and WTO SPS. However, we ask the Agency to consider whether it can find a practical way to incorporate Codex standards and guidelines into its eventual third-party audit/certification framework in which to protect U.S. public health through the most practical and achievable approaches — even “out of the box” approaches — like using Codex standards as a baseline against which audits and certifications could be conducted.

b. FDA Question/Request:

Should FDA recognize [or accredit] any of these programs? Should FDA participate in future modifications to any of these programs? If so, in what capacity?

AMERISCI Response/Comment:

FDA need not necessarily be the accrediting body or one of the accrediting bodies in this program. It should not serve this function under its current funding and structural limitations and without enacting legislation like the FDA Globalization Act, which would fund such activity through accreditation fees. FDA could implement a system, such as that proposed in the Safe Feast Act, whereby the Agency would recognize independent, third-party private sector accrediting bodies that would, in turn, serve as the principal accrediting bodies for the potentially numerous auditing and certifying bodies. While we do not question FDA's technical competence to serve as *the* accrediting body, we are concerned that the Agency's resources are not sufficient to take on that responsibility. Absent substantial additional appropriated funds through legislation that would allow the Agency to collect user fees for the program from entities seeking accreditation, we do not believe the Agency should assume the role of accrediting body and we believe implementation of an accreditation system could be left to the private sector.

Whichever accreditation system is adopted, we do believe that it is essential for FDA to formally *recognize* qualified auditing and certification bodies that have been properly accredited. Once the Agency determines the appropriate criteria on which to determine the acceptable performance of auditing and certifying entities and once private sector accreditation bodies accredit the auditors and certifiers, FDA should provide formal recognition to such certified entities. The recognition should perhaps be in the form of a formal letter over signature by a senior official in the Office of Regulatory Affairs acknowledging the firm's status as an accredited auditor and/or certifier. The letter could be followed by the posting of the auditor and/or certifier's name and area of specialization — *e.g.*, all foods, seafood only, dairy only, fruit/vegetable only, etc. — on an FDA web page dedicated to such listings.

FDA should also maintain general oversight of the accreditation system and could conduct periodic reviews of the effectiveness and performance of the accrediting bodies. The exact nature of FDA oversight will depend on the eventual number of accrediting bodies and the number of auditors and certifiers.

As stated above, we believe FDA can contribute most effectively to the growth and effectiveness of third-party certification programs by clearly and unambiguously defining the commodity-specific criteria, or specific food safety checklists for each category of foods, against which the audits and certifications must be performed.

3. Obstacles to More Widespread Private Sector Use of Third-Party Certification Programs

a. FDA Question/Request:

What are the obstacles to private sector participation in these third-party certification programs? FDA seeks information about any barriers that may exist to using third-party certification programs.

AMERISCI Response/Comment:

In our opinion, the principal barrier previously inhibiting the widespread use of third-party certification was the lack of adequate funding for U.S. federal agencies charged with regulating the food industry. This lack of funding prohibited FDA from actively acknowledging the merits of such private sector programs in public health protection and from encouraging third-party involvement in the U.S. food safety system. We believe, with adequate funding, FDA can be the most effective government entity to encourage third party certification. FDA has always maintained it is ultimately the food industry's responsibility to produce safe food, but its recent efforts to encourage private companies to use third parties to complement existing federal and state regulatory systems for food safety will have a profound influence on the efforts of these companies. Importantly, the Agency's current efforts will remove many actual and perceived obstacles to the growth of effective third-party certification programs for food safety.

Regarding other obstacles, we believe there is general confusion within the industry about what constitutes an audit and certification approach that would be "acceptable" to FDA for particular categories of foods. What exactly is it that FDA believes should be certified? For a given food, does the Agency expect that certification for safety can only be valid if *all* applicable FDA regulations and guidelines are addressed and proven to be followed? Is it acceptable to identify and certify a specified subset of food safety attributes or hazards that are "reasonably likely to occur," *i.e.*, a HACCP-like approach for all foods? For fresh fruits and vegetables, should an audit and certification attest to compliance with the Agency's Good Agricultural Practices guidelines, even though these are not regulations? For pet foods, what extraneous chemical contaminants should be examined and be subject to certification to demonstrate their absence?

In this context, we believe the FDA should provide practicable, commodity-specific guidance to narrow the scope of possible food safety attributes that auditors and certifiers must consider. Such specific FDA guidance will enhance the reliability and credibility of a third-party certification system.

b. FDA Question/Request:

Are retailers and suppliers aware of these programs? Are these programs widely available?

AMERISCI Response/Comment:

We believe that many retailers and suppliers are aware of the various audit and certification programs and that the services are widely available. However, in the absence of positive incentives to use the programs, many retailers are not inclined to purchase such services.

c. FDA Question/Request:

Are they cost effective? Are there particular obstacles for small businesses?

AMERISCI Response/Comment:

In the interests of brand protection and due diligence to prevent liability losses, most larger agri-food companies and many medium size companies would consider food safety audit and certification programs to be very cost effective and a necessary cost of doing business. The costs of these programs, while they can be expensive, are not prohibitive when compared with the costs of recalls and other liabilities associated with non-complaint products. Therefore, large and medium size agri-food businesses are likely to be able to afford these services.

Small businesses are much less likely to be positioned to afford comprehensive auditing and certification programs. Small businesses, particularly, might benefit by FDA clearly specifying what subset of food safety attributes apply to what foods, thereby enabling the smaller businesses to determine whether they can purchase services for only those attributes most likely to be associated with their products.

AMERISCI suggests that if FDA were to implement a program with fees for voluntary certification, such as those proposed by the FDA Globalization Act, FDA consider setting these fees on a graduated scale, based on the size or revenue of the company seeking certification.

4. Incentives to Increase Participation in Third-Party Certification Programs

a. FDA Question/Request:

What incentives would increase participation in these third-party certification programs? We would like to know what incentives could increase participation in these certification programs.

AMERISCI Response/Comment:

We believe that all three of the incentives enumerated by FDA in this Notice — (1) expedited entry at U.S. ports of entry, (2) publicly available lists of certified firms, and (3) the use of certification status as one criterion for scheduling FDA risk-based inspections — would encourage food producers and U.S. importers and retailers to participate in accredited certification programs.

b. FDA Question/Request:

[W]ould expedited treatment at U.S. ports of entry significantly encourage foreign suppliers to participate or domestic firms to make participation by foreign or domestic suppliers a condition of doing business with them?

AMERISCI Response/Comment:

Expedited FDA review at U.S. ports, accomplished by assigning a higher “may proceed rate” to certified foreign establishments in the Agency's electronic import review system, may be a very significant incentive for foreign firms to participate. FDA assigns “may proceed rates,” or percentages of import entries that are cleared for entry into U.S. commerce without detailed Agency examinations, according to the risk that particular foods from particular countries or firms present — the lower the risk, the higher the “may proceed rate.” We believe that foreign firms will seek to become “certified” if they are assured by FDA that such certification will result in a higher may proceed rate for their products. We do not, however, believe it is necessary to limit imports from uncertified firms to ports of entry where an FDA laboratory is located, as Section 111 of the FDA Globalization Act would do. This would not add a significant incentive, could unduly burden ports with laboratories, could harm ports which do not have laboratories, and is unnecessary because products could be shipped quickly for necessary testing or could be tested by local third party testing companies near the port of entry.

c. FDA Question/Request:

Would making the names of certified firms publicly available, such as through a publicly accessible database, significantly encourage participation in these programs by foreign or domestic suppliers?

AMERISCI Response/Comment:

Similarly, we believe that many food producers, especially foreign firms, will strive to become certified if they are assured that FDA will acknowledge their certification by means of an Agency web page that lists the firm as being in good regulatory standing with FDA and states that the firm has been inspected, audited, and otherwise found to be in substantive compliance with applicable FDA regulations by an accredited auditing/certifying body, “approved” by FDA. The web page, in our opinion, should be arranged by country (signified by national flags and maps) and featured prominently on the FDA web site so that foreign firms and U.S. importers and retailers can easily access it.

Both of these incentives — expedited entry and public listing of certification status — are powerful marketing tools for any foreign firm wishing to export foods to the United States. U.S. importers and retailers can use the information to identify prospective suppliers whose food safety credentials have been assessed and found to be satisfactory. Market forces will likely drive U.S. importers toward only those foreign suppliers on the “certified list.”

d. FDA Question/Request:

Would FDA considering certification as one factor in determining inspection priorities provide a significant incentive for foreign or domestic firms to participate?

AMERISCI Response/Comment:

While the third incentive above, certification as a criterion for FDA inspection frequency, may have a cosmetic appeal to some foreign food producers, it is not as attractive an incentive as the other two. The frequency of FDA inspection of overseas food producers is already quite low. Therefore, there may be little credibility for FDA to say it will inspect a particular foreign firm “less frequently” if it is certified when, in fact, it is already inspected very infrequently. So, of the three incentives, this one is of marginal importance, at least for foreign firms. Nonetheless, we recommend that it be retained as a listed incentive, particularly in light of possibly increased inspection frequencies that could be implemented upon the passage of the Food and Drug Globalization Act.

e. FDA Question/Request:

Are there other incentives that would increase participation for [suppliers of] imported foods? For [suppliers of] domestic foods?

AMERISCI Response/Comment:

With regard to other incentives, we know, historically, FDA has not been willing to sanction the use of the FDA logo or other use of the Agency name or acronym to signify “approval” of particular FDA-regulated food products. We understand the Agency's long-established reluctance to permit regulated food industries to suggest that their products are somehow “approved by FDA.” Yet, we believe that there may be considerable benefit for the Agency to reassess its reluctance, and to sanction an “FDA approved” statement on the labels of foods that have been produced under an eventual, accredited food safety certification program. Such a statement, if permitted to be used by firms participating in an accredited program ultimately overseen by FDA, would be a “gold standard” incentive that producers and retailers around the world would strive to achieve for their labels and marketing programs. This may be a unique, novel, and especially valuable incentive for FDA to consider.

Additional incentives for private companies to be certified would be created by the other initiatives with regard to protecting food safety. For example, requiring companies to institute food safety plans, such as the plans that would be required by Section 102 of the FDA Globalization Act or Section 4 of the Safe FEAST Act, will encourage companies to utilize the services of third parties to obtain auditing and certification of those programs.

C. Conclusion

AMERISCI thanks the FDA for the opportunity to provide comments on this important issue. We believe FDA leadership in encouraging private companies to seek certification and auditing service will provide exponential benefits for the safety of our Nation's food supply. We support the FDA's flexibility, and creativity to maximize the safety benefit derived from its limited resources.

We look forward to learning more as FDA moves forward in developing its framework for third-party auditing and certification systems applicable to food safety.

Sincerely yours,

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