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FSMA – Import Control Building Capacity/Compliance

Food Safety Forum

Washington, DC 20JUL2011

FSMA – Sec. 301

"Each importer shall perform risk-based foreign supplier verification activities for the purpose of verifying that the food imported … into the United States is as safe as food produced and sold within the United States"

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Verification Activity - Audit

"Verification activities … may include … annual on-site inspections, checking the hazard analysis and risk-based preventive control plan of the foreign supplier…"

"Verification activities … may include monitoring records for shipment, lot-by-lot certification of compliance … and periodically testing and sampling shipment."

"Records … shall be maintained for a period of not less than 2 years and shall be made available promptly to (the FDA) upon request."

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How Do We Comply

Partnered with Intertek to establish a Global Supplier Audit Program for high risk suppliers and their supply chain.

- Global Visibility – provided through intranet portal
- High risk suppliers are based on primary COO – Asia, India, and Mexico.
- High risk ingredients based on risk assessment – processed spices, processed dehydrated vegetables, and food chemicals
- Supply chain includes field, processed ingredient, packaging, warehouse and distributor.
- Audit scope – food safety, quality management systems, and food defense.
  - Will accept Griffith Labs approved third party audits in lieu of Intertek.

Added a Global Spice Network Leader – monitors and educates India spice suppliers.

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Supply Chain Audit Letter

December 2010

Food Safety and Food Security Audit Requirement

To our Valued Suppliers:

Food Safety is the number one priority for Griffith Laboratories as well as every one of our customers. Beginning Jan. 1, 2011, Griffith Laboratories and our affiliated companies, Custom Culinary® Foods and Innova Foods will begin the next phase of our successful audit program. We will be expanding our supply chain to include distributors, packaging, and field audits in addition to our continual focus on our critical suppliers. To assure that your company is providing Griffith Laboratories with safe and wholesome ingredients we will be requiring you to participate in our updated supplier audit program based on the critical products / service that you supply to our system.

Griffith Laboratories has partnered with a third party audit firm, Intertek Inc. (previously RQA).to administer the 2.0 – 2.5 day on-site Food Safety and Food Security audit on our behalf. Griffith Laboratories recognizes the importance of GFSI (Global Food Safety Initiative) and will possibly accept a complete audit report (BRC, IFS, SQF, or FSSC 22000) in lieu of this requirement. The GFSI report will be reviewed to determine the necessity of an Intertek audit. The Intertek audit will focus on the effectiveness and execution of your food safety, food security and supplemental programs which are critical for our mutual success. The purpose of the audit is to validate your current programs, identify opportunity areas and capture best practices.

You will be contacted directly by Intertek who will provide you with all the necessary documentation and instructions for the audit process. The audit cost will be billed to you directly by Intertek and will be established by combining the base rate of the audit and travel expenses to your facility. Intertek has offices located around the world so the travel expenses should be kept to a minimum (estimates will be provided prior to the audit). You will need to supply them with a Purchase Order number for their invoice which will be based on Net 30 day payment terms. You are required to respond back to Intertek within 30 business days to schedule the audit.

This audit is a requirement for you to continue to supply Griffith Laboratories and its associated customers. A successful audit result will satisfy the global audit requirement for Griffith Laboratories. Upstream supplier management has become a critical facet of the audits we participate in with our customers and this will help fulfill our requirements in that respect and help ensure a continued positive supply chain relationship.

We look forward to continuing to build a strong partnership with you during this program.

Please let either of us know if you have any questions or comments regarding this new food safety and food security requirement or the Griffith Laboratories overall food safety program.

Sincerely,

Michael J. Cherry

Michael Cherry
Vice President – Global Food Safety & Quality Systems
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John McCarville
Senior Vice-President – Global Supply Chain & IT
Phone: (708) 239-2526

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Audit Criteria

Intertek / Griffith Laboratories Ingredient Supplier Audit Rev3

Score Summary Page **Company Name**

<- Do Not write in this cell. Name copies from front page.

Section No.	Section	Possible Points	Total Points	Total %	Weight	Weighted Total Possible	Weighted Total Actual	Weighted % Score	"Bolded" Item Scoring Issues (Do Not Write)
1	**Sanitation**	**36**	**36**	**100.0**	**0.90**	**68.0**	**68.0**	**100.0**	
2	Chemical Program	12	12	100.0	0.10	13.0	13.0	100.0	
3	**HACCP**	**33**	**33**	**100.0**	**1.00**	**66.0**	**66.0**	**100.0**	
4	**Allergen/Sensitizing**	**21**	**21**	**100.0**	**0.90**	**40.0**	**40.0**	**100.0**	
5	Foreign Material	**36**	**36**	100.0	**0.90**	**68.0**	68.0	100.0	
6	Glass & Brittle Plastic	12	12	100.0	0.10	13.0	13.0	100.0	
7	Lubricants	6	6	100.0	0.10	7.0	7.0	100.0	
8	Cross Contamination Prevention	9	9	100.0	0.10	10.0	10.0	100.0	
9	**Traceability**	**15**	**15**	**100.0**	**0.60**	**24.0**	**24.0**	**100.0**	
10	Product Returns and Salvaging	9	9	100.0	0.10	10.0	10.0	100.0	
11	**Pest Control**	**42**	**42**	**100.0**	**0.40**	**59.0**	**59.0**	**100.0**	
12	**Internal Audit Program**	**18**	**18**	**100.0**	**0.50**	**27.0**	**27.0**	**100.0**	
13	GMP (Good Manufacturing Practices)	39	39	100.0	0.40	55.0	55.0	100.0	
14	Inbound Inspection	9	9	100.0	0.10	10.0	10.0	100.0	
15	Bulk Materials	6	6	100.0	0.10	7.0	7.0	100.0	
16	Raw Material and Packaging	48	48	100.0	0.40	67.0	67.0	100.0	
17	Non-Conforming Product	18	18	100.0	0.30	23.0	23.0	100.0	
18	Labels	15	15	100.0	0.30	20.0	20.0	100.0	
19	Vendor Approval Program	15	15	100.0	0.40	21.0	21.0	100.0	
20	Laboratory	78	78	100.0	0.40	109.0	109.0	100.0	
21	**Process and Quality Control**	**24**	**24**	**100.0**	**0.40**	**34.0**	**34.0**	**100.0**	
22	Quality Systems Documentation	18	18	100.0	0.10	20.0	20.0	100.0	
23	Record Review	12	12	100.0	0.10	13.0	13.0	100.0	
24	**Food Defense**	**57**	**57**	**100.0**	**0.50**	**86.0**	**86.0**	**100.0**	
25	Quality Management	9	9	100.0	0.10	10.0	10.0	100.0	
26	**Training**	**15**	**15**	**100.0**	**0.50**	**23.0**	**23.0**	**100.0**	
27	**Facility**	**51**	**51**	**100.0**	**0.40**	**71.0**	**71.0**	**100.0**	
28	Maintenance Program	24	24	100.0	0.30	31.0	31.0	100.0	
29	Utilities	18	18	100.0	0.20	22.0	22.0	100.0	
30	Customer Service & Complaints	6	6	100.0	0.10	7.0	7.0	100.0	
31	Product Specifications	9	9	100.0	0.10	10.0	10.0	100.0	
32	**Corrective Action**	**6**	**6**	**100.0**	**0.50**	**9.0**	**9.0**	**100.0**	
33	Crisis management	9	9	100.0	0.10	10.0	10.0	100.0	
34	Management of the Regulatory Inspection Process	6	6	100.0	0.20	7.00	7.0	100.0	
35	Food Adulteration Control	6	6	100.0	0.10	7.00	7.0	100.0	
	Total	**747**	**747**			**1077.00**	**1077.00**		**0.00**

Ratings		
Assessment	Points	%
Acceptable	915.45	100.0
Caution	807.75	
Unsatisfactory	806.67	

Rating This Report

Acceptable

"**BOLDED**" sections (left) indicate an automatic audit failure if the score for that section is judged **UNSATISFACTORY and/or less than 50%**.

%Ranges Associated with Ratings	
Acceptable	≥ 85.0
Caution	84.9 - 75.0
Unsatisfactory	< 75.0

Program includes corrective action plan follow-up

Verification Activity – Ingredient

"Verification activities … may include … annual on-site inspections, checking the hazard analysis and risk-based preventive control plan of the foreign supplier…"

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How Do We Comply – Current and Future

- Supplier COA
  - Current - Manual review versus agreed upon specification.
  - **Future - E-COA Pilot Project - Predictive Risk**

Automatic approval of supplier COA versus established business rules which will free up Quality technicians to validate supplier test results.

Enterprise Data Review – visibility of trend reports and other statistical measures at P.O level across GLUS with global scope implications .

- Raw Material Testing

Periodic testing of Raw Materials for physical, chemical, microbiological attributes.

Focus on known food adulterants – illegal dyes, pesticides, heavy metals, residual chemicals etc.

Verification Activity - Records

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Summary

- Know your supplier and their supply chain.
- Utilize third party audit firm or in-country personnel to monitor foreign suppliers.
- Validate RM COA test results at a defined frequency.
- Centralize key records for rapid accessibility.

Challenges

- The “new “ adulterant
- Compliance to requirements
- Readily accessible records

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Questions

- Will FDA consider leveraging GFSI Accredited Certification model and Global Markets Program?
- Will the FDA evaluate the European Rapid Alert System for Food and Feed as part of the coalition effort?

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Thank You