ERM

3352 128th Avenue
Holland, Michigan
49424

Telephone: +1 616 399 3500
Fax: +1 616 399 3777

www.erm.com

December 14, 2018

Mr. Dennis Colley, President/CEO
Fibre Box Association
500 Park Blvd, Suite 985
Itasca, IL 60143

Reference: 0486082

Subject: Microbiological Status of Corrugated Containers – 2018 Annual Review Study

Dear Mr. Colley,

Fresh produce has been documented by the US Center for Disease Control and Prevention (CDC) as a leading source of food-borne illness (CDC, 2015). With the passage of the US Food Safety Modernization Act (FSMA) in 2011, the supply chain has become an even greater source of regulatory scrutiny for growers, shippers and even retailers. FSMA now requires US entities take a proactive rather than reactive approach to food safety (US FDA, undated). Although food-borne illness has not been directly associated with shipping and transport containers, the potential for containers to harbor and transfer microbial loads to the fresh produce placed in those containers has been documented (Danyluk, 2012; Sanders, 2015a; Warriner, 2013).

To confirm the continued due diligence by corrugated manufactures to provide clean containers, an annual sampling regimen has been established by the Fibre Box Association (FBA) and its member companies. This report summarizes the results of the 2018 annual testing.

PROJECT BACKGROUND

The Fibre Box Association (FBA) has conducted multiple evaluations of the microbial cleanliness of corrugated containers from its member companies across various regions in the United States (US) since 2014. This current report, sponsored by the FBA, summarizes the results of a recent survey (2018 Annual Review) that assesses the microbial status of corrugated containers at a customer facility. The FBA is committed to this self-evaluation program to confirm that the microbial loads on corrugated containers continue to meet acceptable limits.

Acceptable microbial levels for produce storage and transport containers are not currently defined by any regulatory agencies in the US. A European Union (EU) Commission Decision (2001/471/EC) states that the total viable microorganism count on containers for transport of fresh meat or poultry should not exceed 10 colony forming units (CFU)/cm^2, while the value of *Enterobacteriaceae* should not exceed 1 CFU/ cm^2 (European Commission, 2011). These limits have been subsequently employed as a benchmark level by the Ireland Food Authority and the New South Wales Food Safety Authority for clean and sanitized food contact surfaces (Ireland Food Authority, 2006; New South Wales Food Safety Authority, 2013).

In a publicly available, peer-reviewed study, Cunningham defined the acceptable levels of aerobic microorganisms on food contact surfaces as 125 CFU/50 cm^2 (equal to 103.4 CFU/930 cm^2) as the

upper limit for a clean and sanitized food contact surface (Cunningham et al., 2011). Dr. Keith Warriner of the University of Guelph, in his evaluation of containers used for the transport of fresh produce specified that less than 10^3 CFU *Enterobacteriaceae*[1] or thermotolerant coliforms[2]/container would be representative of sanitary conditions and be deemed acceptable (Warriner, 2013).[3]

This acceptance criteria, established by Warriner, was used to evaluate data from previous field studies on the cleanliness of both corrugated containers from multiple manufacturers and reusable plastic containers (RPCs) across the US and Canada (Sanders, 2015b). In that initial review, all corrugated containers tested (N=360) had microbial loads below 1,000 CFU/container (Sanders, 2015a).

Follow up annual assessments in 2016 and 2017, showed that the two pathogenic indicator organisms (*Enterobacteriaceae* and thermotolerant coliforms) were not present at levels exceeding acceptable limits on containers supplied by various FBA corrugated member manufacturers (Sanders, 2015a; Sanders, 2016).

PROJECT METHODOLOGY

For the 2018 assessment, containers manufactured by an FBA member company were collected and sampled at an industrial site located in Tennessee. Sampling and laboratory analysis were performed by Primus Laboratories of Santa Maria, CA, using the attached protocol (Attachment 1: Corrugated Container Sampling and Testing Protocol). This protocol was based on prior sampling and testing protocols developed by Dr. Trevor Suslow of the University of California.

In summary, the protocol specifies that a total of 48 containers be selected for evaluation from the top, middle and bottom of eight different pallets. Two sponge samples, one of the interior bottom and one of the interior sides and hinges be collected for a total of 96 samples. Each sample is to be assessed for the presence of thermotolerant coliforms and *Enterobacteriaceae;* these organisms are often used as indicator organisms for the presence of *E.coli* and *Salmonella spp*., respectively.

RESULTS

The microbial levels on the interior surfaces of the containers were determined and assessed against the acceptable limits as specified determined by Warriner (Warriner, 2013). No samples had levels of either thermotolerant coliforms or *Enterobacteriaceae* above acceptable limits, in fact 40/48 containers detected no organisms. A summary of the results are presented in Table 1.

Table 1: Organisms per Container (Thermotolerant Coliforms and *Enterobacteriaceae*)[4]

Sampling Location	Number of Containers Assessed	Microbial Load per Container	
		≤10 CFU	>10 - ≤100 CFU
Tennessee, United States	48	40	8

[1] *Enterobacteriaceae* are often evaluated as an indicator for *Salmonella spp.*

[2] Thermotolerant Coliforms are often evaluated as an indicator organism for *Escherichia coli* (*E.coli*).

[3] 10^3 can also be expressed as 1,000 or log 3.

[4] The data used to generate these tabular data can be found in Attachment 2.

CONCLUSION

The 2018 annual assessment was performed in continuation of the industry-wide corrugated container cleanliness studies performed in 2014, 2016 and 2017, sponsored by the FBA.

100% of the corrugated containers sampled in this 2018 annual survey showed that the levels of *Enterobacteriaceae* and thermotolerant coliforms were well within acceptable limits. These current data show the continued due diligence on the part of individual manufacturers and the corrugated industry to provide clean containers to their customers.

Yours sincerely,
Environmental Resources Management, Inc

Maryann Sanders
Product Stewardship Technical Director

John Markey
Partner-in-Charge

Attachments:

1. Corrugated Container Sampling and Testing Protocol
2. 2018 Summary of Annual Test Data

Attachment 1

Corrugated Container Sampling and Testing Protocol

Corrugated Container Sampling and Testing Protocol (2018 Annual Survey)

This protocol provides information and methodologies for the follow-up microbial assessment / cleanliness evaluation of corrugated containers used for the storage and transport of fresh produce. Container sampling will occur at multiple field sites across the United States with laboratory analyses being performed at Primus Laboratories Santa Maria, CA location. The protocol was originally developed by Maryann Sanders and Primus Laboratories with input from Trevor Suslow and the Fibre Box Association.

1. Sampling Sites:

   Corrugated containers will be sampled at a single industrial location in the southern Midwest region (Tennessee).

2. Sampling Date:

   Sampling will occur on a single day

3. The container selection and sampling process will be conducted following Good Laboratory Practices (GLP). The containers chosen for sampling as well as actual sponge samples will be handled according to standard GLP chain of custody technique to ensure sample integrity and identity.

4. Container Selection:

   a. Containers will be selected for sampling from two different corrugated manufacturers (if available). If not available, pallets from a single manufacturer may be sampled. Any pallet wrappings will be inspected for evidence of substantial soil/dust deposits or other foreign materials. If deposits are observed alternative pallets will be selected. If all pallets have external deposits on pallet wrappings a dry-brush procedure will be used to exclude as much as practical before removing the wrapping. Regardless of final condition, wrappings will be removed by technical staff wearing sterile disposable gloves and pulled outward and down from the top rather than lifting over the palletized stack.

      After the pallet wrapping is removed, individual containers will be removed from the pallet for microbial sampling, by technical staff wearing new sterile gloves. Samples will be chosen from the bottom, middle and top of the pallet. Chosen containers will be handled by an exterior surface during unstacking and selection. Gloves will be changed as necessary to mitigate cross-contamination.

   b. Forty eight total containers will be selected for microbial sampling:

      i. Two different lots (shipments) will be assessed per location.

         Note: Where available, the lots should be from different Corrugated manufacturers. If lots from two different corrugated manufacturers are not available, samples should be taken from two different lots from the same corrugated manufacturer.

      ii. Twenty four containers will be sampled per corrugated shipment.

      iii. Four pallets per shipment.

      iv. Six containers per pallet.

      v. Two containers from the top of the pallet, two from the middle and two from the bottom of each pallet.

5. On-site Sampling Area:

   An on-site area to conduct the swabbing of each unfolded corrugated box will be established with effective separation from on-going local operations, de-palletizing and selection activities, and any other potential sources of contamination or sampling interference. The on-site area will be prepared to facilitate proper aseptic technique in sampling/sample handling:

   a. An on-site work bench or table, small folding table, or similar platform will be used for sampling activities

   b. Prior to sampling, the table surface should be sprayed with a hard-surface sanitizing antimicrobial (bleach and/or 70% alcohol), and/or covered with a new sheet of protective lab paper. This activity will be performed between each pallet being tested.

6. Container Identification:

   Each container selected for sampling will be labeled with a unique identifier and include:

   a. Pallet specific prefix to include a corrugated manufacture identification number (to be provided) and a pallet-specific identifier.

   b. Container specific information to include:

      i. Position on the pallet: T (top), M (middle) or B (bottom)

      ii. Consecutive number: 1-6

7. Microbial Sampling:

   a. Sampling of the container will be performed using aseptic techniques, and in accordance with Primus Labs SOP 14-20 “Environmental (Sponge) Sampling”.

   b. Two microbial sponges will be taken per container

      i. One sponge will be used to wipe the entire interior bottom surface.

      ii. One sponge will be used to wipe the interior sides and associated container joints.

8. Sample Transportation:

   a. All individual sample bags containing swabs/sponges will be uniquely labeled with permanent ink or bar-code label and placed in a master container per individual corrugated box, pallet location, pallet and delivery.

   b. A “Sample Log Sheet” will be generated for each sampling event, reflecting transit time and receipt at the laboratory. This Sample Log Sheet will be signed by the Sampler and Laboratory Personnel to verify its accuracy.

   c. All samples will be placed in a cooler with blue ice, with the temperature of the cooler and three individual sample bags recorded upon receipt at the laboratory.

   d. If samples are not processed immediately upon receipt at the laboratory, they will be placed in a secure area in a walk-in cooler or refrigerator at 2.0 to 4.0°C. Total time from sampling to processing is not to exceed 24 hours.

9. Microbial Sample Identification:

   Each microbial sample will be labeled with the container identifier and a notation regarding what part of the container was sampled.

   a. Interior bottom – B

   b. Interior side/corners – S

10. Standard Microbial Methods:

    a. All microbial swabs/sponges will be processed in triplicate using standard quantitative microbiological methods for the Enterobacteriaceae and Coliforms. Sponges will be processed in accordance with Primus Labs SOPs 14-05 (Coliforms) and 14-116 (Enterobacteriaceae), respectively.

    b. The number of colony forming units (CFU) for each of the triplicate samples will be recorded.

    c. The average CFU per swab and per surface area swabbed will be generated and recorded.

11. Laboratory Data Reporting:

    Results of standard microbial analyses including individual sample and the sample averages (per sponge and per surface area) will be compiled and submitted as raw tabular data.

Attachment 2

2018 Summary of Annual Test Data

2018 Annual Corrugated Test data

Samples Taken

Number of Containers Sampled	Number of Samples (2/container)
48	96

Total organisms per Container

Number of Corrugated Containers Sampled	Number of Corrugated Containers with <10 CFU/Container	Number of Corrugated Containers with ≥10 but <100 CFU/Container
48	40	8

Total organisms per Sponge Sample

Number of Sponge Samples (two samples/Container)	Number of Sponge Samples with <10 CFU/Sample	Number of Sponge Samples with ≥10 but <100 CFU/Sample
96	87	9

Coliforms per Container

Number of Corrugated Containers Sampled	Number of Corrugated Containers with <10 CFU/Container	Number of Corrugated Containers with ≥10 but <100 CFU/Container
48	40	8

Coliforms per Sponge Sample

Number of Sponge Samples (two samples/Container)	Number of Sponge Samples with <10 CFU/Sample	Number of Sponge Samples with ≥10 but <100 CFU/Sample
96	87	9

***Enterobacteriaceae* per Container**

Number of Corrugated Containers Sampled	Number of Corrugated Containers with <10 CFU/Container	Number of Corrugated Containers with ≥10 but <100 CFU/Container
48	48	0

***Enterobacteriaceae* per Sponge Sample**

Number of Sponge Samples (two samples/Container)	Number of Sponge Samples with <10 CFU/Sample	Number of Sponge Samples with ≥10 but <100 CFU/Sample
96	96	0