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Mr. Dennis Colley
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Corrugated Packaging Alliance
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Subject: Assessing the Potential of Single-Use Corrugated and Multi-Use Plastic Containers to Harbor and Transfer Microbial Loads

Dear Mr. Colley:

Although food-borne illnesses have not been directly associated with shipping and transport containers, fresh produce has been documented by the Centers for Disease Control and Prevention (CDC) as a source of organisms associated with food-borne illness (CDC, 2015). Utilizing information from the U.S. Food and Drug Administration (FDA), the United Nations Food and Agriculture Organization, peer-reviewed scientific publications and recently performed studies on both single-use corrugated and multi-use reusable plastic containers (RPCs), a comprehensive review of the potential for these containers to harbor microorganisms and subsequently transfer microbes to product placed within them was conducted (Sanders, 2014a; Sanders 2014b; Sanders 2015).

The U.S. FDA Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables indicates that: "*Containers used for ready-to-eat fresh produce should be cleaned and sanitized…"* and further that *"Operators should examine… and develop procedures to track individual containers from the farm, to the packer, distributor, and retailer, in as much detail as possible."* (U.S. FDA, 1998). This indicates that regulators have considered the potential of containers to be a contributing factor in food borne illnesses.

The document, Management of reusable plastic crates in fresh produce supply chains: A technical guide published by the United Nations, indicates that bacteria are not only capable of attaching and remaining on container surfaces as a biofilm, but that these biofilms may transfer organisms to and from materials they come in contact with, including produce (Raspusas and Rolle, 2009). Raspusas and Rolle state that, *"Plastic crates must, however, be appropriately managed and maintained in order to avert any risks associated with their use. Once infected, disease can spread to healthy produce as well as to the contact surfaces of plastic crates."* The document further indicates that, *"Proper physical and hygienic management of plastic crates is equally important in order to safeguard against chemical, physical and microbiological risks."* (Raspusas and Rolle, 2009)

Researchers, including Dr. Michelle Danyluk of the University of Florida, have investigated the potential transfer of the microorganisms, possibly embedded in biofilms, present on food contact surfaces to fresh produce. Specifically, she investigated the bio-transfer potential of *Salmonella spp*. to transfer from

tomatoes to shipping cartons and from shipping cartons to clean produce. Her research showed that under no conditions was the transfer of *Salmonella spp.* to and from product greater than when used, soiled cartons, were evaluated. She states, "…*reused tomato cartons may be a source of contamination for subsequent tomatoes packed in these cartons*." (Danyluk, 2012)

As both corrugated containers and RPCs can be used to store, ship and display product (primarily produce and poultry), the potential for both types of containers to contribute microbial loads to the food chain was evaluated. It is important to note that corrugated containers are recommended by the packaging industry for single-use only, with clean, new corrugated containers provided for each use; RPCs on the other hand are new to the distribution center only initially during their estimated life-cycle of 39 uses.

1. **Multi-use Reusable Plastic Container (RPC) Research Summary:**
   Although RPCs would be anticipated to be clean and relatively free of microbial contamination on first use, based on the heat applied during the molding process, normal use may lead to microbial contamination of, and biofilm establishment on the RPC when used multiple times (Raspusas and Rolle, 2009). Subsequent use of RPCs requires processing (washing, sanitization, drying, and storage) with chemicals (detergents and sanitizing agents) to maintain cleanliness. Microbial contamination may occur due to environmental conditions, contaminated product or cross contamination from other contaminated containers. This microbial contamination can rapidly adapt and form a biofilm (<24 hours); biofilms are generally more resistant to standard cleaning and sanitization procedures, especially if they are not well controlled or sufficiently rigorous to penetrate and remove the biofilm. This formation of biofilms, results in RPCs with significant microbiological carryover.

   To assess the ability of RPCs to develop biofilms, a laboratory study was conducted to determine if food borne pathogens could establish a biofilm on the material and secondarily, to evaluate the ability of common methods of sanitization to disrupt and remove the biofilms. The work showed that of the food pathogens evaluated, *Listeria spp., E. coli* and *Salmonella spp.,* all were able to form biofilms on RPC coupons and that viable (live) organisms remained even when the materials were cleaned with common sanitizers at recommended use rates (Clayborn et. al, 2015; WBA Analytical, 2014).

   RPC field sanitation surveys in the U.S. and Canada were also performed, identifying a significant percentage of RPCs with microbial loads above what would be expected for containers that were sufficiently cleaned and sanitized. In Canada, Dr. Keith Warriner of the University of Guelph indicated that, "…*it was evident that the sanitary status of the containers was dependent on the batch tested."* (Warriner, 2013) This study further concluded that, *"… the RPC were insufficiently cleaned prior to delivery to the Growers."* (Warriner, 2013) In a similar study performed in California, Dr. Trevor Suslow from the University of California-Davis found a high degree of variability in number of viable bacteria on the interior, food contact surfaces of RPCs in the field; values greater than 1,000,000 organisms per container were identified (Suslow, 2014). A further review of Dr. Suslow's results showed that 30% of containers identified as visibly clean had microbial loads above acceptable sanitation levels while 42.5% of containers that appeared grossly dirty exceeded those same levels. A follow-up Canadian field survey on RPC cleanliness was performed by Dr. Warriner in 2014. The Conclusion of the survey report state that, "*The results of the study have confirmed that a high proportion of RPC are of poor sanitary status due*

to inadequate sanitation or post-cleaning contamination. Of concern is the high prevalence of food safety indicators…" (Warriner, 2014).

2. **Single-Use Corrugated Container Research Summary:**
Corrugated container manufacturers have managed the microbial cleanliness of their finished goods for years through the use of manufacturing processes with sufficient time/temperatures to mitigate the presence of microorganisms on the finished goods (Sanders, 2011).

To verify the ability of those processes to result in clean containers for use in the produce industry, a CPA member company provided the results of their routine microbiological testing of finished product; this testing was a singular component of the their overall internal due diligence. Finished product testing from more than 40 facilities over the past five years has shown microbial levels well below acceptable levels, including the absence of pathogenic bacteria such as *Listeria spp*. and *Salmonella spp*. (Sanders, 2014b)

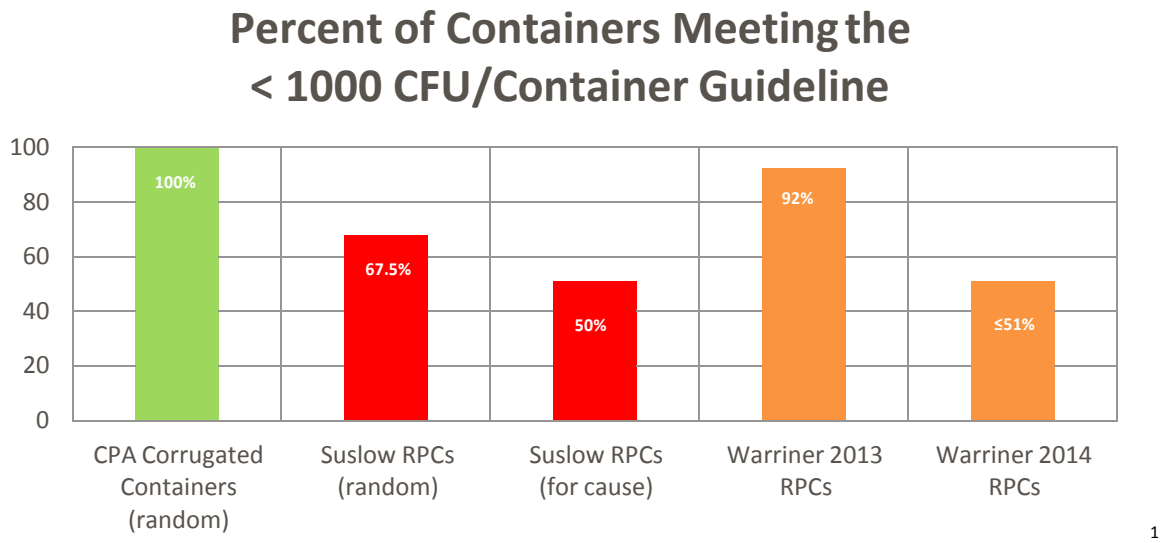
More recently, multiple CPA member companies have announced that they are pursuing certification of their U.S. based food contact container plants against the Global Food Safety Initiative (GFSI). Two of the Hazard and Critical Control Point (HACCP) based standards that meet the rigors of the GFSI benchmarking process include the International Featured Standard (IFS) PACsecure Standard and the Safe Quality Food (SQF) Code. The IFS PACsecure Standard is a food safety standard developed with the support of Agriculture Canada and industry leaders designed specifically for packaging manufacturers. SQF certification provides assurance that a product, process or service complies with regulatory, international and scientifically proven standards for safety. (IFS PACsecure, 2015; SQF, 2015)

A field survey of corrugated containers at multiple distribution centers across the U. S. was performed by the Corrugate Packaging Alliance (CPA); it evaluated the cleanliness of corrugated containers from multiple corrugated container manufacturers at five different customer locations across the U.S. The corrugated survey, which mimicked the Suslow RPC survey, confirmed the cleanliness of the corrugated containers at the distribution center, with all containers meeting acceptable sanitation standards (Sanders, 2015).

3. **Comparative analysis – Single-Use vs. Multi-Use**:
The available field surveys allow for a comparative analysis of the microbial loads present on two container types at the distribution centers. The microbial loads present on single-use corrugated containers and multi-use RPCs from the field were compared to provide relative levels of microbial loads that may be present when fresh produce is placed within the container. The acceptable level used in all the surveys for *Enterobacteriaceae* (indicator organism for *Salmonella spp*.) and Coliforms (indicator organism for *E. coli*) was >1000 colony forming unit (CFU)/container. Although no specific regulatory limits related to microbial contamination were identified, the 1000 CFU/container limit as specified by Dr. Warriner in his 2013 study as an acceptable sanitation limit were used consistently across all data for comparison purposes. (Warriner, 2013) This limit is also specified as an acceptable level in multiple European Guidelines. (FSAI, 2006; NSWFA, 2013)

When the results of the available field surveys are compared to the acceptable limit, 100% of corrugated containers met acceptable sanitation standards while percentages as low as 50% of RPCs evaluated did not meet these same standards.

Figure 1 provides a visual overview of the comparison of the various study results as compared to the acceptable sanitation criteria for *Enterobacteriaceae and* Thermotolerant Coliforms.



[1]

Figure 1. Percentage of Containers Meeting Acceptable Sanitation Standards (10^3 CFU/container)

[1] Figure 1 depicts the *Enterobacteriaceae* levels from all datasets and the Thermotolerant Coliforms levels for both RPCs and corrugated container testing in the field as compared to the acceptable sanitation level for these organisms.

Conclusion:

Fresh produce has been documented by the CDC as a source of microbial contamination leading to food-borne illness (CDC, 2015) and the U.S. FDA has specified that, "*Containers used for ready-to-eat fresh produce should be cleaned and sanitized…"* (FDA, 1998), indicating that regulators consider food storage and transport containers to be a potential contributing factor in the transmission of organisms resulting in food borne illnesses.

The Corrugated Industry has worked diligently over multiple years to ensure that containers they provide to the food industry are clean and meet or exceed customer, consumer and regulatory expectations. The Corrugated Packaging Alliance has continued to develop appropriate data-based documentation that showcases the cleanliness of corrugated containers while exposing the potential of RPCs to harbor levels of microorganisms above acceptable sanitation standards even after the RPCs were cleaned and sanitized according to standard industry practices. Field data confirm that 100% of single-use corrugated containers meet acceptable sanitation standards while a percentage of multi-use RPCs failed to meet these same acceptance criteria in each of the three surveys performed.

The data support the industry conclusion that based on food safety concerns, single-use corrugated containers are the best choice for the transport of fresh produce.

Sincerely yours,
HALEY & ALDRICH, INC.

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REFERENCES

1. Centers for Disease Control and Prevention (CDC). 2015. Foodborne Outbreaks: List of Selected Multistate Foodborne Outbreak Investigations. http://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html. Accessed January.

2. Clayborn J, Adams J, Baker CA, Ricke, SD. 2015. Assessment of Salmonella spp. Attachment to Reusable Plastic Containers Based on Scanning Electron Microscopy and BAX® PCR. Journal of Food Research; Vol. 4, No. 2; 2015, pp 166-175.

3. Danyluk M. and Schneider K. 2012. Pathogen transfer risks associated with specific tomato harvest and packing operations. Center for Produce Safety.

4. European Commission, 2011. Commission Decision of 8 June 2001 laying down rules for the regular checks on the general hygiene carried out by the operators in establishments according to Directive 64/433/EEC on health conditions for the production and marketing of fresh meat and Directive 71/118/EEC on health problems affecting the production and placing on the market of fresh poultry meat. June 8. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:165:0048:0053:EN:PDF. Accessed February 4, 2015.

5. Food Safety Authority of Ireland (FSAI). 2006. 3rd Trimester National Microbiological Survey 2006 (06NS3): Examination of the microbiological status of food preparation surfaces. https://www.fsai.ie/uploadedfiles/food_prep_surfaces.pdf. Accessed February 4, 2015.

6. IFS PACsecure. 2015. IFSPACsecure food safety certification selected by International Paper. http://www.pac.ca/ePromos/promos/pac0650/pac0650-ifs-pr.html. Accessed March 15, 2015.

7. New South Wales Food Authority (NSWFA). 2013. Environmental Swabbing: A guide to method selection and consistent technique. FI170/1303. http://www.foodauthority.nsw.gov.au/_Documents/science/environmental_swabbing.pdf. Accessed February 4, 2015.

8. Raspusas, R, Rolle, R. Management of Reusable Plastic Crates in fresh produce supply chains – a technical guide. Food and Agriculture Association of the United Nations, Regional Office for Asia and the Pacific. Bangkok, 2009.

9. Safe Quality Food Institute. SQF Code - A HACCP-Based Supplier Assurance Code for the Food Industry. http://www.sqfi.com/wp-content/uploads/SQF-Code_Ed-7.2-July.pdf. Accessed March 16, 2015.

10. Sanders, M. 2011. High temperature short time (HTST), and Higher heat short time (HHST) microbial risk reduction review. Internal International Paper report. July 11.

11. Sanders, M. 2014a. Assessing the Potential of Reusable Plastic Containers (RPC) to Harbor and Transfer Microbial Loads. Internal International Paper report. October.

12. Sanders, M. 2014b. Microbiological Status of Finished Paper/Corrugated Boxes. Internal International Paper report. November 19.

13. Sanders, M. 2015. Field Study to Assess the Microbiological Status of Corrugated Containers and Other Produce Storage and Shipping Containers upon Delivery at the Customer Location. Internal Corrugated Packaging Alliance report, February.

14. Suslow, T. 2014. Assessment of General RPC Cleanliness As Delivered for Use in Packing and Distribution of Fresh Produce. University of California at Davis. Department of Plant Sciences. October 20.

15. United States Food and Drug Administration (FDA), Center for Food Safety and Nutrition, 1998. Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables. October, 1998. Available at: http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM169112.pdf.

16. Warriner, K. 2013. Microbiological standards for Reusable Plastic Containers within Produce Grower Facilities. University of Guelph, Department of Food Science, June.

17. Warriner, K. 2014. Microbiological standards for Reusable Plastic Containers within Produce Grower Facilities within Ontario and Quebec. University of Guelph, Department of Food Science, October.

18. WBA Analytical, 2014. Research Study II. Internal International Paper Study. May 8.