February 24, 2014

Dear Lynn,

Thank you for GPI's comments, dated October 31, on the draft TPCH report, *Glass Matrix Test Methods Evaluation for Toxics in Packaging.* Below are TPCH's responses to your comments, developed in consultation with Ron Ohta, CA DTSC Project Manager and Alex Stone, the Project Quality Assurance Manager. Where applicable and noted below, changes were also made to the report.

GPI challenges the draft report and its conclusion on the basis of several arguments that TPCH respectfully refutes. Some GPI comments also indicate a misunderstanding or misinterpretation of the study objectives and supporting documentation. Other comments were considered and the report was modified accordingly.

The following responses address several overarching themes in GPI's comments first, followed by a paragraph by paragraph response.

1) The validity of XRF analysis and its use in the study are challenged.

   **TPCH Response**: The draft report compared laboratory results derived from two types of samples: certified reference materials and retail samples. The metal concentration for retail samples was determined using x-ray fluorescence (XRF) analysis. XRF is a valid method described in EPA SW-846 6200 for soil sediments and ASTM method F2617 for homogeneous polymeric materials. TPCH and member states have extensive experience with XRF analysis, have done several studies comparing XRF with conventional laboratory methods, and have found good agreement between XRF and EPA Method 3052. Further, the draft report uses XRF values as one of two (or three) reference values, and does not rely solely on XRF values in the evaluation of laboratory results.

2) Statistics and study objectives are questioned.

   **TPCH Response:** It was not the intent of this study to analyze a statistically significant number of samples or to obtain a statistical significant data set. This was stated in the Sampling and Analysis Plan (SAP), dated January 2012. The validity of Method 3052 was not the objective. The objectives were stated in the SAP and restated in the draft

report. The study objectives were qualitative in nature, the conclusions are qualitative, and do not require statistical numbers. The study results are indicative and sufficient for TPCH's conclusions.

3) Questions regarding the variability found in test results.
   a. Paragraph 3, "…the Draft Report reveals a significant degree of variability even by laboratories testing the same sample using the same test method."

      **TPCH Response:** Variability was within allowed ranges. All laboratories expect variability in test results because of differences in matrices and laboratory staff and equipment. EPA generally allows ± 25% as an acceptable range of variability among laboratory results. For this reason, in the TPCH study ± 25% was selected as the acceptable range of variability in the evaluation of results. The variability that we found in the EPA 3052 test results was within this acceptable range.

   b. Paragraph 4, "The variability in results might be explained by differences in sample preparation methods by the laboratories."

      **TPCH Response:** One of the primary objectives of the study was to determine if sample preparation was a variable. The study demonstrated variability in sample preparation methods (e.g., EPA Method 3052 vs. EPA Method 3050B).

   c. Paragraph 5, "EPA verification of that test method [Method 3052] showed variability in the parts per billion, not parts per million. So when properly applied, this test method can achieve results that are relevant to standards that are expressed in parts per million. The results in the Draft Report do not, however, support this conclusion."

      **TPCH Response:** The EPA Method 3052 performance results tabulated and presented in the Tables at the end of the Method are expressed as ug/g, which is equivalent to mg/kg or ppm. (http://www.epa.gov/wastes/hazard/testmethods/sw846/pdfs/3052.pdf)

4) Use of equivalent methods. Comment in paragraph 6: "We cannot agree with the recommendation of test methods 'equivalent' to EPA Method 3052."

   **TPCH Response**: The use of this terminology was misleading and therefore has been changed from "equivalent method" to "comparable method" in the report. "Comparable methods" were procedurally similar to EPA Method 3052, but labeled /numbered as an internal standard operating procedure. It is a common practice for a laboratory to take a standard test method and write more detailed, laboratory-specific standard operating procedures to ensure uniform and consistent application. Two footnotes were added in the report to clarify the use of the term.

   Do note that none of the "in house" methods were determined to produce equivalent results to EPA Method 3052.

5) The use of XRF analysis to demonstrate non-compliance. See GPI letter paragraph 7.

**TPCH Response**: The draft report states: "Analytical testing may be used to confirm metal concentrations and the compliance status of glass matrices." The draft report does not explicitly address the use of XRF for regulatory enforcement, since this is not within the scope of TPCH. The use of XRF for determining non-compliance for enforcement purposes is at the discretion of individual states as well as regulated entities.

6) Request to reference the exemption for recycled content in the Model is 200 ppm. (See GPI letter paragraph 8).

**TPCH Response**: The recycled content exemption in the Model is not entirely relevant to this draft report, since the study is not specific to recycled content. However, a footnote has been added stating that the recycled content limit in the Model was changed to 200 ppm based upon input from the glass industry as an achievable limit, although the change has so far only been adopted by one state. The recycling exemption in the original legislation expired in most of the other member states.

7) GPI provides additional comments as an attachment. Any comments not already addressed are considered here.

- Bullet 1. Lab selection was intended to mimic the marketplace; that is, regulated entities select laboratories based on their credentials and representation of their capabilities.
- Bullet 2. The objective stated was not an objective of the study. As previously mentioned statistics and objectives were stated in the SAP (See comment #2).
- Bullet 3. The analytical methods were consistent as defined in the SAP, dated January 2012, and in the draft report, page 11 and Table 2.
- Bullet 4. See comment 2. As stated above, TPCH followed the parameters outlined in the SAP developed for the project. No statistical goals were defined in the SAP.
- Bullet 5. The results demonstrate that the variability in laboratory results is attributable to the sample preparation method.
- Bullet 6. The objective of this study was to evaluate different sample preparation and dissolution methods. This explains the variability in the test results as discussed in the results and conclusion sections of the draft report.
- Bullet 7. The Project Quality Assurance Manager reviewed QA/QC data from laboratories to ensure quality and consistency of results.
- Bullet 8. Laboratory results for all samples are presented in Appendix A. TPCH adhered to the parameters of the SAP developed for the project. The SAP did not require a statistical valid number of samples. The validity of Method 3052 has already been demonstrated by EPA. The goals as stated in the SAP were to determine practical applications of the methods; therefore the SAP only specified the use of

simple statistical applications to determine mean values and variance. None of the report conclusions are based on statistical results.

- Bullet 9. Please refer to Comment #3 and discussion of statistics above.
- Bullet 10. CA DTSC retains copyright on contract reports.

Sincerely,

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Patricia Dillon

Program Manger

Toxics in Packaging Clearinghouse

Cc:

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