



**Recycled
Paperboard
Technical
Association®**

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The Recycled Paperboard Technical Association's Food Packaging Safety Guidance and Chemical Testing Protocol

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Introduction

In 1962, the U.S. Food and Drug Administration (FDA) promulgated a food additive regulation to allow the use of pulp from reclaimed fiber in food packaging (27 FR 6338, July 4, 1962). That regulation was modified in 1973 (38 FR 18096-18101, July 6, 1973). This food additive regulation is now codified in 21 CFR 176.260 and recognizes that the sources of reclaimed fiber may be either '*industrial waste from the manufacture of paper and paperboard...*' or '*salvage from used paper and paperboard...*'. In both cases, the regulation stipulates that the material may not bear or contain '*any poisonous or deleterious substance...that migrates to the food except as provided in the regulations...*'.

In the late 1990's, the public showed an increased interest in conservation efforts. There was a corresponding increase in paper recycling rates. In response, certain paper manufacturers collaborated to develop Good Manufacturing Practices for the industry on the manufacture of paper and paperboard from recycled fiber for use in food packaging applications. In 1999, the Recycled Paperboard Technical Association and American Forest & Paper Association (AF&PA) jointly published a **Guidance for Industry** on *The Use of Pulp From Reclaimed Fiber as a Component of Paper and Paperboard Products for Food Packaging Under 21 C.F.R. 176.260*.

This **Guidance for Industry** outlines the steps necessary to help ensure compliance with 21 C.F.R. 176.260 as follows:

1. Exclusion of potential sources of contaminated reclaimed paper and paperboard.
2. Inspection of incoming materials in order to minimize introduction of contaminated reclaimed paper and paperboard.
3. Identification of potential substances and periodic analysis of the finished products to determine whether they are present and, if so, at what specific levels.
4. Determination of the regulatory status of the specific amount of any substance found to be present in the final product in order to assure compliance with the Food, Drug, and Cosmetic Act and implementing regulations.
5. Maintenance of adequate company records.

Around the same time, the RPTA issued the first edition of its *Chemical Testing Protocol for Food Contact Paperboard Made from Recycled Fiber* (RPTA Protocol) as a tool to help manufacturers of recycled paper and paperboard comply with steps 3 and 4 of the **Guidance for Industry** as listed above.

The RPTA Protocol

The RPTA Protocol is a tool that was developed through the collaborative efforts of industry experts, outside consultants, and experts in the area of health-risk assessment. It is used by RPTA members and licensees to help ensure that paperboard manufactured from recycled fiber complies with the 21 CFR 176.260 and California's Proposition 65 with regard to unintentional chemical constituents, and may be used safely for food-contact packaging.

The first issue of the RPTA Protocol contained a list of over 150 chemicals along with their corresponding health risk based allowable concentrations. The Protocol was used by certain recycled paper manufacturers to evaluate levels of unintended chemical constituents in their paper as part of their regulatory compliance evaluation. The Protocol also contained information on how to use the test data, as well as steps manufacturers can take should their results deem additional study is needed.

Initially, chemicals were selected for inclusion based on the potential for their presence because they are common industrial and commercial contaminants. Classes of chemicals contained in the list include:

- Heavy Metals
- Pesticides
- Phthalates
- Poly Aromatic Hydrocarbons
- PCB's
- Volatile organic Compounds
- Semi-Volatile Organic Compounds

The list of chemicals contained in the Protocol is not static. The list is periodically revised to include new chemicals which could potentially be found in recycled fiber streams and that have potential health affects. In addition, the allowable concentrations are subject to change as new information about any health effects becomes available. RPTA and its current and former outside consultants (Keller and Heckman and ENVIRON) have monitored for changes to the underlying toxicological data used to develop the allowable concentrations for the chemicals, and updated the information contained in the Protocol as necessary. In 2007, RPTA issued its 4th update to the original Protocol document.

Additional testing requirements

In an effort to provide more comprehensive guidance to RPTA members in terms of testing requirements to help the members ensure compliance with FDA regulations and demonstrate that recycled paperboard is safe for food-contact packaging applications, RPTA developed a draft 'Auxiliary Guidance Document For Food Contact Paperboard Made From Recycled Fiber – Second Edition'. The

three areas covered in that Auxiliary Guidance are: 1) monitoring bacteriological activity, 2) conducting extraction analysis of the paperboard, and 3) CONEG metals.

Conclusions

The RPTA Protocol is a confidential and proprietary tool that helps the user assess its compliance with 21 CFR 176.260 requirements for manufacturing packaging in direct contact with food. The RPTA Protocol also is a living document that draws upon the knowledge of recognized experts in the field of risk assessment, authoritative scientific literature and commonly accepted safety assessment techniques to present a methodology for achieving this purpose.

The RPTA Protocol is periodically revised or amended as new scientific information become available. The Protocol is a licensed product of RPTA. The Protocol and its revisions and amendments are available only to RPTA members and licensees. For information on becoming a RPTA member or licensing the Protocol please call the RPTA office at (847) 622-2544 or e-mail rpta@rpta.org.