

Minutes
RadTech Food Packaging Alliance
Thursday, October 9, 2003
9:30 a.m. – 4:00 p.m.

1. The meeting was called to order by G. Cohen and R. Golden. G. Cohen noted the meeting would be conducted under RadTech's Antitrust Policy. Introductions were made.
2. R. Golden reviewed the meeting agenda and explained the decision to not include a review of the basic rules governing the clearance of components of food packaging based on a review of this topic at two prior meetings on July 16, 2003 and August 11, 2003. M. Marrapese noted that Keller and Heckman's 4th annual food packaging law seminar will be held in Washington, D.C. on October 29, 2003. Members were also referred to www.packaginglaw.com for additional background information.
3. R. Golden proceeded to review the Alliance Objective, which is "to accomplish one or more successful Food Contact Notification (FCN) filings for UV/EB workhorse materials and maximize the utility of the FCN(s) to formulators." With respect to this Objective, the following actions occurred:
 - E. Maguire motioned to amend the Objective to specify that the purpose was to "maximize the utility of the FCN(s) to Alliance members." This amendment was accepted.
 - E. Maguire motioned to add to the Objective a date certain for completion of the project. A general timeframe of 18 months was discussed, but it was decided to wait to add a date certain until the members of the Alliance had been finalized and a work plan had been established.
 - E. Maguire raised whether filing the FCNs was a tactical approach rather than an objective, and whether the Objective should be revised to reflect that the purpose of Alliance is to serve as a catalyst to expand food contact uses of UV/EB materials by Alliance members. It was agreed that this was a valid point that would be taken under advisement.
4. E. Maguire identified the need to determine whether the Alliance FCN will serve as simply a catalyst for subsequent FCNs by individual companies or whether the formulation cleared by the FCN would have immediate utility. M. Marrapese indicated that Keller and Heckman considered the group of 8 materials to be the maximum number of components that would be feasible to clear initially within the budget under consideration. T. Kauffman of Rohm and Haas suggested that a FCN for the 8 proposed components or ones similar to them would have immediate utility.
5. R. Golden, L. Borodinsky, and M. Marrapese led a discussion of the benefits of the project to suppliers, formulators, equipment manufacturers and end users:

- Formulators could market products with migration levels higher than 50 parts per billion (ppb), with the specific level to be established by the FCN in conjunction with a dietary exposure assessment using the existing toxicology data available through the Specialty Acrylates and Methacrylates (SAM) panel's participation in the Environmental Protection Agency's (EPA's) High Production Volume (HPV) test program.
 - Broad commercial formulations with even a very limited set of cleared "workhorse" materials are possible because formulators will be able to add other materials cleared by FDA's regulations (e.g., §§ 175.300, 175.105, 176.170) for the specific intended use to the FCN formulation without additional clearance needs.
 - Supplier members could sell to customers that are both members and non-members of the Alliance.
 - Formulator members would be able to select the components to be included in the FCN, and increase their knowledge of the process for preparing and seeking additional FCNs.
 - The FCN could be written so as to permit Formulator members to obtain components from supplier members or non-member suppliers, providing that the non-member supplier materials met the conditions of the FCN.
 - Formulator and end user members would be able to include their desired applications, specifications, restrictions, limitations and quality control testing in the FCN and understand the process conditions necessary to obtain this clearance.
 - The FCN would serve as a vehicle for familiarizing end users with UV/EB applications and for increasing the confidence of the market in the use of these materials.
 - The FCN will establish a public baseline for what FDA will accept in designing UV/EB formulations for food packaging uses.
 - The FCN could provide increased commercial opportunities for members whose names will be publicly associated with a UV/EB material cleared for use in food packaging on the Food and Drug Administration's (FDA's) database.
 - Formulators that are not members of the Alliance who purchase from suppliers that are not members of the Alliance cannot legally market the Alliance's FCN formulation for food packaging use without establishing an independent basis for a clearance, e.g., by filing their own FCN.
 - Equipment suppliers will understand the process conditions necessary to obtain this clearance.
6. When the meeting resumed, L. Borodinsky reviewed the components of an Alliance FCN

- He indicated that the FCN could include a number of workhorse components and that FCNs are routinely structured so as to permit the use of a component within a range of levels and in combination with other cleared materials.
 - He indicated that Keller and Heckman would rely on input from Alliance members to identify the intended conditions of use for the FCN, and that the FCN would be structured to provide maximum flexibility and uses as would be allowed based on the results of extraction testing and the toxicology data. Cans and flexible packaging were identified as desired applications for coating and adhesive formulations presented in the FCNs.
 - The test samples could be designed to take into account the ability to react the components under consideration in different ways to yield different extraction results. If the test sample and the intended conditions of use to be simulated by the testing were sufficiently “worst case”, there is no requirement to conduct extraction testing for lower residual monomer and photoinitiator levels or less severe use conditions, as these are generally assumed to result in less severe migration.
 - Disclosable and non-disclosable aspects of the filing were covered. Information associated with FCNs that are available to the public through the Freedom of Information Act (FOIA) includes extraction data (except for the identity of confidential migrants), toxicology data, and the identity of the submitters themselves. This is the case for any similar filing to FDA, including a Threshold of Regulation (TOR) filing.
 - In addition, a description of the formulation that identifies the functional components would be public, similar to how components are made public in FDA’s regulations, except that a FCN may only be used by the submitters and their customers.
 - He indicated that details of the manufacturing process, sample preparation, purity levels, catalysts, residuals, and decomposition products may be held confidential. The mechanism for providing proprietary information and maintaining its confidentiality in a group process such as this one is for individual Alliance members to establish confidential Master Files with FDA if a decision is made to withhold certain information from other Alliance members and the public.
 - Because certain process information need not be disclosed, companies that are not Alliance members are not easily able to determine or respond to FDA with confidence that their non-cleared formulation is the same as the one that is cleared through the FCN.
7. K. Hrebner raised the possibility of a two phase approach, with phase one consisting of a “paper submission” alternative that would entail having the FCN supported by a toxicology assessment rather than extraction testing. In addition, he suggested structuring the FCN to support a number of UV/EB components or categories or families of components rather than a single formulation made up of certain components. These alternative suggestions were favorably received and the group

discussed raising them with FDA in a preconsultation meeting. The timing and form of the request for FDA feedback was discussed. A preconsultation meeting could help to educate FDA about UV/EB materials and could generate suggestions by FDA that could simplify or otherwise modify the Alliance's approach. Keller and Heckman strongly recommended that a work plan be developed by the Alliance to bring to the discussion with FDA.

8. M. Marrapese commented on the role of the FCN process for bringing greater recognition to the use of these materials and to expand food contact uses beyond what has been accomplished by the industry through the use of the TOR approach with its 50 parts per billion (ppb) migration limit and the functional barrier doctrine.
9. In response to a question from E. Maguire, M. Marrapese indicated that after a FCN is made public, obtaining a similar FCN by others outside the Alliance could take from one year to 18 months.
10. The following parameters were identified for inclusion in the work plan that the Alliance will develop for defining the scope of the FCN. Alliance members will need to:
 - Decide whether to design a commercially viable formulation or one that serves as a catalyst for future commercialization opportunities only.
 - Select the desired intended conditions of use.
 - Finalize a list of candidate components to include representative, multifunctional workhorse monomers and one to three photoinitiators.
 - Select candidate components that are representative of an adhesive or a coating or both.
 - identify possible degradation products in selecting candidate components.
 - Decide upon a UV or an EB formulation or both.
 - Discuss whether to suggest categories of components be cleared and design a formulation containing materials representative of the categories.
 - Consider the merits of a two phase approach consisting of a paper study and extraction testing.

Some attendees expressed the desire for more certainty on the points above prior to forming the Alliance. For this purpose, a list of candidate materials has been made available to attendees as well as a proposed budget and contribution schedule that incorporates work associated with these items. In addition, R. Golden noted that it should be generally recognized that these items form the bulk of the actual work before the Alliance and that one of the benefits of joining the Alliance will be to have a seat at the table in making these decisions.

11. T. Johndahl asked when the ability to participate in the Alliance would close. R. Golden responded that there would be a reasonable period of time after the Alliance is formed for others to join, and that the decision whether and when to close the period for accepting additional participants would be made by the Alliance.
12. G. Cohen confirmed that membership in the Alliance would be open to non-RadTech members.
13. A budget of \$217,000 was proposed and reviewed by M. Marrapese. This figure includes the cost of running two extraction test samples and includes 10% in additional costs for unanticipated expenses. M. Marrapese noted that administrative costs would be provided by RadTech, resulting in substantial savings.
14. M. Marrapese presented a proposed assessment structure of \$12,500 for raw material suppliers, \$7,500 for formulators, and \$5,000 for all others which would include equipment suppliers and end users. At a projected participant level of 9 suppliers, 9 formulators, and 9 all others, this assessment structure would meet the projected budget. These rates are inclusive of all fees and costs of the project and are based on continued participation by the interested companies attending today's meeting. These fees are subject to change +/- 20 percent depending on actual Alliance participation. Funds would be collected and work begun only after determination of sufficient participation. Funds would be retained in an escrow account dedicated for this purpose and would be drawn upon on a monthly basis as required.
15. The issue of the appropriate assessment for suppliers of raw materials with formulating operations was duly noted and tabled for a later discussion.
16. As a mechanism for determining sufficient participation, M. Waite suggested that Alliance participants indicate the maximum amount they would individually be willing to contribute to participate in the Alliance in the letter of intent to be signed by all participating companies.
17. A meeting summary, letter of intent, and budget with a break out of the toxicity analysis portion of the project will be distributed to meeting participants within the next week.
18. Remaining agenda items were tabled for discussion at the next meeting. The meeting adjourned at 4:00 p.m.