MEMORANDUM

December 3, 2001

TO: Marla Donahue

FROM: Richard S. Silverman
       Ann M. Boeckman

RE: Aromatic Amines and Flexible Packaging

Aromatic amines are a class of organic compounds that may arise from a variety of natural and synthetic sources. Certain aromatic amines have been shown to cause cancer, others are of toxicological concern, and still others are of no public health consequence. It has long been known that aromatic isocyanates, which are used to produce adhesives that bond together individual layers of flexible plastic laminates, may react with water to form primary aromatic amines (PAA) that are of toxicological concern. No health risk is presented, however, so long as good manufacturing practices (GMPs) are observed, including the allowance of adequate time for the adhesive to cure fully.

Recent press reports in Europe have characterized the possible presence in food of PAAs as a significant health problem that is linked to the use of flexible packaging materials. In one widely publicized—and subsequently discredited—news report, the Danish magazine Boersens Nyhedsmagasin claimed to have uncovered evidence of PAAs in food at unsafe levels. The report attributed the PAA findings to food packaging that contained isocyanate-based adhesives.

You asked that we provide an explanation of the approaches taken in the United States and the European Union (EU) to manage the PAA issue as it pertains to flexible packaging. In response to your request, this memorandum provides a summary of U.S. and EU safeguards that are designed to prevent the
presence in food of PAAs associated with isocyanate-based adhesives. For the sake of brevity, we focus on migration-related requirements, which are of greatest relevance to the recent controversy in Europe.

I. THE U.S. APPROACH

To ensure that food is not adulterated with PAAs or other substances, the Food and Drug Administration (FDA) has prescribed the circumstances under which adhesives may be safely used in food packaging materials. 1/ An adhesive must be separated from food by a "functional barrier," which serves as a nonpermeable obstacle to migration. Each manufacturer is responsible for determining, with migration testing as necessary, whether a particular material is capable of serving as a functional barrier to migration of adhesive components. Limited allowances are permitted for contact that may occur within the bounds of good manufacturing practice (GMP). 2/

To the extent that adhesive components are able to migrate through a laminate, the laminate fails to meet FDA's "functional barrier" requirement, and additional safeguards are necessary to ensure that the packaging materials do not adulterate the food. For instance, with respect to "boil-in-bags," it became apparent that plastic laminates may not serve as a "functional barrier" to migration of isocyanates or diisocyanates at high temperatures. Accordingly, FDA issued regulations to deal with these laminate applications specifically. 3/

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1/ 21 C.F.R. § 175.105.

2/ For aqueous and fatty foods, where the risk of migration is greatest, FDA has specified that contact must not exceed a trace amount at the edge exposure between packaging laminates that may occur within the limits of GMP. Packaging seams or laminates must remain firmly bonded without visible separation under normal conditions of use.

II. THE EUROPEAN UNION

A. Legal Framework

In the EU, plastic materials and articles that may come into contact with food are regulated pursuant to Directive 90/128/EEC of 23 February 1990, as amended. This directive provides a list of "monomers and other starting substances" that may be used to manufacture plastic materials, and a list of authorized "additives" that may be incorporated into plastic materials. The list of authorized monomers contains a number of isocyanates and diisocyanates that may be used in packaging materials in the EU. The Directive states that it does not yet contain, however, a list of materials that may be used specifically in the production of adhesives. Accordingly, the regulation of adhesives is not considered to be fully "harmonized" and it is necessary to consult the laws of individual Member States to determine the status of materials used in adhesives.

Isocyanate monomers used in food packaging applications are subject to several restrictions under Directive 90/128/EEC and other provisions of EU law. Of particular interest is the most recent amendment to Directive 90/128/EEC, which added PAA migration limits for materials manufactured using aromatic isocyanates. 4/ These limits prohibit the release of PAAs in a detectable quantity, using a method with a detection limit of 0.02 mg/kg in food or food simulant. Directive 90/128/EEC also specifies the maximum permitted quantity of "residual" isocyanates that is permitted in finished materials or articles. This "residual" limit provides that isocyanates may not be used in food contact materials at a level that exceeds 1 mg/kg (as the isocyanate moiety) in the finished packaging material. The Member States are required to implement the new PAA migration limits by November 30, 2002.

In addition to these isocyanate-specific requirements, all packaging materials are subject to a general requirement that constituents of food packaging must not be transferred to food in a manner that could endanger human health. 5/ All plastic materials must also comply, unless specifically exempt, with an "overall

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migration limit” of 10 milligrams per square decimetre of surface area (mg/dm\(^2\)) established in EU law. 6/

**B. Reaction to News Report Regarding PAAs in Food**

Interest in the European regulation of flexible packaging materials heightened with a news report published August 13, 2001 by the Danish business magazine *Boersens Nyhedsmagasin*. The report relayed results of testing conducted by the Steins Laboratorium, which revealed the presence of aromatic amines in food packaged with flexible packaging materials. The report compared the test results with a national German limit of 0.002 mg/kg, which is 10 times lower than the level ultimately incorporated into Directive 90/128/EEC, and asserted that flexible packaging materials are unsafe for food contact uses.

The sampling and analytical methods relied upon in the news article have been widely questioned, if not discredited. Shortly after the article published, the Steins Laboratorium itself issued a press release cautioning that the results were preliminary, that the findings had not been validated, and that the results cannot be considered to “prove that the packaging liberates aromatic amines to the foodstuffs.” 7/

The results have also been called into question by the Danish Veterinary Food Administration (DVFA). Following a comprehensive review of the matter, the DVFA concluded that the sampling, the migration tests, and the analyses failed to satisfy the usual conditions for the analysis of migration of PAAs from plastic packaging materials to foodstuffs. 8/ The DVFA found that, in general, erroneous procedures had been followed and incorrect conditions had been used with regard to the choice of food simulants and the chosen duration and temperature of the migration tests. The DVFA concluded that the results presented by the magazine could not be used as reliable documentation for the claim of

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excessively high PAA migration. To complete the investigation, the DVFA asked *Boersens Nyhedsmagasin* to provide more data, but we understand that no additional data are expected.

The Danish authorities have requested their regional “Food Control Centers” to monitor the situation closely and to carry out strict controls to ensure that migration of aromatic amines from the packaging materials is in line with the EU standards. The prevailing opinion appears to be, however, that “there seems not to be a general problem concerning the migration of PAA from flexible plastic laminates.” 9/

The European Commission informed the European Scientific Committee on Food (SCF) of the study and asked the Committee if the available information was adequate to allow an assessment of any hazard to consumers. A European Working Group on Food Contact Materials (made up of Member State and European Commission experts) met in early September 2001 and was asked to examine this question as a matter of urgency. At the SCF plenary meeting held on September 25-26, 2001 the SCF issued a statement on the report in the Danish magazine. 10/ The SCF concluded that in order to evaluate the possible implication of the findings on public health, additional data should be requested relating to the identity of the aromatic amines, the methodology employed, and the sampling of food and packaging samples. The SCF requested that the Commission obtain such information and stated that it would review the issue once all the data are available.


10/ Statement of Scientific Committee on Food on the recent report on primary aromatic amines in food and packaging samples in a Danish magazine, SCF/CS/PM/GEN 89 (26/09/2001).
To date, the European Commission has not received the requested information. We understand that should such information become available, the earliest opportunity for the Food Contact Materials working group to discuss it would be during its next meeting on February 4-6, 2002. It is our impression, however, from our European colleagues’ conversations with Commission officials and the Danish authorities, that debate on the issue has already calmed down significantly and is not expected to flare up again in the near future.

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If there are any questions regarding this information, or if we can be of assistance in any other way, please let us know.