ENVIRONMENTAL WORKING GROUP

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May 4, 2007

Dr. David Acheson
Assistant Commissioner for Food Protection
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Acheson:

We are encouraged to see the Food and Drug Administration's new commitment to food safety demonstrated by the creation of a new agency position and your appointment as the Assistant Commissioner for Food Protection. This position and emphasis is long overdue. The first major issue you face in your new position, melamine contamination in food, is certainly the perfect place for you to begin turning around the public's well-founded and growing doubt about FDA's ability to ensure the safety of our food supply.

On May 2nd you stated in the *Washington Post* that "We [the FDA] do not believe there is any significant threat of human illness from this [new-found melamine contamination in chicken and pork]." Given that this same contaminant in pet food has been responsible for countless animal deaths around the country in recent weeks, and in light of your statement, we are writing to request that you fully disclose the scientific and policy basis for your assertion that this toxic chemical food contaminant poses little risk to the public. We are concerned, based on our own history of interactions with the FDA on important food safety issues including mercury in seafood and benzene in soft drinks, that the agency may in fact not have an adequate scientific or analytical basis to support it's sweeping assurances that melamine poses no significant threat to the public health.

We are requesting, therefore, that you make public all Agency analyses and records of deliberation leading to this conclusion, and records of all meetings and other contacts with companies, trade associations, and other parties with a financial interest in FDA's actions on this matter.

As you know, an assertion that a food contaminant poses no "significant threat of human illness," must be based on an analysis of human exposure and risk. For a chemical under such intense scrutiny as melamine, we believe the Agency must, in the interest of public health and transparency, release any and all analyses that confirm that your safety assertions are, indeed, backed up with scientifically sound, rigorous assessment of public health risk. We are particularly interested in your analyses and findings related to:

- The levels and extent of melamine in the food supply, including historic levels;
- Risks for people who eat chicken, pork, or other melamine-contaminated foods frequently;

- Risks for people who may be particularly vulnerable to the effects of melamine because of pre-existing health problems such as kidney disease;
- Data available to FDA to fill the significant gaps noted in the International Agency for Research on Cancer's (IARC's) most recent review of melamine, in which IARC determined that melamine can cause cancer in animals but also noted a complete absence of reproductive studies, developmental data, and studies of the safety of melamine in cases of human exposure.

Over the years we have witnessed the erosion of public trust in FDA stemming from disclosure of FDA's close relationships with the industries it regulates, and from its failure to provide the public with complete, timely, and accurate information on issues of importance to public health ranging from mercury in seafood to benzene in soda. We note in particular that in 2002 FDA issued seafood consumption advice for consumers based primarily on focus group testing in lieu of scientific analyses. FDA e-mails obtained by EWG at that time indicated that the agency had not conducted a formal risk assessment for mercury in seafood, even as it was poised to issue a final seafood health advisory for the metal. This correspondence from an FDA staffer also raised the distinct possibility that the agency had been providing health guidance on mercury in seafood for years without ever having formally assessed the risk it presented to pregnant women and their unborn babies. As events played out, FDA ultimately did conduct a risk assessment to back up its advice, but only after being forced to do so through our public challenge.

In our experience, this was not an isolated event. In 2006 it was only after independent tests showed high levels of benzene in juices and sodas that the FDA admitted its failure to monitor for the cancer-causing chemical in beverages, instead leaving it to industry for over 20 years to enforce a voluntary agreement to limit the carcinogen. As with mercury in seafood, the FDA simply assumed that benzene levels in drinks were safe, with no assessment of the actual risks, even as consumption of soda and juice drinks by children skyrocketed.

We hope that with your appointment comes a new commitment at FDA to build public trust and to protect the food supply and public health through solid scientific analysis. We hope that these changes can begin with your handling of the melamine situation.

Thank you for your attention to this matter.

Sincerely,

Ken Cook
President