August 11, 2016

Electronic Submission
Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Styrene Information and Research Center (SIRC); Filing of Food Additive Petition. Docket No. FDA-2016-F-1444-0001

Dear Sir or Madam:

We the undersigned submit comments to Food and Drug Administration (FDA) regarding the food additive petition submitted by Keller and Heckman LLP on behalf of the Styrene Information and Research Center (SIRC) and posted for public comment in Docket No. FDA-2016-F-1444-0001. Petitioner has requested that FDA amend its food additive regulations to no longer provide for the use of styrene as a synthetic flavoring substance and adjuvant in food because these uses of styrene have been abandoned.

We respectfully ask FDA to review the above mentioned food additive petition only after the agency has made a final decision on Food Additive Petition FAP 5A4810 filed on August 17, 2015 (Docket No. FDA-2015-F-4317-0001) by Center for Science in the Public Interest (CSPI) et al. CSPI's petition asked FDA to remove its approval of seven synthetic flavors or adjuvants, including styrene, from 21 CFR §172.515 because they are not safe for use in food. Both petitions address the same use of styrene, but FDA filed SIRC's petition eight months after CSPI's. FDA filed the CSPI petition almost one year ago and the statutory deadline for making a final decision has already passed.

If FDA makes a final decision on the SIRC petition before the CSPI petition, it sets troubling precedents. First, it leaves unresolved the safety issue, essentially allowing a foreign or domestic company to restart its use by simply self-certifying the use of the substance as "generally recognized as safe" (GRAS) without notifying the agency. Second, it encourages industry to only consider whether something is abandoned in order to preempt a safety decision. While we support a policy of removing abandoned uses from the agency's regulations, it should be done proactively not once the agency has started a review based on safety. If the SIRC petition were allowed to preempt the CSPI petition, industry will not have an incentive to proactively submit abandonment petitions before a safety petition is filed.

Moreover, FDA is statutorily required to regulate food additives and prevent the use of those that are unsafe. 21 U.S.C. § 348. Failure to make a determination as to the allowable use of the additives about which the CSPI petition raises questions of safety on the basis that the uses have been abandoned (i.e. without regard to whether they are safe) would fall short of FDA's statutory duty. This is especially so because styrene enters the diet at measurable levels from uses other than as a flavor.

Therefore, the signatories of these comments strongly believe that the SIRC petition should not take precedence over CSPI's FAP 5A4810 which is approaching its one-year filing anniversary.

For more information, contact Tom Neltner at tneltner@edf.org with a copy to Eve Gartner egartner@earthjustice.org, Cristina Stella cstella@centerforfoodsafety.org, Erik Olson at eolson@nrdc.org , Jessica Almy at jalmy@cspinet.org, and Maricel Maffini at drmvma@gmail.com.

Sincerely,

Tom Neltner
Environmental Defense Fund

Caroline Cox
Center for Environmental Health

Cristina Stella
Center for Food Safety

Jessica Almy
Center for Science in the Public Interest

Michael Hansen
Consumers Union

Peter Lehner and Eve Gartner
Earthjustice

Scott Faber
Environmental Working Group

Jack Leonard and Joan Ketterman
Improving Kids' Environment

Erik Olson
Natural Resources Defense Council

Maricel Maffini
Independent Consultant