

August 18, 2016

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

RE: Society of Plastics Industry, Inc. (SPI); Filing of Food Additive Petition. Docket No. FDA-2016-F-1805

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 Society of Plastics Industry, Inc. (SPI) and posted for public comment in Docket No. FDA-2016-F-1805. Petitioner has requested that FDA amend its food additive regulations to no longer provide for the use of potassium perchlorate as an additive in closure-sealing gaskets for food containers because this use has been abandoned.

We respectfully ask FDA to reject SPI food additive petition.

SPI polled three companies who have submitted FAPs that resulted in the listing of potassium perchlorate in 21 CFR § 177.1210 and are still operating to verify that they do not:

1. Currently manufacture potassium perchlorate for use in component of closures with sealing gaskets for food containers in the US;
2. Currently import potassium perchlorate for use as a component of closures with sealing gaskets for food containers in the US;
3. Intend to manufacture or import potassium perchlorate for use as a component of closures with sealing gaskets for food containers in the US in the future; and
4. Currently maintain any inventory of potassium perchlorate for sale or distribution into commerce that is intended to be marketed for use as a component of closures with sealing gaskets for food containers in the US.

In its petition, SPI has not considered overseas uses and manufacturing; therefore, their rationale for abandoned uses is not conclusive. In a globalized economy, the assurances presented by SPI are insufficient.

Additionally, 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 4B4808 filed on December 31, 2014 (Docket No. FDA-2015-F-0537-0004) by Natural Resources Defense Council (NRDC) et al. NRDC's petition asked FDA to remove its approval of potassium perchlorate as an additive in closure-sealing gaskets for food containers, revoke the Threshold of Regulation exemption No. 2005-006 to no longer exempt the use of sodium perchlorate monohydrate as a conductivity enhancer in antistatic agents for use in finished articles in contact

with dry foods, and issue a new regulation to prohibit the use of perchlorate in antistatic agents for use in food-contact articles because these uses are not safe.

Both petitions address the same use of potassium perchlorate, but FDA filed SPI's petition 18 months after NRDC's. FDA filed the NRDC's petition 20 months ago and the statutory deadline for making a final decision has already passed.

If FDA makes a final decision on the SPI petition before the NRDC petition, it sets troubling precedents. First, it leaves unresolved the safety issue, essentially allowing a foreign or domestic company to restart its use of perchlorate 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 SPI petition were allowed to preempt the NRDC 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 NRDC petition raises questions of safety on the basis that one of the uses has been abandoned (i.e. without regard to whether they are safe) would fall short of FDA's statutory duty. This is especially so because perchlorate enters the diet at measurable levels from uses other than closure-sealing gaskets for food containers.

Therefore, the signatories of these comments strongly believe that the SPI petition should be rejected and not take precedence over NRDC's FAP 4B4808 which is approaching its two-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,

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