EDF and others take FDA to court to demand action on carcinogenic flavors petition

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On May 2nd, EDF and other consumer health advocates filed a lawsuit to force the Food and Drug Administration (FDA) to make a final decision on our food additive petition, which asked the agency to reverse its approvals of seven carcinogenic synthetic flavors. Earthjustice is representing EDF in this petition for a writ of mandamus to the court of appeals. We did not take this action lightly. However, with the statutory deadline for a decision passing more than 20 months ago, we saw little chance that FDA would act without court oversight.

Our food additive petition narrowly focused on one specific issue where the law and science were clear, and laid out our review of both the scientific literature and the law concluding that the seven chemicals

were no longer safe. FDA formally accepted the petition for filing – essentially confirming it was complete – which triggered a 180-day deadline under the statute to make a final decision. That deadline passed in August 2016 without a decision by FDA.

Additives can't be carcinogenic

In 1958, Congress enacted a law requiring that FDA reject food additives found to induce cancer in humans or animals. Over the years, the National Toxicology Program (NTP), the program designated by Congress to make cancer determinations, found that seven synthetic flavors – benzophenone, ethyl acrylate, methyl eugenol, myrcene, pulegone, pyridine, and styrene – approved by FDA in the 1960s did indeed induce cancer. Thus, FDA could not permit use of these additives in food if approval were sought today.

The law is clear and absolute that carcinogens must not be intentionally added to food. Seeing no action by FDA to remove its approvals of these food additives on its own action, in 2015 consumer health advocates petitioned the agency to act.

We thought the decision would be straightforward for several reasons. First, NTP concluded that styrene and methyl eugenol were reasonably anticipated to be human carcinogens, as stated in the Congressionally-mandated Report on Carcinogens that it prepares every two years on behalf of the Department of Health and Human Services, of which FDA is a part. It also found that all induced cancer in two animal species. Second, other science-based organizations had also assessed the chemicals and reached similar conclusions. Third, thousands of other flavors are available to choose from, including botanical spices, and thus, industry has many alternatives.

After we submitted the petition, an industry trade association petitioned to FDA claiming that use of styrene as a flavor was abandoned.

The statutory deadline for an FDA decision on our request passed in August 2016. After waiting more than a year and a half past the deadline for FDA to act, the petitioners are asking the Ninth Circuit Court of Appeals to order FDA to make a decision.

Ensuring food additives are safe, including those previously approved, must be FDA's priority

Every week, FDA approves new chemicals to be intentionally added to food, used to make food packaging, and used in food processing equipment. Some of these decisions are made with limited information – often less than FDA's guidance says it needs to make an informed decision on whether there is reasonable certainty the proposed chemicals' uses will cause no harm. The agency usually takes 120 to 180 days to make these decisions.

However, when it comes to chemicals it has already approved, the agency lacks a systematic review process to reassess their safety as new evidence emerges. The exception is when the evidence is overwhelming, as is the case of partially hydrogenated oils (aka artificial *trans* fats) – the only time FDA has reversed an approval in the past several decades over industry objection.

So instead, consumer health advocates have to make the investment and lay out the evidence demonstrating the uses don't meet the legal safety standard in the form of a food additive petition. The law obligates the agency to review and make a final decision within 180 days – about

the same time the agency gives itself to approve new chemicals. But thus far, the agency's track record for responding has been poor.

FDA's priority must be resolving safety concerns with existing chemicals over approval of new ones. So far, concerns with safety all too easily take a backseat to the deadlines for new chemicals. If FDA lacks the resources or authority to get the information it needs, it should make that clear to Congress. But in the meantime, the agency must address public health threats/risks first.

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