

United States Senate

WASHINGTON, DC 20510

May 26, 2020

Stephen Hahn, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20857

Dear Mr. Hahn,

We write today regarding needed clarification on the Food and Drug Administration (FDA) Guidance Document updated on April 15, 2020, titled, “Guidance for Industry: Temporary Policy for Preparation of Certain Alcohol—Based Hand Sanitizer Products During the Public Health Emergency (COVID—19).” Further clarification is needed for the renewable fuel industry, which has gone to great lengths to produce hand sanitizer to aid hospitals and communities.

Iowa leads the nation in biofuel production with 43 ethanol plants capable of producing over 4.5 billion gallons annually and has 11 biodiesel plants with the capacity to produce nearly 400 million gallons annually. This production helps support 43,000 jobs throughout the Iowa economy.

As the coronavirus pandemic spread, local and state governments instituted stay at home orders which led to gasoline use in the United States plummeting to 50—year lows around the country. From March 8th to April 4th, total miles driven dropped by 58 percent.

This forced many renewable fuels producers across the state to idle or stop production of the fuel that fills gas tanks across the United States. But rather than wait for the economy to rebound, biofuel producers across Iowa shifted production to manufacture hand sanitizer to help meet the needs of nursing homes, long—term care facilities, hospitals, and other vulnerable members of communities across the state.

As more of the economy gets reopened, the need for hand sanitizer at schools, restaurants, churches, factories, and other locations will continue to grow. While the FDA has taken action to prevent a potential shortage, further clarification is needed to help businesses have certainty on the future of hand sanitizer manufacturing.

On March 27, the FDA released guidance that ethanol used for hand sanitizer production does not need to meet United States Pharmacopeia (USP) or Food Chemical codex (FCC) standards as long as other purity standards were met. Based on this guidance, biofuel manufacturers made investments and began production of alcohol for hand sanitizer.

On April 15, the FDA inexplicably revised this guidance to require ethanol made for hand sanitizer adhere to USP or FCC standards unless otherwise approved and requested ethanol companies submit data regarding any impurities. Our staff has received conflicting messages about FDA’s concerns and what standard applies for alcohol for use in hand sanitizer. At one point, the indication was that FDA had become concerned that gasoline or other fuel additives might come into contact with ethanol in the production process, which appears to reflect a misunderstanding of how ethanol plants operate. Gasoline is not present at ethanol plants, and alcohol for hand sanitizer that is produced at ethanol plants does not come in contact with gasoline, benzene, or other petroleum contaminants.


More recently, Iowans have said that most, if not all, submitted samples of ethyl alcohol have been rejected. It appears that these rejections may be based on levels of acetaldehyde, a substance that occurs naturally in the distillation process, comparable to what is common in alcoholic beverages. We note that Health Canada – the Canadian government’s equivalent to FDA – has published a temporary standard that slightly relaxes limitations on acetaldehyde so that ethanol producers may help meet the growing need for hand sanitizer. We trust the FDA will use science and data to ensure the proper threshold for acetaldehyde in hand sanitizer, and I encourage you to consider Canada’s approach. The guidance issued on April 15th should be updated once more to clarify the threshold for acetaldehyde to give regulatory certainty and end the confusion that renewable fuel manufacturers currently face. This is simply good government.

While understanding the need for safe, effective, and affordable hand sanitizer for our country, we ask that you immediately review your risk analysis and criteria for evaluating samples of ethanol from renewable fuel manufacturers. We appreciate the work that the FDA has done so far to combat COVID-19 and ask that you follow up with our offices by June 2, 2020, to ensure our country has a robust supply of hand sanitizer to ensure a reopening that is safe and sterile.

Sincerely,



Chuck Grassley
United States Senator



Joni K. Ernst
United States Senator