



September 24, 2020

Andrew Wheeler
Administrator, US Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: EPA-HQ-OPP-2017-0336 Public Participation for New Active Ingredient *Pseudomonas fluorescens* strain ACK55

Submitted electronically at [regulations.gov](https://www.regulations.gov).

Dear Mr. Wheeler:

On behalf of the Cystic Fibrosis Foundation, thank you for this opportunity to provide comments to the Environmental Protection Agency (EPA) regarding “Public Participation for New Active Ingredient *Pseudomonas fluorescens* strain ACK55.” We urge the agency to take further steps to ensure the protection of vulnerable populations from potentially harmful impacts of products containing *P. fluorescens*, including those living with cystic fibrosis (CF) as well as immunocompromised individuals.

Background on cystic fibrosis and the CF Foundation

The Cystic Fibrosis Foundation is a national organization actively engaged in the research and development of new therapies for CF – a rare, life-threatening genetic disease that affects more than 30,000 people in the United States. The buildup of thick, sticky mucus in the lungs characteristic of the disease makes people with CF particularly prone to viral and bacterial infections that can lead to dramatic losses in lung function. Many people with CF suffer from difficult-to-treat acute or chronic respiratory infections, and these infections can become life-threatening if not addressed adequately.

***P. fluorescens* may pose a health risk to individuals with CF**

P. fluorescens is a relative of *Pseudomonas aeruginosa*, the leading cause of chronic lung infection and increased mortality in CF and certain immunocompromised individuals. *P. aeruginosa* infects approximately 75 percent of adults with CF and can be acquired either from the environment or transmitted between patients.

P. fluorescens is uncommonly isolated in patients with CF, and its role in chronic infection and loss of lung function is not known at this time.¹ However, we do know that *P. fluorescens* isolated from the lungs of CF patients is genetically similar to strains detected in the environment,² suggesting that this is the source of the infection.

Further actions are needed to protect vulnerable populations from adverse impacts of increased *P. fluorescens* exposure

More information is needed to understand if CF patients exposed to higher levels of *P. fluorescens*, such as might occur with the use of this bacteria in a bioherbicide, would be at greater risk of contracting infection compared to the risk associated with levels of this organism currently found in the environment. The data evaluation record, dated May 2, 2018, does not include any studies to assess the risk of infection for immunocompromised individuals related to increased exposure to *P. fluorescens*. We therefore request that studies be conducted to determine whether immunocompromised individuals and those at high risk of infections from opportunistic bacteria, including patients with CF, may be harmed by increased exposure to *P. fluorescens* prior to approval of this new active ingredient. Such studies would address a knowledge gap about the risk posed by potential exposure to *P. fluorescens* through its use as a bioherbicide.

Furthermore, product labeling should convey the potential risks for vulnerable populations and the onus should be on the company to ensure transparency on the potential safety risk of these products, even if we cannot quantify the risk at this time. We recommend clear labeling of the potential risks of the products for individuals with relevant underlying health conditions who may be consumers of the products or inadvertently exposed to the product after field application. The product label should address the potential risks of exposure to persons with CF and other diseases as appropriate.

Finally, we request that the *P. fluorescens* strain ACK55 be made available in an appropriate strain culture collection such as the American Type Culture Collection. In the event that an individual with CF develops lung infection due to *P. fluorescens* after exposure to this bioherbicide product, the availability of the product strain, together with the strain recovered from the infected persons, is necessary to establish whether the product was the source of infection.

Once again, we thank you for your attention and consideration of people with CF as you further evaluate the use of *P. fluorescens* in herbicides. We stand ready to work alongside the EPA in

¹ Scales BS, Dickson RP, LiPuma JJ, Huffnagle GB. Microbiology, genomics and clinical significance of the *Pseudomonas fluorescens* species complex, an unappreciated colonizer of humans. *Clin Microbiol Rev* 27:927-948. 2014. PMC4187640

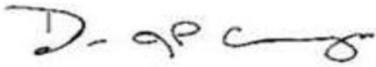
² Scales BS, Erb-Downward JR, Huffnagle IM, LiPuma JJ, Huffnagle GB. Comparative genomics of *Pseudomonas fluorescens* subclade III strains from human lungs. *BMC Genom* 16:1032. 2015. PMC4672498

pursuing further evaluation of the impacts of human health for this proposed new active ingredient.

Sincerely,

A handwritten signature in black ink, appearing to read "William R. Skach".

William Skach, MD
Executive Vice President and Chief Scientific Officer
Cystic Fibrosis Foundation

A handwritten signature in black ink, appearing to read "JP Clancy".

JP Clancy, MD
Vice President of Clinical Research
Cystic Fibrosis Foundation