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THE 3 LETTERS THAT SHOULD STRIKE FEAR INTO EVERY FOOD EXECUTIVE'S HEART – AND THE 3 STEPS YOU CAN TAKE TO PROTECT YOUR COMPANY

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What are the 3 letters that should strike fear into the heart of every food executive? No, the 3 letters are not F-D-A. Although the Food and Drug Administration is quite powerful, the agency can only wield that power against a particular food company when it has the evidence to do so.

The 3 letters we are referring to are W-G-S – which stands for Whole Genome Sequencing – because this new scientific tool can give FDA that evidence – indeed, compelling evidence that a food needs to be recalled and, potentially, that a food facility needs to be shut down. In this way, WGS is truly revolutionizing food safety.

Here is what we mean. Even though there are hundreds of types of Salmonella – the most prevalent pathogen – each individual Salmonella strain found has its own unique gene sequence. Think of it like a super fingerprint.

The FDA (and sister agency, the Centers for Disease Control and Prevention, or CDC) are compiling huge data bases which contain these unique identifiers for all types of Salmonella, as well as for other pathogens, primarily Listeria *monocytogenes* and E. Coli 0157:H7.

For the past several years, every time FDA tests food products or takes environmental samples from a food facility and finds a pathogen, the agency determines the specific WGS and puts it on file in its database. Similarly, whenever doctors or hospitals make a medical diagnosis of foodborne illness based on human testing, they are required to report that to state health authorities, who in term report to the CDC database. Any confirmation of human illness is also linked to a unique WGS.

Those two databases have now been linked with each other – so if FDA has pathogen data from a food product and/or a food facility with the same WGS, FDA will conclude that the contamination came from that food facility. Similarly, if the CDC has data on a particular person getting sick and that person has bacteria with the same WGS as from the FDA databank, then that link is made.

In either case -- presto! -- FDA will determine that the company needs to recall the product, and the company will then have to demonstrate that its facility is pathogen-free before resuming operations. Some companies are able to take the needed remedial actions to re-open successfully, while others have decided it is more economical to just close the facility. Either way, it is very costly to the company.

And if there are clinical cases, a company also faces product liability challenges.

We have worked with quite a number of companies who have faced this challenge and, believe us, it is painful for them.

So how do you prevent it from happening to you? Here is a 3 step guide:

1. **Find the problem first**. It is imperative that all food companies have strong environmental testing programs so you can find and remediate any pathogens before the FDA finds them. If you find it first, then there is a high likelihood you will fix the problem before it becomes a public one. Your position is strengthened if you also conduct finished product testing under a "test and hold" program.

2. **Create a strong food safety culture in your company**. Create incentives for employees to "seek and destroy" pathogens. One of FDA's new slogans is: if you did not find any pathogens last year, it means you were not looking hard enough. Employees always feel the pressure to keep a high level of production, but they need to feel an equal obligation to find problems early and fix them before they become big ones.

3. **Document your diligence**. If you can show FDA you have done extensive environmental and/or product testing, that can be used in some cases to show why a recall is not needed, or in other cases that a much more limited recall would be sufficient than might otherwise be the case. Your records are your protection. Document your testing program, and further document corrective actions taken as a result.

One last point: don't be in denial. These new WGS techniques are uncovering many more, smaller outbreaks than even a few years ago. Therefore, problem spots that literally fell under the radar screen in years past are now coming to the surface. It is far too common for companies that "never had a recall" to face an existential threat due to WGS.

As the saying goes, being forewarned is forearmed. Be proactive to protect your company from an unexpected WGS finding when the FDA comes knocking at your door.

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