



*Where the subject may be perishable  
but the insight isn't.*

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## **Discussion Of FDA's Unclear Sprout Guidelines By Jonathan's Sanderson And Rutgers' Schaffner**

*Jim Prevor's Perishable Pundit, June 4, 2009*

We've written previously of the tendency of the FDA to provide vague, almost meaningless, guidance. For example, as part of our [extensive coverage](#) of the alfalfa sprout recall, we ran a piece titled, [Recommendation For An 'Appropriate' Seed-Screening Program Shows FDA Unwilling To Take Responsibility For its Recommendations](#), which pointed out that by recommending an "appropriate" seed screening program the FDA gives itself an "out" and would declare any future food safety outbreak as *ipso facto* proof that the seed screening program was not appropriate.

Equally, we've been getting e-mails and calls as one sprouter after another points out that some other sprouter is not following FDA guidelines. Yet, when we get down to details, it turns out that the guidelines are not quite clear.

Bob Sanderson has an inventive mind and often contributes to the Pundit, you can see some of his work here:

[\*Pundit's Mailbag — The Acceptance Of Risk\*](#)

[\*Pundit's Mailbag — Sprout Lessons Echo Food Safety Dilemma\*](#)

[\*Pundit's Mailbag — More On Manure\*](#)

[\*Pundit's Mailbag — The Tyranny Of Economics And The Goals Of Fairtrade\*](#)

[\*Pundit's Mailbag — Can Irradiation Follow The Path Of Pasteurization?\*](#)

[\*Pundit's Mailbag — A Look At Organic Versus Conventional Yields\*](#)

[\*Pundit's Mailbag — Irradiation, Pasteurization and Labeling\*](#)

[\*Pundit's Mailbag — Pesticides And Cancer\*](#)

[\*Pundit's Mailbag — Food Prices And Free Markets\*](#)

In addition to running his own company with his wife, Barbara, this year Bob functions as President of the [International Sprout Growers Association](#). Together they are working on a seminar/convention to be held in Chicago on June 17-20. You can register [here](#).

We asked Pundit Investigator and Special Projects Editor Mira Slott to see if we could get some clarification on FDA guidance for sprouters:



Bob Sanderson  
President  
[Jonathan's Sprouts](#)  
Rochester, Massachusetts

Q: Could you shed more light on the issue of decontaminating seeds with an antimicrobial treatment before sprouting? Do you agree with FDA's recommendations? Why or why not?

A: *In its [1999 Guidance for Reducing Microbial Food Safety Hazards for Sprouted Seeds](#), FDA recommends a rigorous seed wash. At the same time, it is not definitive on what kind of treatment.*

Q: Are you saying the FDA guidance is unclear?

A: *There are three interventions — one is a treatment, one is preproduction testing, and one is every-batch production testing. The treatments don't have consistent effects. Different people have different views on this. I joined the [International Association for Food Protection \(IAFP\)](#) originally, in part, to hear [Dr. Donald Schaffner](#) speak on the subject, and became immersed in the food safety establishment and the research.*

*Bob Rust of [International Specialty Supply \(ISS\)](#) has made a terrific effort of putting together a complete library of research that exists on sprouts. His website is comprehensive. Not everyone in the industry is well-versed on these complex issues.*

Q: [In a study](#) simulating pathogen behavior during the sprout production process, Dr. Donald Schaffner concluded: "Seed disinfection is a highly variable process, with no method yet proven to completely eliminate pathogens." He continued, "In our simulation, seed disinfection alone was unable to guarantee safe sprouts. Seed disinfection can reduce the percentage of contaminated batches, particularly when prevalence and concentration are low, but it can also reduce the likelihood of detecting positive batches with postproduction sampling. Because of this finding, we wish to stress that having data on the prevalence and concentration of pathogens in implicated seed lots is imperative to truly evaluate the effectiveness of seed disinfection. Data on the effect of disinfection on naturally contaminated production-sized batches are also needed..." [Editors note: You can read further analysis by Dr. Schaffner of published sprout seed sanitation studies [here](#).

A: *The way it's phrased makes all the difference. Someone could say questionable effectiveness. Someone else could say not 100 percent effective. The truth is, no one really knows. In certain instances lab research shows that it works, and in others it doesn't.*

*The way FDA worded the recommendation is problematic. It says treatments shown to reduce microbial levels in seeds should be used prior to the sprouting process, and then FDA adds parenthetically, "such as 20,000 ppm calcium hypochlorite". This is not a requirement or regulation; it is guidance. FDA is just recommending this procedure. "Such as" implies choice. Yet in 10 years, FDA hasn't revised this and hasn't given other "such as" examples of treatments.*

Q: While FDA singles out the example of 20,000 ppm [calcium hypochlorite](#), it also seems to give companies wiggle room to utilize other antimicrobial treatments that have been approved for reduction of pathogens in seeds or sprouts. However, FDA does not provide a list of those approved treatments in the guidance document. How is the industry responding?

A: *There is some fine print in the guidance that you can use something else if it's legal.*

*If you look at the wording in the guidance, FDA is flexible in terms of its position. But in the market, it's become almost like regulation. The quandary is that some customers say if you're following FDA's guidance you have to use the 20,000 ppm calcium hypochlorite treatment. Their lawyers in turn advise clients; retailers require an affidavit or evidence to ascertain a company is following the guidance. FDA's guidance can be interpreted in different ways, but some buyers are insisting you use the 20,000 ppm calcium hypochlorite treatment. In certain cases, people view it as a violation of FDA recommendations and you're out of compliance if not following the "such as".*

Q: How widespread is use of this treatment? What other options are there?

A: *There have probably been 30 or 40 different chemicals they've tried, and a number of them seem to show effectiveness comparable to this chlorine, but FDA hasn't said you can also use these. It's a can of worms for them.*

*For many sprout producers, they get the bag, put the seed in a tub and use the 20,000 ppm chlorine treatment, while some are using other treatments, no one really knows. FDA isn't always inspecting. There is some state inspection, as well as some third party auditing. In Massachusetts, it's different than in California.*

Q: What kind of treatment is Jonathan's Sprouts using? What is your assessment of a 20,000 ppm chlorine disinfectant?

A: *We all feel the treatments and their effectiveness are all over the map. That's why my tendency is to plead the fifth. The question is too narrow in scope and the answer may be meaningless in evaluating the effectiveness of a company's food safety interventions.*

*The question reminds me of how people must have felt when they were asked, have you ever been member of the communist party?! If Jonathan's ever had an outbreak, God forbid, I envision lawyers would try and use my comments to argue negligence, even though we are abiding by FDA regulations and taking the most scientifically prudent food safety actions to reduce the risk of pathogens.*

*The problem is that because FDA's guidance is nebulous, a retailer might conclude that a company using a 20,000 ppm calcium hypochlorite seed wash produces a safer product, where the opposite might in fact be true. For example, a company conducting comprehensive post production testing has a high statistical probability of catching pathogens. Ironically, a seed disinfection treatment decreases the likelihood that a problem could be caught in post production testing.*

*I'd rather go on record to say the science behind the treatment is not what it might be. It was put through in a hurry, and known to be inconsistent in its effectiveness. Another thing I find troubling is that the seed disinfection is only a recommendation, but FDA doesn't require it. We're definitely using a chlorine wash. Remember if you asked a sprouter if he follows FDA recommendations and he ever said no, it would be like if you asked Obama if he went to church and he said no, the world would come apart.*

*We're going to address FDA's recommendation at the [International Sprout Growers Association \(ISGA\)](#) Convention later this month [June 17-20] in Chicago.*

Q: What do you hope to accomplish at the convention?

A: *Many business people want to know conditions for doing business. I want to know reasoning behind the conditions, the science and whether it makes sense. The challenge we're facing is whether the industry can set its own standards. Someone has to sign on the bottom line, this is OK; this isn't OK. I'm also trying to get legal expertise and learn the consequences based on different scenarios and on what food safety standards a company has implemented.*

Q: Is there something unusual about the [recent finding of lysteria monocytogenes](#) in Chang Farm bean and soy sprouts? Aren't most sprout recalls related to salmonella contamination? In any case, The FDA doesn't require testing for listeria in sprouts. Sidney Chang, owner of the Whatley, Massachusetts company, emphasized that it followed FDA guidelines to test for salmonella and E. coli O517:H7, but in the future will expand its pathogen testing.

*A: Sprouts are getting a lot of scrutiny. Lysteria monocytogenes is a very dangerous organism. For years, it's been known this could be a problem with sprouts, but never has it been until recently with the Chang Farm bean and soy sprouts recall. Why the change? I don't know if it's a worse problem or just looking that way. I don't see why something wouldn't exist 20 or 30 years and is now popping up. You expect sampling for listeria in display cases and cold wet places, or where people are handling product. You could find all kinds of pathogens there.*

*I believe the lysteria monocytogenes discovery in the Chang Farm case was in a retail warehouse. Lysteria is very common in the environment so people don't want to do a lot of testing because they'll find it. It doesn't necessarily mean there is more on sprouts than anything else. I say this with a lot of apologies and ask to be corrected. Some of these discoveries are one-in-a-million, or at such a low level it wouldn't make anyone sick.*

*There have been a number of sprout recalls in the past year or two where no one got sick but salmonella was found in product, and also some outbreaks where people got sick. In two or three instances, samples from retail or distribution warehouses tested positive for pathogens. If you just take a package at random, and it tests positive, either you're finding a needle in a haystack or these are common.*

Q: Jonathan's Sprouts undertakes [extensive testing measures](#), both pre- and post-production. Based on his laboratory work, Dr. Schaffner concluded testing seeds prior to production proved mostly ineffective in detecting pathogens. However, he emphasized that post-production testing of sprouts or irrigation water appeared to have a very high likelihood of detecting contaminated batches of sprouts. Could you tell us more about your testing procedures and the rationale behind them?

*A: At Jonathan's, before we even bring that seed into production, we take a sampling to grow and test for pathogens. With a needle a foot-and-a-half long, we stab every bag and get seeds. We require a minimum sample of 3 kilograms (about 6.5 pounds); some from every bag. We won't use the seed until we get the lab results back.*

*In the study, it mentioned that pre-production testing was not very productive overall. However, it noted it was quite effective if the seed lot was heavily contaminated. Still, something could get through it. The preproduction testing will reduce the likelihood finding it in post-production. I invented a probability chart, but put a note on the bottom: "If contamination is uniformly distributed through the seed lot."*

*It's not difficult or expensive to test seed, but the process does not absolutely eliminate the possibility that contaminated seed will be missed. The sad part of it is there is no way to scientifically or statistically know how effective it is. In the real world, you never know distribution of pathogens. On the one hand, if they are hidden in the corner of one bag, you could easily miss them in testing, and it will spread in the particular batch that contains that bit. On the other hand, chances are not nearly as bad as if the pathogens are spread through the whole seed lot, yet if they spread, you would probably catch it.*

Q: How do you determine a statistically valid sampling program? And how do you know a company is doing one?

*A: The problem is some grower says, "I test seed, and the bag comes in 'tested pathogen free'." It's nonsense! There is no statistically valid program. If pathogens are distributed in such and such a way and you take such and such a sample, the statistic is X... How big is the sample? What is the distribution? It really bugs me.*

*In a number of outbreaks in the past, people tested the seed and found pathogens in it. It stands to reason if they tested seed before sprouting, the results would be questionable. Testing of seed in pre-production is not in the guidance.*

*We grow using a microbial enrichment process. If pathogen is present at low levels in the seed, it will get much higher in the sprouting process. If you just take some of the seed before sprouting and test it, you almost never find anything. Testing wasn't done right. Some epidemiological investigations are suspect because those involved didn't know how to test.*

*We test every bag in the lot, a minimum total of 3 kilos, which we put in a bucket with water, drain and grow for a few days. After 48 hours of growth, we test the water. Most seed sampling done in the past hasn't had the growing stage. If you just take a tiny bit of seed and send it to a lab and crush it, you most likely won't find pathogens.*

**Q:** Beyond questions of effectiveness, do you have any other objections to treating seeds with 20,000 ppm calcium hypochlorite?

*A: It's very rare that we find anything, and there are downsides. It's very irritating to people using it, skin gets hot, and it affects eyes and respiration. It's a very dangerous substance. In the FDA guidance, it says to use protective clothing, and results of using it are very inconsistent. Will it really reduce likelihood of making anyone sick? The question needs to be answered in the context of other intervention methods.*

*In addition to testing seed before sprouting, FDA also recommends testing every batch, taking irrigation water and testing that. If you have contamination in sprouts, which is a small likelihood, will you find it anyway? If you have very low levels of pathogens and use very strong treatment, it may get rid of it or knock it way down and you'll miss it with your testing. If you miss it in testing, will it make anyone sick? Studies are examining other types of treatments. I've read about hydrogen peroxide instead of chlorine.*

*These pathogens have zero tolerance, but hardly anyone in the fresh produce business is testing for them. No other fresh product can even begin to get the kind of detection we can get from sprouting because the irrigation water has run over the batches.*

*With carrots, for example, hundreds of gallons of water are used, but if you had a positive in the water, you would never know which batch of carrots it was in.*

*Earthbound Farms was a great company before they were involved in the spinach outbreak, and is a great company now. They do [sampling](#), and they find things occasionally. Not everyone does testing. In the meat business, when they do testing and find a problem, they cook the meat. In the produce industry, where product is normally eaten raw, we don't have a kill step.*

**Q:** What about irradiation?

*A: If you irradiate to the point you've got everything, the seed won't grow. You can irradiate sprouts, but they will be sterile. It can be done. If irradiation wouldn't damage the seed at all, I would have no basis of opposing it. [I don't like the idea](#). Once it becomes the standard, then everyone has to do it.*

*The stronger the dose, the more damage to the seed. Some have recommended lower dose with other treatments; maybe chlorine in addition to irradiation. Another part of this is the problem with drug-resistant organisms out there. You go to the hospital and get sick...*

*If you succeed in sanitizing the seed without killing it, it's still wide open to workers' hands, or contaminated clothes and other potentially contaminated areas through the distribution process. Once you create a sterile situation, you have to maintain it.*

*It could require sprouts grown in a clean lab.*

*Back when we started growing sprouts in the first 5 or 10 years, big corporations like Campbell's Soup showed interest, and then said it's not worth it because of the food safety issues.*

*I know that there have been lab experiments where chlorine has not eliminated pathogens and some growers that said they used chlorine still experienced an outbreak.*

*As far as I know, there have been no outbreaks from companies that have tested the seed pre-production and every batch post-production. If you do all this testing, the chances of having a problem are very, very small. I feel pretty strongly that one seed company might be doing a better job than another, and growers have to do the testing. If a problem happens again from that company, they need to say they will do business with someone else. Until much better treatments are available, the industry has to have rigid testing. FDA is too busy and too poor. I've made it my thing to follow the science on it.*

*The way I'm hoping to get around this issue is by bringing people together at this convention in Chicago June 17 through 20. [Editors note: You can see details on the [agenda](#) and register for the convention [here](#)].*

*The convention will be a great place for networking; FDA people will there, state health inspectors, third-party auditors, and we're going to focus on this testing and put some teeth into it. FDA just isn't in a position to take this on. When we get inspected, it's a state inspector; he may send his results to FDA, but FDA is not able to get into that detail. My goal is to put together an inspector's checklist to make available to all state inspectors and third-party auditors; here's what should be included in the testing program.*

*Ideally, testing will be audited and companies can receive some type of verification seal. It wouldn't be able to say guaranteed clean, but it would be inspected to a certain standard. I'm not assuming that the idea will be that well-received because for a lot of smaller growers it will require major costs. Sprouters get tired of people telling them what to do.*

Q: Could you provide some perspective on the financial investment?

*A: Probably between 5 and 10 cents a package to do a really good job. The buyer may have two companies saying they're doing everything right for food safety, but they don't know, and neither does the sprout grower. There needs to be a third-party who knows how to evaluate a program.*

*This is not simple. It's difficult to do a good sampling. Generally FDA recommends sending samples out, unless a company has a professional lab in-house. But even sampling details on how to do it right need to be spelled out. If you're doing the sampling wrong, the results will be skewed. TJ Fu from the [National Center for Food Safety and Technology](#) developed testing protocols for sprouts. She'll be at the convention to talk about sampling and what we can be doing better.*

*The conference may draw people that wouldn't ordinarily come. A lot of the Leafy Greens people are very worried about food safety issues and don't have a kill step either. In the washing process of lettuce, the levels of chlorine are tiny. The whole subject of sampling and testing is extremely timely.*

It is amazing sometimes to think that 5 or 10 cents a package is a big part of what causes so much trouble.

We think the industry conference is a great idea and encourage people to register [here](#).

We also remind everyone of the piece we ran [yesterday](#) in which we requested one retailer and one grower (not a sprouter) to be willing to work with us on a pilot project to learn what is involved both scientifically and cost-wise in growing alfalfa seed specifically for human consumption. Primus has been kind enough to donate its services and ISS has agreed to process the seed.

Don't feel intimidated... it is just a pilot project so the acreage required is small and the retail commitment very moderate. It is, however, a chance to enhance industry learning and participate in advancing the industry and consumer interest in food safety. If you are a grower or retailer interested in working with us on this exciting project, please e-mail us right [here](#).

Many thanks to Bob Sanderson, President of Jonathan's Sprouts and this year's President of the International Sprout Growers Association, for helping to clarify such murky issues for the trade.

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At Bob Sanderson's advice, we wanted to learn more about the work that Professor Donald Shaffner is doing in this area at Rutgers. We asked Pundit Investigator and Special Projects Editor Mira Slott to find out more:

[Donald Schaffner](#), Ph.D  
Extension Specialist in Food Science/Professor  
[Rutgers University](#)  
New Brunswick, New Jersey



Q: What are your key findings in studying pathogen behavior in sprouts?

*A: I need to break the topic into two issues: disinfection and sampling. Scientists are continuing to work on disinfection treatments. Nature is a logarithmic function; you'll never get complete elimination of pathogens. You may get 90 percent reduction, or 99 percent, but you can add as many 9s as you want and you'll never get 100 percent elimination. You may drive the level so low it's no longer of practical importance. It's a good thing that scientists are going to continue to look at disinfection treatments across the board, not just for sprouts but for many commodities.*

Q: Your comments here on pathogen reduction through disinfection treatments sound much more hopeful than in your earlier study conclusions, where you describe treatments as "[highly variable.](#)"

*A: The nature of the sprout production process is you put these seeds into a warm moist environment with ample nutrients. If even a single salmonella cell is present, it will multiply, its progeny will divide and its progeny will survive and you'll find significant salmonella cells present.*

*We concluded that there may be situations where sampling is a more effective control measure than disinfection. It goes against conventional wisdom. What makes testing so beneficial in the case of the sprouting process is two fold: it causes multiplication of the pathogen, plus it's an aqueous environment, where you can take a large sample of irrigation water and the sample improves the probability of detecting a pathogen.*

*That disinfection is not 100 percent effective, whereas we know the sprouting process 100 percent is increasing any pathogens to higher levels. This amplifying and multiplying of the cells allows us to detect any pathogens and throw the contaminated batch out. It is not conventional food safety wisdom to focus on the testing rather than the prevention. FDA did come out with guidance for both disinfection and testing. Most people in the industry focus on the first part disinfection and not as much on testing.*

Q: Bob Sanderson of Jonathan's Sprouts, and Bob Rust of International Specialty Supply are strong advocates of stringent testing measures. However, both are concerned that the industry is all over the board when it comes to the kinds of treatment protocols and testing methods being employed, creating an additional challenge in determining the most effective strategies for reducing the risk of pathogens.

*A: One of the things we can all agree on — Bob Rust, Bob Sanderson and the collective community — is that we care about the safety of sprouts. When people say they are disinfecting, we must ask exactly what protocols are they using, and in testing the same question must be asked.*

*It is incumbent on FDA and CDC to ask in-depth questions to companies, down to the nitty gritty gory details of their disinfection approach and the equivalent on sampling approach. Until we know exact methods of the testing — how much seed did you use, was it irrigation water, was it in advance of sprouting — it is not possible to perform a meaningful investigation. We'll never get away from subjectivity, but we can conduct a scientific risk-based analysis to determine the most effective food safety strategies.*

Q: How do you translate advances in technology and simulated, controlled lab analysis to the real volatile world?

*A: With respect to disinfection and testing, the technology is constantly changing. There are better chemicals and approaches for both, new ways to concentrate water, more advanced genetic methods to look for DNA. Technology is a moving target.*

*If we knew the prevalence and concentration of the pathogen in the seed, and we had information on the effectiveness of disinfection and sampling techniques, we could compare one technology to another. Using a risk assessment or computer model, we would be able to determine relative levels of risks of different schemes.*

*It is complicated, but it is understandable and it is quantifiable. If we knew more about the disinfection techniques and sampling techniques being used, we could begin to say, out of the five different sampling programs out there, don't use number three and number five because they really don't work and this is why. The problem is we don't know what the industry is doing.*

*Two companies say they're sampling, but could you tell which protocol is more effective? How can we get a heterogeneous industry to step up and talk about the different protocols for disinfection and sampling to develop the most effective standards?*

*The issue is not so much that sampling of seed is ineffective. We ought to really harness the actual simulation that sprouting has for pathogens. To sample seeds like billiard balls is silly when we could use the sprouting process to increase the concentration of pathogens that might be present.*

*One of the findings of our analysis is that if seed disinfection is strong, it may drive levels down to a point where you don't pick up pathogens in later testing. But realize the consumer will test every bite. If we feed 10,000 people, and only 10 get sick, that's a rate of 1 in a 1,000, but even a low fraction of contamination is serious.*

Q: As a scientist, what is your take on irradiation?

*A: It's a great technology, but expensive and not always appropriate. Even irradiation is not 100 percent effective. I think it's a tool. The sprout seeds are living entities that maintain biological activity so they'll sprout when you apply appropriate processes.*

*With irradiation, you could end up having sterile seeds. It may still be cost prohibitive. Ideally, you want to treat with irradiation at the end of the pipeline in the finished product stage. It might be easier and more cost effective to treat at the seed level, but it raises the issue that sanitized seeds could become contaminated later. It's complicated.*

Q: Are you involved with new technologies that could help the sprouting industry reduce contamination in the production process?

*A: In the work we do, we're much more interested in doing an analysis, comparing the effectiveness of different technologies and relative variability. We're not involved in the primary work. New compounds are being developed all the time. Chlorine is nasty stuff, it's great at killing bacteria but it doesn't like human skin. People are always looking for compounds not dangerous to humans. Both are living things, so this is the problem.*

*We looked at published data in literature on the degree of inactivation of different compounds. Our analysis showed sprout seed decontaminates are highly variable.*

*In the studies we looked at, investigators deliberately contaminated seed with pathogens. In the real world, pathogens are not homogeneously distributed, they may be sporadic.*

Q: In this regard, doesn't it become exponentially more complicated if a company mixes seed lots?

*A: If a company blends lots, it must keep good records. You could get one big dirty lot if blending contaminated seed into non-contaminated seed. Clearly seeds grown for planting should have a different microbiological standard than seeds for food people are going to eat.*

*FDA doesn't want to endorse a particular alternative. A lot of methods are endorsed based on research studies, but it can become another issue when looking at how to translate those methods to industry applications. In other segments of industry, companies have resources to do that. Sprout growers are not large multinational corporations.*

*Financial investment seems daunting to many. It's very much the concern of the folks in the sprouting industry. Often what happens, the larger players put pressure on the entire industry. Everyone suffers if the whole industry is not behind the food safety program. The sprout industry*

*has struggled, in part because many small sprouters don't have the technical savvy of a Bob Sanderson or Bob Rust.*

How do you motivate people to change? An excellent meeting to go to is the [International Association of Food Protection](#) in Dallas this July where you'll find the food safety movers and shakers.

We thank Dr. Schaffner and find his thoughts intriguing. What a fascinating paradigm shift for food safety. Whereas everyone has been focused on decreasing pathogens, he is suggesting a second look. Maybe we should allow pathogens to multiply so we could catch them through rigorous testing programs. Certainly not applicable to all items but one wonders if controlled environment agriculture, if structured with this paradigm in mind, couldn't be effective on things such as tomatoes?

Certainly worth further investigation as in the wake of [Salmonella Saintpaul](#) outbreak last summer we learned that certain greenhouse varieties grow for such extended periods that the industry is losing its traditional protection that most fields only grow for a few weeks.

We applaud Dr. Schaffner's remarks about attending IAFP in Dallas and think that the ISGA sprout specific conference, for which you can register [here](#), is another good option.

We also appreciate Dr. Schaffner's remark that "Clearly seeds grown for planting should have a different microbiological standard than seeds for food people are going to eat." — This gives us an opportunity to remind growers that we are still seeking a grower who will grow some alfalfa under conditions appropriate for human consumption. We have arranged with Primus to give you, as a grower, the tools you need to do this. Please join us in this effort by asking for more information right [here](#).

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