

Flatland Hydroponics Inc.

Growers and Distributors of exceptional quality
specialty produce

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FDA Dept. of Health and Human Services
Docket Management Branch (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

December 13, 1999

Re: Docket No. 99D-4488 and 99D-4489 Recommended changes

Dear Sirs,

After carefully analyzing the recommendations for laboratory procedures and sanitation steps, We find that overall they are a good list of common sense procedures long overdue for our industry and we want to applaud your efforts in this direction. There are however three points that we would request that you consider changing. The points and reasons for each are outlined below.

- 1.) Testing for positive controls is dangerous and should not be done by those working in a sprout operation, whether in house or outside. It definitely should not be done in the same labs as routine daily testing of sprouts and/or spent irrigation water. A lab using live pathogens requires a high level certification and should be the responsibility of the test kit manufacturers, not the sprouters. Basically, if the kits are not reliable in 99% of field testing conditions at least 99% of the time then maybe the FDA shouldn't be recommending them? If pH, seasonal factors, type of seed, etc. are a concern in the effectiveness of the test kits, then perhaps these factors should be explained in detail so that they can be taken into consideration. Or perhaps you could change your recommendations to include adjustments for such variations for the testing processes to be effective. To put this into perspective... we are confident that if you assign this to your economist and push the numbers to it, you will see that requiring positive control testing might reduce the risk of contaminated product reaching the consumers by one or two percent, but it will increase the cost to the sprout grower by two or three hundred percent.



recycled & recyclable

99D-4488

99D-4489



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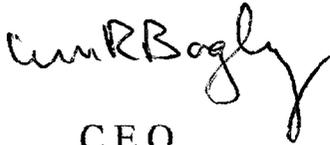
- 2.) Having a lab physically separated from the growing/harvesting areas is unreasonable because it will delay the vital results in 90% of the situations thus pressuring growers to sell a batch before results are in. It also basically mandates the expense of outside testing for small and medium sized growers because they are either incapable financially or mentally to run a lab to these standards. We would agree that if smaller (or any size) sprout growers are not able to keep up with the required testing then they should be forced out of business. However, by making testing standards reasonable, (reduce the risk by 98% rather than shooting for 99.9%) we can correct the trend of outbreaks within months, rather than years, because it will take a while to locate, document, (catch) and shut down non-compliant growers. An off premises lab is also unnecessary if positive control testing (point #1 above) is not required or done out of house. In summary: Having an in-house-lab (especially one with windows looking out to production areas) is a great help in encouraging employees to work using GMP's and helps instill respect & understanding of micro-biological testing with quicker more relevant results.
- 3.) If a batch of sprouts or spent irrigation water test positive for a pathogen, it should not be necessary to discard all seed or much less all sprouts from the same lot of seed. First of all, sprout growers need to assume and understand that all seed must be considered contaminated. Seed producers and distributors will never be able to guarantee that all seed of a particular lot is free of pathogens, because in dry storage, there will be little microbe migration or growth. To test all of the seed, they would have nothing left to sell. On the contrary once seed is germinated using common commercial methods, even one salmonella laden mouse dropping can now easily grow and contaminate all seed/sprouts that share the same water or physical proximity because of the ideal growing conditions. That is why it is good to require at least one antimicrobial immediately prior to sprouting (I.E. 20,000ppm presoak sanitation step). If a particular batch of spent irrigation water tests positive, it is an indication that the sanitation step was not effective and the batch should be re-tested or discarded. Other sprouts already grown from the same lot of seed, at worst should be impounded pending confirmatory testing, not discarded. There is also no necessity to discard unused seed of the same lot because it is all contaminated anyway. It is the responsibility of the sprout grower to properly disinfect the seed prior to sprouting. If this can be done and microbiologically confirmed, it should be

allowed into commerce, and the fear of similar seed lots, if properly stored and separated, should not be a factor.

Thank you for your time and attention to our companies review and comment. We have been very appreciative of the way in which the FDA and related government bodies have dealt with the sprouting industry. We have found your approach and interactions with us rational, in good faith, and open minded which has created the best possible atmosphere for good communication and rapid well conceived solutions to our industry problem.

In Partnership for Food Safety,

William Bagby



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