



DEMETER ASSOCIATION, INC.

For Certification of BIODYNAMIC AGRICULTURE

December 15, 1997

Dockets Management Branch
FDA
12420 Parklawn Drive, Rm 1-23
Rockville, MD 20857

Docket # 97N-0451 HFA-305
184 91 DEC 22 P2:29

Re: Guidelines on microbial safety of produce

CONCERN #1: YOU ARE NOT GIVING THE AFFECTED SEGMENTS OF THE POPULATION TIME TO RESPOND

My most immediate concern is that this issue is on a super fast track with no time for the public, which includes farmers and processors, to even know about the Draft Guideline, let alone to comment on it. The draft contains some areas of major impact to the farm population, and only a tiny percentage of the affected farms have even heard of the draft. It has been introduced Dec 1, presented at public hearings Dec 1 and 3 for which there was not enough time for preparation. and the public comment period will end Dec. 19, exactly 19 days after the draft was introduced. This is a mockery of the process of public comment. It seems as though there has been intent to avoid comment. You are not acting in good faith with the farm population which will be most affected by the guidelines you eventually adopt.

CONCERN #2: THE DRAFT TARGETS U.S. FARMERS WHEN THE MAIN PROBLEM APPEARS TO LIE OUTSIDE OUR BORDERS.

The impression is that the ax will fall on U.S. producers, when by and large most of the microbial problems have come from other areas. Since most of the problem is off-shore, why is FDA targeting domestic growers and shippers?

CONCERN #3: THE NECESSITY OF WILDLIFE CONTROL IN GROWING AREAS

The guideline is totally unrealistic in assuming that wildlife can be excluded from produce growing areas. A fence to exclude deer costs thousands of dollars. Most of our certified farms are very small. The cost of a deer fence would be a major investment, and one that could not be passed on to the consumer. There is no practical way to exclude woodchucks, rabbits, field mice, foxes, coyotes, and in the West, gophers. These creatures are not excludable, which much experience demonstrates. If exclusion were possible, it would be costly and labor intensive. This would have to be done for every produce growing area, of which there could be several on one farm.

CONCERN #4: EXCLUDING WILDLIFE FROM IRRIGATION SOURCES

These same costs in dollars and time would apply to excluding wildlife from surface irrigation sources, and may even

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be greater. A pond used for irrigation would have to be roofed over to exclude the water fowl that may fly in. If this guideline is put into effect, I see all surface irrigation sources being off limits.

As to flowing water sources, how can any farmer control what happens to the river, or creek, and when? Even subscribers to an irrigation district have no control over what happens to that water or when it happens. This week's water is not the same as last week's, or yesterday's, or next week's. Eventually rivers and streams would have to become off-limits for irrigation of produce. Even if a drip system was practical in the given situation, there is simply no way to prevent the next rain from splashing what is on the ground onto the lettuce.

CONCERN #5: WHERE DO YOU STOP?

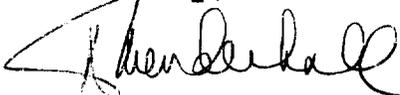
If you establish guidelines for farmers and their workers, and processors and their workers, and truckers, there are still many hands down the line that touch produce. Is the consumer who picks up a bunch of grapes, looks at them, and puts them back again expected to wear rubber gloves? I believe that you are in danger of wanting to make the produce handling environment as aseptic as a hospital operating room.

CONCERN #6: WILL THE GUIDELINES BECOME REGULATIONS?

It is assumed that this is the eventual intent and outcome. There are many things here which will be a major disruption for the agricultural sector if the guidelines become Regulations. If the intent is for guidelines only, then the draft can be lived with and accepted as the ideal condition. But in the real world, the ideal situation is hardly ever found. Workers do not report their illnesses because they cannot afford to miss work. Farmers cannot turn compost piles completely inside out or outside in without investing \$10-20,000 for a machine they don't otherwise need. No one monitors that restaurant workers wash their hands after certain activities, and it is not practical for the farm crew chief to do this either.

SUMMARY: I hope this gives you some idea of how disastrous it would be to force these guidelines on the agricultural community. I hope most emphatically that you will leave the draft as a guideline. As guidelines, they work. As regulations, they would not work.

Sincerely,



Anne Mendenhall, Director



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