March 15, 2007

Mr. Hank Giclas
Vice President Science and Technology
Western Growers Association
Box 2130
Newport Beach, California 92658

Dear Mr. Giclas:

These comments are submitted on behalf of The Organic Center in response to the March 4, 2007 draft of the document "Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain, 2nd Edition."

The Western Growers Association (WGA) and the team of individuals working on the "Good Agricultural Practices Metrics" (GAP Metrics) deserves recognition and thanks for your willingness over the last four months to consider suggestions from a broad spectrum of individuals, groups and stakeholders, including the Center. Important and positive changes have been adopted in the two most recent drafts, including significant changes in the soil amendment and composting criteria that we previously recommended.

We have carefully reviewed the March 4th draft and wish to offer additional suggestions to clarify certain technical aspects of the acceptance and testing criteria, and to further expand margins of safety along the leafy greens supply chain. Our focus is predominantly on the water quality and soil amendments and other crop production inputs provisions.

Given that the 2007 production season has begun, we recognize that it is vital for a set of GAPs to be adopted and implemented this season. We applaud your recognition that the GAP Metrics must remain a living document. Important progress will be made in 2007 in understanding the epidemiology of recent outbreaks and the best practices to prevent future outbreaks. New insights gained will likely require reconsideration of certain sections of the GAP Metrics.

Some of the changes suggested herein by the Center, and other organizations, will take time to fully consider, refine, and implement, but hopefully will become part of the program by the end of the year, fully applicable to production in the 2008 season. In the last section of these comments, we highlight the need for two vital changes in the GAP Metrics to assure their cost-effectiveness and continual improvement:

- Target testing and preventive measures to higher-risk circumstances, and
- Assure transparency in test results to maximize progress in scientific understanding and in extending margins of safety.

Water

Under "best practices" (page 9), the draft states that the risk of crop contamination associated with different irrigation methods should be evaluated, but no actions are required. A large body of research shows that there are significantly greater risks of crop contamination associated with overhead sprinkler irrigation systems, compared to drip or in furrow irrigation. Consideration should be given to requiring pre-harvest product testing on fields where high-risk irrigation methods are used, unless water testing on a given field shows that the water is very clean. Other options to assure adequate margins of safety on fields that are irrigated with sprinklers should also be considered, until more is known about the relative risk across irrigation methods.

In the provision on page 10 addressing use of surface water for irrigation after a storm event, the Metrics should acknowledge that significant spikes in pathogen levels can occur after a major runoff event and that surface water should be retested prior to use for irrigation to assure that the acceptance criteria are not exceeded.

As argued in our previous comments, the Center still believes that all water sources used for irrigating leafy greens should be tested at least once for *E. coli* O157. Additional *E. coli* O157 tests should also be required when the applicable generic *E. coli* standard is not met.

For the 2007 season, we see no alternative to reliance on the recreational water quality standard of less than 126 MPN generic *E. coli* per 100 milliliter of water. We also support the decision to use the cut-off of 235 MPN/100 ml for individual test results, as well as the < 576 MPN/100 ml of generic *E. coli* as the maximum level allowed under any circumstance. However, the basis of the recreational water quality standard is a 1980s era EPA risk assessment carried for a completely different reason. There is much better science available today to set health-protective standards for generic *E. coli* and *E. coli* O157 in irrigation water and water used in leafy green processing.

We recommend that the Food and Drug Administration, in cooperation with the California Department of Health Services, commission a fst-turnaround assessment by the National Academy of Sciences on the scinetifc basis for these standards. A preliminary set of recommendations should be produced by early 2008, in time for adoption next year in the revised GAP Metrics. The NAS committee should also be asked to address the research needs to develop a final set of standards governing food borne pathogen levels in irrigation water and water used in processing plants.

Soil Amendments

We appreciate the substantive changes already made in the GAP Metrics compost process validation and acceptance provisions. Some clarifications are needed, however, in assuring their consistent application.

In the narrative section setting forth best practices (page 18), growers are instructed not to use "incompletely composted…" animal manures. This key term requires a clear definition that rests upon proven science. In addition, the definition needs to be linked to proven and feasible laboratory test methods. We suggest such an approach later in this section.

On page 19, the use of soil amendment application techniques is required that "control, reduce, or eliminate likely contamination of surface water and/or edible crops." The risks assisted with different application methods are circumstance specific. Growers need must clearer guidance, and better information on the impacts f application methods on risk levels. Certain known, high-risk application methods should be prohibited, and other very-low-risk methods required or encouraged. The list or recommended and prohibited methods, under defined circumstances, will evolve over time as research sharpens understanding of the epidemiology of pathogens in the field.

In Table 2 (page 20), the time required for active composting at a minimum of 131 degrees needs to be extended to five days from three, both in the case of enclosed or within vessel composting, and aerated static pile composting.

In the case of windrow composting, the Metrics should call for "three to five or more turnings as needed in response to regional climatic conditions," instead of the current requirement of "a minimum of five turnings." In colder regions, or during winter months, turning compost piles five times during the minimum 15 day period will excessively cool the piles and make it difficult to meet the requirement of sustaining temperatures at or above 131 degrees for 15 days.

The March 4 version of the Metrics adds a new provision that addresses the completeness of the composting process – "After curing, a carbon-to-nitrogen ratio of 25:1 shall be achieved." We strongly support adding provisions addressing compost stability, completeness, and maturity, and certainly the C:N ratio is one indicator of compost maturity. However, a C:N ratio of 25 is very lenient and suggests that only minimal composting has occurred. Most experts agree that a fully finished and stable compost should have a C:N ratio between 10 and 15.

We suggest that this C:N ratio standard be lowered in 2007 to "no greater than 20," and in the 2008 season, it should be further lowered to, or close to 15. In addition, we recommend that the an additional provision be added after the C:N ratio standard that addresses more comprehensively compost maturity and stability. We recognize that it will take some time to develop this new standard, but feel it can and should be put in place by the 2008 season. The new provision should draw on the excellent work carried out by the California Integrated Waste Management Board and its report proposing an index of compost maturity. With some additional work, focusing in particular on the results of recent research, the proposed compost maturity index could be updated and adapted to fit into the GAP Metrics as a second criterion governing compost quality. This addition will deliver both food safety and crop quality benefits.

It is important that all laboratories, field auditors, farmers and processors, and regulators understand how to apply the revised acceptance criteria, which we strongly support.

For fecal coliforms, the standard of less than 1000 MPN/gram should be on a dry weight basis, following the newly promulgated and more accurate EPA Method 1680.

For the Salmonella and *E. coli* O157 standards of non-detect in 30 grams of test material, the Metrics should clarify that this standard applies to fresh weight compost (i.e. composts ranging from 40% to 60% moisture).

Comparable clarification of the basis for acceptance criteria needs to be made in many other sections of the GAP Metrics (e.g., soil amendments containing animal manure that has been physically heat treated, nonsynthetic crop inputs, and in all decision tree figures).

In Table 3 covering nonsynthetic crop treatments (e.g., compost teas, blood meal, fish emulsions), we recommend an interim prohibition against liquid foliar applications of compost teas or bloodmeal. These materials are rarely applied as liquids during the growing season, and in light of uncertainties in associated risks, such applications should not be allowed, unless a grower or processor agrees to test the crop soon before harvest for the presence of the three target pathogens and shows that the crop is not contaminated.

Under the acceptance criteria, the term "solids" needs to be defined as any material with greater than 30% solids, to conform with routine industry norms.

Two Critical Generic Needs

The targeting of testing, remedial actions, and preventive measures relative to projected risks will be essential in order to broaden margins of safety, while also keeping the industry viable economically.

Several key *E. coli* O157 and Salmonella risk factors are known and should drive the scope and intensity of testing and preventive actions. The industry will not be able to afford adherence to all the additional testing and precautionary measures that will be both prudent and necessary in the case of higher-risk fields and circumstances, especially in the next few years as research develops a more sophisticated assessment of risk factors and relative risk distributions across landscapes, farming systems, and production inputs.

For example in Table 1 on water use metrics and actions, the frequency of testing can safely be reduced for water sources that consistently test well within acceptance criteria. It is a waste of money and laboratory resources to test deep well water once a month after four or eight previous tests have all shown the water to contain pathogens at levels well below acceptance criteria. On the other hand, there are instances where even more frequent and thorough testing should be required before allowing a water source to be used.

It will also be possible over the next few years to divide fields into low, moderate, and high-risk categories. The intensity of testing and field audits can be adjusted downward on the low-risk fields, especially after a few years of data confirm the absence of any pathogens in harvested product. More intensive testing and monitoring on moderate risk fields will help determine whether such fields are, in fact, more probe to pathogen contamination, and why or why not. This information will help farmers and food safety specialists adjust future GAPs customized to specific fields, and the unique or periodic risks associated with a specific field. In general, leafy greens for fresh cut applications should not be grown on high-risk fields, such as those subject to flooding, near beef cattle or dairy farms, or fields with a record of contamination. A clear process, governed by a set of conservative (i.e risk averse) standards, should be set forth in a future version of the Metrics to explain how, and under what circumstances a grower or land owner can request a reconsideration of a classification of a given field.

A second key generic change is needed in several places throughout the Metrics. The effectiveness of the Metrics rests heavily on the multiple requirements for testing for pathogens. Remedial actions are triggered in cases where an acceptance criterion has been exceeded. The Metrics leave too much room for interpretation regarding what remedial actions are necessary prior to a given water source or soil amendment or production inputs being used. In addition, the success of the entire program rests on the accuracy of the testing, the proper interpretation of test results, and the immediate initiation of required remedial actions in the event a sample of water, compost, or production input does not meet the applicable criteria.

For this reason, strong measures are needed to assure that the core provisions of the Metrics are followed and adhered to, especially in cases where a test shows that an acceptance criterion has not been met. Accordingly, a responsible government authority needs to be given the responsibility to monitor the accuracy and frequency of testing carried out by farmers, water users, compost manufacturers, and others selling production inputs that fall under the GAP Metrics.

The responsible government authority might differ as a function of the target of testing. Regional water quality boards might carry out the monitoring of water testing; a state licensing authority like the California Integrated Waste Management Board might be tasked with monitoring compost testing and certification programs. But the goals would be the same – to monitor the quality and frequency of testing, to assure that test results are reported as required to various entities, and to conduct unannounced spot testing to confirm the results reported to the responsible authority. Any irregularities or deviations in testing programs or results would trigger an immediate investigation, and if necessary, additional remedial measures. Individuals or companies found to knowingly violate the rules would face severe penalties and consequences, including losing the right to produce for the leafy green industry or sell inputs to farmers growing leafy greens.

A second key change is needed in the interest of transparency, consumer confidence, and to advance the state of the art in food safety assurance programs. Whenever a sample of water, compost, or a production input shows a level of a target pathogen over the

acceptance criteria, a report should be made within a very short time frame (e.g., two days) to the responsible government authority. Timely identification of higher-risk water, inputs, or circumstances is the single most essential ingredient growers, processors, government regulators, private sector auditors, and researchers need to rapidly target the sources of potential problems so that food safety margins of safety can be expanded cost-effectively.

Clearly, methods must be put in place to assure that passing this information to a government entity does not trigger unjustified punitive measures, nor subject growers or input manufacturers to unwarranted remedial measures or liability. But on the other hand, regulators, researchers and auditors will move ahead, looking for a needle in a haystack, in the absence of timely information of where food borne pathogens are appearing above acceptance criteria.

The rapid development of an extensive database on samples found to contain pathogens above acceptance criteria would dramatically accelerate progress toward science-based, cost-effective remedial and preventive measures. The economic damage caused to the spinach industry across the nation in the wake of the 2006 outbreak drives home the reality that all growers and processors could be vulnerable if and when corners are cut or worrisome tests results are not adequately investigated.

The food safety program adopted by the California leafy greens industry must not be designed to punish growers or manufacturers that do not follow the rules and are caught when the next major outbreak is investigated. The plan must prevent lapses in adherence to the GAP Metrics, and as a result, prevent future outbreaks. The only way to assure that the GAP Metrics are followed is independent verification of required testing and reporting requirements. The only way for the GAP Metrics, and all the activity and testing generated by them to advance the food safety state of the art is to target everyone's efforts on the places and ways that food borne pathogens are gaining a presence in the system. The only way to do so is to require the reporting of test results above acceptance criteria to some responsible government authority so that appropriate follow up actions can be taken.

Thanks for considering these comments. The Organic Center welcomes your openness to push the envelop in the pursuit of wider margins of leafy green food safety.

Sincerely,

Dr. Charles Benbrook
Chief Scientist