

APPENDIX B:

TECHNICAL BASIS DOCUMENT FOR
*COMMODITY SPECIFIC FOOD SAFETY GUIDELINES FOR THE
LETTUCE AND LEAFY GREENS SUPPLY CHAIN
2ND EDITION*

APRIL 18, 2007

Introduction

This document serves as a supplementary source of information to the 2nd Edition of the *Commodity Specific Food Safety Guidelines for Lettuce and Leafy Greens Supply Chain (CSG2)*. In the 2nd Edition, metric guidelines and action levels were established for a variety of process areas judged to be potential contributors to the risk of microbial contamination. During the development process, many stakeholders identified a need for a document that provided the basis and rationale for the choice of metric; this document is intended to serve that need.

Although a number of relatively minor changes are incorporated into this version of the CSG2, the majority of changes were in the following distinct areas:

1. Water Sources and Uses
2. Soil Amendments
3. Non-Synthetic Crop Treatments
4. Flooding
5. Environmental Assessments: Animal Activity in Field (Wild or Domestic)
6. Environmental Assessments: Crop Land & Water Source Adjacent Land Use

This document discusses the Technical Basis for the proposed metrics in these six areas. In general, a three-tier approach was used to identify appropriate metrics:

1. A comprehensive literature review was conducted to establish whether a scientifically valid basis for establishing a metric has been published.
2. If the literature review did not identify published scientific support for an appropriate metric, existing standards or metrics supported by authoritative or regulatory bodies were adopted.
3. If neither scientific studies nor existing standards or metrics from authoritative bodies supported adoption of a specific metric, consensus among industry representatives and/or other stakeholders was sought.

The following sections provide a detailed explanation of the processes and rationale for derivation of each metric.

Water Sources and Uses

Metrics for water sources and uses must consider (1) which microorganisms to test for and the test methods, (2) action levels to apply, and (3) appropriate responses. An ideal test method would detect all pathogenic organisms present; however, this is not scientifically or economically feasible for many reasons:

- Concentrations of pathogenic microbes can vary widely in fecal matter. Hence, if testing focuses on specific pathogens, the presence of fecal contamination may not be detected even if significant contamination is present (Ashbolt *et al.* 2001; World Health Organization 2004). While continuous monitoring or daily testing might more reliably detect these microbes, this approach is economically unfeasible.

- Existing test methods may not be able to detect the wide variety of pathogenic organisms that might contaminate water (World Health Organization 2004). Even if water is routinely tested for the more common pathogenic organisms, this does not guarantee other pathogens are not present.

Given the reasons above, and guidance and/or comments from various regulatory agencies (US EPA 1986; California Department of Health Services (CDHS) and California Department of Food and Agriculture (CDFA) 2006; US FDA 2006), use of an “indicator” microbe was determined to be the most effective and efficient testing approach. Testing for generic *E. coli* is considered the best available indicator of a fecal contaminated water source.

Generic *E. coli* is generally non-pathogenic; thus, using this as an indicator organism results in action levels that are not necessarily health risk-based. Although increasing levels of generic *E. coli* in a water source are likely to correlate with increasing health risk, “bright line” levels of generic *E. coli* above which health risks are unacceptable can not rationally be established. Action levels based on generic *E. coli* concentrations should not be considered as separating “safe” or “unsafe” levels—they should only be considered as indicators of fecal contamination or increasing bacteriological densities.

To set generic *E. coli* action levels for water used in agricultural applications, it was decided that it would not be possible to use one set of levels for all uses. For instance, water that contacts edible portions of plants should likely have more stringent standards than water that does not contact edible portions of plants. In order to address this issue, use-specific standards were created for three uses determined to be most critical to lettuce and leafy green food safety:

- Pre-harvest foliar applications. Where edible portions of the crop are contacted by water (e.g. overhead sprinkler irrigation, pesticides/fungicide application, etc.).
- Pre-harvest non-foliar applications. Where edible portions of the crop are not contacted by water (e.g., furrow or drip irrigation, dust abatement water).
- Post-harvest direct contact applications. (e.g. re-hydration, core in field, harvest equipment cleaning, bin cleaning, product cooling, product washing).

For each use category, a rolling average and single sample maximum metric was set. These metrics were based on water quality standards developed by the U.S. EPA in their risk assessment of *E. coli* in recreational waters were used to establish action levels (US EPA 1986;2003). U.S. EPA determined that the geometric mean of *E. coli* in recreational water systems should not exceed 126 MPN *E. coli*/ 100 mL to protect against unacceptable risk of waterborne diseases. In addition to this geometric mean value, they also determined single sample maximum values for various beach-use types. These single sample maximums are based on certain confidence levels of the geometric mean value of 126 MPN. For a “Designated Beach,” U.S. EPA used the 70% confidence level, which is a value of 235 MPN/100 mL. For rarely used beaches, they used the 95% confidence level of 576 MPN/100 mL. These three guidelines were used to establish action levels for pre-harvest water uses. All pre-harvest water uses must meet the geometric mean requirement of 126 MPN/100 mL, but foliar applications must adhere to the lower 235 MPN/100 mL metric while non-foliar applications use the less strict 576 MPN/100 mL standard. The use of these values is bolstered by the adoption of the 126 MPN/100 mL geometric mean and 576 MPN/100 mL values by the state of Arizona as irrigation water quality standards.

For post-harvest direct contact applications, it was determined that stringent requirements should be met due to the potential high-risk for cross-contamination, as well as the lack of additional steps to remove or reduce contamination. Hence, the metric for this standard has been set at <2 MPN/100 mL, which is essentially the limit of detection. Guidelines for continuous monitoring of disinfectant in post-harvest systems are also provided in the CSG2 to facilitate meeting this strict standard.

A complete list of the various action levels is outlined in Table 1 in the CSG2, while decision tree explaining their use is shown in Figures 1A, 1B, and 1C.

Appropriate locations for water testing were also evaluated. Initially, testing the “source” of the water was thought to be most appropriate. However, several comments mentioned that testing at the source may miss contamination introduced into the distribution systems (US FDA 2006). Hence, the current draft specifies testing as close to the point-of-use as possible. If water is found to be above action levels at this location, then additional testing and the initiation of a sanitary survey are required.

Soil Amendments

Considerably more guidance exists for establishing metrics for soil amendments than water sources. Many regulatory bodies have set guidelines for production of soil amendments as well as acceptable levels of microbial organisms in finished products. A complete list of the metrics is provided in Table 2. Decision trees are found in Figures 2A and 2B.

Manure

The application of manure to lettuce and leafy green production fields is thought to be a high risk practice, and CSG2 discussions have centered on completely disallowing this practice. Initially, allowing use of manure in fields used for production of lettuce and leafy greens with a suitable application interval (120 days as suggested in the National Organic Program guidance) (USDA 2002) was considered; however, this use was prohibited after discussion and comments received from multiple stakeholders. Given the long survival period of bacteria in raw manure (over 120 days in some references), it was determined that the 120 day period was not acceptable, and that raw manure should not be used in the production of lettuce and leafy greens. However, in order not to completely restrict the use of land that has at some point had raw manure applied, a one-year waiting period prior to planting lettuce and leafy greens was considered appropriate.

Composted Soil Amendments

Due to the existence of California state regulations regarding the production of compost (CCR Title 14 - Chapter 3.1 - Article 5 2007), these guidelines were essentially adopted “as is” for the CSG2, with the addition of *E. coli* O157:H7 testing as an additional safeguard. These guidelines largely rely upon fecal coliforms as the indicator pathogens. Some comments have recommended testing for generic *E. coli* as opposed to fecal coliforms; however, because fecal coliforms are hardier and guidance does not exist for *E. coli* levels in compost, tests for fecal coliform were considered more technically feasible and conservative relative to generic *E. coli* (Jin *et al.* 2004; Entry *et al.* 2005).

A three hurdle process was considered to be sufficient for safe application of composted soil amendments to lettuce and leafy green crops. The first hurdle requires use of a validated process for compost production; the second requires microbial testing, and the third requires

applying an application interval to minimize risk from remaining pathogenic microorganisms.

A 45-day application interval was deemed appropriate due to the three hurdle metric design. Raw manure must be composted with an approved process and pass testing requirements before an application interval is observed. Some commenters supported the use of the National Organic Program's 120-day waiting period for use of raw manure. However, because the 120-day period is specific to raw (uncomposted) manure, it was judged reasonable to shorten this period to 45-days.

Physically Heat Treated Soil Amendments

Due to limited information related to the process and expected microbial populations found in physically heat treated soil amendments, metrics were primarily based on the composting metrics described above. Some processes are discussed in the literature (US EPA 1994; Bellows and Baker 2005); this information was used to set some metrics for temperature and contact times. Most of these U.S. EPA based requirements are for biosolids, but are considered to be appropriate for application to raw manure. Because the process for physically heat treating manure is much more controlled than composting, a stricter requirement for fecal coliform concentrations (<10 MPN) was considered reasonable for heat treated soil amendments.

Due to the stricter testing requirements and more tightly controlled process used with heat treated soil amendments, if a validated process is used no application interval is required for these types of amendments. If the process is not validated, a 45-day application interval was deemed appropriate due to the three hurdle metric design. Some commenters supported a longer application interval such as the National Organic Program's 120-day waiting period for use of raw manure. However, because the 120-day period is specific to raw (uncomposted or heat treated) manure, it was judged reasonable to shorten this period to 45-days.

Non-Synthetic Crop Treatments

Due to limited information related to the process and expected microbial populations found in non-synthetic crop treatments, metrics were primarily based on the composting metrics described above. However, due to the foliar application of many of these types of treatments, a more stringent guideline was considered to be appropriate for microbial testing (i.e., <10 MPN fecal coliform and negative for *E. coli* O157:H7 and *Salmonella* sp.). Specific metrics are found in Table 3 of the CSG2, and a decision tree for these treatments can be found in Figure 3.

Due to the stricter testing requirements and used with non-synthetic crop treatments and their intended use as foliar applicants, if a validated process is used no application interval is required for these products. If the process is not validated, a 45-day application interval was deemed appropriate due to the three hurdle metric design.

Flooding

The flooding definition applied in CSG2 is based on the definition accepted in the first CSG document. Although some comments related to possible changes in this definition, since there is no consensus at this time, the original definition was retained.

The distance not to be harvested from the high-water mark of any flood event was selected to be 30 feet, based on the turn-around distance of farm equipment to prevent cross-contamination. This distance may be increased if there is the uncertainty about the location of the high-water mark or if some equipment has a greater turning radius— whether to increase this distance is to be determined by an appropriately trained food safety expert, with possible consultation with other experts as necessary.

The required waiting period after flooding prior to planting (60 days) was selected based on comments from regulatory bodies; these comments were consistent with original time periods based on USDA NOP guidance on use of manure (i.e., it was assumed that the worst-case flooding event would be equivalent to use of raw manure on fields) (USDA 2002). This 60-day prior to planting time period is roughly equivalent to 120-days prior to harvest depending on the specific growing season of the crop, and was considered to be easier to implement in the field. An option to reduce this time period to 30 days is provided if growers can demonstrate, through a valid sampling program that soil microbial levels are lower than those required for composted soil amendments. The development of the soil sampling plan and the sampling itself must be undertaken by a reputable third-party environmental consultant or laboratory.

Regardless of the use of the standard 60-day period or the 30-day period, all decisions related to use of flooded land should be made with the consultation of a qualified food safety professional. This person should have the same qualifications as described in the Environmental Assessments section below.

Environmental Assessments

In order to maintain vigilance over the conditions associated with the production of lettuce and leafy greens, periodic monitoring of production fields is required. This monitoring requires visual observation of field conditions with focus on animal activity and neighboring land uses. This monitoring should begin one week prior to planting and continue through the growing cycle. In addition, two formal assessments must also be conducted, one within one week prior to harvest and the other at harvest.

Animal Activity in Field (Wild or Domestic)

The metrics developed for assessing animal intrusions in production fields were based on best professional judgment about proper assessment and corrective actions. In general, it was assumed that continuous monitoring for this type of event was not feasible, so periodic monitoring as well as pre-harvest and harvest formal assessments were determined to be a viable alternative.

Research has shown that not all animals are of equal risk for spreading pathogenic organism to food crops. The CSG2 has identified the following animals deemed to pose the greatest risk: cattle, sheep, goats, deer, and pigs (CDC 2006).

In general, due to the likely subjective issues in determining whether or not an animal intrusion is significant and presents a risk of contaminating lettuce or leafy green produce, the CSG2 specifies that a trained food safety professional be involved in decisions related to animal intrusion. The qualifications for this person are as follows:

- The design and implementation of Food Safety programs and systems for Fresh Produce operations from farm to market is a complex task requiring significant knowledge from several fundamental areas of science. Personnel entrusted with management level responsibility for Food Safety in the Fresh Produce Industry must at a minimum have a sound background in basic microbiology, chemistry, and statistics. Moreover, a solid understanding of the principles of food safety as applied to agricultural production is also required.
- Each Fresh Produce production operation involved in growing, harvesting, and / or packing will have an appropriately qualified individual whose primary job function is development, implementation, and supervision of a comprehensive Food Safety program. This person should be a direct full time employee; however, for some smaller operations where this is impractical a continuous, contractual, relationship involving at least quarterly direct involvement with the operation is acceptable.
- At a minimum the individual will have some training in relevant fields of science including but not limited to biology, food science, chemistry, and botany. Experience in actual Food Safety operations especially those related to Fresh Produce is strongly recommended.

These requirements recognize the fact that Food Safety in the Fresh Produce Industry is an endeavor based on scientific principles and that significant formal training is required to prepare individuals for Food Safety management responsibilities in the industry.

Once the food safety professional has been involved in a possible animal intrusion situation, too many subjective situations regarding animal intrusion situations may occur to definitely outline metrics for all of them. The food safety professional will use their best professional judgment to determine whether or not to harvest product, how much buffer distance should be assigned for various intrusions, and whether remedial options might reduce or eliminate risk from intrusions. The only established metric for this area is that crop with any evidence of fecal material may not be harvested, and if fecal material from an animal of concern is found, a one row by one row section of produce surrounding the fecal material shall not be harvested. This distance was selected using best professional judgment based on practicality in the field.

Crop Land & Water Source Adjacent Land Use

Developing metrics related to acceptable distances from production fields to various adjacent land and water uses was difficult due to a dearth of scientific literature on the topic, and the many different environmental factors that might be encountered in the field. In order to provide some basis for determining these distances, the various types of land uses were first characterized according to their relative risk (the land uses of possible concern were first selected during various grower/processor meetings in the fall of 2006). For instance, active

composting operations were considered to have a relatively high risk, while normal water ways were considered to have a lower risk.

Once the relative risk associated with each type of land or water was agreed upon, acceptable proximate distances from the land/water were determined. The use of a “proximate” metric instead of a defined lower or upper boundary was considered appropriate due to the myriad factors that might be found in a particular environment. A “one size fits all” strategy did not seem reasonable. Due to the lack of suitable science for defining “safe” distances, almost all of the distance metrics were determined by best professional judgment between the authors, growers/producers, and the expert reviewers of the document. These stakeholders also produced a list of factors that might necessitate increasing or decreasing some of the distances. As additional science is brought to bear on this issue, it is anticipated that the metrics will change accordingly.

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