#### LETTUCE/LEAFY GREENS COMMODITY SPECIFIC GUIDANCE

1. **PRODUCTION & HARVEST UNIT OPERATIONS**

1. 2. GENERAL REQUIREMENTS
2. In addition to the area-specific requirements discussed in latter sections, there are several general requirements
3. that are part of an effective best practices program. These requirements are outlined below.

###  The Best Practices Are:

1.  A written Leafy Greens Compliance Plan shall be prepared that specifically addresses the Best Practices listed
2. in this document. This plan shall address at least for the following areas: water, soil amendments,
3. environmental factors, work practices, and field sanitation.
4.  Handlers shall have an up-to-date growers list with contact and location information on file.
5.  The handler shall comply with the requirements of The Public Health Security and Bioterrorism Preparedness
6. and Response Act of 2002 (farms are exempt from the Act) including those requirements for recordkeeping
7. (traceability) and registration...
8.  Designate an individual responsible for their operation’s food safety program. Twenty-four-hour contact
9. information shall be available for this individual in case of food safety emergencies.
10.  Risk assessments (such as pre-season and pre-harvest assessments) must be conducted following the
11. requirements in Issues 5 and 14 of the Metrics and following applicable Appendix I: Pre-harvest Testing
12. Guidance.
13.  When risk assessments (such as pre-season assessments and pre-harvest assessments) determine there is
14. elevated risk then pre-harvest testing is required.
15.  When doing pre-harvest testing for elevated risk it must be conducted in accordance with Appendix C’s
16. section for Risk-based Pre-harvest Product Sampling and Testing Protocol. (See Appendix C, Section IV
17. language in Issue 17: Detailed Background Guidance Information)
18.  Laboratories used for any analytical parameters (microbial, chemical, etc.) required in the metrics must be
19. certified and/or accredited for the analytical methods being reported and the matrices being analyzed (water,
20. soil, soil amendment, product, etc.). Certification and accreditation must be recognized by State, Federal, or
21. internationally bodies (ISO).
22. o Note: It may be appropriate for proprietary or modified methods to be used but there must be assurances
23. that the results are consistent with accredited methodologies.
24.  Perform root cause analysis after any incident that has a high likelihood of causing a foodborne illness or injury
25. (i.e., high risk adjacent land concern, positive pre-harvest pathogen test, water system non-compliance, high
26. risk health or hygiene incident, soil amendment concern, traceability failure, field fecal contamination, etc.).

1. 5. ENVIRONMENTAL ASSESSMENTS
2. This section addresses assessments that shall be completed and documented prior to the first seasonal planting,
3. within one week prior to harvesting and during harvest operations. These environmental assessments are intended
4. to identify any issues related to the produce field, adjacent and nearby land use, and/or animal hazards that may
5. present a risk to the production block or crop (see Tables 0 and 6).

###  The Best Practices Are:

1.  Prior to the first seasonal planting and within one week prior to harvest, perform and document an
2. environmental risk assessment of the production field and surrounding area. Focus these assessments on
3. evaluating the production field for possible animal hazards or other sources of human pathogens of concern,
4. assessing adjacent and nearby land use for possible sources that might contaminate the production field, and
5. evaluating nearby water sources for the potential of past or present flooding.

##### o Assessment of Produce Field

1. Evaluate all produce fields for evidence of animal hazards and/or feces. If any evidence is found, follow
2. procedures identified in the “Production Locations - Encroachment by Animals and Urban Settings.”
3. Evaluate potential environmental sources of contaminants near production locations after a change in
4. weather conditions or weather events that could impact the original risk assessment of the field or
5. block and follow procedures identified in the “Production Locations - Climatic Conditions and
6. Environment” section below.

##### o Assessment of Adjacent and Nearby Land Use

1. Conduct and document a detailed risk assessment that evaluates risk level of all land and water~~ways~~
2. sources adjacent and nearby to all production fields for possible sources of human pathogen of
3. concern. These sources include, but are not limited to manure storage, compost storage and
4. operations, biosolids, CAFOs, AFOs, grazing lands, domestic animals/hobby farms, ~~surface~~ water
5. storage and conveyance, habitat/riparian area, sanitary facilities, septic systems, and non-leafy green
6. crops (See Table 0 and Appendix H: Risk Assessment Tool for further detail). If any possible ~~uses~~
7. sources on adjacent or nearby lands that might result in produce contamination are present, consult
8. with the metrics and refer to Appendix Z.
9. o At any time prior to planting, during the growing of the crop, or during the period when harvest
10. operations are occurring, if on farm or adjacent and nearby land activities result in a possible higher risk
11. situation, conduct additional risk assessments, and perform additional mitigations as necessary.

##### Assessment of CAFOs

1. Conduct and document a rigorous pre-season environmental assessment of any Concentrated Animal
2. Feeding Operation that may impact your operation. Include, to the degree possible, communication
3. with the CAFO operator and/or third-party operator to document Best Management Practices (BMPs)
4. within the facility, examination of the CAFO for locations and risk associated with composting, storage,
5. sick pens, dead piles and other internal operations, examination of traffic routes associated with the
6. CAFO and examine settling and manure ponds for any signs of leakage. Note if the CAFO drainage or
7. discharge is a possible source of contamination. Record the approximate number of animals within the
8. CAFO and the method used to determine.
9. Conduct and document a pre-harvest assessment that confirms no changes in pre-season conditions.
10. Note if any discharge events that may impact your crop or operations; changes in weather condition
11. or weather events occurred during the production period.
12. Water sources that are proximate to a CAFO may pose additional risk and should be closely evaluated.
13. Refer to Appendix A: Agricultural Water System Assessment.

##### o Assessment of Historical Land Use

1. To the degree practical, determine and document the historical land uses for production fields and any
2. potential issues from these uses that might impact food safety (i.e., hazardous waste sites, landfills, etc.).

##### o Assessment of Flooding

1. Evaluate all produce fields for evidence of flooding. If any evidence is found, follow procedures identified
2. in the “Flooding” section below.
3.  Prior to the first use of a production block intended for spinach, evaluate the soil for the presence of
4. cadmium. If cadmium is determined to be present, further evaluation and mitigation may be necessary (see
5. Section 17). Cadmium concentration is generally stable and further evaluation is unnecessary over time.
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###  TABLE 0. Crop Land and Water Source Adjacent and Nearby Land Use

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|  |  | **Considerations for Risk Analysis** |
| **Adjacent and Nearby Land Uses** | **Current Metric** | **Risk Factors** | **Mitigation Factors** |
| **Animal operations** | **AFOs** | 30 feet(no composting) 400 feet (with composting) | Distance, topography, water runoff, number of animal units, wind direction, history | Pre-harvest pathogen testing, water treatment, vegetative buffers, barriers, increased buffers, animal and insect monitoring |
| **CAFO** | 1200 feet / 1 mile | Distance, topography, water runoff, number of animal units, wind direction, history | Pre-harvest pathogen testing, water treatment, vegetative buffers, barriers, increased buffers, animal and insect monitoring |
| **Grazing Lands** | 30 feet | Distance, topography, water runoff, number of animal units, wind direction, history | Pre-harvest pathogen testing, water treatment, vegetative buffers, barriers, increased buffers, animal and insect monitoring |
| **Domestic Animals/Hobby Farms** | 30 feet | Distance, topography, water runoff, number of animal units, wind direction, history | Pre-harvest pathogen testing, water treatment, vegetative buffers, barriers, increased buffers, animal and insect monitoring |
| **Compost/Soil Amendment Operations** | **Compost Operations**(Manure or Animal Products) | 400 feet | Distance, timing of production, production process, volume of production, topography, water runoff, wind direction, history | Preventive barriers, pre-harvest pathogen testing, knowledge of process, water treatment |
| **Non-synthetic Soil Amendment Pile**(containing manure or animal products) | 400 feet | Distance, timing of production, production process, volume of production, topography, water runoff, wind direction, history | Preventive barriers, pre-harvest pathogen testing, knowledge of process, water treatment |
| **Non-synthetic Soil Amendment Pile**(not containing manure or animal products) | 400 feet | Distance, timing of production, production process, volume of production, topography, water runoff, wind direction, history | Preventive barriers, pre-harvest pathogen testing, knowledge of process |
| **Biosolids** | 400 Feet | Distance, timing of production, production process, volume of production, topography, water runoff, wind direction, history | Preventive barriers, pre-harvest pathogen testing, knowledge of process |

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| **Non-leafy green crops** | **Cannabis/hemp, cover crops, dates, flowers, grapes, other** | The approximate safe distance depends on risk and mitigation factors | History of risk identification, distance from adjacent operation, topography, crop production timeline, foreign object, animal/bird attractant, grazing animals, harvest practices. | Physical barriers, pre-harvest pathogen testing, increased monitoring, knowledge of process |
| **Water Source and Systems** | **Well Head distance from Untreated Manure** | 200 feet | History of risk identification, distance from adjacent operation, topography, opportunity for water run off through or from untreated manure, or composting operations, soilleaching | Adjacent operation management practices, Increased monitoring, preventive barriers, type of system (closed vs open), water treatment |
| **Surface Water Distance from Untreated Manure** | 100-300 feet | History of risk identification, distance from adjacent operation, topography, opportunity for water run off through or from untreated manure or composting operations, flooding, soil leaching | Adjacent operation management practices, increased monitoring, preventive barriers, water treatment |
| **Water Storage and Conveyance systems** | 30--300 feet | History of risk identification, distance from adjacent operation, topography, flooding, animal Intrusion, trash and debris, excessive vegetation, integrity of water storage, conveyance and distribution | Adjacent operation management practices, increased monitoring, type of system (closed vs open), water treatment |
| **Urban Settings** | **Homes or other building with a septic leach field** | 30 feet | History of risk identification, distance,topography, leach field status (active vs inactive), runoff | Preventive barriers, knowledge of septic field |
| **Other Environmental Considerations** | **Habitat/Riparian Area** | The approximate safe distance depends on risk and mitigation factors. | History of risk identification, distance from potential risk, topography, potential for animal intrusion, physical hazards | Preventive barriers, increased monitoring |

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2. Growers should check for local, state, and federal laws and regulations that protect riparian habitat, restrict removal of vegetation or habitat, or
3. restrict construction of wildlife deterrent fences in riparian areas or wildlife corridors. Growers may want to contact the relevant agencies (e.g., the
4. Regional Water Quality Control Board and state and federal fish and wildlife agencies) to confirm the details of these requirements.

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| 286 1281 |  17. DETAILED BACKGROUND GUIDANCE INFORMATION  |
| 1282 |  **Required Reference Documents**  |
| 1283 | 1. FDA Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables |
| 1284 | ([www.foodsafety.gov/~dms/prodguid.html](http://www.foodsafety.gov/~dms/prodguid.html)) |
| 1285 | 2. UFFVA Food Safety Auditing Guidelines: Core Elements of Good Agricultural Practices for Fresh Fruits and |
| 1286 | Vegetables |
| 1287 | 3. UFFVA Food Safety Questionnaire for Fresh Fruits and Vegetables |
| 1288 | 4. National GAPs Program Cornell University: Food Safety Begins on the Farm: A Grower Self-Assessment of |
| 1289 | Food Safety Risks |
| 1290 |  **Appendix C - Section IV – Version July 1, 2021**  |
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| 1292 | **IV. Risk-based Pre-harvest Product Sampling and Testing Protocol** |
| 1293 | SOPs should be developed and applied, as needed, for risk-based observations and events including, but not |
| 1294 | limited to: |
| 1295 | * When pre-plant environmental assessments identify a potential risk judged to be acceptable with applied
 |
| 1296 | mitigation strategies, but during the pre-harvest assessment the actual risk changes, such that the risk |
| 1297 | exposure (i.e., likelihood of contamination) is judged to be uncertain and warrants increased testing. |
| 1298 | * When irrigation water exceeds generic E. coli water quality standards or when Type B → A water
 |
| 1299 | treatment fails to achieve acceptance criteria as established by the LGMA-approved guidelines. |
| 1300 | * When there are hazards with uncertain specific risk associated with adjacent land features or uses such as
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| 1301 | runoff; storm-associated flooding; animal intrusion; potential windborne contamination from surrounding |
| 1302 | or adjacent animal holding, transfer, or feeding operations; and potential windborne contamination from |
| 1303 | composting operations or staging and application of compost on adjacent fields. |
| 1304 | * Other unforeseen sources or incidents potentially resulting in crop contamination.
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| 1305 | * Situations described in the California LGMA pre-harvest testing guidance, which lists elevated risk factors
 |
| 1306 | that can trigger pre-harvest testing. |
| 1307 | **Target organisms** |
| 1308 | * Shiga toxin-producing *E. coli* (STEC including specific tests targeting *E. coli* O157:H7)
 |
| 1309 | * *Salmonella enterica*.
 |
| 1310 | **Measurement criteria** |
| 1311 | * The recommended acceptable and conforming result is no molecular-confirmed positives in a defined lot
 |
| 1312 | for: |
| 1313 | o STEC (including *E. coli* O157:H7 and/or *stx* 1 or 2 and, minimally, *eae* as the primary genetic |
| 1314 | attachment factor target) or |
| 1315 | o *Salmonella* |
| 1316 | * A qualified service lab can explain the platform(s) they offer and how these are validated or certified for
 |
| 1317 | these targets. |

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| 1318 | **Timeline for sampling and testing** |
| 1319 | * Conduct risk-based product testing as soon as an unanticipated or previously unrecognized hazard is first
 |
| 1320 | observed to establish whether detectable contamination has occurred (1st round of risk-based testing). |
| 1321 | * Repeat risk-based product testing at the scheduled product harvest date (2nd round of risk-based testing)
 |
| 1322 | within 4-7 days of harvest) if: |
| 1323 | o The hazard is observed prior to routine sampling. |
| 1324 | o The initial risk-based test result is negative. |
| 1325 | o The crop is not destroyed. |
| 1326 | * Conduct a root cause analysis to determine what may have led to the unforeseen or unaccounted for
 |
| 1327 | hazard (i.e., a contamination risk from a recognized adjacent or seasonal hazard judged to be acceptable |
| 1328 | within established guidelines or an actual risk exposure resulting in detectable contamination of the |
| 1329 | harvested or unharvested product). |
| 1330 | **Size of lot to be sampled** |
| 1331 | * For risk-based testing purposes, lot size may not exceed one acre.
 |
| 1332 | * Sampling of less than one acre should follow the same sampling plan as one acre.
 |
| 1333 | **Sample number and size** |
| 1334 | * The total sample mass of leafy greens (N) per the designated lot must equal 1,500 grams. The total
 |
| 1335 | sample mass (N) can be divided into subsamples within a lot as long as the total mass tested is 1,500 |
| 1336 | grams per designated lot. |
| 1337 | * An N=60 sampling plan would consist of 60 samples for a nominal total mass of 1,500 grams per 1-acre
 |
| 1338 | lot. |
| 1339 | * Plant density may be considered in an individual product testing SOP. However, the foundation for sample
 |
| 1340 | number and lot size must meet the current equivalent acceptance criteria (see workbook) for achieving a |
| 1341 | standardized recommended confidence in detecting target contaminants (STEC and *Salmonella*) at the |
| 1342 | level predicted to result in an outbreak. |
| 1343 | **Sampling plan** |
| 1344 | * The following method may help develop the greatest level of confidence in detecting non-uniformly
 |
| 1345 | distributed contamination, if present: Divide a 1-acre lot or field-level block into a grid and conduct |
| 1346 | systematic sampling within each grid starting at a randomized location with a predetermined spacing |
| 1347 | basis. For example, every third bed and approximately every quartered position of the bed length within |
| 1348 | each grid. |
| 1349 | * In the case of directional risk, biased sampling of a field’s edge/border beds may be appropriate. Yet not
 |
| 1350 | all scenarios are the same. Experience informs us that contaminant deposition may not be uniquely |
| 1351 | defined by edge proximity. For instance, when bioaerosols drift from a point source, deposition may be |
| 1352 | more central than strictly at the field edge closest to the source. |
| 1353 | **Sample collection** |
| 1354 | * Using reasonable aseptic sample collection techniques, select leaves from the edible portion of plants.
 |
| 1355 | Focus on leaves that would contact harvest tools, mechanized harvest equipment, or harvest workers’ |
| 1356 | gloves and apparel. |
| 1357 | * Incorporate basic crop characteristics into tissue sampling strategies such as tender leaf crops vs. head
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| 1358 | lettuce (e.g., romaine). Sample tender leaf crops such as baby spinach to include the full leaf blade and |

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| 1359 | basal petiole. Sampling should include full leaves or sections of a full head rather than pinching off the |
| 1360 | upper quarter of a single leaf or leaves on an individual plant. |
| 1361 | * Do not trim and discard leaves that would not be included with harvested product but focus on the areas
 |
| 1362 | of the plant/field that would be at greatest risk for crop contamination including but not limited to the |
| 1363 | following: inner leaves, outer leaves, and wrapper leaves. Additionally, when assessing the possibility of |
| 1364 | contamination via furrow irrigation water or animal intrusion, collect leaf samples from beds at the |
| 1365 | irrigation discharge point of the field - the head row area. |
| 1366 | * Place each sample in a sterile container or sealable sample bag and include the specific sampling location
 |
| 1367 | in documentation, either by a planned randomized location on a field map or by operator point-to-point |
| 1368 | or app-based walking GPS-time-tracked tagging. |
| 1369 | * Place samples in a cooler with adequate ice packs, but do not freeze. A double layer sheet of craft or
 |
| 1370 | butcher paper as a barrier between samples and gel-ice is helpful to prevent tissue freeze injury. If using |
| 1371 | water-based ice (not recommended), ensure the product is protected from potential cross-contamination |
| 1372 | from melting ice. |
| 1373 | * Fill out the chain of custody form with the sample collection information.
 |
| 1374 | * Select a qualified third-party service or laboratory for sample analysis. It is in your best interest to select a
 |
| 1375 | validated or performance tested method for pathogen testing (AOAC, Performance Tested Certification, |
| 1376 | etc.) that the laboratory is qualified / accredited to perform. |
| 1377 | * Confirm the service laboratory utilizes validated methods for sample mass to enrichment buffer ratios and
 |
| 1378 | time for pre-enrichment, matched to the target detection platform. You should understand the general |
| 1379 | specifications and basics of the test method you have selected, focusing on detection limits and time to |
| 1380 | results. |
| 1381 | * Samples must be transported promptly and at the right temperature as required under your specific
 |
| 1382 | sampling method protocol. Service laboratories generally specify this transfer time to be consistent with |
| 1383 | test method certification. For instance, within 48 hours if the arrival temperature is assured to be |
| 1384 | between 33˚F and 41˚F. |
| 1385 | * Make sure deviations from these recommendations for investigative purposes are communicated and
 |
| 1386 | documented on Chain of Custody forms. |
| 1387 | **Remedial actions** |
| 1388 | Remedial actions may vary depending on how sampling lots are defined and the outcome of a root cause analysis |
| 1389 | (RCA). |
| 1390 | * Conduct an ARCA to make a concerted effort to determine what may have led to the detectable
 |
| 1391 | contamination on product. Based on the findings of your RCA: |
| 1392 | o Consider the potential for recurrence of the hazard or associated risk identified through the RCA. How |
| 1393 | likely is it that future plantings might be affected by the same hazard? |
| 1394 | o Consider the suitability/safety of the area where a pathogen was detected for replanting a fresh |
| 1395 | consumed leafy green crop for the remainder of the season. |
| 1396 | * Do not harvest from the lot where a pathogen was detected. Destroy the crop in this area.
 |
| 1397 | * Clean and sanitize all equipment utilized to destroy the crop upon exiting the field. Consider swabbing
 |
| 1398 | equipment after crop destruction as part of your RCA effort. |
| 1399 | * Document all remedial actions including both considerations adopted and those evaluated but not
 |
| 1400 | implemented. All documentation must be available for verification from the responsible grower. |
| 1401 |  |