

Good agricultural and collection practices and good manufacturing practices for botanical materials

Company Information

Company name		
Street Address		
City/State	C	ountry
Contact name	C	Contact phone
Contact email	C	Company website
Botanical material	<describe ad<="" botanical="" material="" of="" operation="" p="" scope="" the=""></describe>	Idressed by this form>
operation		

This form is for use in conjunction with <u>Section 3 Cultivation</u>. Supporting information for specific elements can be attached to this form.

Many factors must be considered and controlled in the cultivation of botanicals, from the choice of farm location through the applications of pesticides and fertilizer. These factors can significantly influence both the quality of the botanicals grown and the economics of the farming operation.

This section outlines recommended practices to ensure the quality and freedom from contamination of the crops produced. In addition, farmers of produce crops such as lettuce are usually (depending on certain exemptions) subject to the additional agricultural practice requirements established in 21 CFR Part 112.

Access to water of sufficient quantity and quality is essential to farm operations, and many crops rely on irrigation to supplement water received from normal rainfall.

The growth and development characteristics of individual plants, as well as the plant part destined for use, should guide field management practices. Various strategies can be implemented to protect and maintain the crop and to maximize the success of the harvest.

C3 Cultivation		Assessment ¹			
Element	Description	N/A	Meet	Partial	Deficient
C3.1 Propa	gation material				
C3.1 i)	Seeds and other propagation material (roots, rhizomes, vegetative cuttings, tissue				
	culture explants, spores, etc.) are obtained from reliable sources such as reputable				
	vendors, seed banks, or harvest from existing plants.				
Comments					
C3.1 ii)	Propagation material is clearly labeled and recorded with the identity, origin, date of				
	collection or harvest, and other relevant descriptors where applicable.				
Comments					
C3.1 iii)	Steps are taken to ensure the correct botanical identity of seeds and other propagation material.				
Comments		•			
C3.1 iv)	Seed lots are verified to be of appropriate purity, health, and cleanliness.				
Comments					
C3.1 v)	Records are kept of each lot of propagative material used.				
Comments					
C3.1 vi)	Retention samples are kept of each lot of propagative material.				
Comments					
C3.2 Cultiv	ation site				
C3.2 i)	Cultivation sites are evaluated to ensure suitable for cultivation of the intended crop and				
	for its intended purpose.				
Comments	!				
C3.2 ii.1-	Soil is sampled in accordance with appropriate sampling plans and tested as appropriate.				
6)					
Comments					
C3.2 iii.1-	Water sources are tested as appropriate to evaluate and monitor suitability for use in				
3)	cultivation of food and for the cultivated crop.				
Comments					
C3.2 iv.1-	Information relevant to the site location and setting is recorded and maintained for an				
8)	appropriate length of time.				
Comments	:				

C3 Cultivation		Assessment ¹			
Element	Description	N/A	Meet	Partial	Deficient
C3.2 v.1-	A thorough history of prior uses of the cultivation site has been prepared and maintained				
7)	for an appropriate length of time.				
Comments					
C3.3 Fertilia	zer use				
C3.3 i)	Fertilizer use is determined by soil sample analysis and the ratios of nutrients required.				
Comments					_
C3.3 ii)	Consideration is given to the benefits of using fertilizer compared to the effects such use				
	may have in the environment.				
Comments					
C3.3 iii)	Use of chemical fertilizers complies with any applicable Federal, state and local				
	regulations.				
Comments					
C3.3 iv)	Fertilizer stocks are kept away from water supplies and harvested crop materials.				
Comments					
C3.3 v)	Chemical fertilizers are used and stored in accordance with all label instructions or				
	recommendations.				
Comments			•		
C3.3 vi.1-	Manure- and/or compost-based fertilizers used have been properly produced and are				
5)	appropriate for food crops.				
Comments			•		
C3.3 vii.1)	Packaged fertilizers and containers of diluted or prepared fertilizer are properly labeled				
	at all times.				
Comments			•	T	
C3.3 vii.2)	Personnel applying crop fertilizers have been properly trained.				
Comments			•		
C3.3 vii.3)	Adequate safety protection is provided for personnel applying or handling fertilizers.				
Comments	<u></u>				
C3.3 vii.4)	Appropriately clean equipment and supplies are used to apply fertilizer and are				
	appropriately decontaminated and/or disposed after use.				
Comments					

C3 Cultivat	B Cultivation		Assessment ¹				
Element	Description	N/A	Meet	Partial	Deficient		
C3.3 vii.5)	Fertilizers are applied to optimally promote growth of the crop and to ensure the						
	fertilizer has appropriately broken down before harvest.						
Comments		•			•		
C3.3 vii.6)	Water-soluble foliar fertilizers are applied within 24 hours of preparation.						
Comments		•					
C3.3 vii.7)	Water used for mixing any soluble fertilizer is potable or meets established criteria for						
	agricultural irrigation water.						
Comments	:						
C3.3 vii.8)	Fertilizers are applied in a manner that does not contribute to contamination of water						
	supplies.						
Comments	:						
C3.3 vii.9)	Fertilizer use is authorized by the buyer of the crop, or the buyer is provided with an						
	opportunity for review and approval.						
Comments	:						
C3.3	Records of fertilizer use are maintained.						
vii.10)							
Comments	!						
C3.4 Irrigat	ion						
C3.4 i.1)	All water sources used in crop production (e.g., on-farm well(s), open irrigation canal(s),						
	reservoir(s), a municipal supply, or other sources) are identified.						
Comments							
C3.4 i.2)	Monitoring for contaminants of concern such as heavy metals, microorganisms, and						
	pesticide residues has been established and analytical reports are maintained.						
Comments							
C3.4 i.3)	The irrigation type is based on considerations of cost, water conservation, plant health,						
	and the risk of increased vector-borne diseases.						
Comments					_		
C3.4 i.4)	Irrigation systems or equipment are maintained in good working condition to prevent						
	water waste and contamination of crops.						
Comments	:						

C3 Cultivat	C3 Cultivation		Assessment ¹			
Element	Description	N/A	Meet	Partial	Deficient	
C3.4 i.5)	Irrigation is applied according to the needs of the crop and in a manner that adequately avoids runoff.					
Comments	:					
C3.4 i.6)	Irrigation practices conform to all local or state water district regulations.					
Comments						
C3.4 ii)	Irrigation-related records are maintained for at least several years.					
Comments	:					
C3.5 Crop r	naintenance and protection					
C3.5 i)	Tilling, mulching, and other cultivation practices are adapted to the requirements of the specific crop and to minimize weeds.					
Comments						
C3.5 ii)	Measures such as thinning, topping, bud nipping, pruning and shading are used to control the growth and development of the plant.					
Comments						
C3.5 iii)	Crop rotation plans are used to maintain soil fertility.					
Comments						
C3.5 iv)	Companion planting strategies are used such as interplanting.					
Comments						
C3.5 v)	Fields are monitored for undesirable weeds and controlled as appropriate. Any weeds containing tropane or pyrrolizidine alkaloids are eliminated before harvesting.					
Comments						
C3.5 vi)	Integrated pest management practices are used.					
Comments						
C3.5 vii.1)	Pesticides are applied to crops at the minimum effective rates, and only by properly trained personnel with the proper application equipment and personal protective equipment.					
Comments						
C3.5 vii.2)	All pesticides used are approved for use on the specific crop by both local and U.S. federal governments at application levels intended to meet established tolerance levels for the crop as applicable.					
Comments	:					

C3 Cultivation		Assessment ¹			
Element	Description	N/A	Meet	Partial	Deficient
C3.5 vii.3)	Pesticide application and storage are in accordance with label instructions and all				
	regulations.				
Comments					
C3.5 vii.4)	Pesticide stocks are stored away from water supplies and harvested crop materials.				
Comments					
C3.5 vii.5)	Pesticides are applied sufficiently in advance of harvest to comply with label instructions				
	and any relevant regulations.				
Comments					
C3.5 vii.6)	Records of pesticide use are maintained for at least several years.				
Comments		•			•
C3.5	Records of crop maintenance and protection are established for each cycle of cultivation				
viii.1-2)	and harvest and are maintained for an appropriate length of time.				
Comments		•			•
C3.6 Other	considerations				
C3.6 i)	When genetically modified seeds or vegetative stock are used as propagation material,				
	cultivation practices conform to all relevant federal and regional regulations, both at the				
	agricultural location and in the countries in which the material may be sold and the use				
	of genetically modified propagation material is disclosed.				
Comments					
C3.6 ii)	When cultivating organic crops, cultivation is performed in accordance with all relevant				
	federal and regional regulations governing organic certification and the organic status of				
	the crop in records and labeling to ensure that downstream recipients of materials				
	produced from these crops are informed of the organic status.				
Comments	:				
C3.6 iii)	Environmental stewardship practices are incorporated in the cultivation operation.				
Comments	:				
C3.6 iv)	Crops being grown as covered produce under 21 CFR Part 112 comply with the				
	requirements of those regulations.				
Comments					
¹ Assessme	nts are used to indicate the degree of compliance or adherence to the specific element.				<u> </u>
N/A = This	element is not applicable to the operation				

C3 Cultivation			Assessment ¹			
Element	Description	N/A	Meet	Partial	Deficient	
Meet = Full	y compliant or adherent to the element					
Partial = Gre	eater than 50% compliant to the element					
Deficient =	Less than 50% or no compliance to the element					
Lattoct that s	all the information contained in this form is correct to the host of my knowledge					
I attest that all the information contained in this form is correct to the best of my knowledge.						
Signature:	Date:					