

PROPOSED COTTAGE FOOD REGULATION SHM #6 (04/05/16)

COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Division of Environmental Health and Sustainability

6 CCR 1010-15

**RULES AND REGULATIONS GOVERNING THE PRODUCTION OF
TIER 2 COTTAGE FOODS IN THE STATE OF COLORADO**

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TABLE OF CONTENTS

15.1	Authority	1
15.2	Scope and Purpose	1
15.3	Applicability	1
15.4	Definitions	1
15.5	General Requirements	4
15.6	Product Labels	4
15.7	Point of Sale	5
15.8	Tier 2 Cottage Food Producer Requirements	5
15.8.1	Registration	5
15.8.2	Training	5
15.8.3	Water Quality Testing	6
15.8.4	Sewage Disposal	6
15.8.5	Process Review	6
15.8.6	Recordkeeping	7
15.9	Enforcement	7
15.9.1	General	7
15.9.2	Penalties	8

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3 **Division of Environmental Health and Sustainability**

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7 **RULES AND REGULATIONS GOVERNING THE PRODUCTION OF TIER 2 COTTAGE FOODS**
8 **IN THE STATE OF COLORADO**

9
10 **15.1 Authority**

11
12 These rules and regulations are promulgated pursuant to Section 25-4-1614(10), of the
13 Colorado Revised Statutes (C.R.S.), and represent the additional requirements for the
14 production of tier 2 cottage foods.

15
16 **15.2 Scope and Purpose**

- 17
18 A. This regulation shall govern the production and sale of tier 2 cottage foods produced
19 under the Colorado Cottage Food Act, Section 25-4-1614, C.R.S.
20
21 B. This regulation does not apply to:
- 22 1. Retail food establishments as defined in Section 25-4-1602(14), C.R.S.;
 - 23 2. Wholesale food manufacturer or storage facility as defined in Section 25-5-
24 426(2)(f), C.R.S.;
 - 25 3. Tier 2 cottage food producers who earn more than ten thousand dollars in net
26 revenue per year from the sale of each eligible food product produced;
 - 27 4. Individuals or business producing food items not allowed by Section 25-4-
28 1614(2)(b)(I), C.R.S.;
 - 29 5. Production of Tier 1 foods as defined in Section 25-4-1614(2)(a)(b)(I)(A), C.R.S.
- 30
31 C. Tier 2 cottage food producers are not subject to the requirements of the Colorado
32 Retail Food Establishment Rules and Regulations and the Wholesale Food Regulations
33 Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human
34 Food.
35

36 **15.3 Applicability**

- 37 A. These rules and regulations shall apply to tier 2 cottage foods produced as defined in
38 Section 25-4-1614(2)(b)(I), C.R.S.
39

40 **15.4 Definitions**

- 41 A. The following definitions shall apply in the interpretations and the enforcement of
42
43
44
45
46
47
48

49 these regulations unless the context clearly states otherwise:
50

- 51 1. Adulterated means as stated in the *Colorado Pure Food and Drug Act*, Section
52 25-5-410, C.R.S.
- 53
54 2. Contamination means the presence of infectious microorganisms or chemicals
55 at levels toxic to human health in or on the body, environmental surfaces,
56 articles of clothing, and/or in food or water.
- 57
58 3. Department means Colorado Department of Public Health and Environment or
59 its authorized agents or employees.
- 60
61 4. Drinking Water means water that meets criteria as specified in Section 25-1.5-
62 2, C.R.S., *Colorado Primary Drinking Water Regulations*. Drinking water is
63 traditionally known as "potable water."
- 64
65 5. Equilibrium pH means the condition achieved when all components, liquid and
66 solid, have the same pH.
- 67
68 6. Fermented Vegetables means live probiotic vegetables that are exposed to
69 conditions that allow acid-producing microorganisms to reduce the pH to 4.6 or
70 lower and includes the foods commonly referred to as kimchi and sauerkraut.
- 71
72 7. Food Contact Surfaces means those surfaces of equipment and utensils with
73 which food normally comes in contact, including surfaces which food may
74 drain, drip, or splash back onto.
- 75
76 8. Home means a primary residence occupied by the producer producing cottage
77 food.
- 78
79 9. Low-acid Vegetables means vegetables have a pH above 4.6. The acidity in
80 these vegetables is insufficient to prevent the growth of the bacterium
81 *Clostridium botulinum*.
- 82
83 10. Nonpotentially Hazardous means, for the purpose of this regulation, any food
84 that when stored under normal conditions without refrigeration, will not
85 support the rapid and progressive growth of microorganisms that cause food
86 infections or food intoxications.
- 87
88 11. pH means a numeric scale used to specify the acidity or alkalinity of a solution
89 or product. Solutions or products with a pH less than 7 are acidic and solutions
90 with a pH greater than 7 are alkaline or basic.
- 91
92 12. Pickled Vegetables means low-acid vegetables that have been preserved in
93 vinegar, brine, or a similar solution resulting in a finished product equilibrium
94 pH of 4.6 or lower.
- 95
96 13. Process Authority means person(s) or organization(s) having expert knowledge

- 97 of pickling processing requirements who examines the recipe for ingredients,
98 preparation methods, product packaging and storage, and food safety
99 precautions required to produce a safe product. A process authority must have
100 access to facilities for making such determinations.
101
- 102 14. Process Plan means a plan for the manufacture of Tier 2 foods that includes the
103 product(s) to be produced, standardized recipes, and lab analysis.
104
- 105 15. Producer means a person who prepares nonpotentially hazardous foods in a
106 home kitchen or similar venue for sale directly to consumers. A producer may
107 only be:
108
- 109 a. An individual who is a resident of Colorado; or
110
- 111 b. A limited liability company formed in Colorado, consisting of two or
112 fewer members, and of which all members are residents of Colorado.
113
- 114 c. For the purposes of this regulation, Producer only applies to tier 2
115 producers.
116
- 117 16. Production Kitchen means a home kitchen or commercial, private or public
118 kitchen used for the production of tier 2 cottage foods.
119
- 120 17. Registrant means a producer of tier 2 cottage foods.
121
- 122 18. Registration means the enrollment process required by the Department and
123 completed by a producer to become eligible to produce tier 2 cottage foods
124 under the *Colorado Cottage Food Act*, Section 25-4-1614, C.R.S.
125
- 126 19. Sanitizer means an effective bactericidal treatment by a product that is
127 registered with the U.S. Environmental Protection Agency and provides enough
128 concentration of chemicals for sufficient time to reduce the bacterial count,
129 including pathogens, to a safe level.
130
- 131 20. Single-Use Gloves means food-grade gloves used for only one task, discarded
132 when damaged, or when the task is complete. Multi-use gloves are prohibited.
133
- 134 21. Standardized Recipe means a process authority approved recipe that has been
135 tested for consistency of product.
136
- 137 22. Tier 2 Cottage Food means pickled vegetables that have an equilibrium pH
138 value of 4.6 or lower.
139
- 140 23. Venue means the location where a consumer takes possession of the tier 2
141 cottage food product, which includes, but is not limited to, the producer's
142 premises, the producer's roadside stand, a farmer's market, a community
143 supported agriculture organization, and other similar venues where the product
144 is sold directly to consumers.

145 24. Wholesome means food found in sound condition, clean, free from adulteration
146 and otherwise suitable for human consumption.
147

148 **15.5 General Requirements**
149

150 A. Tier 2 producers shall be in good health and be free from communicable disease while
151 preparing cottage food.
152

153 B. The production kitchen and storage areas used to produce tier 2 cottage food products
154 shall be maintained in a clean and sanitary condition and free of pests.
155

156 C. Producers shall wash their hands and exposed portions of their arms for at least 20
157 seconds with soap and warm running water and dry with single-use towels:
158

159 1. Before and during food preparation, as necessary;
160

161 2. After engaging in any activities that contaminate their hands and/or exposed
162 portions of their arms, including, but not limited to, before leaving the
163 restroom, after caring for animals or dependents, and before putting on single-
164 use gloves, if used, and;
165

166 3. Hand antiseptics/sanitizers may not be used in place of proper handwashing.
167

168 D. All food contact surfaces, equipment, and utensils used for the preparation or
169 packaging of any tier 2 cottage food products shall be appropriate for food production
170 and maintained in good repair.
171

172 E. Food contact surfaces and utensils shall be washed, rinsed, sanitized, and air dried
173 before each use.
174

175 1. Sanitizers shall have a U.S. Environmental Protection Agency registration
176 number, be designated as a food contact surface sanitizer, and be used in
177 accordance with labeled instructions, including concentration, contact time,
178 method, and surfaces.
179

180 2. Household bleach used shall be free of compounds to enhance the scent or
181 other compounds that may adversely affect its use as a sanitizer.
182

183 3. Sanitizers must be properly stored.
184

185 **15.6 Product Labels**
186

187 A. Tier 2 cottage foods shall have an affixed label in accordance with the requirements
188 outlined in Section 25-4-1614(3)(a), C.R.S., that includes:
189

190 1. Identification of the product;
191

192 2. The producer's name and address at which the food was prepared;

- 193 3. The producer’s current telephone number or electronic mail address;
194
195 4. The date on which the food was produced;
196
197 5. A complete list of ingredients;
198
199 6. Registration number as issued by the Department; and
200
201 7. The following disclaimer: “This product was produced in a home kitchen that is
202 not subject to state licensure or inspection and that may also process common
203 food allergens such as tree nuts, peanuts, eggs, soy, wheat, milk, fish, and
204 crustacean shellfish. This product is not intended for resale.”
205

206 **15.7 Point of Sale**

- 207
208 A. Products produced under 25-4-1614(2)(b)(I), C.R.S., shall be sold from avenue as
209 defined in 15.4(A)(25) directly to the ultimate consumer and shall not be sold or
210 distributed outside of Colorado.
211
212 B. A producer shall not in any way display, convey or imply that the products produced
213 and offered for sale or distribution are endorsed, approved, or certified by the
214 Department.
215
216 C. A producer selling tier 2 cottage foods shall conspicuously display a placard, sign, or
217 card at the point of sale and/or website with the following disclaimer:
218
219 1. “This product was produced in a home kitchen that is not subject to state
220 licensure or inspection. This product is not intended for resale.”
221

222 **15.8 Tier 2 Cottage Food Producer Requirements**

- 223
224 ~~A. Cottage food producers producing Tier 2 foods as defined in Section 15.4(A)(24), shall~~
225 ~~meet the following additional requirements.~~
226

227 **15.8.1 Registration**

- 228
229 A. Tier 2 cottage food producers shall register with the Department by no later than 60
230 days after the effective date of these regulations, and on or before January 1 of each
231 year thereafter on a form supplied by the Department. Tier 2 cottage food producers
232 that begin production after January 1, shall register with the Department immediately
233 upon beginning production of cottage foods.
234

235 **15.8.2 Training**

- 236
237 A. Tier 2 cottage food producers shall take a food safety course that includes basic food
238 handling training and comparable to, or is a course given by, the Colorado State
239 University extension service or a state, county, or district public health agency.
240

- 241 | 1. Curriculum shall include:
242 |
243 | a. Hygienic practices;
244 |
245 | b. Food handling;
246 |
247 | c. Sanitation;
248 |
249 | d. Household vector; and
250 |
251 | e. Labeling, record keeping, and other best practices.
252 |
253 | B. Tier 2 cottage food producers shall complete additional course work that concentrates
254 | on the pickling and fermentation of vegetables.
255 |
256 | C. Proof of food handler training shall be provided at the time of registration and
257 | annually for registration renewal.
258 |

259 | **15.8.3 Water Quality Testing**

- 260 |
261 | A. Tier 2 cottage food producers shall provide proof of available safe drinking water in
262 | the production kitchen used to produce the Tier 2 Cottage Food. Proof may consist of:
263 |
264 | 8. Municipal/city water bill from a Colorado public water system; or
265 |
266 | 9. Annual well water testing results for total coliforms and nitrates from a
267 | certified water testing laboratory.
268 |
269 | B. Proof of water quality shall be provided at the time of registration and with each
270 | annual registration renewal.
271 |

272 | **15.8.4 Sewage Disposal**

- 273 |
274 | A. Tier 2 cottage food producers shall provide proof of appropriate sewage disposal in the
275 | production kitchen used to produce the Tier 2 cottage food. Proof may consist of:
276 |
277 | 1. Municipal/city wastewater disposal bill from a Colorado public wastewater
278 | system; or
279 |
280 | 2. Current septic permit or septic inspection results.
281 |
282 | B. Proof of sewage disposal shall be provided at the time of registration and with each
283 | annual registration renewal.
284 |

285 | **15.8.5 Process Review**

- 286 |
287 | A. At the time of registration, Tier 2 cottage food producers shall provide a process plan
288 | to the Department for review prior to the production of any Tier 2 foods. Process plans

289 may include, but are not limited to:

- 290
- 291 1. A public domain of standardized recipes; or
 - 292
 - 293 2. pH test results from a laboratory to assure an equilibrium pH of 4.6 or lower; or
 - 294
 - 295 3. A letter of approval from a process authority.

296

297 **15.8.6 Recordkeeping**

- 298
- 299 A. Finished pH values and equilibrium pH values shall be recorded for every five hundred
 - 300 jars or at minimum once a year for Tier 2 cottage food produced. Copies of all records
 - 301 shall be maintained and available to the Department for three years from the date of
 - 302 the batch.

303

304 **15.9 Enforcement**

305

306 **15.9.1 General**

- 307
- 308 | A. A food product produced pursuant to the regulation is subject to food sampling
 - 309 | inspection, and seizure by the Department or a county, district, or regional health
 - 310 | agency pursuant to Section 25-5-406, C.R.S. of the Pure Food and Drug Law, if it is
 - 311 | determined that the food product is misbranded, **adulterated** or if a consumer
 - 312 | complaint has been received or if the product is suspected in an injury or foodborne
 - 313 | illness outbreak.
 - 314
 - 315 | B. Tier 2 cottage food producers shall be given a reasonable time to comply with the
 - 316 | registration and labeling requirements of the law and the process controls established
 - 317 | in section 15.8.5.

318

319 ~~15.10.2 Tier 2 Registration and Revenue~~

320

321 ~~Tier 2 cottage food products produced and entered into commerce without~~

322 ~~registration may be confiscated and destroyed by the Department. In such cases,~~

323 ~~subsequent production of the cottage food is not allowed until the producer registers~~

324 ~~with the Department.~~

325

326 ~~Tier 2 cottage food producers earning net revenues in excess of those allowed under~~

327 ~~Section 25-4-1614(2)(e), C.R.S. will have their cottage food registration revoked. Such~~

328 ~~producers shall immediately cease cottage food production activities and contact the~~

329 ~~Department for further instructions on registering as a wholesale food manufacturer or~~

330 ~~retail food establishment operator in accordance with Section 25-5-426(4)(a) and 25-4-~~

331 ~~1606 C.R.S.~~

332

333 ~~15.10.3 Training, Process Controls, and Labeling~~

334

335 ~~Tier 2 Cottage cottage food producers which fail to secure and maintain current~~

336 ~~training as required in Sections 15.98.2 and 15.10.2 and 25-4-1614(2)(C), C.R.S. are~~

337 | ~~not eligible for registration and/or annual registration renewal.~~

338 | ~~Tier 2 cottage foods produced and entered into commerce without following process~~
339 | ~~controls detailed in their registration application may be confiscated and destroyed by~~
340 | ~~the Department. In such cases, subsequent production of the cottage food is not~~
341 | ~~allowed until the amended registration is reviewed by the Department.~~

342 | ~~Cottage food products entered into commerce without proper labeling may be~~
343 | ~~confiscated and destroyed by the Department. In such cases, subsequent production of~~
344 | ~~the cottage food is not allowed until all required labeling is affixed to the cottage~~
345 | ~~food products and reviewed by the Department.~~

346 | **15.109.2 Penalties**

- 347 | A. If the Department finds that a ~~person is not in conformance with these rules and~~
348 | ~~regulations or the provisions of 25-4-1614 et. seq., C.R.S., the Department may assess a~~
349 | ~~civil penalty of five hundred dollars (\$500).~~ Tier 2 cottage food producer is in
350 | violation of Section 15.9.1 they will be subject to the enforcement provisions of the
351 | Pure Food and Drug Law.