

[PROPOSED COTTAGE FOOD REGULATION SHM #5 \(03/01/16\)](#)

**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 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 Labeling .....	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 .....	6
15.8.3	Water Quality Testing .....	6
15.8.4	Sewage Disposal .....	6
15.8.5	Process Review .....	7
15.8.6	Recordkeeping .....	7
15.9	Enforcement .....	7
15.9.1	General.....	7
15.9.2	Penalties .....	8

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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.).  
14

15 15.2 Scope and Purpose

16  
17 A. This regulation shall govern the production and sale of Tier 2 Cottage Foods produced  
18 under the Colorado Cottage Food Act, Section 25-4-1614, C.R.S.  
19

20 B. This regulation does not apply to:

- 21  
22 1. Retail food establishments as defined in Section 25-4-1602(14), C.R.S.;
- 23  
24 2. Wholesale food manufacturer or storage facility as defined in Section 25-5-  
25 426(2)(f), C.R.S.;
- 26  
27 3. Cottage food producers who earn more than ten thousand dollars in net  
28 revenue per year from the sale of each eligible food product produced;  
29
- 30 4. Individuals or business producing food items not allowed by Section 25-4-  
31 1614(2)(b)(I), C.R.S.;
- 32  
33 5. Production of Tier 1 foods as defined in Section 25-4-1614(2)(a)(b)(I)(A),  
34 C.R.S..  
35

36 15.3 Applicability

37  
38 A. These rules and regulations shall apply to Tier 2 cottage foods produced as defined in  
39 Section 25-4-1614(2)(b)(I), C.R.S.  
40

41 15.4 Definitions

42  
43 A. The following definitions shall apply in the interpretations and the enforcement of  
44 these regulations unless the context clearly states otherwise:  
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- 46 1. Adulterated means as stated in the *Colorado Pure Food and Drug Act*, Section  
47 25-5-4, C.R.S.  
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2. Contamination means the presence of infectious microorganisms or chemicals at levels toxic to human health in or on the body, environmental surfaces, articles of clothing, and/or in food or water.
  3. Department means Colorado Department of Public Health and Environment or its authorized agents or employees.
  4. Drinking Water means water that meets criteria as specified in Section 25-1.5-2, C.R.S., *Colorado Primary Drinking Water Regulations*. Drinking water is traditionally known as “potable water.”
  5. Equilibrium pH means the condition achieved when all components, liquid and solid, have the same pH.
  6. Fermented Vegetables means vegetables that are exposed to conditions that allow acid-producing microorganisms to reduce the pH to 4.6 or lower and includes the foods commonly referred to as kimchi and sauerkraut.
  7. Food-Contact Surfaces means those surfaces of equipment and utensils with which food normally comes in contact, and those surfaces from which food may drain, drip, or splash back onto surfaces in contact with food.
  8. Home means a primary residence occupied by the producer producing cottage food.
  9. Low-acid Vegetables means vegetables have a pH above 4.6. The acidity in these vegetables is insufficient to prevent the growth of the bacterium *Clostridium botulinum*.
  10. Nonpotentially Hazardous means, for the purpose of this regulation, any food that when stored under normal conditions without refrigeration, will not support the rapid and progressive growth of microorganisms that cause food infections or food intoxications.
  11. pH means is a numeric scale used to specify the acidity or alkalinity of a solution or product. Solutions or products with a pH less than 7 are acidic and solutions with a pH greater than 7 are alkaline or basic.
  12. Pickled Vegetables means low-acid vegetables that have been preserved in vinegar, brine, or a similar solution resulting in finished product pH of 4.6 or lower. Pickled vegetables do not include salsas.
  13. Process Authority means person(s) or organization(s) having expert knowledge of pickling processing requirements and having access to facilities for making such determinations.
  14. Process Plan means a plan for the manufacture of Tier 2 foods that includes the product(s) to be produced, standardized recipes, equipment used in the

- 97 production of these products, along with the products associated labels and lab  
98 analysis.  
99
- 100 15. Producer means a person who prepares nonpotentially hazardous foods in a  
101 home kitchen or similar venue for sale directly to consumers. A producer may  
102 only be:  
103
- 104 a. An individual who is a resident of Colorado; or  
105
- 106 b. A limited liability company formed in Colorado, consisting of two or  
107 fewer members, and of which all members are residents of Colorado.  
108
- 109 c. For the purposes of this regulation, Producer only applies to Tier 2  
110 producers.  
111
- 112 17. Production Kitchen means a home kitchen or commercial, private or public  
113 kitchen or similar venue for sale directly to consumers.  
114
- 115 18. Registrant means a producer of Tier 2 cottage foods.  
116
- 117 19. Registration means the enrollment process required by the Department and  
118 completed by a producer to become eligible to produce Tier 2 cottage foods  
119 under the *Colorado Cottage Food Act*, Section 25-4-1614, C.R.S.  
120
- 121 20. Relish means a cooked or pickled sauce usually made with vegetables or fruits  
122 and often used as a condiment; can contain avocado, mango, etc.  
123
- 124 21. Sanitization means effective bactericidal treatment by a process that provides  
125 enough concentration of chemicals, registered with the U.S. Environmental  
126 Protection Agency, for sufficient time to reduce the bacterial count, including  
127 pathogens, to a safe level.  
128
- 129 22. Single-Use Gloves means gloves used for only one task, discarded when  
130 damaged, or when the task is complete. Multi-use gloves are prohibited.  
131
- 132 23. Standardized Recipe means a recipe that has been tested for consistency of  
133 product. Standardized recipes shall include the common name of the product;  
134 the ingredients; the exact weight or volume of each ingredient; preparation  
135 instructions; cooking time and temperatures, if required, time necessary to  
136 achieve an equilibrium pH of 4.6 or lower; and serving size or recipe yield.  
137
- 138 24. Tier 2 Cottage Food means pickled vegetables that have an equilibrium pH  
139 value of 4.6 or lower.  
140
- 141 25. Venue means the location where a consumer purchases and takes possession of  
142 the cottage food product, which includes, but is not limited to, the producer's  
143 premises, the producer's roadside stand, a farmer's market, a community  
144 supported agriculture organization, , and other similar venues where the

145 product is sold directly to consumers. This does not include internet sales,  
146 grocery stores, restaurants, and other licensed retail food establishments and  
147 food manufacturers.

148  
149 26. Wholesome means food found in sound condition, clean, free from adulteration  
150 and otherwise suitable for human consumption.

151  
152 **15.5 General Requirements**

153  
154 A. Tier 2 producers shall be in good health and be free from communicable disease while  
155 preparing cottage food. Reportable communicable diseases and disease outbreaks shall  
156 immediately be reported to the Department.

157  
158 B. The kitchen and storage areas used to produce cottage food products shall be  
159 maintained free of rodents and insects.

160  
161 C. Producers shall wash their hands and exposed portions of their arms for at least 20  
162 seconds with soap and warm running water and dry with single-use towels:

- 163  
164 1. Before and during food preparation, as necessary;  
165  
166 2. After engaging in any activities that contaminate their hands and or exposed  
167 portions of their arms including but not limited to before leaving the restroom,  
168 after handling soiled equipment or utensils, after caring for animals or  
169 children, after engaging in other domestic activities such as personal cooking,  
170 laundry, smoking, eating, or telephone use, and before putting on single-use  
171 gloves and;

172  
173 3. Hand antiseptics/sanitizers may be used in addition to but not in place of  
174 proper handwashing.

175  
176 F. All food contact surfaces, equipment, and utensils used for the preparation or  
177 packaging of any cottage food products shall be maintained in good repair, washed,  
178 rinsed, and sanitized before each use.

179  
180 1. Sanitizers shall have a U.S. Environmental Protection Agency registration  
181 number and designation as a food contact surface sanitizer, be registered with  
182 the Colorado Department of Agriculture, and used in accordance with labeled  
183 instructions and 40 CFR 180.940 including concentration, contact time,  
184 method, and surfaces.

185  
186 2. Household bleach used shall be free of compounds to enhance the scent or  
187 other compounds that may adversely affect its use as a sanitizer.

188  
189 **15.6 Product Labeling**

190  
191 A. Cottage foods shall be labeled in accordance with the requirements outlined in Section  
192 25-4-1614(3)(A), C.R.S., and include an affixed label that includes:

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208
1. Identification of the product;
  2. The producer’s name and current telephone number or electronic mail address;
  3. The address at which the food was prepared;
  4. Registration number as issued by the Department;
  5. A complete list of ingredients; and
  6. The following disclaimer: “This product was produced in a home kitchen that is not subject to state licensure or inspection and that may also process common food allergens such as tree nuts, peanuts, eggs, soy, wheat, milk, fish, and crustacean shellfish. This product is not intended for resale.”

209 B. Labels shall conform to standard labeling guidance.

210  
211 C. ~~Eggs sold under Section 25-4-1614(2)(b)(II), C.R.S., shall be labeled in accordance with~~  
212 ~~Section 35-21-105, C.R.S.~~

213  
214 **15.7 Point of Sale**

215  
216 A. Products produced under 25-4-1614(2)(b)(I), C.R.S., must be sold from an appropriate  
217 venue directly to the ultimate consumer and shall not be sold or distributed outside of  
218 Colorado.

219  
220 B. A producer shall not in any way display, convey or infer that the products produced  
221 and offered for sale or distribution are endorsed, approved, or certified by the  
222 Department or its authorized agents or employees.

223  
224 C. A producer selling cottage foods shall conspicuously display a placard, sign, or card at  
225 the point of sale with the following disclaimer:

- 226  
227 1. “This product was produced in a home kitchen that is not subject to state  
228 licensure or inspection. This product is not intended for resale.”

229  
230 **15.8 Tier 2 Cottage Food Producer Requirements**

231  
232 A. Cottage food producers producing Tier 2 foods as defined in Section 15.4(A)(24), shall  
233 meet the following additional requirements.

234  
235 **15.8.1 Registration**

236  
237 A. Tier 2 cottage food producers shall register with the Department by no later than 60  
238 days after the effective date of these regulations, and on or before January 1 of each  
239 year thereafter on a form supplied by the Department. Tier 2 cottage food producers  
240 that begin production after January 1, shall register with the Department immediately

241 upon beginning production of cottage foods.

242

### 243 15.8.2 Training

244

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

248

249 B. Tier 2 cottage food producers shall complete additional course work that concentrates  
250 on the pickling and fermentation of vegetables.

251

252 C. Proof of food handler training shall be provided at the time of registration and  
253 annually for registration renewal.

254

255 D. Curriculum shall include:

256

257 1. Hygienic Practices;

258

259 2. Food Handling;

260

261 3. Sanitation;

262

263 4. Household Vector; and

264

265 5. Labeling, Record Keeping, and other best practices.

266

### 267 15.8.3 Water Quality Testing

268

269 A. Tier 2 cottage food producers shall provide proof of available safe drinking water in  
270 the production kitchen used to produce the Tier 2 Cottage Food. Proof may consist of:

271

272 1. Municipal/city water bill from a Colorado public water system; or

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274 2. Annual well water testing results for total coliforms and nitrates from a  
275 certified water testing laboratory.

276

277 B. Proof of water quality shall be provided at the time of registration and with each  
278 annual registration renewal.

279

### 280 15.8.4 Sewage Disposal

281

282 A. Tier 2 cottage food producers shall provide proof of appropriate sewage disposal in the  
283 production kitchen used to produce the Tier 2 cottage food. Proof may consist of:

284

285 1. Municipal/city wastewater disposal bill from a Colorado public wastewater  
286 system; or

287

288 2. Current septic permit or septic inspection results.

289  
290 B. Proof of sewage disposal shall be provided at the time of registration and with each  
291 annual registration renewal.  
292

### 293 15.8.5 Process Review

294  
295 A. At the time of registration, Tier 2 cottage food producers shall provide a process plan  
296 to the Department for review prior to the production of any Tier 2 foods. Process plans  
297 may include, but are not limited to:

- 298  
299 1. A public domain of standardized recipes; or  
300  
301 2. pH test results from a laboratory to assure an equilibrium pH of 4.6 or lower; or  
302  
303 3. A letter of approval from a process authority.  
304

### 305 15.8.6 Recordkeeping

306  
307 A. Finished pH values and equilibrium pH values shall be recorded for every five hundred  
308 jars or at minimum once a year for Tier 2 cottage food produced. Copies of all records  
309 shall be maintained and available to the Department for three years from the date of  
310 the batch.  
311

## 312 15.9 Enforcement

### 313 15.9.1 General

314  
315  
316 A. A food product produced pursuant to the regulation is subject to food sampling  
317 inspection, and seizure by the Department or a county, district, or regional health  
318 agency pursuant to Section 25-5-406, C.R.S. of the Pure Food and Drug Law, if it is  
319 determined that the food product is misbranded, adulterated or if a consumer  
320 complaint has been received or if the product is suspected in an injury or foodborne  
321 illness outbreak.  
322

323 B. Tier 2 cottage food producers shall be given a reasonable time to comply with the  
324 registration and labeling requirements of the law and the process controls established  
325 in section 15.8.5.  
326

### 327 ~~15.10.2 Tier 2 Registration and Revenue~~

328  
329 ~~Tier 2 cottage food products produced and entered into commerce without~~  
330 ~~registration may be confiscated and destroyed by the Department. In such cases,~~  
331 ~~subsequent production of the cottage food is not allowed until the producer registers~~  
332 ~~with the Department.~~  
333

334 ~~Tier 2 cottage food producers earning net revenues in excess of those allowed under~~  
335 ~~Section 25-4-1614(2)(e), C.R.S. will have their cottage food registration revoked. Such~~  
336 ~~producers shall immediately cease cottage food production activities and contact the~~

337 Department for further instructions on registering as a wholesale food manufacturer or  
338 retail food establishment operator in accordance with Section 25-5-426(4)(a) and 25-4-  
339 1606 C.R.S.

340  
341 **15.10.3 Training, Process Controls, and Labeling**

342  
343 ~~Tier 2 Cottage cottage food producers which fail to secure and maintain current~~  
344 ~~training as required in Sections 15.98.2 and 15.10.2 and 25-4-1614(2)(C), C.R.S. are~~  
345 ~~not eligible for registration and/or annual registration renewal.~~

346  
347 ~~Tier 2 cottage foods produced and entered into commerce without following process~~  
348 ~~controls detailed in their registration application may be confiscated and destroyed by~~  
349 ~~the Department. In such cases, subsequent production of the cottage food is not~~  
350 ~~allowed until the amended registration is reviewed by the Department.~~

351  
352 ~~Tier 2 Cottage cottage food products entered into commerce without proper labeling~~  
353 ~~may be confiscated and destroyed by the Department. In such cases, subsequent~~  
354 ~~production of the cottage food is not allowed until all required labeling is affixed to~~  
355 ~~the cottage food products and reviewed by the Department.~~

356  
357 **15.109.2 Penalties**

- 358  
359 A. If the Department finds that a ~~person is not in conformance with these rules and~~  
360 ~~regulations or the provisions of 25-4-1614 et. seq, C.R.S., the Department may assess a~~  
361 ~~civil penalty of five hundred dollars (\$500). Tier 2 cottage food producer is in~~  
362 ~~violation of Section 15.9.1 they will be subject to the enforcement provisions of the~~  
363 Pure Food and Drug Law.