Cannabis Products Safety Education:
Records and Recalls

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Department of Food Science and Technology
University of California, Davis
University of California Division of Agriculture and Natural Resources
Record-keeping requirements (26160)

- Licensee shall keep accurate records of commercial cannabis activity
- Maintained for a minimum of seven years
- Licensee shall provide records upon request
- Kept on the premises of the licensed location
- Refusal to provide records is a violation
- Failure to maintain or provide records shall result in a citation and fine (up to $30,000)
Batch Production Record (40258)

- Written batch production record every time a batch of cannabis product is manufactured
- Shall include:
  - UID and the batch or lot number of cannabis product and UIDs of all cannabis or cannabis products used in the batch
  - Equipment and processing lines used in producing the batch
  - Date and time of maintenance, cleaning, and sanitizing of the equipment and processing lines used in producing the batch or cross reference to corresponding records
  - The identity and weight or measure of each component used
  - Statement of the actual yield and a percentage of expected yield at appropriate phases of processing
  - Actual results obtained during any monitoring operation
  - Results of any testing or examination performed during batch production or cross reference to such results
  - Certificate of Analysis issued for the batch by the licensed testing laboratory which shall be added to the record after regulatory compliance testing has been completed
Batch Production Record (40258)

• Contain actual values and observations obtained during monitoring and during verification activities
• Be accurate, indelible, and legible
• Be created concurrently with performance of the activity documented
• Be as detailed as necessary to provide a history of work performed
  • Information to identify any associated manufacturing premises
  • The date and time the activity was performed
  • The signature or initials of the person performing the activity
  • The identity of the product, the UID, and the batch or lot number
Types of records: GMPs and Product Quality Plan

**Verification**

Article 3, §40230, (x)

Application of methods, procedures, tests, or other evaluations, in addition to monitoring, to determine whether a control measure or combination of controls measures is or has been operating as intended to establish the validity of the quality control procedures.

**Validate**

Article 3, §40230, (w)

Obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or quality control procedures as a whole, when properly implemented, is capable of ensuring the quality of a cannabis product or effectively controlling an identified hazard.

**Monitor**

Article 3, §40230, (i)

Conduct a planned sequence of observations or measurements to assess whether preventive measures are operating as intended.
Good Manufacturing Practices

1. Facility
   - Cleaning and sanitation
   - Pest control

2. Equipment
   - Cleaning and sanitation
   - Storage
   - Maintenance/repair
   - Temperature monitoring

3. Personnel
   - Training
Periodic monitoring of continuous temperature record on cooler

E.X. Company
123 Happy Lane
Productivity, USA

Temperature Chart
(Cooler #1)
2/3 – 2/9/2014

Temperature limit met?
Yes/No _________

Reviewed by: ___________
Review date: ___________
Employee Training Record

- Records could be kept in individual personnel files and summarized for easy access as follows:

<table>
<thead>
<tr>
<th>Employee Training Course</th>
<th>Location</th>
<th>Date Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personal hygiene training</td>
<td>Quality Assurance Manager</td>
<td>November 15, 2020</td>
</tr>
<tr>
<td>ServSafe Food Handler training</td>
<td>Safe Food Alliance</td>
<td>February 28, 2020</td>
</tr>
<tr>
<td>Good manufacturing practices (GMPs)</td>
<td>Cornell University Distance Learning Center</td>
<td>March 15, 2020</td>
</tr>
<tr>
<td>ServSafe Manager training</td>
<td>Safe Food Alliance</td>
<td>March 1, 2020</td>
</tr>
</tbody>
</table>

Date issued: dd/mm/yy
Supersedes: dd/mm/yy
## Sanitation record example

### Daily Sanitation Control Record – Cannabis infused chocolate chip cookie with pecans

<table>
<thead>
<tr>
<th>DATE:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Condition &amp; Cleanliness of Food Contact Surfaces</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Equipment cleaned and sanitized (S/U)*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Sanitizer type and strength: <em>Quaternary ammonium compound, 200 ppm</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Cookie line (ppm)*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Dish room dip tank (ppm)*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Prevention of Cross-Contact</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Cleaning after cookies with pecan (S/U/NA)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Condition &amp; Cleanliness of Non-food Contact Surfaces</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Floors and wall splash zones cleaned and sanitized (S/U)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Sanitizer type and strength: <em>Quaternary ammonium compound, 400-600 ppm</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Floors and wall splash zones (ppm)*</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

* S = Satisfactory, U = Unsatisfactory  
+ Enter ppm measured per test strip  
& NA = not applicable because pecan cookies run after other products

Verification signature: Date:
Product Quality (Safety) Plan

Evaluate potential risks to cannabis product quality (safety)
• Hazard identification (analysis)

Implement preventive measure to mitigate each potential risk
• Determine critical control points
• Establish critical limits/Validation

Identify methods to evaluate and monitor the effectiveness of preventive measures to mitigate identified potential risks
• Monitoring
• Corrective actions
• Verification
Cooking as a “preventive measure” for *Salmonella* in cookies

**Form Title: Daily Cooker Temperature Log**

- **Firm Name:**
- **Firm Location:**
- **UID:**
- **Lot Number:**
- **Product Identification:** Cannabis infused chocolate chip cookie with pecans
- **Operational Limits:** Oven temperature 350°F, 15 minutes
- **Critical Limits:** Oven temperature 350°F, 8 minutes

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Oven Number</th>
<th>Oven Temp (°F)</th>
<th>Cook Time (minutes)</th>
<th>Critical Limit Met (Yes/No)</th>
<th>Oven Operator (Initials)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

**Verification Reviewer Signature:** Date of Review:

**Date issued:** dd/mm/yy

**Supersedes issue:** dd/mm/yy

Required as this is a hazard that requires a preventive measure.
Allergen label check as “preventive measure”

**Form Title:** Allergen Label Check Monitoring Log  
**Firm Name:**  
**UID:**  
**Product Identification:** Cannabis infused chocolate chip cookies with pecans  
**Parameters:** All finished product labels must declare the allergens present in the formula:

Allergens on label: *wheat, eggs, milk, pecans*

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Lot Number</th>
<th>Proper Label Applied (Yes/No)</th>
<th>Line Operator (Initials)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

**Verification Reviewer Signature:**  
**Date of Review:**  
**Date issued:** dd/mm/yy  
**Supersedes issue:** dd/mm/yy
## Corrective Action example for allergen preventive measure

**Corrective Action Form**

<table>
<thead>
<tr>
<th>Firm Name:</th>
<th>Firm Location:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

**Product:** Cannabis infused chocolate chip cookies with pecans

**UID:**

**Date of Record:** 6 February 2020

**Code or Lot Number:** AY123

**Date and Time of Deviation:** 2:15 pm, 5 February 2020

**Description of Deviation:** Labels for cannabis infused chocolate chip cookies with pecans did not include pecans because the operator selected the wrong stack of labels. The issue was discovered by the operator loading packages into cases.

**Actions Taken to Restore Order to the Process:**
1. Production was halted when error was discovered.
2. Product was segregated back to the last good check.
3. Product was relabeled with the correct label.
4. Line operator was retrained on how to check the label before placing a new stack on the line and the importance of doing so. The procedure was emphasized with all operators as a teachable moment.

**Person (name and signature) of Person Taking Action:** P.K. Lead  Pat K Lead

**Amount of Product Involved in Deviation:** 50 packages

**Evaluation of Product Involved with Deviation:** All relabeled product was double checked to ensure that the correct label was in place.

**Final Disposition of Product:** Released

**Reviewed by (Name and Signature):**

<table>
<thead>
<tr>
<th>Date of Review:</th>
</tr>
</thead>
</table>
Form Title: Daily Thermometer Accuracy Verification Log

Firm Name: Firm Location:

Product Identification: Cannabis infused chocolate chip cookie with pecans

**Verification**: Check each thermometer daily for accuracy. Temperature must be $\pm x{^\circ}F$ from the standard.

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Instrument Number</th>
<th>Boiling Water Check</th>
<th>Within Specification (Yes/No)</th>
<th>Line Operator (Initials)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

**Verification Reviewer Signature**:  
Date issued: dd/mm/yy  
Supersedes issue: dd/mm/yy
**Thermometer Calibration Record Example**

**Form Title:** Quarterly Thermometer Calibration Log

**Product Identification:** Check each thermometer quarterly against a thermometer traced to a recognized standard. Temperature must be ±x°F from the standard.

<table>
<thead>
<tr>
<th>Date of Calibration</th>
<th>Instrument Number(s)</th>
<th>Method of Calibration</th>
<th>Calibration Results</th>
<th>Within Specification (Yes/No)</th>
<th>Line Operator (Initials)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Verification:** Reviewer Signature: Date of Review:

Date issued: dd/mm/yy  Supersedes issue: dd/mm/yy
Validation Records, When Applicable

• Potential information used to support decisions made in the Product Quality Plan
  • Process authority validation records
  • In-plant studies or challenge studies
  • Information on emerging hazards
  • Recognized academic or research institution studies
  • Peer reviewed journal articles
  • Industry or regulatory guidance documents
  • Lack of customer and consumer complaints related to food safety
Validation of kill step in cookies

Research Note

Survival of *Salmonella* during Baking of Peanut Butter Cookies

AMANDA A. LATHROP,† TIFFANY TAYLOR, AND JAMES SCHNEPF

Food Science and Nutrition Department, California Polytechnic State University, San Luis Obispo, California 93407, USA

MS 13-408: Received 27 September 2013/Accepted 18 November 2013

ABSTRACT

Peanuts and peanut-based products have been the source of recent *Salmonella* outbreaks worldwide. Because peanut butter is commonly used as an ingredient in baked goods, such as cookies, the potential risk of *Salmonella* remaining in these products after baking needs to be assessed. This research examines the potential hazard of *Salmonella* in peanut butter cookies when it is introduced via the peanut-derived ingredient. The survival of *Salmonella* during the baking of peanut butter cookies was determined. Commercial, creamy-style peanut butter was artificially inoculated with a five-strain *Salmonella* cocktail at a target concentration of 10⁶ CFU/g. The inoculated peanut butter was then used to prepare peanut butter cookie dough following a standard recipe. Cookies were baked at 350°F (177°C) and were sampled after 10, 11, 12, 13, 14, and 15 min. Temperature profiles of the oven and cookies were monitored during baking. The water activity and pH of the inoculated and uninoculated peanut butter, raw dough, and baked cookies were measured. Immediately after baking, cookies were cooled, and the survival of *Salmonella* was determined by direct plating or enrichment. After baking cookies for 10 min, the minimum reduction of *Salmonella* observed was 4.8 log. In cookies baked for 13 and 14 min, *Salmonella* was only detectable by enrichment reflecting a *Salmonella* reduction in the range of 5.2 to 6.2 log. Cookies baked for 15 min had no detectable *Salmonella*. Results of this study showed that proper baking will reduce *Salmonella* in peanut butter cookies by 5 log or more.

\begin{table}
\centering
\begin{tabular}{|c|c|c|c|c|}
\hline
Time (min) & Center & Side & Corner & Total (\% positive) \\
\hline
10 & 3/3^b & 3/3^c & 3/3 & 9/9 (100) \\
11 & 3/3 & 3/3 & 3/3 & 9/9 (100) \\
12 & 3/3 & 3/3 & 3/3 & 9/9 (100) \\
13 & 1/3 & 1/3 & 2/3 & 4/9 (44) \\
14 & 0/3 & 1/3 & 2/3 & 3/9 (33) \\
15 & 0/3 & 0/3 & 0/3 & 0/9 (0) \\
\hline
\end{tabular}
\caption{Survival of *Salmonella* in peanut butter cookies baked at 350°F when prepared with contaminated peanut butter^a}
\end{table}

^a Peanut butter was inoculated with the bacterium at an average concentration of 8.22 log CFU/g; the average initial *Salmonella* load in the cookie dough was 6.21 log CFU/g.

^b One sample had an estimated plate count of 1.4 log CFU/g.

^c One sample had an estimated plate count of 0.7 log CFU/g.
Resources for kill-step validation for baked goods

- Basic round top cake muffins: *Salmonella*
- Crispy cookies: *Salmonella*
- Cheesecake: *Salmonella*
- Flour tortilla: *Salmonella*
- Fruit filled pastry: *Salmonella*
- Hamburger buns: *Salmonella*
- Nut muffin: *Salmonella*
  
  Soft cookies: *Salmonella*
  100% whole wheat multigrain bread: *Salmonella*
  Yeast raised doughnuts: *Salmonella*
## Validation of kill step in cookies

### Process Data:

<table>
<thead>
<tr>
<th>Time (m)</th>
<th>Core Temp. (°F)</th>
<th>F Value (min)</th>
<th>Log Reduction</th>
<th>Cum. Log Reductions</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.250</td>
<td>100</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>0.500</td>
<td>125</td>
<td>0.06</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>0.750</td>
<td>150</td>
<td>0.49</td>
<td>0.01</td>
<td>0.01</td>
</tr>
<tr>
<td>1.000</td>
<td>175</td>
<td>3.70</td>
<td>0.07</td>
<td>0.08</td>
</tr>
<tr>
<td>1.250</td>
<td>200</td>
<td>28.10</td>
<td>0.52</td>
<td>0.60</td>
</tr>
<tr>
<td>1.500</td>
<td>200</td>
<td>28.10</td>
<td>0.52</td>
<td>1.12</td>
</tr>
<tr>
<td>1.750</td>
<td>200</td>
<td>28.10</td>
<td>0.52</td>
<td>1.64</td>
</tr>
<tr>
<td>2.000</td>
<td>200</td>
<td>28.10</td>
<td>0.52</td>
<td>2.16</td>
</tr>
<tr>
<td>2.250</td>
<td>200</td>
<td>28.10</td>
<td>0.52</td>
<td>2.67</td>
</tr>
<tr>
<td>2.500</td>
<td>200</td>
<td>28.10</td>
<td>0.52</td>
<td>3.19</td>
</tr>
<tr>
<td>2.750</td>
<td>200</td>
<td>28.10</td>
<td>0.52</td>
<td>3.71</td>
</tr>
<tr>
<td>3.000</td>
<td>200</td>
<td>28.10</td>
<td>0.52</td>
<td>4.23</td>
</tr>
<tr>
<td>3.250</td>
<td>200</td>
<td>28.10</td>
<td>0.52</td>
<td>4.75</td>
</tr>
<tr>
<td>3.500</td>
<td>200</td>
<td>28.10</td>
<td>0.52</td>
<td>5.27</td>
</tr>
<tr>
<td>3.750</td>
<td>200</td>
<td>28.10</td>
<td>0.52</td>
<td>5.79</td>
</tr>
</tbody>
</table>

### Diagram

- **Process Lethality:** D-Reductions: 8.39
- **Product Temp. (°F):**
- **Product Time (min):**
E.G. Food Company Omelet Cook Validation Study

Determination of lethal cook temperatures for Salmonella in egg products

Section 3-401.11 (A) (2) of the Food Code (a credible source for science-based recommendations) identifies the following time and temperature combinations as adequate for cooking raw egg-containing products:

• 145°F (63°C) for 3 minutes
• 150°F (66°C) for 1 minute
• 155°F (68°C) for 15 seconds
• 158°F (70°C) for <1 second (instantaneous)

Conclusion: A critical limit of $\geq 158^\circ$F (70°C) for <1 second (instantaneous) will effectively manage the risk of Salmonella in omelets based on the Food Code. Use of pasteurized eggs adds an extra margin of safety.
Determination that a congealed omelet is a valid visual cue for achieving a lethal temperature.

It is well established that coagulation of eggs protein is a function of temperature. Lowe\(^1\) reported that whole egg coagulates at 158°F (70°C), but commented that addition of milk can elevate the coagulation temperature. Stadelman and Cotterill\(^2\) also discuss the influence of non-egg components on elevation of coagulation temperature. Therefore a study was conducted to determine temperatures achieved when omelets coagulated under routine operating conditions and to determine the frequency of temperature measurements.

A calibrated infrared thermometer was used to measure the temperature of the surface of omelets when they were cooked to desired doneness by 10 operators – 5 omelets for each of 10 operators on 3 separate days, for a total of 150 measurements. The omelet batter for each of the 3 separate days used different lots of eggs and milk. Omelets were prepared using standard procedures – one cup of omelet batter was deposited into oiled omelet pans on the high heat setting. Each pan was swirled and edges of the omelet were lifted with a spatula to allow uncooked (liquid) batter to flow under the cooked portion until coagulation was complete, no liquid batter is present, and the surface is no longer shiny.

Conclusion: The minimum temperature observed was 162°F (72°C), which is more than adequate to assure temperatures are above the critical limit of ≥ 158°F (70°C). The maximum temperature observed was 170°F (77°C). Temperatures will be monitored four (4) times per shift to provide ongoing documentation.


Recalls

Licensees shall establish and implement written procedures for recalling cannabis products determined to be misbranded or adulterated

Procedures include:

- Factors that necessitate the recall
- Personnel responsible for implementing the recall procedures
- Notification protocols
  - Customers
  - Licensees that supplied or received product
  - Instructions for general public and licensees to return recalled product
- Procedures for the collection and destruction of recalled products
### Determining if a Recall Action Necessary

<table>
<thead>
<tr>
<th>Problem reported by</th>
<th>Initial Action</th>
<th>Decisions</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory agency believe your product is causing illness</td>
<td>Assemble recall team and ask agency if recall is recommended</td>
<td>If no recall is needed: Document why not and action.</td>
<td>If recall is needed:</td>
</tr>
<tr>
<td>News media story on problem with a type of food you produce</td>
<td>Assemble recall team, review internal records</td>
<td></td>
<td>Assign responsibilities</td>
</tr>
<tr>
<td>Internal QC or customer information suggest a potential problem</td>
<td>Assemble recall team and review internal records</td>
<td></td>
<td>Gather evidence</td>
</tr>
<tr>
<td>Health Department believes your product is causing illness</td>
<td>Assemble recall team, contact appropriate regulatory agency</td>
<td>Evaluate situation: decide if, what and how much product to recall</td>
<td>Analyze evidence</td>
</tr>
</tbody>
</table>

### Information Templates for FDA Communication

**PRODUCT INFORMATION:**
Modify the "Product Description, Distribution, Consumers and Intended Use" form as needed to reflect only the product involved, including:
- Product name (including brand name and generic name)
- Product number/UPC or product identification
- Remove any names of products that are not involved in the recall

Assemble **TWO COMPLETE SETS of ALL labeling** to the Local FDA District Recall Coordinator. Include:
- Product labeling (including ALL private labels)
- Individual package label
- Case label (photocopy acceptable)
- Package inserts
- Directions for Use
- Promotional Material (if applicable)

**CODES (Lot Identification Numbers):**
- **UPC code(s) involved:**
- **Lot number(s) involved:**
- **Lot numbers coding system:** *Describe how to read your product code:*

**Expected shelf life of product:**
### Recall Plan Example

<table>
<thead>
<tr>
<th>PLANT NAME:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ADDRESS:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Position</th>
<th>Name, Title</th>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>RECALL coordinator</td>
<td></td>
<td>Office: xxx-xxx-xxxx</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mobile: xxx-xxx-xxx</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fax: xxx-xxx-xxxx</td>
</tr>
<tr>
<td></td>
<td></td>
<td>email: xxxxxxxxxx</td>
</tr>
<tr>
<td>Most responsible</td>
<td></td>
<td>Office: xxx-xxx-xxxx</td>
</tr>
<tr>
<td>individual</td>
<td></td>
<td>Mobile: xxx-xxx-xxx</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fax: xxx-xxx-xxxx</td>
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<tr>
<td></td>
<td></td>
<td>email: xxxxxxxxxx</td>
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<tr>
<td>Public contact:</td>
<td></td>
<td>Office: xxx-xxx-xxxx</td>
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<tr>
<td></td>
<td></td>
<td>Mobile: xxx-xxx-xxx</td>
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<td></td>
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<td>Fax: xxx-xxx-xxxx</td>
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<tr>
<td></td>
<td></td>
<td>email: xxxxxxxxxx</td>
</tr>
</tbody>
</table>

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**RECALLING FIRM Contacts**

*Provide this information to FDA for clear communication:

**Manufacturer name:** [Name and address]

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**REASON FOR THE RECALL:**

**Explain in detail how product is defective or violative:**

**Explain how the defect affects the performance and safety of the product, including an assessment of a health risk associated with the deficiency, if any:**

**If the recall is due to the presence of a foreign object, describe the foreign objects’ size, composition, hardness, and sharpness:**

**If the recall is due to the presence of a contaminant (cleaning fluid, machine oil, paint vapors), explain level of contaminant in the product. Provide labeling, a list of ingredients and the Material Safety Data Sheet for the contaminant:**

**If the recall is due to failure of the product to meet product specifications, provide the specifications and report all test results. Include copies of any sample analysis:**

**If the recall is due to a label/ingredient issue, provide and identify the correct and incorrect label(s), description(s), and formulation(s):**

**Explain how the problem occurred and the date(s) it occurred:**

**Explain if the problem/defect affects all units subject to recall, or just a portion of the units in the lot subject to recall:**

**Explain why this problem affects only those products/lot subject to recall:**

**Provide detailed information on complaints associated with the product/problem:**

- Date of complaint
- Description of complaint - include details of any injury or illness
- Lot Number involved

*If a State agency is involved in this recall, identify Agency and contact.*
VOLUME OF RECALLED PRODUCT:

Total quantity produced

Date(s) produced

Quantity distributed

Date(s) distributed

Quantity on HOLD

Indicate how the product is being quarantined

- Estimate amount remaining in marketplace
  - distributor level
  - customer level

Provide the status/disposition of marketed product, if known, (e.g., used, used in further manufacturing, or destroyed).

DISTRIBUTION PATTERN:

Number of DIRECT accounts (customers you sell directly to) by type

<table>
<thead>
<tr>
<th>Type</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>wholesalers/distributors</td>
<td></td>
</tr>
<tr>
<td>repackers</td>
<td></td>
</tr>
<tr>
<td>manufacturers</td>
<td></td>
</tr>
<tr>
<td>retail</td>
<td></td>
</tr>
<tr>
<td>consumers (internet or catalog sales)</td>
<td></td>
</tr>
<tr>
<td>federal government consignees</td>
<td></td>
</tr>
<tr>
<td>foreign consignees (specify whether they are wholesale distributors, retailers or users)</td>
<td></td>
</tr>
<tr>
<td>Geographic areas of distribution, including foreign countries</td>
<td></td>
</tr>
</tbody>
</table>

CONSIGNEE LIST

Provide this list to the local District Recall Coordinator. Include US customers, foreign customers and federal government consignees (e.g., USDA, Veterans Affairs, Department of Defense).

Commercial customers

<table>
<thead>
<tr>
<th>Name</th>
<th>Street Address</th>
<th>City</th>
<th>State</th>
<th>Recall contact name</th>
<th>Contact phone number</th>
<th>Recalled product was shipped?</th>
<th>Recalled product was sold?</th>
<th>Recalled product may have been shipped or sold</th>
</tr>
</thead>
</table>

Was product sold under Government Contract?

Yes    No

If yes, include contact name and information above AND complete information below.

<table>
<thead>
<tr>
<th>Contracting Agency</th>
<th>Contract Number</th>
<th>Contract date</th>
<th>Implementation date</th>
</tr>
</thead>
</table>

School Lunch Program:

If product was sold to federal, state or local agency for the school lunch program, complete table and notify "ship to" (so they can retrieve product) and "bill to" customers (so they can initiate the sub-recall).

<table>
<thead>
<tr>
<th>Consignee</th>
<th>Quantity</th>
<th>Sale date</th>
<th>Shipment date</th>
</tr>
</thead>
</table>
## Recall Strategy:

<table>
<thead>
<tr>
<th>Level in the distribution chain</th>
<th>Included</th>
<th>Rationale if &quot;No&quot;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wholesale/Distributor</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Retail</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

### Instructions for Consignee Notification

Write instructions on how consignees will be notified (i.e. by mail, phone, facsimile, e-mail). NOTE: It is advisable to include a written notification so customers will have a record of the recall and your instructions. Include instructions such as:

- How letters will be sent to customers (e.g. overnight mail, first class mail, certified mail, facsimile)
- Draft phone script, if you decide to use phone. NOTE: If initial notification is by phone, be prepared to provide a copy of the phone script to FDA
- Draft recall notification (see example on last page) for website and instructions for posting it, if applicable. NOTE: The web is not recommended as a sole means of customer notification.
- Draft instructions for consignees on what to do with recalled product. If there is a recall, FDA will want a copy of final instructions.
- Consider what to do for out-of-business distributors.

### Effectiveness Checks

Effectiveness checks by account – Consider filling in the consignee’s recall contact name and information to make it easier to contact them in the event of a recall.

<table>
<thead>
<tr>
<th>Consignee</th>
<th>Recall contact</th>
<th>Date contacted</th>
<th>Method of contact</th>
<th>Date of response</th>
<th>Number of products returned or corrected</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

### Effectiveness check summary - to be provided to FDA periodically

<table>
<thead>
<tr>
<th>Date of notification</th>
<th>Method of notification</th>
<th>Number of consignees notified</th>
<th>Number of consignees responding</th>
<th>Quantity of product on hand when notification received</th>
<th>Number of consignees not responding and action taken</th>
<th>Quantity accounted for</th>
<th>Estimated completion date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

### Product destruction/reconditioning

- Provide a proposed method of destruction, if applicable.
- If the product is to be “reconditioned”, explain how and where the reconditioning will take place. It is recommended that you provide details of the reconditioning plan to your local FDA District Recall Coordinator before implementation. All reconditioning must be conducted under any applicable GMPs.
- Describe how reconditioned product will be identified so it is not confused with recalled (pre-reconditioned) product.
- It is recommended that you contact your local FDA District Recall Coordinator prior to product destruction. FDA will review your proposed method of destruction and may choose to witness the destruction.
- You and your customers should keep adequate documentation of product destruction (and whether or not destruction was witnessed by an FDA investigator).
- Field corrections, like product relabeling, be performed by recalling firm representatives, or under their supervision and control. Contact your local FDA District Recall Coordinator prior to release of reconditioned goods.
DRAFT Recall Notice

[Company Name] Voluntarily Recalls [insert summary info] Representing [X quantity] [No Other Products Affected--]

Contact
Consumer:
1-xxx-xxx-xxx

Media Contact:
xxx-xxx-xxxx

FOR IMMEDIATE RELEASE – [date] – [Company name] is voluntarily recalling [X] Lot Codes of [COMPANY/BRAND name] [insert specific product name and description], representing [insert quantity], [insert reason for recall].

This action relates only to [COMPANY NAME] products with any of these Lot Codes printed on the package:

- [insert lot codes]

No other Lot Codes, or any other [COMPANY NAME] products, are involved in this action.

Only these specific lot codes are impacted. Customers are asked to remove all product with codes listed below out of distribution immediately. Customers may call the number listed or visit our website for instructions on what to do with the product.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>LOT CODE</th>
<th>ITEM NO.</th>
</tr>
</thead>
<tbody>
<tr>
<td>[Company Name] [insert product name(s)]</td>
<td>[insert product codes(s)]</td>
<td>[insert item number(s)]</td>
</tr>
</tbody>
</table>

[Company Name] is conducting this voluntary recall because [insert product name(s)] [modify as necessary]. We have not received any reports of illness associated with this product, but we are voluntarily recalling this product out of an abundance of caution.

For more information or assistance, please contact us at 1-xxx-xxx-xxx (Monday to Friday, 9:30 a.m. to 5 p.m. EST) or via our website at www.xxx.com.
January 11, 2021

Cannabis Products Safety Education: Records and Recalls

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