Variance Request Packet

A fill-in cover letter, a worked rationale statement, and the pre-submission checklist — for a food establishment variance under FDA Food Code 8-103.11.

The three things the Code requires

1. A statement of the proposed variance, citing the relevant section.
2. An analysis of the rationale for how the hazards that section addresses will be addressed by your proposal.
3. A HACCP plan, where one is required.

Before you write anything. Ask your health department for its own application form and fee, and ask which code edition and section numbers it enforces. Many departments bill review by the hour, so a weak first submission is the expensive one.

Part A — Cover letter template

Replace everything in [brackets]. Keep the three numbered headings: reviewers look for them.

[Date]

[Name], Environmental Health Division
[County / City] Health Department
[Address]

Re: Variance request — [process, e.g. cold smoking of salmon] — [Business name], permit no. [____]

Dear [Name],

[Business name] requests a variance under [state code section adopting FDA Food Code 8-103.10] for the process described below. Nothing in this process will begin before written approval is received.

1. The requirement we ask to modify. We request a variance from _____ [state code section], which requires a variance before _____ [the activity named in that section].

We propose to: _____ _____
[Say what you will do, with numbers: the food, the process, times and temperatures, packaging, shelf life, where it is sold.]

2. How the hazard will be controlled instead. [See Part B. Name the hazard the rule targets, the barriers you substitute, a number for each, and where each number came from.]

3. HACCP plan. The HACCP plan for this process is attached, covering the products, the food safety issues of concern, a flow diagram identifying each critical control point, the critical limits, the method and frequency of monitoring and of supervisor verification, the corrective actions, and the records kept by the person in charge. Blank copies of every log form are at Appendix [__].

If this variance is granted, [Business name] will comply with its terms.

Yours sincerely,

_____
[Name], [Title] · [Phone] · [Email]

Attachments to list

- **A** HACCP plan
- **B** Flow diagram for each product
- **C** Process authority or lab validation
- **D** Validation batch results
- **E** Blank log forms
- **F** Training plan and staff records
- **G** Product label and shelf-life statement
- **H** [Anything your department asks for]

Part B — The rationale statement

This is the item that decides most reviews. It is not an argument that the rule is unnecessary; it is a demonstration that the hazard the rule exists to prevent is controlled another way.

The four moves

Move	What to write
1. Name the hazard	Which organism or risk the code section exists to control, and why the normal rule controls it
2. Name your barriers	The controls you substitute — ideally more than one, each sufficient on its own
3. Give each a number	A measurable critical limit: a pH, a water activity, a salt concentration, a temperature and time
4. Show where the number came from	Process authority letter, published standard, or laboratory results — attached, not asserted

Worked example (fictional operation)

The hazard the section addresses. The requirement exists because smoking below 135°F does not destroy *C. botulinum* type E spores, which germinate in a reduced oxygen package at refrigeration temperatures, and because *L. monocytogenes* grows on ready-to-eat fish in extended refrigerated storage.

The barriers we substitute. Three independent controls, any one of which prevents toxin formation on its own:

- A brine step producing **water phase salt of 3.5% or higher** in the finished product, verified by laboratory analysis of each production lot.
- **Frozen storage at 0°F or below** from packaging until sale, monitored continuously and logged twice daily.
- A **30-day maximum shelf life** from packaging, printed on every package.

How we know the numbers hold. The 3.5% water phase salt limit comes from [process authority], whose validation letter dated [date] is at Appendix C. Results for three validation lots are at Appendix D. Brine concentration, smoke cycle and freezer temperature are each a critical control point in the attached plan.

What not to write

Avoid	Why it fails
"We have done this for years with no complaints."	Absence of past harm is not evidence of control.
"Our staff are experienced and careful."	A variance is granted to a process, not to people.
"Other businesses locally do this."	Irrelevant to your file, and invites an unhelpful question.
"The product looks and smells fine."	*C. botulinum* toxin changes no taste, smell or appearance.

Your rationale — draft here

Hazard the rule targets	
Barrier 1 + critical limit	
Barrier 2 + critical limit	
Barrier 3 + critical limit	
Source of each limit	

Part C — Pre-submission checklist

Each line below is a documented reason requests get returned. Hourly review fees mean every one you fix now is money kept.

The required items

- ☐ The department's own application form is complete and the **fee is paid** — an unpaid or incomplete file is often not processed at all
- ☐ The **state or county** code section is cited, not only the federal Food Code number
- ☐ The proposed process is described with **numbers**: food, times, temperatures, packaging, shelf life, point of sale
- ☐ The rationale names the **hazard**, the **barriers** and a **limit for each**
- ☐ Every scientific limit has **validation attached** (process authority letter or laboratory results)
- ☐ A **HACCP plan** is attached covering products, hazards, CCPs, limits, monitoring, verification, corrective actions and records
- ☐ A **flow diagram** is included for each product — a written description is not a flow diagram
- ☐ Every CCP states **who** monitors, **how** and **how often**
- ☐ Every CCP has a **corrective action** — "discard the product" is one part of one
- ☐ **Blank copies of every log form** are attached
- ☐ A **training plan** is included
- ☐ A sentence stating you will **comply with the terms** of the variance if granted

Before the field evaluation

- ☐ The **equipment can actually meet the plan** — continuous monitoring, calibrated probes, labelling
- ☐ Staff named in the plan have been **trained and the training recorded**
- ☐ Log forms are **printed and in place** where the work happens
- ☐ Any outstanding **review fees are paid** — several departments require this before they will visit

After approval. Health departments commonly state that no change or modification may be made to an approved variance or HACCP plan without prior review, and that modifications are charged as a new review. Changing the recipe, packaging, equipment, process or owner is a change. Ask in writing first.

Need the HACCP plan that goes with this? AuditBinder turns your answers into a complete binder — flow diagram, hazard analysis, CCP summary and blank monitoring logs, ready to attach. One-time purchase from $47, no subscription: **audit-binder.com/pricing**

A template for drafting, not a filed document, and not legal advice. The FDA Food Code is a model: it binds you only where your state or county has adopted it, and section numbers, forms and fees differ. Confirm every requirement with your own health department. Based on FDA Food Code 8-103.10 and 8-103.11 as adopted in Washington (WAC 246-215-08110 and 08115), Hawaii Department of Health variance guidance, and the published processes of Southern Nevada Health District and Public Health — Seattle & King County, read November 2026. © 2026 AuditBinder.