DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Food Safety and Applied Nutrition

Qualified Facility Attestation for Human Food Facility

Form Approved: OMB No. 0910-0751
Expiration Date: October 31, 2021
See PRA Statement on page 3.

If entering by hand, use blue or black ink only.

Section 1 – FACILITY INFORMATION

Facility Registration Number

Facility Name

Facility Address

Address 1 *(Street address, P.O. box, etc.)*

Address 2 *(If applicable; apartment, suite, unit, building, floor, etc.)*

City | State/Province/Territory

Country | ZIP or Postal Code

Telephone Number *(Include area code)* | FAX Number *(Include area code)*

E-mail Address

Section 2 – TYPE OF NOTIFICATION

a. ☐ Initial Submission (21 CFR 117.201(c)(2)(i)) – Complete Sections 3, 4 and 5 only.

b. ☐ Biennial (Renewal) Submission (21 CFR 117.201(c)(2)(ii)) – Complete Sections 3, 4 and 5 only.

c. ☐ Status Change (21 CFR 117.201(c)(3)) – Complete Section 6 only.

Section 3 – QUALIFICATION FOR MODIFIED REQUIREMENTS *(Fill out only if Section 6 does not apply.)*

Human food facilities may be exempt from the preventive controls regulations in 21 CFR part 117, primarily in subparts C and G, with associated requirements in subparts A, D, E, and F, under 21 CFR 117.5(a). Check the appropriate box to indicate the reason why your facility is a qualified facility.

When including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate:

☐ The above-named facility qualifies for the exemption as a "very small business" as defined in 21 CFR 117.3 because, during the preceding three calendar years, the facility (including any subsidiaries and affiliates) averaged less than $1,000,000, adjusted for inflation, per year, in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee).

☐ The above-named facility qualifies for the exemption as a "qualified facility" as defined in 21 CFR 117.3 because:

(1) during the preceding three calendar years, the average annual monetary value of the food manufactured, processed, packed, or held at the facility that was sold directly to qualified end-users (as defined in 21 CFR 117.3) exceeded the average annual monetary value of the food sold by the facility to all other purchasers; **and**

(2) the average annual monetary value of all food sold during the preceding three calendar years was less than $500,000, adjusted for inflation.

Section 4 – COMPLIANCE WITH 21 CFR 117.201 *(Fill out only if Section 6 does not apply.)*

Check the box to indicate how your facility is in compliance with 21 CFR 117.201(a)(2).

☐ I, as the owner, operator, or agent in charge of the above-named facility, (1) have identified the potential hazards associated with the food being produced, (2) am implementing preventive controls to address the hazards, **and** (3) am monitoring the performance of the preventive controls to ensure that such controls are effective. (21 CFR 117.201(a)(2)(i).) I understand that I am required to maintain records to support this attestation, but that I am not required to submit those records with this attestation. (21 CFR 117.201(f).)

☐ The above-named facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law including relevant laws and regulations of foreign countries. This is based on my knowledge, as the owner, operator, or agent in charge of the above-named facility, of the facility's licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight. (21 CFR 117.201(a)(2)(ii).) I understand that I am required to maintain records to support this attestation, but that I am not required to submit those records with this attestation. (21 CFR 117.201(f).)

Section 5 – ATTESTATION STATEMENT *(Fill out only if Section 6 does not apply.)*

I attest that, to the best of my knowledge and belief, the information provided in this Qualified Facility Attestation is true, accurate and complete and that the above-named facility qualifies for the exemption requested. I understand that, as the owner, operator, or agent in charge of the above-named facility, I must maintain those records relied upon to support these attestations (21 CFR 117.201(f)) and make those records promptly available to a duly authorized representative of the Secretary of Health and Human Services for official review and copying upon oral or written request (21 CFR 117.320). I also understand that under 18 U.S.C. 1001, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

Signature	Date

Printed Name and Title:

Please check one option below that best describes your relationship to the facility.

☐ Owner ☐ Operator ☐ Agent in Charge

Please provide your contact information below if it differs from the facility information provided in Section 1.

Contact Address

Address 1 *(Street address, P.O. box, etc.)*

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City	State/Province/Territory

Country	ZIP or Postal Code

Telephone Number *(Include area code)*	FAX Number *(Include area code)*

E-mail Address

Section 6 – STATUS CHANGE *(If applicable)*

Human food facilities that have changed status from a "qualified facility" to "not a qualified facility" must notify FDA of that change in status by July 31 of the applicable calendar year. Check the box below to indicate a status change.

☐ The above-named facility is no longer a "qualified facility" as defined in 21 CFR 117.3 based on the annual determination.

Signature	Date

Printed Name and Title:

Please check one option below that best describes your relationship to the facility.

☐ Owner ☐ Operator ☐ Agent in Charge

Please provide your contact information below if it differs from the facility information provided in Section 1.

Contact Address

Address 1 *(Street address, P.O. box, etc.)*

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City	State/Province/Territory	ZIP or Postal Code

Country

Telephone Number *(Include area code)*	FAX Number *(Include area code)*

E-mail Address

If section 6 applied to you, refer to the FDA return address noted beneath Section 6.

Return your completed Form FDA 3942a to the following FDA address:

U.S. Food and Drug Administration
(HFS-681)
5001 Campus Drive
College Park, MD 20740

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 30 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."