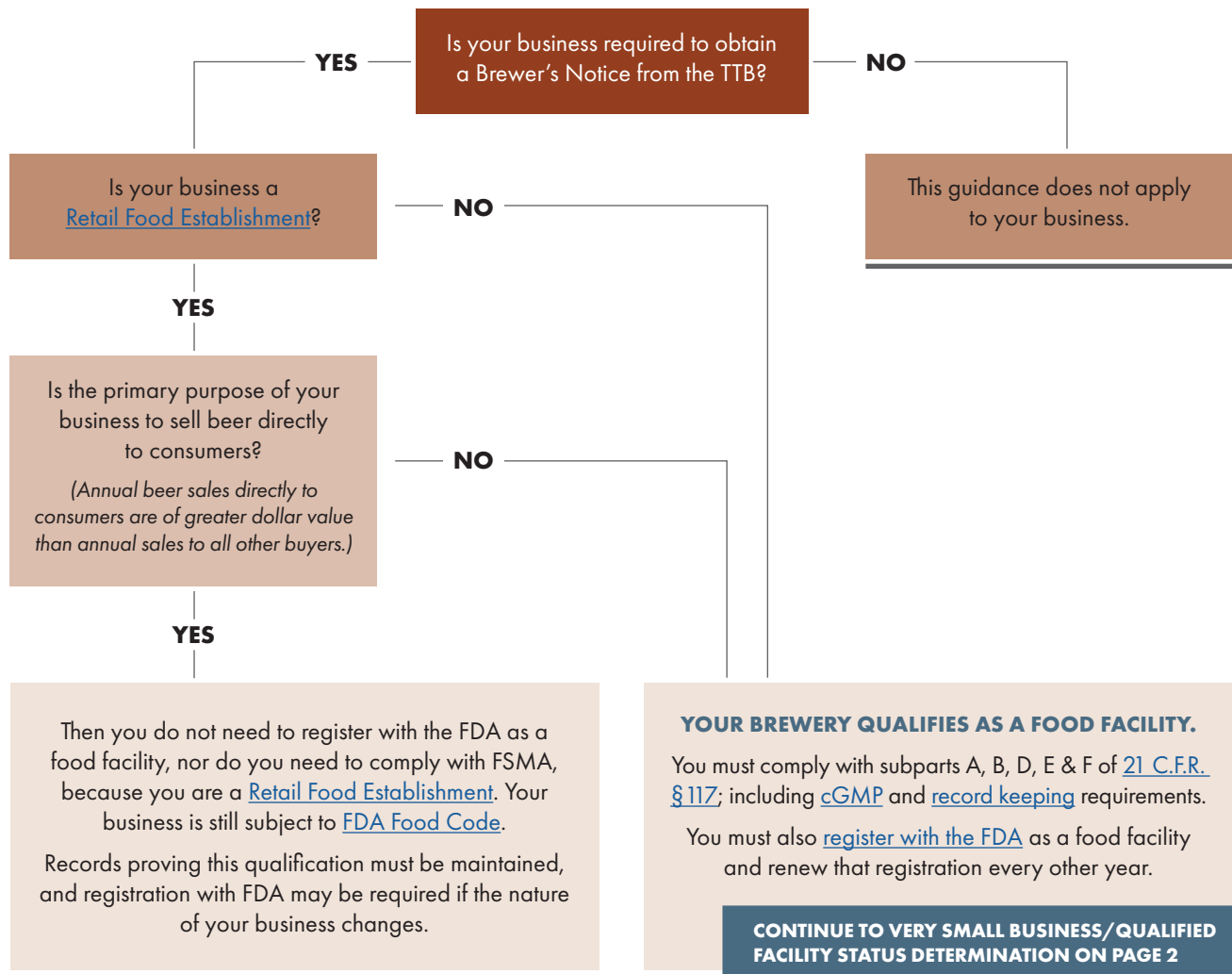




# FDA REGISTRATION & FSMA COMPLIANCE FLOW CHART FOR THE BREWING INDUSTRY

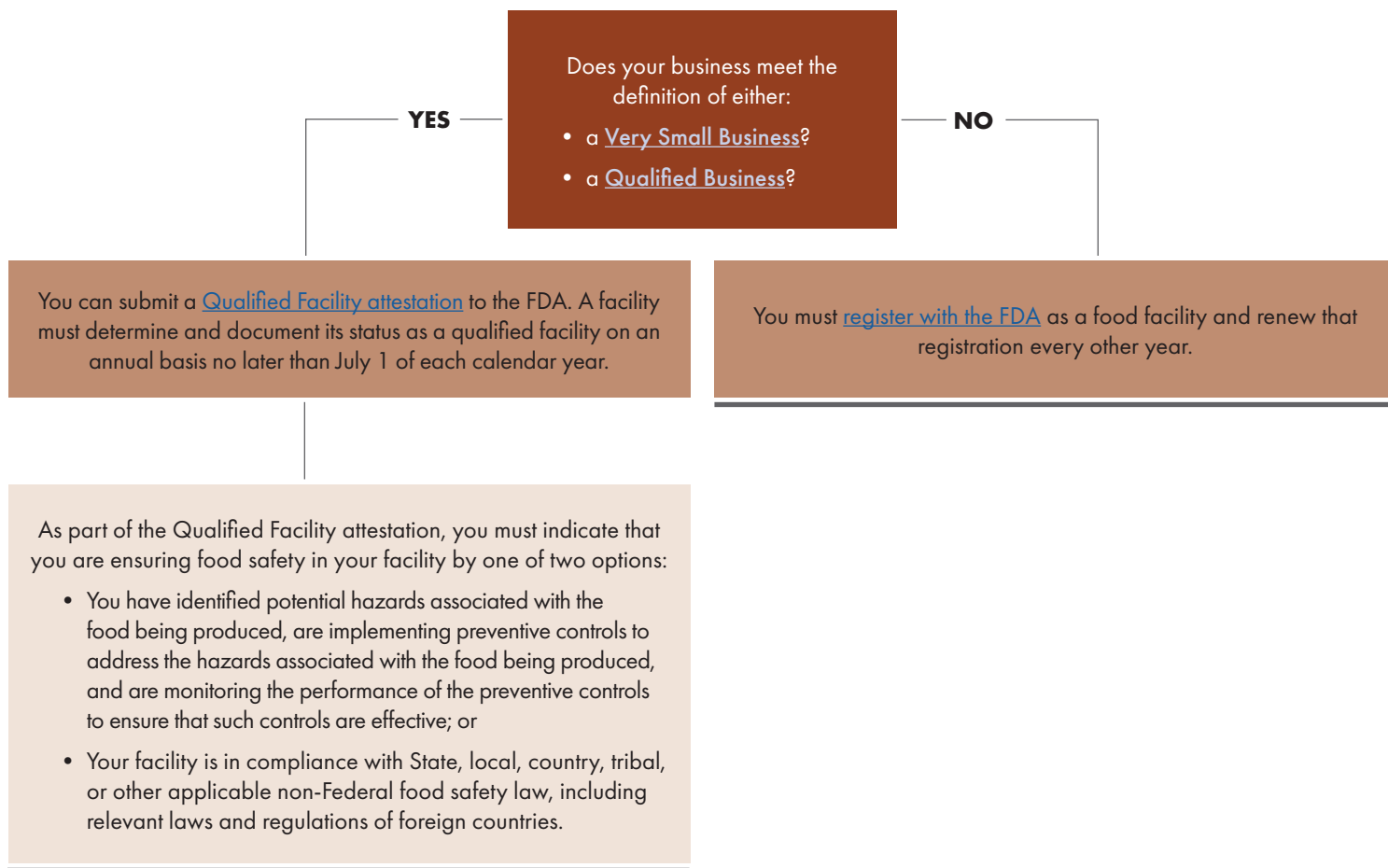
For breweries, Food Safety Modernization Act (FSMA) compliance entails registration with the Food and Drug Administration (FDA) as a food facility and compliance with aspects of Preventive Controls for Human Foods Rule, [21 C.F.R. §117](#). Some exemptions apply but are not guaranteed.

## Q1. Does the FSMA apply to my brewery?



If you knowingly or unknowingly create a food safety hazard, the FDA has the authority to remove any exemptions that may apply to your business and require compliance with every aspect of 21 C.F.R. §117.

## Q2. Do I qualify for an exemption?



### Applicable [Definitions](#):

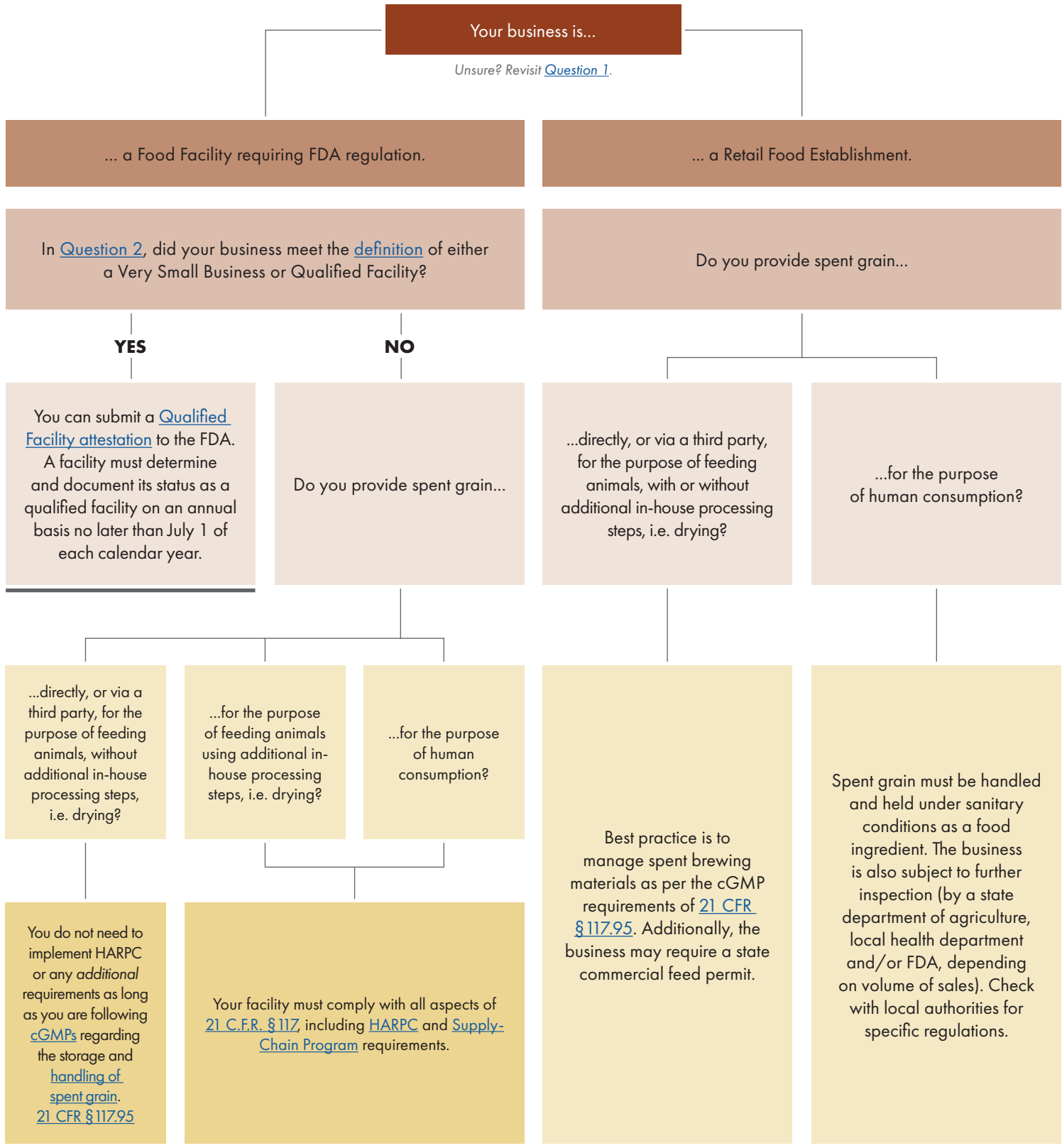
**Qualified Facility** (21 C.F.R. § 117.3, 21 C.F.R. § 117.201) means (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility to which both of the following apply:

1. During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to *qualified end-users* (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and
2. The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation.

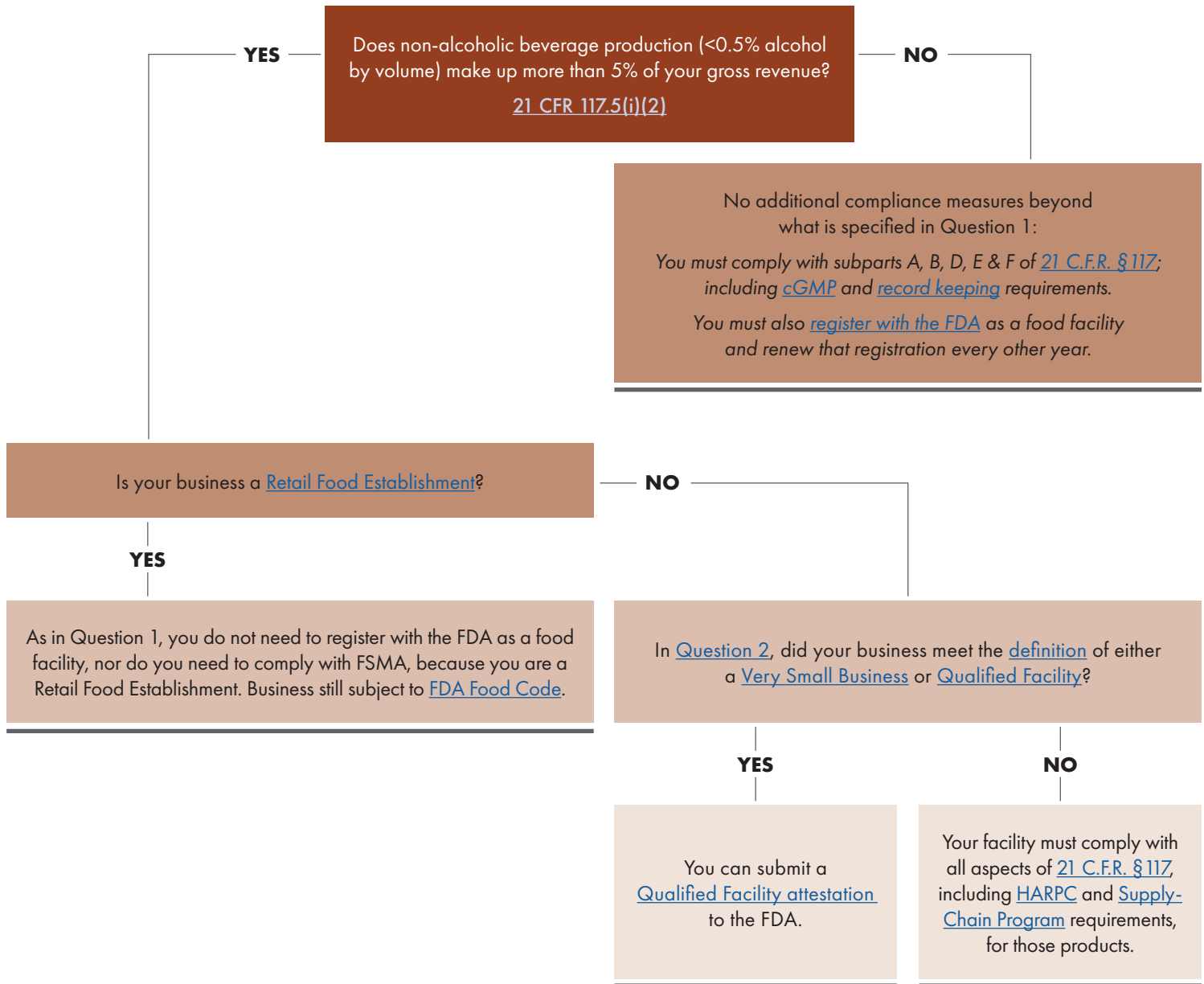
**Very small businesses** (21 C.F.R. § 117.3) means businesses averaging less than \$1 million per year (adjusted for inflation) in annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale)

**Qualified end-user**, with respect to a food, means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227 of this chapter) that: (1) Is located: (i) In the same State or the same Indian reservation as the qualified facility that sold the food to such restaurant or establishment; or (ii) Not more than 275 miles from such facility; and (2) Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

# Q3. What spent grain handling procedures are required of FDA Registered Food Facilities?



# Q4. How does alcohol-free beverage production impact FSMA compliance?



**References:**

- FDA [Food Code](#)
- FDA [Facility Registration](#) Information
- FDA Facility Registration [Guidance](#)
- Retail Food Establishment Exemption [Flowchart](#)
- Food and Drug Administration [FSMA info page](#)
- Preventive Control for Human Foods Rule ([21 C.F.R. § 117](#))
- FDA [Guidance for Qualified Facility Attestation](#)

