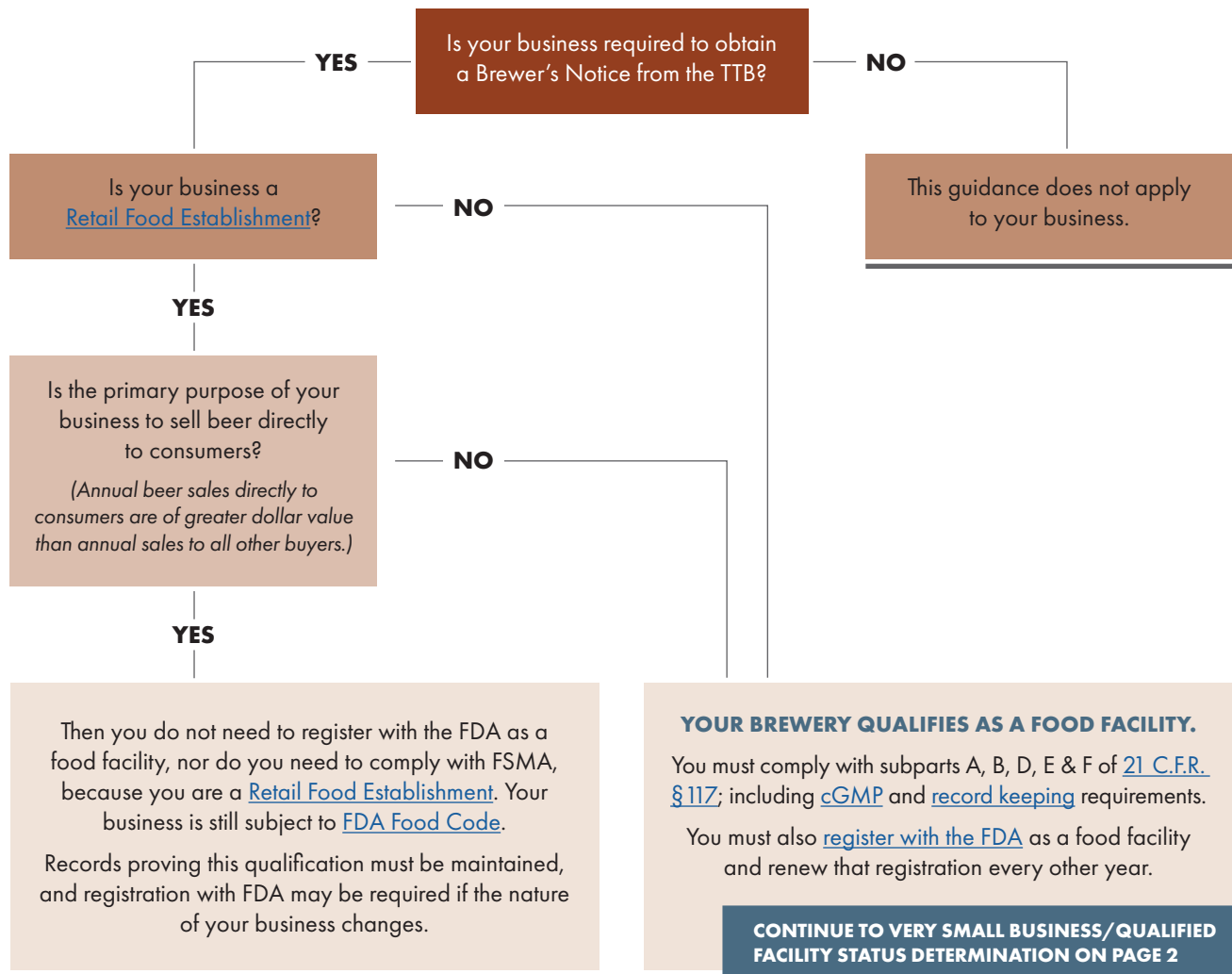




FDA REGISTRATION & FSMA COMPLIANCE FLOW CHART FOR THE BREWING INDUSTRY

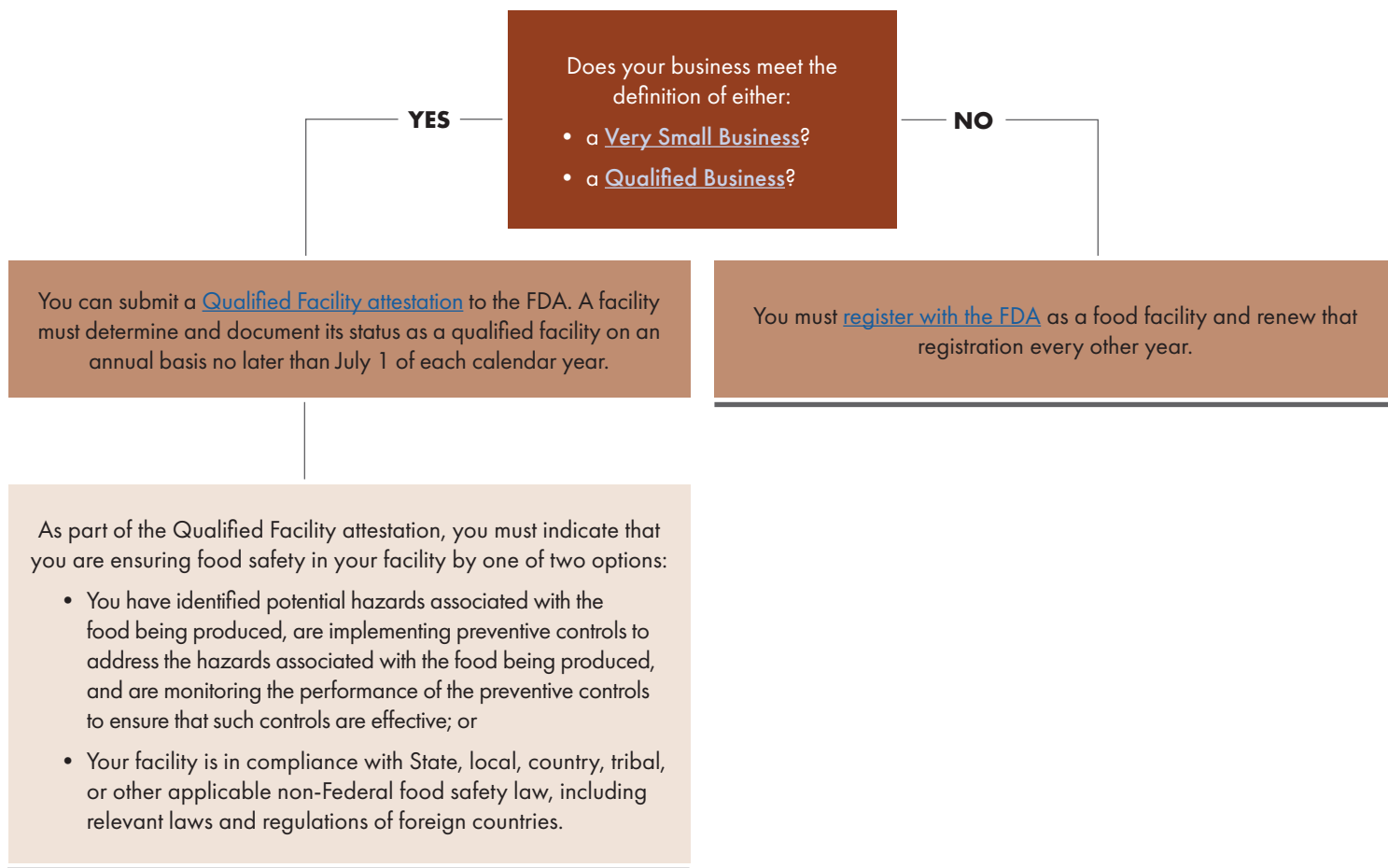
For breweries, Food Safety Modernization Act (FSMA) compliance entails registration with the Food and Drug Administration (FDA) as a food facility and compliance with aspects of Preventive Controls for Human Foods Rule, [21 C.F.R. §117](#). Some exemptions apply but are not guaranteed.

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:

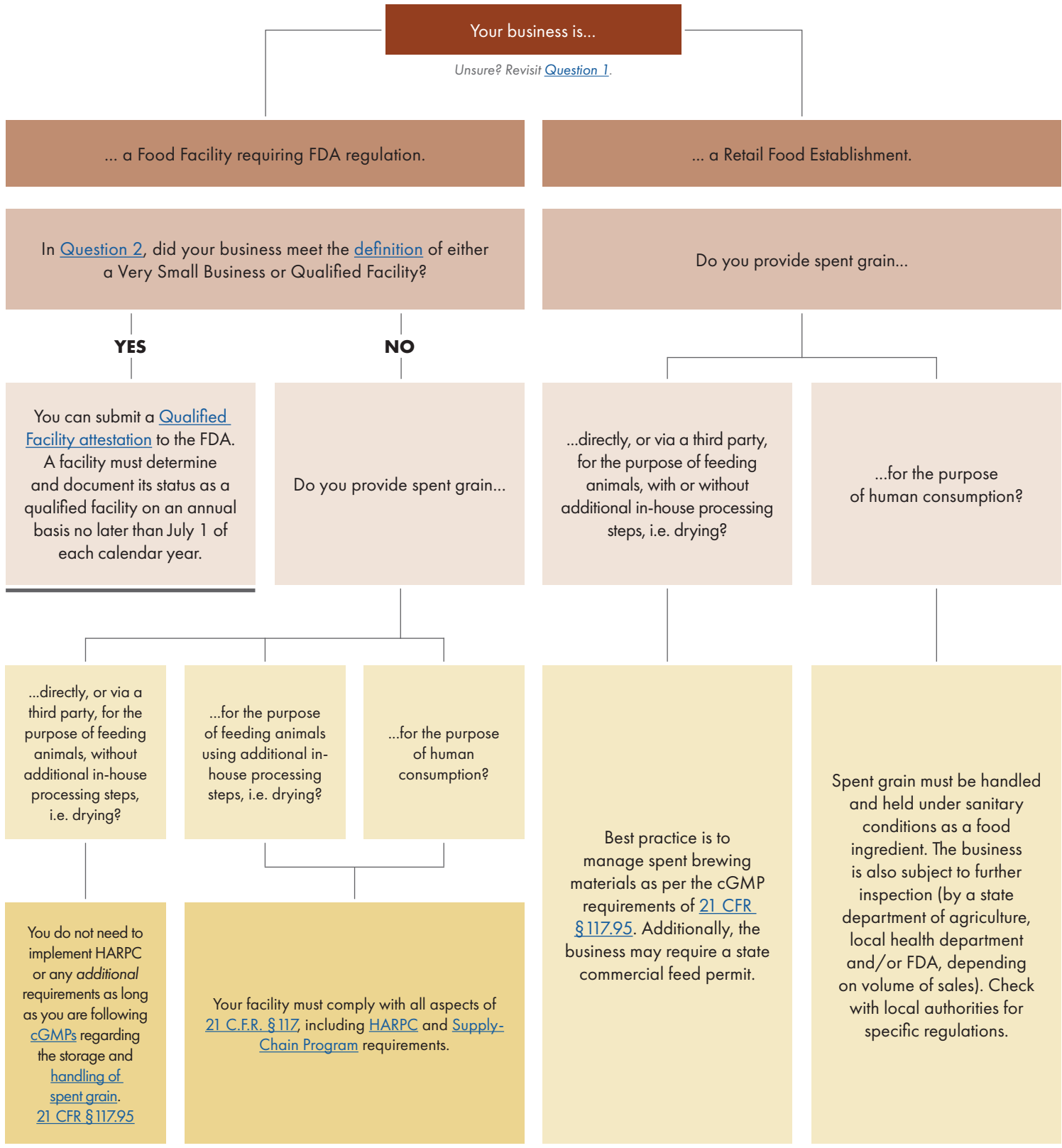
Qualified Facility (21 C.F.R. § 117.3, 21 C.F.R. § 117.201) means (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or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

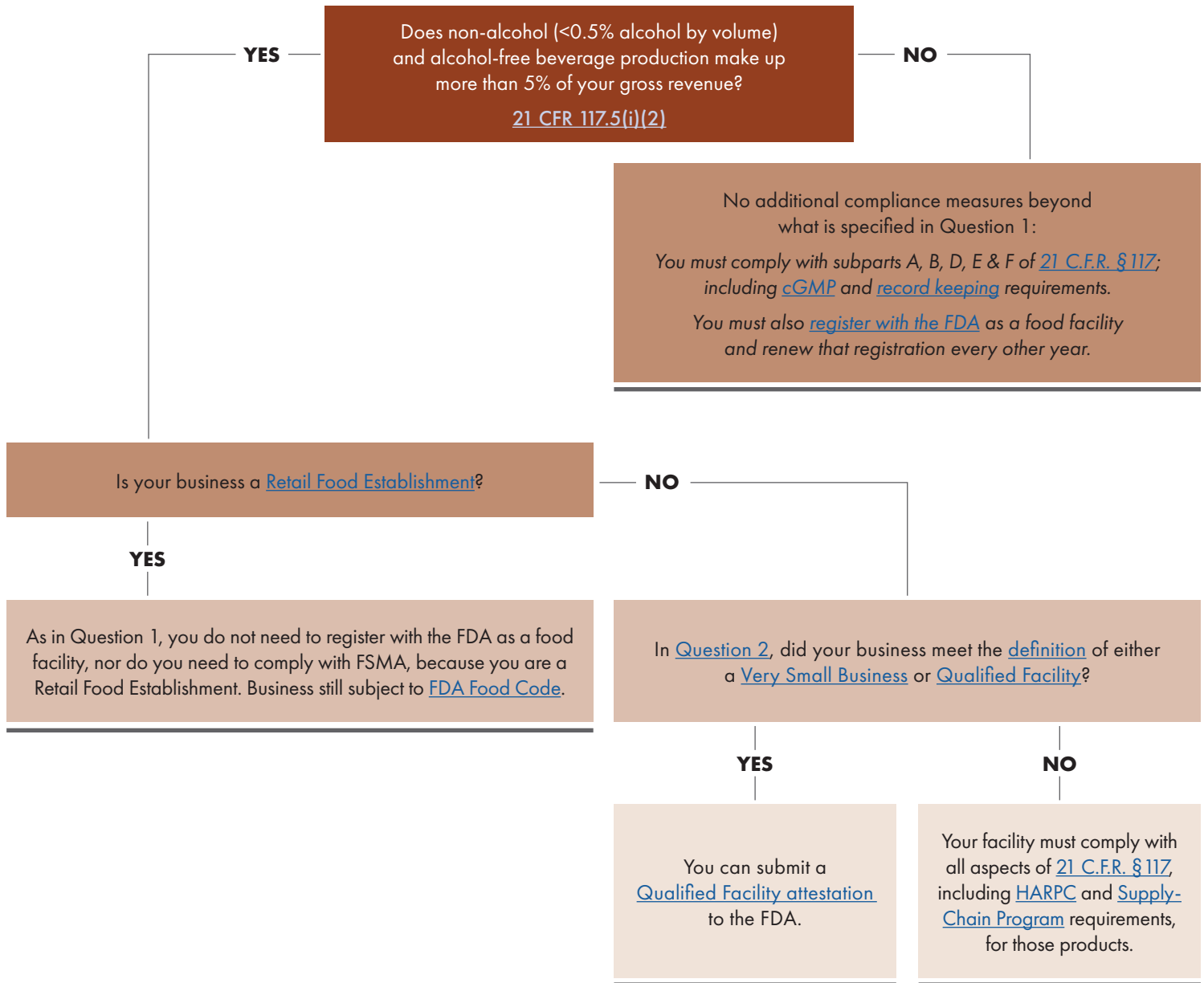
Very small businesses (21 C.F.R. § 117.3) means businesses averaging less than \$1 million per year (adjusted for inflation) in annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale)

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 non-alcohol and 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](#)

