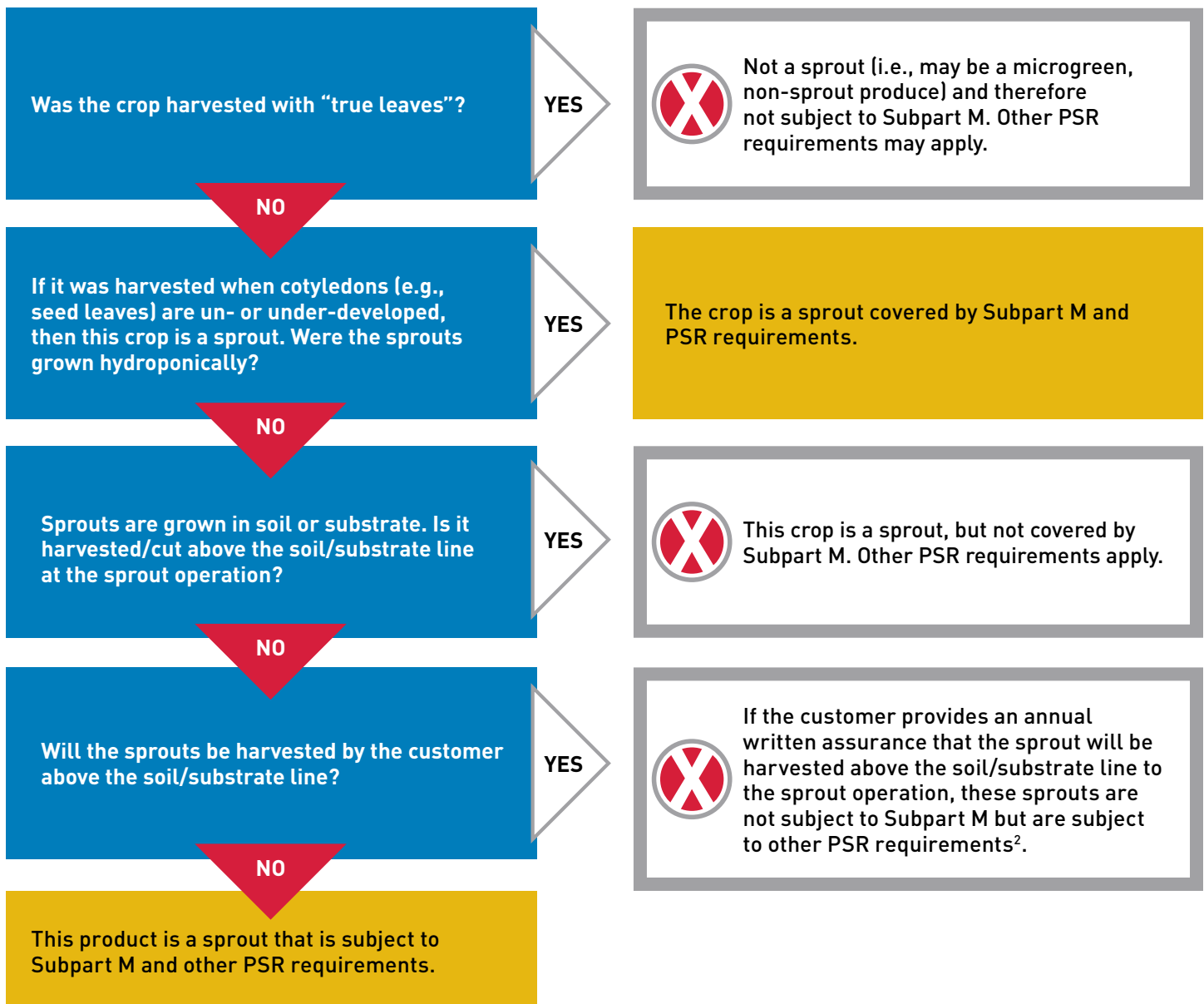


STANDARDS FOR PRODUCE SAFETY (21 PART 112)

Determining Coverage under Subpart M of the Produce Safety Rule

The requirements in 21 CFR Part 112, Subpart M (Sprouts) apply to the growing, harvesting, packing and holding of all sprouts except sprouts that are grown in soil or non-soil substrates (e.g., mats, perlite or other growth media) and that are harvested above the soil or substrate line without their roots (§ 112.141). Below are the factors to consider when determining whether sprouts are subject to the sprout-specific requirements of Subpart M in the Produce Safety Rule (PSR)¹.



¹ Sprouts may be further commercially processed to create sprouted seed products (e.g., canned, shelf-stable mung bean sprouts; sprouted seed butters; powdered sprouted seed products; dehydrated sprouts). These products are not covered by the Produce Safety Rule. The Produce Safety Rule only applies while sprouts are raw agricultural commodities. Once the sprouts have been transformed into processed foods, other requirements may apply, such as under 21 CFR 117.

² In the Federal Register of January 5, 2018 (83 FR 598), we published a notification of availability of a guidance document titled “Policy Regarding Certain Entities Subject to the Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs.” In that guidance document, we stated that we intend to exercise enforcement discretion regarding the written assurance requirements of 21 CFR part 112 (the Produce Safety Rule). We intend to exercise such discretion until we can complete a rulemaking process to consider options for the assurance requirements. See: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-policy-regarding-certain-entities-subject-current-good-manufacturing-practice-and>

STANDARDS FOR PRODUCE SAFETY (21 PART 112)

Determining Coverage under Subpart M of the Produce Safety Rule

The requirements in 21 CFR Part 112, Subpart M (Sprouts) apply to the growing, harvesting, packing and holding of all sprouts except sprouts that are grown in soil or non-soil substrates (e.g., mats, perlite or other growth media) and that are harvested above the soil or substrate line without their roots (§ 112.141). Below are the factors to consider when determining whether sprouts are subject to the sprout-specific requirements of Subpart M in the Produce Safety Rule (PSR)¹.

Text version

Was the crop harvested with “true leaves”?

- If yes, this crop is not a sprout (i.e., may be a microgreen, non-sprout produce) and therefore not subject to Subpart M. Other PSR requirements may apply.
- If no, it was harvested when cotyledons (e.g., seed leaves) are un- or under-developed and therefore this crop is a sprout. Were the sprouts grown hydroponically?
 - If yes, this crop is a sprout covered by Subpart M and PSR requirements.
 - If no, sprouts are grown in soil/substrate. Is it harvested/cut above the soil/substrate line at the sprout operation?
 - If yes, this crop is a sprout, but not covered by Subpart M. Other PSR requirements apply.
 - If no, will the sprouts be harvested by the customer above the soil/substrate line?
 - If yes, if the customer provides an annual written assurance that the sprouts will be harvested above the soil/substrate line to the sprout operation, these sprouts are not subject to Subpart M but are subject to other PSR requirements².
 - If no, this product is a sprout that is subject to Subpart M and other PSR requirements.

¹ Sprouts may be further commercially processed to create sprouted seed products (e.g., canned, shelf-stable mung bean sprouts; sprouted seed butters; powdered sprouted seed products; dehydrated sprouts). These products are not covered by the Produce Safety Rule. The Produce Safety Rule only applies while sprouts are raw agricultural commodities. Once the sprouts have been transformed into processed foods, other requirements may apply, such as under 21 CFR 117.

² In the Federal Register of January 5, 2018 (83 FR 598), we published a notification of availability of a guidance document titled “Policy Regarding Certain Entities Subject to the Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs.” In that guidance document, we stated that we intend to exercise enforcement discretion regarding the written assurance requirements of 21 CFR part 112 (the Produce Safety Rule). We intend to exercise such discretion until we can complete a rulemaking process to consider options for the assurance requirements. See: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-policy-regarding-certain-entities-subject-current-good-manufacturing-practice-and>