

Questions and Answers related to FSIS Notice 34-12

For the purpose of this regulation, the Agency defines “in commerce” as product that is out of the producing establishment’s direct control and is in distribution (e.g., in another Federal establishment, in a warehouse, distribution center, retail facility, restaurant, or other institution). Note that if the product has moved to another establishment that is owned by the same corporation, the product would not be considered “in commerce.”

1. **Q.** Are meat and poultry establishments to report to District Offices (DO) every instance of product adulteration or misbranding?

A. Yes. Under 9 CFR 418.2, the notification regulation, establishments are required to promptly (within 24 hours of learning or determining) report to DOs all instances of adulterated or misbranded meat or poultry product received by or originating from the establishment *that has entered commerce*.
2. **Q.** Is the producing establishment required to notify the DO, per 9 CFR 418.2, if the adulterated or misbranded product is still under direct control of the producing establishment?

A. No. If the entire lot of product that the producing establishment has determined is adulterated or misbranded is under the producing establishment’s direct control, the regulation does not require it to notify the DO. Establishments are to follow their Hazard and Critical Control Point (HACCP) plans for the control and disposition of the product and the customary inspection controls and re-inspection requirements as set out in 9 CFR 318.2, 318.3, and 381.145.
3. **Q.** Under what circumstances does the Agency consider the producing establishment to have direct control of a product?

A. The Agency will consider product under the producing establishment’s direct control if it is:

 - 1) at the establishment;
 - 2) located on the premises owned by the producing establishment;

- 3) at a sister establishment owned by the same corporation when no portion of the lot has been released for sale or use;
 - 4) at a warehouse owned by the establishment or corporation;
 - 5) on a truck or other conveyance owned or operated by the establishment or corporation;
 - 6) offsite under company control (e.g., seal) or FSIS control (FSIS seal accompanied by FSIS Form 7350-1)
4. **Q.** Are warehouses where FSIS provides Identification Service, egg product plants, or retailers required to notify DOs of adulterated or misbranded product?
- A.** No. 9 CFR 418.2 is applicable only to official meat and poultry establishments.
5. **Q.** Are meat and poultry establishments required to notify DOs of all consumer complaints they receive alleging adulteration or misbranding of product?
- A.** No. Each instance of a consumer complaint is not required to be reported to DOs. However, if the establishment determines, based on information gathered in a response to a consumer complaint, that adulterated or misbranded product was shipped or received in commerce or is in commerce, then 9 CFR 418.2 requires that the establishment notify the DO within 24 hours of making such a determination.
6. **Q.** Are DOs to notify the Recall Management Staff (RMS) of all instances of adulterated or misbranded product reported to them?
- A.** No. Before contacting RMS, a District Office is to evaluate each instance of adulterated or misbranded product reported to it; to investigate, if necessary, to gather any other pertinent information; and to determine whether the situation potentially warrants a recall. If the DM or designee determines that the situation may warrant a recall, he or she should contact RMS.
7. **Q.** Are establishments within the same corporation required to notify DOs if adulterated or misbranded product moves among the establishments?

A. No. In this case, product would not be in commerce.

8. **Q.** Does 9 CFR 418.2 require establishments that receive products that they learn or determine are contaminated with foreign material or are otherwise adulterated or misbranded to report such incidents to the DO?

A. Yes. Under 9 CFR 418.2, establishments are required to promptly (within 24 hours of learning or determining) notify the DO of adulterated or misbranded meat or poultry product that has entered commerce and was received by, or originated from, the official establishment.

9. **Q.** If an establishment receives product that is misbranded because of a failure to meet a labeling requirement, and there is no indication of a health or food safety concern, is it required to notify the DO?

A. Yes. Section 418.2 requires the report of any misbranded or adulterated product in commerce. The DO is to collect and evaluate all pertinent information related to the situation. If the violation does not create a health or safety issue, the DO may contact the Labeling and Program Delivery Division (LPDD) directly. LPDD will then contact the establishment and work with it to resolve the situation.

10. **Q.** If raw deboned product is shipped from one Federally inspected facility to a second Federally inspected facility for further processing, would the presence of a small bone chip or fragment be considered reportable to FSIS?

A. No. Establishments are not required to notify their DO of quality defects like bone chips or bone fragments found during further processing if the bone chips or fragments do not adulterate or misbrand the product. Establishments would be required to notify their DO if bone particles are present in such significant amounts, distributed throughout the product, that they make the product unsound, unhealthful, unwholesome, or otherwise unfit for human food and, therefore, adulterated (21 U.S.C. 453 (g)(3) or 601(m)(3)). Establishments would also be required to notify the DO if bone-in product (e.g. drumsticks) is in a container of product labeled

“boneless,” so as the product is misbranded (21 U.S.C. 453(h)(1) and (9) or 601(n)(1) and (9)).

11. **Q.** If the receiving establishment has already notified its DO that it has received adulterated or misbranded product, is the producing establishment also required to notify its DO after learning that it has shipped adulterated or misbranded product?

A. Yes. The producing establishment must also notify the appropriate DO within 24 hours after learning that it has produced and shipped adulterated or misbranded product.