

Questions and Answers related to the [Final Rule](#) "Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products"

**Question 1: What raw ground beef products are covered by the Final Rule?**

Answer: The [Final Rule](#) does not apply to specific products. It requires that official establishments or retail stores that grind raw beef keep records concerning their grinding activities. If official establishments have records to show that the product they grind is going to be fully cooked, the record requirements in the Final Rule do not apply.

**Question 2: For the Final Rule, how is a ground beef lot defined?**

Answer: Under 9 CFR 320.1(b)(4)(iii), a ground beef lot is defined, for the purpose of **raw ground beef** recordkeeping, as the amount of ground beef produced during particular dates and times, following clean up and up until the next clean up. All of the information specified in 9 CFR 320.1(b)(4)(i) must be recorded for each raw ground beef production lot, including the identity of supplier(s) and the time when each cleaning of grinding equipment and related food-contact surfaces occurs.

This lot definition is separate from FSIS sampling of *E. coli* O157:H7, where, pending test results, official establishments must define and hold the sampled lot on the basis of microbiological independence from other production lots. FSIS has issued guidance on defining a lot in this context in [Directive 10.010.1, Sampling Verification Activities for Shiga Toxin-Producing Escherichia Coli \(STEC\) in Raw Beef Products](#), and in the [FSIS Compliance Guideline for Controlling Meat and Poultry Products Pending FSIS Test Results](#). Retailers have the option to hold potentially implicated product when FSIS samples and tests for *E. coli* O157:H7 as part of its in-commerce surveillance. See [Directive 8010.1, Methodology for Conducting In-commerce Surveillance Activities](#). If a retailer opts to hold product pending receipt of the sampling results, it must similarly show microbiological independence, typically through information related to grinder and food contact surface cleaning and the source materials used. A "lot" in this context is not necessarily limited to the ground beef produced between cleanings.

**Question 3: If an official establishment or retail store switches source materials but does not do a complete grinder clean up, do the regulations allow the subsequent product to be a separate lot?**

Answer: No, if the grinding equipment and product contact surfaces are not cleaned, all of the product that came in contact with that equipment since the last clean-up is considered part of the same lot due to the opportunity for cross-contamination.

**Question 4: For the Final Rule, is a lot defined by the USDA, the official establishment, or the retail store?**

Answer: For the purpose of the raw ground beef recordkeeping regulation, USDA has defined a lot as the amount of ground raw beef produced during particular dates and times, following clean up and until the next clean-up (9 CFR 320.1(b)(4)(iii)). In accordance with this definition, the actual size of each lot will depend on the production practices of an official establishment or retail store.

**Question 5: For the Final Rule, must each lot of raw ground beef produced at an official establishment or retail store be from a single supplier?**

Answer: No, the Final Rule requires that the official establishment or retail store maintain the specified information for each raw ground beef lot that includes "the establishment numbers of establishments supplying material" and the "supplier lot numbers and production dates" (9 CFR 320.1(b)(4)(i)). The Agency realizes that there may be more than one source supplier for a lot of raw ground beef product produced by the retailer or establishment.

**Question 6: For the Final Rule, must the grinding log at the retail store contain an individual entry for a customer-requested grind?**

Questions and Answers related to the [Final Rule](#) "Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products"

Answer: Not necessarily. An additional entry is not needed if the customer-requested product is ground at the same time and from the same supplier production lot as other material being ground. If a retailer grinds materials from a different supplier, or the same supplier but a different production lot or date, it will have to record the customer grind as a separate lot.

**Question 7: If an official establishment or retail store makes meatloaf, do all the spices and other ingredients, in addition to ground beef components, need to be included in the records?**

Answer: No, the official establishment or retail store only needs to maintain grinding records for beef ground at the establishment or store. The establishment or store is not required to record the same information for spices and other ingredients used in the raw ground beef product.

**Question 8: In a facility that houses both a federally-inspected official establishment and a retail store, which FSIS program staff will verify whether the retail store complies with the new recordkeeping requirements for ground beef?**

Answer: The FSIS Office of Investigations, Enforcement and Audit (OIEA) Compliance Investigators will verify whether the retail store complies with the recordkeeping requirements by following the instructions found in [FSIS Directive 8010.1, Methodology for Conducting In-Commerce Surveillance Activities](#). The in-plant FSIS Office of Field Operations (OFO) Consumer Safety Inspectors will verify whether the official establishment meets the new recordkeeping requirements.

**Question 9: If the source material used to grind the raw beef product does not contain a readily identifiable lot number, what should be recorded on the grinding record?**

Answer: If the supplier lot number on the source material is not apparent, FSIS recommends that the official establishment or retail store contact the supplier for the lot number information. If no lot number is available to be recorded at that time, FSIS recommends that the grinder write down any other available supplier or source material information that may facilitate a swifter traceback, such as bar code numbers, invoice numbers, etc.

**Question 10: What are the penalties for a retail store if the required records are not maintained? What are the penalties for an official establishment if the required records are not maintained?**

Answer: If a retail store fails to maintain the required records, FSIS personnel may issue a Notice of Warning or in the event of repeated violations, request the Department of Justice to initiate a civil proceeding to enjoin the defendant from further violations of the applicable laws and regulations, or take other action as authorized by law.

If FSIS personnel find non-compliance at an official establishment, the Agency could issue noncompliance records (NRs), warning letters, or in the event of repeated violations, refer the matter for additional enforcement actions, as authorized by law.

**Question 11: If FSIS discovers that the required records are not being maintained by the retail store or official establishment, will FSIS request a recall?**

Answer: Unless there is reason to believe that there is adulterated or misbranded product in commerce, FSIS will not request that the official establishment or retail store recall the product corresponding to the records that were not maintained.

**Question 12: Is the use of ditto marks an acceptable way to carry information down to the next line of the grinding log without having to write the information all over again?**

Answer: Yes, ditto marks may be used as long as the information is identical.

Questions and Answers related to the [Final Rule](#) "Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products"

**Question 13: Besides raw ground beef, does the Final Rule apply to other non-intact raw beef produced by an official establishment or retail store?**

Answer: No, the rule requires that official establishments or retail stores that grind raw beef keep records concerning their grinding activities. The final rule does not apply to other activities such as mechanically-tenderizing or needle-injecting raw beef.

**Question 14: If an official establishment or retail store is purchasing ground beef that it portions and repackages, is it required to keep records under this Final Rule?**

Answer: No, an official establishment or retailer store is not subject to the [Final Rule](#), unless it actually grinds the raw beef.