

Update on Hay Transportation Regulations

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In response to a large number of questions regarding the new hay transportation regulations now required by FDA, this article has been created in an effort to clarify some of the issues generating confusion and concern. As a follow-up to the initial ruling released by FDA in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, FDA generated a set of Q and A's that pose specific scenarios of food/feed commerce, many of which are common questions asked by hay growers and sellers alike. Below are a few of the more common questions asked by hay producers, retailers and consumers. These examples of various farming situations help in better understanding the record-keeping requirements of FDA, specifically hay utilization and hauling situations.

Recall that 'farms' are excluded from these regulations. The FDA defines 'farms' as "facilities that manufacture, process, pack or store food, provided that all food used in such activities is grown, raised or consumed on that farm or another farm under the same ownership". In other words, those who grow hay for use exclusively on their own farms do not have to comply with the new changes if all of their hay stays on-farm. In addition to this, those farms that sell hay to another farm for use as feed (consumers) are exempt and do not have to comply (See Q 4.6).

Another definition that should be understood is 'harvesting'. Harvesting is considered by FDA to "encompass those activities traditionally performed during the removing of a crop from the field through the safe storage of the crop. Thus, drying and chopping activities that are an essential part of the harvest process and which are traditional farming operations for a particular crop are activities covered by the 'farm' definition. Harvesting of hay includes cutting, drying, baling and storage of the hay. If, however, a farmer were to remove cut hay from storage and chop the hay to make hay cubes to sell, then establishment and maintenance of records would be required as FDA considers this activity manufacturing/processing of the already stored hay."

*Post-harvest manufacturing or processing is subject to the rule and is non-exempt, unless the material is consumed on the same farm or another farm under the same ownership.

A common question of retailers is whether or not they have to maintain records on every single sale of hay (various quantities) they make. Q 6.7 states that if the annual monetary value of sales to consumers (e.g., horse owners) exceeds annual monetary value of sales to other buyers (e.g., businesses), then the operation is exempt. For many of the hay retail stores in NM, small cash and carry exchanges are common, more than 50% of their sales go to direct consumers, and the exemption would apply.

Exempt	Non-Exempt
Farm – growing, drying, chopping, feeding on own farm or farm under same ownership	Manufacturing/processing hay – e.g., cubing stored hay
Selling to consumers* – e.g., retailers, farm to farm	Brokering hay
Selling hay to another farm to feed their own livestock	Hauling hay for someone else – e.g., commercial trucking company
Trucking your own hay	

*Retailers selling value of >50% of hay to consumers

Selected Questions and Answers Regarding Establishment and Maintenance of Records

4.6 Q: If I sell hay that I grow on my farm to another farm, am I subject to the establishment and maintenance of records provision in the final rule?

A: No, you do not have to establish and maintain records for the hay you grow and sell to another farm or to a direct customer such as a person that owns pleasure horses. 'Harvesting' also includes releasing the crop to another person. Thus, activities associated with the selling of the crop, such as transportation of the hay by the farmer either directly or through a third-party transporter to a buyer is included within the farm exemption. *However, if you purchase hay from another farm under different ownership to resell, then you have to establish and maintain records related to the hay you receive and release.*

4.7 Q: Does a farm have to keep records of who transported hay that was bought or sold?

A: No. If the hay was transported by the farm/seller or farm/buyer, no transportation records are needed. However, if the hay was transported by a person that does not meet the definition of a farm, such as a commercial trucking operation, then the transporter must establish and maintain records.

6.7 Q: Is a retail food establishment (retail animal feed) that employs 10 or fewer full-time equivalent employees still exempt from the requirement to establish and maintain records (but not the record access requirements for existing records), if they sell feed to a business or the feed sold is to be used in animals that will subsequently be sold as food?

A: This establishment is exempt if it meets the definition of a retail establishment as defined in 21 CFR 1.327(e). 21 CFR 1.327(e)(1) states that a retail establishment's primary function is to sell food directly to consumers, and 21 CFR 1.327(e)(3) states that a retail establishment's primary function is to sell food directly to consumers *if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food to all other buyers..* As discussed in the response to Comment 52 in the Final Rule preamble, "food distributed directly to consumers" includes sales of bagged feed, pet food, and feed ingredients/additives over-the-counter directly to consumers and final purchasers for their own animals, unless the feed is to be used in animals that will be sold as food or used to produce food for sale. If this establishment with 10 or fewer full-time equivalent employees qualifies according to the criteria discussed above, it is exempt as provided by 21 CFR 1.327(f).

Section 1.327(d) excludes a retail establishment from the requirement to establish and maintain records for the food it releases, including the source of the finished container in which the establishment has placed the food, *for those products it distributes directly to consumers.*

The term 'food' includes raw agricultural commodities (including hay), animal feed, dietary supplements and dietary ingredients.

Full Q and A descriptions can be found at <http://www.cfsan.fda.gov/~dms/recguid4.html> and should be reviewed to ensure complete understanding and proper compliance. The final rule can be accessed at <http://www.cfsan.fda.gov/~dms/frrecord.html>. Enforcement regulations can be accessed at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1&showFR=1&subpartNode=21:1.0.1.1.1.8>.