AT A GLANCE: KEY POINTS IN THE PRODUCE SAFETY RULE DRAFT GUIDANCE

CHAPTER 5: DOMESTICATED AND WILD ANIMALS (SUBPART I)

What is the goal of this chapter?

To help farmers determine whether there is a reasonable risk that domesticated or wild animals will contaminate produce on their farm, and if so, what they need to do. For example, if there is such a risk, farms will need to assess relevant outdoor areas and partially-enclosed buildings for potential contamination and evaluate any significant findings to determine their impact on the harvest.

> *References to "you" in this document (as well as in the Produce Safety Rule and draft guidance) mean the owner, operator, or agent in charge of a covered farm that is subject to some or all of the requirements of the rule. In addition, unless otherwise specified, we're only talking about produce covered by the rule.*

What kind of animals are we talking about and why is this a concern?

Both domesticated and wild animals can be the sources of microorganisms that can contaminate produce and cause foodborne illness. Domesticated animals include cats, dogs, cows, pigs, chickens and horses. Wild animals include deer, feral hogs, frogs, snakes, raccoons and birds, such as pigeons, crows and migrating geese. They can all carry disease-causing microorganisms in their feces that can survive for prolonged periods of time when deposited in soil and water and could be transferred to people through contaminated produce that enters the food supply.

Does the Produce Safety rule require that animals be excluded from farms?

No. FDA is not asking farms to exclude animals from outdoor growing areas or to destroy animal habitats. Further, in accordance with the Endangered Species Act, the Produce Safety Rule does not authorize farmers to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect any threatened or endangered species. However, we do recognize that animals can carry and transmit pathogens that can contaminate produce and make people sick, so the goal of the Produce Safety Rule is to reduce the likelihood of that kind of contamination.

How can I determine if the requirements in this part of the rule apply to my farm and what are some factors to consider?

First, identify the outdoor areas and partially-enclosed buildings on your farm where activities covered by the produce rule take place during the growing season. Include areas used to store produce, equipment and tools, and food-packing materials.

Then evaluate the probability that wild or domesticated animals on or near your farm, could contaminate the produce or food contact surfaces in these areas. If there's a reasonable risk of contamination, you are subject to this part of the rule.

In determining the probability of contamination from animals, you should evaluate the types of crops that you have, your on-farm practices, and the animals of concern. When evaluating the types of animals that could contaminate your produce, the following factors can be considered:

- Any historical observations about animals on or near your farm
- The presence of animal attractants and habitats (for example, water and food sources, wooded areas and areas that could shelter animals, such as brush or waste piles)
- Nearby land features (such as hills) or land use (such as animal pastures, barns, or concentrated animal feeding operations (CAFOs))
- Measures or structures that limit animal activity or the impact of animal activity (such as ditches, diversion berms or vegetative buffer strips that control runoff containing animal waste)
- Seasonal influences, such as migration routes
- Weather events and conditions (for example, heavy rains or drought)

You should periodically re-evaluate your farms conditions and practices and be aware that changes on or near your farm, such as construction, new cultivation, heavy rains or fires, could affect the movement or presence of animals and, therefore, the risk of contamination.

Once you've determined that the requirements for domesticated and wild animals apply to you, what's next?

You should develop an approach to assessing the relevant outdoor areas and partially enclosed buildings for evidence of potential animal contamination. You should consider the timing and frequency of monitoring these areas, the personnel involved, and how any observations or findings will be reported. This assessment can be tailored to your on-farm practices and conditions and based on your observations and experience.

What should I consider when developing and modifying my approach to assessment?

You should evaluate your approach regularly and make changes as needed over time. The following should be considered in your evaluation:

- The types of animals, including both wild and domesticated animals (both yours and those nearby but not under your control)
- The expected numbers of such animals
- The expected location of animal activity
- The expected frequency of animal activity
- The time of year it occurs (For example, is the animal activity seasonal?)
- The time of day of the animal activity
- Changes in the surrounding environment, such as construction or new cultivation.

Using the available information, you should set the specifics of your approach to assessment, such as monitoring frequency. For example: A farm's outdoor kale growing areas are located near a pond that deer and ducks use as a water source, and ducks and their excreta are observed in the kale growing areas one to two times per month (e.g., less frequently than weekly) during the growing season. The farm must assess these areas for evidence of potential contamination and should monitor the outdoor kale growing areas at least monthly during the growing season.

Conversely, sometimes the available information may point to more frequent monitoring. For example: A farm's outdoor areas for growing blackberries are located near a barn that the farm determines attracts birds for nesting. Birds are frequently (at least weekly) observed in the outdoor growing areas for blackberries, and personnel observed excreta on blackberries near and during harvesting activities. The farm must assess the blackberry growing areas for evidence of potential contamination and should monitor the outdoor blackberry growing areas at least weekly.

Depending on a farm's circumstances, it could be appropriate to monitor less frequently than in the above examples, such as designating a certain number of monitoring events during the growing season.

For more information and examples, see the section entitled "Assessing Relevant Areas for Evidence of Potential Contamination of Covered Produce" in Chapter 5 of the draft guidance, specifically the subsection on developing and modifying your approach to assessment.

How should I perform monitoring activities on my farm?

The factors you consider in developing your assessment approach will help shape the monitoring plan, including the frequency, timing, methods and location of such efforts.

First, you should determine who will conduct monitoring activities. This could mean designating a single individual, or you can ask staff members who are conducting other activities, such as weeding, to monitor for potential contamination while they are doing these other jobs. Anyone doing this work should understand how to identify signs of potential contamination, your assessment approach, including monitoring, and the requirements of the Produce Safety Rule.

Next, you will need to determine how you want monitoring activities to be performed on your farm and how often they should be conducted (see response to the above question for more on this). Monitoring should include visual examination for evidence of potential contamination, looking for animal activity such as chewed, pecked or trampled crops, nests, signs of rooting or bedding, or the presence of animal feces either on or near a fruit or vegetable. You're looking for evidence of animals in contact with or right next to produce.

Monitoring should be scheduled at a time of day when animals are more likely to be present, which could vary depending on the type of animal. You should also consider the factors you identify that influence animal presence on or near your farm when you assign monitoring frequencies and locations.

Finally, you should consider the kinds of information that personnel should report and to whom for further determination of the potential for contamination.

How will I know if evidence of potential contamination is significant?

There is flexibility built into the rule to allow you to decide based on the circumstances on your farm. However, you should consider the extent of the evidence. A single observation of an animal in the growing area may not immediately indicate a problem. However, multiple observations reported over time or observations of animal excreta or crop damage could mean a bigger problem. On the other hand, a single observation of a large number of animals near covered produce, coupled with extensive animal feces on or near produce or a great deal of crop damage could indicate a problem.

What should I do if significant evidence of potential contamination is found?

If you have determined that there is significant evidence of potential contamination on your farm, you will then need to determine whether you can harvest the produce in the affected areas. You may, for example, determine that only a certain part a growing area has been affected and should be designated as an area in which the crops should not be harvested, a "no harvest zone." The specific distance of the "no harvest zone" around observations of animal excreta will likely vary by crop, extent of potential contamination, and other factors.

Can you provide an example of steps a farm might take to ensure that crops potentially contaminated by animals are not harvested?

A worker observes evidence that geese have intruded on lettuce fields, which has resulted in extensive crop damage (e.g., evidence of crop consumption and gnaw or bite marks) and goose excreta on and near the lettuce. It would be appropriate for the worker to report these observations to a supervisor. The supervisor determines that this represents significant evidence of potential contamination, and the produce in the affected fields cannot be harvested in accordance with the Produce Safety Rule. The farm must take appropriate measures and may choose to mark the affected fields with red flags and communicate to workers that the lettuce on those fields will not be harvested.

When it comes to requirements in the Produce Safety Rule aimed at preventing contamination by animals, what else should I know?

Several other chapters in the draft guidance also have information and recommendations on how to prevent animals from contaminating produce:

- Chapter 3 (Health and Hygiene, specifically the sections on "Avoiding Contact with Animals Other Than Working Animals" and "Thorough Hand-washing"),
- Chapter 6 (Growing, Harvesting, Packing and Holding Activities, specifically the section on "Identifying and Not Harvesting Contaminated Covered Produce"), and
- Chapter 7 (Equipment, Tools, Buildings and Sanitation, specifically the sections on "Pest Control," "Domesticated Animals," and "Animal Excreta and Litter from Domesticated Animals.")

For further explanation of the underlined words, see the Key Terms Glossary.

The draft guidance contains more details and examples of FDA's recommendations and current thinking. It is recommended that you review the draft guidance for complete information.