

July 16, 2019

Subject: FDA ban on pentobarbital in animal byproducts used in food for pets and other animals.

Dear Doctor,

The Food and Drug Administration (FDA) has determined that pentobarbital is a hazard in ingredients fed to pets and other animals and that animals euthanized with pentobarbital cannot be used to make animal food. Because the FDA has not established a tolerance for pentobarbital, animal proteins (such as meat and bone meal) and fats tested and found to have detectable levels of pentobarbital present cannot be used in food for any animal. This means that such euthanized animals cannot be rendered.

For euthanized livestock or other large animals to be rendered, non-chemical forms of euthanasia must be used. This letter is to request your assistance in assuring that rendering remains a viable disposal option for animal mortalities, including livestock that must be euthanized.

What can you do?

Using pentobarbital for animal euthanasia is a problem because a renderer cannot distinguish animals that died by chemical euthanasia from those that died from other causes. **We ask that you use other means to euthanize livestock, such as captive bolt or by shooting.**

We recognize that in some cases, it may be necessary to use pentobarbital. In such cases, please clearly communicate, preferably in writing, the limitations for disposing of the carcass with your client. Calling the rendering plant that services the client's farm or operation (toll-free numbers are available) to notify the dispatcher of the farm and type of animal euthanized with pentobarbital would also be helpful. More importantly, however, having an established method for permanently marking animals euthanized with pentobarbital will provide a means for renderers to identify animal remains that cannot be rendered from those that can and should be. Any such identification method must stay with the carcass, not easily removed or lost, consistently applied within a state or region and the use and meaning of the marking communicated to all renderers operating in the area

Ear tags can be easily removed or lost which makes them unacceptable for identifying animals given pentobarbital. Therefore, the preferred method for identifying pentobarbital-euthanized livestock and other large animals is by **prominently marking the head with a large "P" using fluorescent orange colored "All-Weather Paintstik"** (see figure 1).



A solvent based fluorescent orange spray paint, such as Krylon Contractor Marking Paint, may be an acceptable alternative to using Paintstik, so long as the paint will stay on the hide and is not easily washed off or removed. We are not concerned if someone removed the head to hide the fact that an animal was chemically euthanized. Rendering truck drivers are trained to avoid picking up headless carcasses, even if the head can be made available, to avoid inadvertently rendering an animal being tested for bovine spongiform encephalopathy (BSE) or other diseases affecting the brain.

Why is rendering animals euthanized with pentobarbital an issue now?

Historically, horses and other livestock euthanized with pentobarbital or other barbiturates were rendered. This practice was allowed because FDA data indicated animal proteins and fats derived from rendering euthanized animals with other animal byproducts were safe to use in animal food. However, the FDA changed its thinking about pentobarbital because canned pet foods made with meat harvested from euthanized livestock was thought to be the cause of death for several dogs. The tainted pet food contained meat/organs harvested from 3-D/4-D cattle that had not been rendered. Even though no rendered products were implicated in the death of these pets, the FDA banned any detectable amount of pentobarbital in any food for pets and other animals. The scope of this ban means that animals euthanized with pentobarbital can no longer be rendered. The detection limit of the method FDA uses to test for pentobarbital is so low (10 ppb) that rendering one euthanized cow or horse of average size could contaminate an entire day's production of finished fat and proteins with detectable levels of the drug.

Who is Darling Ingredients Inc. and why are we concerned?

Darling Ingredients Inc. ("Darling") is a publicly-traded independent rendering company, which operates 39 rendering facilities located across the United States. Many of Darling's rendering facilities, especially those located in the midwestern and plains states, collect and process livestock that die outside the slaughter chain, such as on-farm mortalities.

Rendered products, such as meat and bone meal and tallow, are frequently used as ingredients in nutritionally balanced foods manufactured for livestock, poultry and companion animals to consume. Therefore, Darling is very concerned about and committed to food safety and is subject to regulations enforced by the FDA, including regulations under the Food Safety Modernization Act (21 CFR Part 507).

Why is it important to permanently identify animals euthanized with pentobarbital or use other methods for euthanasia?

The rendering process does not inactivate or destroy most chemical hazards, including pentobarbital. This means that Darling must either prevent such hazards from entering a rendering plant or test for chemical hazards and make sure contaminated product is sold for non-feed uses. Such test and positive release programs work for rendered fats but are not feasible for animal proteins. Darling must, therefore, exclude materials likely to contain the hazard. Horses are considered a high risk for pentobarbital because they are often considered to be pets and it is difficult to determine if a horse was euthanized with pentobarbital or died from other causes. As a result, Darling and other renderers have stopped processing horses.

The remaining challenge then is to avoid rendering other sources of pentobarbital, including some dairy cattle and livestock from “hobby” farms.

If Darling is not able to establish adequate procedures and safeguards to prevent pentobarbital residues in finished rendered products, we may have to make further changes or curtailments in animal mortality collection practices to comply with FDA guidance and regulations.

Why is it important that animal mortalities be rendered?

Rendering is the preferred method for handling animal byproducts and mortalities. The cooking process used to evaporate water and facilitate separation of the fat and protein rich solids is also validated to kill conventional pathogens, such as bacteria and viruses. The finished products are stable, microbiologically safe and able to be stored. Rendered fats have many uses, such as a source of energy in animal food and non-feed uses such as feedstock to make biofuels. Rendered proteins, however, are used primarily as sources of protein and other nutrients in animal foods or as organic fertilizers for food crops. Darling and the rendering industry contribute to sustainability by recycling water and essential nutrients, capturing carbon to reduce greenhouse gas emissions and have a role in protecting the environment and the health of humans and animals.

The U.S. Fish and Wildlife Service (FWS) published the FWS Fact Sheet **Secondary Pentobarbital Poisoning of Wildlife** (<https://www.fws.gov/mountain-prairie/poison.pdf>) which discussed reports from 16 states where bald and golden eagles, other wildlife and domestic dogs died after scavenging pentobarbital-euthanized animals. FWS concluded that pentobarbital-euthanized carcasses should not be rendered nor, should they be disposed of where wild and other animals can access the carcass. To prevent instances of secondary poisoning, only deep burial, incineration or landfills able to quickly cover carcasses should be considered. Most composting options and certainly abandonment should not be viable options. **In some cases, livestock owners and veterinarians causing such unintentional poisonings may be held liable and subject to fines and/or criminal prosecution under the Migratory Bird Treaty Act, The Bald and Golden Eagle Protection Act or The Endangered Species Act.**

Darling believes its role in collecting and processing animal mortalities is an important biosecurity function and appreciates your assistance in helping address this complex issue so that we can continue providing livestock mortality collection services.

For further information, please contact your local Darling facility. Included is the link to all Darling North America locations <https://www.darlingii.com/locations/north-america>.

Respectfully,

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