Commentary

Information for veterinarians on reporting suspected animal food issues

Jennifer L. Jones DVM
David S. Rotstein DVM, MPVM
Olgica Ceric DVM, PhD
Sarah M. Nemser MS
Renate Reimschuessel VMD, PhD

From the Office of Research, Center for Veterinary Medicine, US FDA, 8401 Muirkirk Rd, Laurel, MD 20708 (Jones, Ceric, Nemser, Reimschuessel); and the Office of Surveillance and Compliance, Center for Veterinary Medicine, US FDA, 7519 Standish Pl, Rockville, MD 20855 (Rotstein).

Address correspondence to Dr. Jones (jennifer.jones@fda.hhs.gov).

The US FDA's Center for Veterinary Medicine (CVM) protects human and animal health by regulating animal drugs and animal food, treats, and food additives.[1] Animal food must be safe and accurately labeled and produced in a sanitary manner.[1,2]

Two recent cases of animal food–related illness involving commercial pet food contaminated with pentobarbital[3] and thyroid tissue[4] highlight the important role veterinarians play in reporting suspected animal food issues. Veterinarians and others in the animal health field (eg, veterinary students and clinic staff) represent an invaluable, front-line partner because they can identify likely cases of food-related illness on the basis of dietary history and clinical signs. For this reason, veterinarians should understand the CVM's role in regulating animal food and their own potential role during an FDA case investigation and should know how to identify and report suspected animal food issues, how to collect and store samples for possible testing, and how a safety report is evaluated. Unfortunately, recent discussions with veterinarians and veterinary students indicate that many in the field are uncertain how to report suspected animal food issues, despite online resources[5–8] and previous publications.[9,10]

Identifying and Reporting a Suspected Animal Food Issue

Veterinarians may encounter 3 types of animal food issues in practice that may or may not be associated with animal illness: inaccurate product labeling, unsafe food or treats, and unsanitary production practices **(Figure 1)**. Veterinarians who suspect an animal food issue should submit a safety report[5,6] and collect diagnostic samples for possible testing by CVM's Veterinary Laboratory Investigation and Response Network (Vet-LIRN) or the FDA Office of Regulatory Affairs. Reports can be submitted by telephone[11] or electronically through the Safety Reporting Portal.[12] Reports submitted through the Safety Reporting Portal can be anonymous and can include attachments such as medical records and product pictures. In instances when multiple animals are affected, veterinarians can include information on all animals in a single report or submit separate reports for each animal.

The safety report should include as much product and animal information as possible.[5] Important information that should be included, if possible, consists of the following items:

- Product name (as given on the label)
- Container type (eg, can or bag) and net weight
- Lot number and best by, best before, or expiration date
- Barcode (Universal Product Code)
- A full description of the issue
- Results of laboratory tests performed on the product, if any
- Recommended storage conditions (eg, room temperature, frozen, or refrigerated)
- How the product was stored, prepared, and handled by the owner
- Date and location where the product was purchased
- How much leftover (open or unopened) product is available

For incidents that involve animal illness, the following important animal information should also be provided[5]:

- Signalment (eg, species, age, sex, neutering status, breed, and weight)
- Time from food consumption to illness onset
- Clinical signs and diagnostic test results
- Why the food is suspected to be the cause of the illness

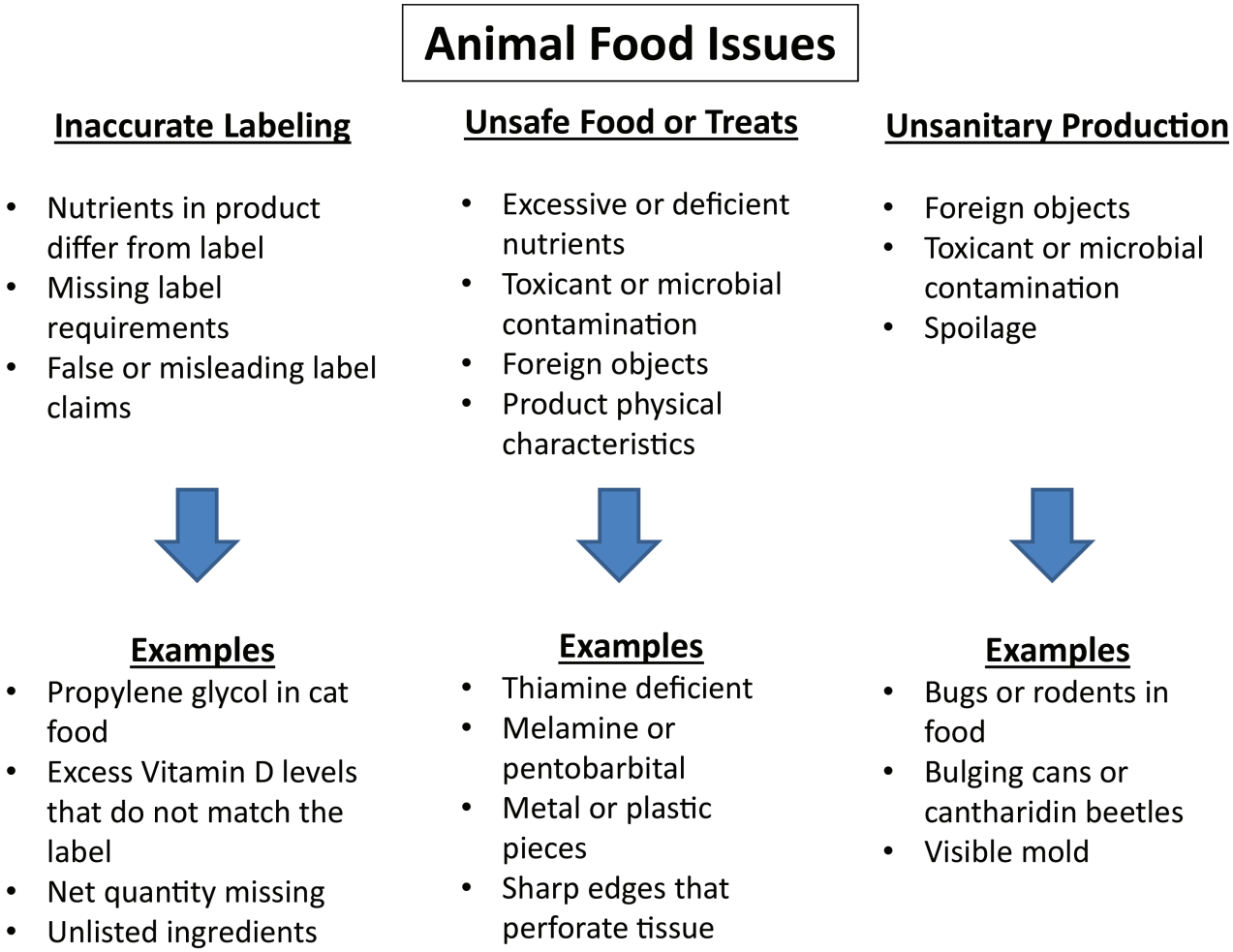

Figure 1—Illustration of the types of animal food issues veterinarians may encounter in practice.

- Whether any preexisting medical conditions were present
- Number of animals that consumed the product and number affected
- How the product was fed (eg, 1 cup, 4 times daily)
- Amount of time spent outdoors unsupervised
- Concurrent foods, treats, medications, and dietary supplements fed
- Whether any people became ill after exposure to the food or animals consuming the food

Collecting and Storing Samples for Possible Testing

After identifying a suspected food-related illness, veterinarians should obtain appropriate diagnostic samples from affected animals along with any leftover open or unopened product for potential testing **(Table 1)**. Veterinarians should clearly label (eg, with animal name and type of sample) and appropriately store (eg, in a temperature-controlled environment free from contamination) samples for 60 days after submitting a safety report. Following evaluation of the safety report, samples may be requested by the FDA Office of Regulatory Affairs for regulatory testing, the CVM Vet-LIRN for investigational testing, or both.

Evaluation of a Safety Report

All animal food–related safety reports are evaluated by a team of epidemiologists, veterinarians, nutritionists, and toxicologists, who consider the following factors in determining whether additional steps will be taken[13]:

- Determination that the FDA regulates the product
- Animal illness or injury reported and any associated health hazards
- Life-threatening product issue
- Likelihood the product caused the illness
- Likelihood the case is isolated or widespread
- Whether adequate product and animal illness information have been provided

Table 1—Appropriate samples to be collected and sample storage conditions when a food-related illness is suspected in animals.

Sample type	Sample	Storage conditions
Animal diagnostic samples	Body fluids Urine Blood or serum Stomach contents	Sealed container, frozen
	Feces (fresh)	Sealed container, refrigerated
	Carcass	Sealed container, frozen
	Tissue Liver Kidney Brain and eye Other*	Neutral-buffered 10% formalin (10:1 fixative-to-tissue ratio), room temperature Unfixed fresh tissue, frozen
	Bacterial isolates	Frozen
	Histologic slides and paraffin-embedded tissue	Protective case, room temperature
Leftover open product	Treats (eg, biscuits or jerky) Dry kibble Wet food in can or pouch Moist or dehydrated raw food Pellets or grain Commercial hay and forage	Sealed container, refrigerated (moist products) or in a cool, dry place out of direct sunlight (dry products)
Unopened product	Treats (eg, biscuits or jerky) Dry kibble Wet food in can or pouch Moist or dehydrated raw food Pellets or grain Hay	Do not open; store at manufacturer's recommended temperature

*Selected on the basis of clinical signs.

Depending on the seriousness of the problem and the severity of illness, the CVM may take any of the following steps[13]:

- Monitor for similar product safety reports
- Initiate regulatory action (eg, regulatory product testing, product recall, or manufacturer inspection)
- Obtain additional information by opening a case investigation

When monitoring for similar product safety reports, CVM does not test the product from the individual report. When initiating regulatory action, a Consumer Safety Officer from the FDA Office of Regulatory Affairs will contact the complainant or veterinarian to collect the food for regulatory testing.[13] Veterinarians can request the results of regulatory product testing by submitting a Freedom of Information Act request.[14] For other regulatory actions, the FDA will post product recall notices[15] and manufacturer inspection citations[16] on its website. When the FDA determines there is a need for additional information, the CVM's Vet-LIRN[17] will contact the complainant or veterinarian to open a case investigation. The Vet-LIRN may then collect animal diagnostic samples for investigational testing.

Vet-LIRN and Case Investigations

The CVM created the Vet-LIRN in 2010, after the 2007 discovery of melamine contaminating certain pet foods. Prior to 2010, the CVM had no mechanism to collect additional diagnostic sample information about a safety report.

The Vet-LIRN obtains additional information to supplement an initial safety report and help inform the CVM's decision-making process. The Vet-LIRN consists of 43 laboratories throughout the United States and Canada, most of which are located at veterinary colleges and state agricultural laboratories. The Vet-LIRN's procedures for veterinarians[18] and owners[19] explain how the program operates and how the public can help during a case investigation.

Potential Veterinarian Roles During an FDA Case Investigation

During a case investigation, the Vet-LIRN requests full medical records and, in some instances, a dietary and environmental exposure interview with the animal owner to develop a diagnostic sample testing plan. The Vet-LIRN asks veterinarians to collect animal diagnostic samples, leftover product, or both and provides veterinarians with materials and instructions for ship-

ping the samples to an appropriate Vet-LIRN laboratory for testing. The laboratories conduct a wide range of pathological (eg, necropsy, histologic examination, and immunohistochemical examination), microbiological (eg, culture and susceptibility testing, PCR assays, and serologic assays), nutrition (eg, testing protein, moisture, fat, vitamin, and mineral content), and toxicological (eg, heavy metals, mycotoxins, and drug residues) tests, with most testing focusing on animal diagnostic samples and, less frequently, on leftover product. Testing performed by the Vet-LIRN is investigational, and the CVM does not use the results for regulatory action. The Vet-LIRN pays for any tests it requests be performed and provides the results to the veterinarian for sharing with the animal owner. On the basis of the laboratory findings, the CVM will decide on whether any further regulatory actions are needed.

Increasing Veterinary Awareness

The CVM received a safety report from a veterinarian for only 1 of the 2 recent incidents involving pet food contaminated with pentobarbital or thyroid tissue.[3,4] Because of the importance of potential animal food–related illness, we encourage veterinary colleges to incorporate information on reporting animal food issues into the curriculum and into discussions with student-based organizations. We also encourage those providing continuing education seminars for veterinarians—whether in-person or through webinars—to incorporate this information into continuing education classes and discussions. And, we hope that professional veterinary organizations will play a role in disseminating this information. Increased awareness empowers veterinary professionals to advocate for their patients' health by increasing animal food safety. Increased awareness also helps ensure that the CVM will receive timely and complete reports about potential animal food issues. Strengthening the partnership between the veterinary community and the CVM will enhance safeguards for animal and human health.

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The authors are affiliated with the US FDA Center for Veterinary Medicine Office of Research (OR) and Office of Surveillance and Compliance (OSC). Dr. Jones and Dr. Ceric are Veterinary Medical Officers with OR's Veterinary Laboratory Investigation and Response Network (Vet-LIRN). Dr. Reimschuessel is the Director of the Vet-LIRN program, and Ms. Nemser is the Vet-LIRN Network Coordinator. Dr. Rotstein is a veterinarian and Consumer Safety Officer with OSC's Complaint Emergency Recall Team.

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