The NASC Adverse Event Reporting System (NAERS®)

More than two decades of ensuring the safety of animal supplements

NAERS® Introduction & Overview

In 2003, the National Animal Supplement Council (NASC) launched the NASC Adverse Event Reporting System (NAERS®), a revolutionary system that provides real-time monitoring through post-market surveillance and tracks both serious and non-serious adverse events for animal supplements. The system, which is continuously upgraded, provides NASC members and regulatory agencies access to qualitative and quantitative data on the safety of animal supplement products and ingredients.

NASC developed and maintains NAERS® to support the ongoing monitoring of adverse events related to animal supplements and to serve as an important early warning system for identifying potential safety concerns. Today, it is widely recognized as the most advanced post-market surveillance system in the world for animal supplements.

NASC member companies that manufacture or market animal health and feed/food supplements are required to enter detailed product information into NAERS®. Required information includes:

- ✓ Product label images.
- ✓ A complete list of all ingredients contained in each product, including the quantity per unit of administration for functional ingredients.

To support ongoing surveillance, each NASC member is also required to:

- ✓ Investigate and resolve every reported adverse event.
- ✓ Submit a monthly report indicating whether any adverse events occurred, including reports when no adverse events are identified.
- ✓ Report quarterly the number of product units shipped to customers.
- ✓ Report individual product Stock Keeping Units (SKUs),[1], which supports the ability to determine the number of adverse events per million administrations by individual, unique ingredients and individual product SKUs.

Today, the NAERS® database tracks more than 100 billion supplement administrations and contains over 200 billion bytes of data for products used by dogs, cats, and horses. By combining adverse event reports with product administration data, the system provides a robust, statistics-based approach to risk assessment that demonstrates the safety profile of individual ingredients within their target species, primarily dogs, cats and horses. This comprehensive risk management system exceeds the post-market surveillance requirements established by the FDA for many approved drug products.

[1] A SKU, or Stock Keeping Unit, is a unique alphanumeric code, typically 8-10 characters long, used to identify a product; a SKU is unique to an individual product and captures all the distinguishing characteristics of the product, such as manufacturer, flavor, unit size, dosage, etc.

Why Tracking Adverse Events for Health & Food Supplements is Imperative

Pet owners, veterinarians, manufacturers, distributors, and retailers all share a common interest in ensuring the safety of animal supplements provided to dogs, cats, and horses and in identifying and addressing any potential safety concerns as quickly as possible. An adverse event is a complaint linking the use of an animal health or nutritional supplement to a negative physical effect or health problem in a dog, cat, or horse. Anyone may report an adverse event by contacting the company listed on the product label. NASC member companies are required to investigate every reported adverse event and upload information about each event to the NAERS® database.

Types of Adverse Events Experienced by Pets	Potential Impact on Animals and the Industry
Adverse Event – A complaint linking a product to any negative physical effect or health problem that may associated with its use.	May be isolated to a particular company or subset of companies because of an ingredient, manufacturing process, or other issue unique to that company.
Serious Adverse Event – An adverse event resulting in a transient incapacitating effect (e.g., rendering an animal unable to function normally, even temporarily, such as during a seizure) or a non-transient (long-term or permanent) health effect. Transient vomiting or diarrhea does not constitute a serious adverse event. A reported serious adverse event requires veterinary follow-up; a layperson's diagnosis alone does not qualify.	May indicate a broader industry concern, such as contamination of a commonly used ingredient or a potentially harmful interaction between ingredients used by multiple manufacturers.

NASC's extensive post-market surveillance data demonstrate that adverse events associated with animal supplements are rare and, when they do occur, typically minor. Reporting adverse events allows pet owners, veterinarians, manufacturers, distributors, and retailers to take prompt action to protect animals from products or ingredients of concern. NAERS® provides NASC and regulators, both in the United States and internationally, with real-time data to assess whether a reported adverse event represents an isolated issue affecting a specific company or product, or a broader concern warranting industry-wide attention. The system's ability to monitor and analyze safety data in real time provides a level of consumer protection that often exceeds the FDA's post-market surveillance requirements for many approved products.

NAERS® Facilitating Transparency and Regulatory Oversight

NAERS® serves as the cornerstone of NASC's comprehensive system of co-regulation. Proprietary algorithms within the NAERS® platform continuously monitor more than **1,400 unique ingredients** contained in over **7,000 products** currently on the market. Using the NAERS® database, NASC generates Ingredient Risk Reports that evaluate the safety profile of individual ingredients and help ensure that products and ingredients do not pose undue risks to animals receiving supplements. Although NAERS®

data remain confidential among NASC members, the FDA, as well as state and international regulatory agencies, may access the database upon request. These regulators have used and recognized NAERS® data in evaluating products and ingredients. For example, the Canadian Veterinary Drugs Directorate uses data from NAERS® to help evaluate ingredients for adding to the "List of Acceptable Substances (LAS)." NASC and NAERS are specifically recognized in the Canadian Food & Drugs Act, which is the equivalent of the U.S. Federal Food, Drug & Cosmetic Act (FFDCA).

Three NAERS® Case Studies: Examples of Success in Protecting Pet Health

Pet Illnesses and Deaths Associated with Treats

Between 2007 and December 31, 2015, FDA reported it received approximately 5,200 complaints of pet illnesses associated with the consumption of chicken (treats, tenders, strips), duck, and/or sweet potato jerky treats, many of which were products imported from China, which according to the FDA produces much of the jerky pet treats sold in the U.S. market. Although at the time treat products were not covered by NASC or entered into NAERS®, FDA once again asked NASC if there was any data that could potentially help inform the agency's investigation into the specific causes of the significant increase in canine and feline deaths. NASC readily ran Ingredient Risk Reports, which assisted in the agency's inquiry. As part of this collaboration, FDA inquired as to whether NASC "had ever considered expanding the scope of NAERS® to include pet treats?" NASC takes seriously the role it plays in ensuring the health, safety, and well-being of companion pets and horses and has since expanded its scope to include "treats" for dogs, cats, and horses.[2]

Early Warning System: Salmonella Contamination

Although Salmonella may not present a specific hazard in animals, it does cause concern for potential harm for humans, especially children who may feed their pets and come in direct contact with pet food that could test positive for the presence of this microorganism, which can cause serious gastrointestinal illness. Due to the concern for human safety, if Salmonella is detected in pet food, it triggers a Class 1 recall.[3]

Circa 2013-2014, data from NAERS® helped NASC identify Salmonella contamination from a raw material: fish meal used to enhance palatability in a product tested positive for Salmonella. NASC was able to isolate the specific source of the contamination and help ensure that the finished product was pulled before it entered the marketplace. There have been two instances where NASC was made aware of Salmonella contamination in supplements, allowing affected companies to be alerted; this enabled the companies to quickly isolate and contain the affected products. This early warning system helped control the situation and prevented a more serious problem for the industry and animal owners.

[2] https://www.petfoodindustry.com/pet-supplements-pro/nasc-news/news/15817138/nasc-expands-quality-seal-program-to-include-pet-treats

[3] https://www.fda.gov/animal-veterinary/outbreaks-and-advisories/fda-and-cdc-investigate-cases-salmonella-linked-pet-food-made-mid-america-pet-food-multiple-brands

Industry-Wide Fatal Pet Food Problem

Beginning late in 2006 and increasing in early 2007, the FDA Center for Veterinary Medicine (FDA-CVM) began receiving reports of an increasing number of dog deaths suspected to be a result of undetermined causes connected with pet food. At the time, FDA had no clear understanding of the possible causes; however, it suspected that something connected to grain-based protein sources might be responsible.[4]

Dr. Lynn Post (ret.), Director of the Office of Surveillance and Compliance, contacted NASC to request any information that might help FDA-CVM narrow down the potential cause of the increasing number of reported dog deaths. Although "supplements" were not involved, NASC was able to quickly search the NAERS® database and run Ingredient Risk Reports for all products containing wheat, corn, soy, and rice. Within a day of receiving the agency's request, NASC shared its findings with FDA-CVM. NASC data showed that there were no issues with supplements and likely helped eliminate grain-based supplements as a possible source of the problem.

Ultimately, it was determined that the combination of melamine and cyanuric acid caused a toxic response in dogs, resulting in kidney failure and prompting numerous recalls. These unfortunate circumstances provided the foundation for the development, enactment, and implementation of the Food Safety Modernization Act (FSMA)[5], which represents the most comprehensive update to the FFDCA since 1958.

Summary

Founded in 2001, NASC is a nonprofit trade association with a clear mission: **To promote the health and well-being of companion animals and horses given animal health and nutritional supplements by their owners and to protect and enhance the animal supplement industry.** NASC carries out this mission in partnership with its more than 300 members for the benefit of millions of dogs, cats, and horses that rely on animal health and nutritional supplements to live their healthiest, happiest lives. NAERS® demonstrates NASC's long-standing commitment to ensuring the safety of animal supplements.

NAERS® serves as the cornerstone of NASC's comprehensive system of co-regulation; NASC is proud to have created the NAERS® system and appreciates the ongoing partnership with FDA to help ensure the provision of safe, beneficial products to dogs, cats, and horses. NASC's expectations and standards for its members include ensuring proper product labeling, consistent with U.S. statutes that define the intended use of products, as well as required compliance with written procedures for process controls established under NASC's current Good Manufacturing Practice (cGMP) standards. To learn more about how NASC ensures the safety of animal health supplements visit www.animalsupplements.org.

[4] 2007 Pet Food Recalls, investigation and causes: https://en.wikipedia.org/wiki/2007_pet_food_recalls
[5] https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma