

PET FOOD INSTITUTE

2025 M Street, NW, Suite 800, Washington, DC 20036 • 202/367-1120 • FAX 202/367-2120 • www.petfoodinstitute.org

OFFICERS

Chairman
James von der Heydt

Vice Chairman
Michael Wright

Treasurer
Dan Reid

Secretary
Peter Cheney

Executive Director
Duane Ekedahl

BOARD OF DIRECTORS

American Nutrition

Best Feeds

Bil-Jac Foods

Dad's Products Co.

Doane Pet Care

Friskies PetCare Co.

Heinz Pet Products

Hill's Pet Nutrition

The Iams Company

Kal Kan Foods

Nabisco Inc.

Old Mother Hubbard

Pet Life Foods

Pro-Pet

Ralston Purina Company

Texas Farm Products

August 4, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5360 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Draft Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds;
Availability

Dear Sir or Madam:

The Pet Food Institute (PFI), which represents the manufacturers of 95% of the commercially produced pet food in the U.S. (an \$11.5 billion industry), appreciates the opportunity to file comments on the above referenced proposal. Our preliminary studies indicate that it could have a major impact on the operation and economics of pet food manufacturers throughout the United States for three reasons.

First, the proposal appears to be somewhat arbitrary in the level selected (10ppm) for "all other species". There appears to be little data which would support limiting fumonisin to this level, or this level at a 50% inclusion rate. PFI would appreciate documentation and analysis of the studies which lead FDA to determine that this is the proper maximum inclusion rate, both in ppm(s) and in percentages in the feed for "all other species", including cats and dogs. FDA says in its background document, "The last grouping was of animal species/classes not mentioned above (e.g. dogs, cats). Often there was no published dietary study with fumonisins in these animals and no historical indication/association of problems from feeding corn." PFI believes that because there is "no historical indication/association of problems from feeding corn", that the assignment of the low 10ppm level is arbitrary and should be raised.

Second, a Grain Inspection, Packers and Stockyards Administration (GIPSA) approved "quick test" for fumonisin does not yet exist, and the contract for development of this test has not yet been let. Thus verification of levels uniformly is an issue. PFI is aware that a commercially available test is in the field, however, it has not to this point been certified by GIPSA.

Finally, PFI is concerned that "guidance documents" by inference become "action levels" in the market place. Since this document appears to be lacking in scientific substantiation for both the arbitrary level of inclusion for cats and dogs, and in the availability of an approved "quick test", PFI requests that the recommendation for cats and dogs be re-evaluated. In light of the lack of "historical indication/association of problems with feeding corn" to these animals, it would appear that re-evaluation would be fair.

Thank you for your consideration of these comments, and please feel free to call if you have questions.

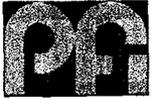
Respectfully,

Nancy R. Cook

Nancy R. Cook
Director, Technical and Regulatory Affairs

00D-1277

C 2



PET FOOD INSTITUTE

2025 M Street, NW, Suite 800, Washington, DC 20036

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5360 Fishers Lane, Room 1061
Rockville, MD 20852