



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0520]

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substances Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review--Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0339. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in

Ruminant Feed--21 CFR 589.2000(e)(1)(iv)

OMB Control Number 0910-0339--Extension

Section 701(a) (21 U.S.C. 371(a)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) gives us the authority to issue regulations for the efficient enforcement of the FD&C Act. Our regulation at 21 CFR 589.2000 provides that animal protein derived from mammalian tissue (with some exclusions) is not generally recognized as safe (GRAS) for use in ruminant feed and is a food additive subject to certain provisions of the FD&C Act (62 FR 30936, June 5, 1997).

This information collection was established because epidemiological evidence gathered in the United Kingdom suggested that bovine spongiform encephalopathy (BSE), a progressively degenerative central nervous system disease, is spread to ruminant animals by feeding protein derived from ruminants infected with BSE. This regulation places general requirements on persons that manufacture, blend, process, and distribute products that contain, or may contain, protein derived from mammalian tissue, and feeds made from such products.

Specifically, this regulation requires renderers, feed manufacturers, and others involved in feed and feed ingredient manufacturing and distribution to maintain written procedures specifying the cleanout procedures or other means and specifying the procedures for separating products that contain or may contain protein derived from mammalian tissue from all other protein products from the time of receipt until the time of shipment. These written procedures are intended to help the firm formalize consistent processes, and then to help inspection personnel confirm that the firm is conducting these processes in compliance with the regulation. Inspection personnel will evaluate the written procedure and confirm it is being followed when they are conducting an inspection.

These written procedures must be maintained if the facility is operating in a manner that necessitates the record, and if the facility makes changes to an applicable procedure or process

the record must be updated. Written procedures required by this section shall be made available for inspection and copying by FDA.

*Description of Respondents:* Respondents include renderers, feed manufacturers, and others involved in feed and feed ingredient manufacturing and distribution.

In the *Federal Register* of January 28, 2022 (87 FR 4626), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received it was not responsive to the four collection of information topics solicited.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Recordkeeping Burden<sup>1</sup>

21 CFR Part	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Written procedures; 589.2000(e)(1)(iv)	225	1	225	14	3,150

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimate of the number of recordkeepers on inspectional data. Based on a review of the information collection since our last request for OMB approval we have adjusted our burden estimate, which has resulted in a decrease of 1,330 hours. Review of our inspection data suggests that the number of facilities that need to conduct these separation practices is gradually decreasing, therefore we have decreased the number of facilities who must comply, as well as the total number of hours needed to comply with this burden.

Dated: August 5, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*