

OMB # 0910-0339

Docket No. 00N-0505

SUPPORTING STATEMENT

Substances Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed

A. JUSTIFICATION

1. Circumstances Making the Information Collection Necessary

Section 701(a) (21 U.S.C. 371(a)) of the Federal Food, Drug, and Cosmetic Act (the act) gives us the authority to issue regulations for the efficient enforcement of the act. On June 5, 1997, we issued a final rule which amended 21 CFR 589.2000 to provide 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 act.

We took this action because epidemiological evidence gathered in the United Kingdom suggests 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. While BSE has yet to be diagnosed in the United States, measures were necessary to prevent the establishment and amplification of this fatal disease in this country and thereby minimize any risk which might be faced by animals and humans.

The rule placed 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.

This is a request for OMB approval of the recordkeeping requirement in the following citation:

21 CFR 589.2000 (e) (1) (iv) - Recordkeeping -

Requirement specifying written procedures be developed and records maintained to ensure separation of mammalian protein from non-mammalian protein intended for use in ruminant feed.

2. Purpose and Use of the Information.

These records would be subject to inspection by Federal and State agencies to assure that ruminant feed does not contain protein derived from mammalian tissues. Records must be retained for a one year minimum period.

3. Use of Information Technology and Burden Reduction.

The regulation does not specifically prescribe the use of automated, electronic, mechanical or other technological techniques or other forms of information technology as necessary for use by firms. Firms have the option of using information technology if they wish.

4. Efforts to Identify Duplication and Use of Similar Information.

There are no other regulations or Federal agencies that require the development and maintenance of recordkeeping of this nature.

5. Impact on Small Business or Other Small Entities.

The recordkeeping provisions are no more burdensome for small firms than for large. The regulations require all affected parties to maintain the same records. The recordkeeping requirements are based on the risk associated with the product.

6. Consequences of Collecting the Information Less Frequently

If there is no requirement to keep these records and no end-product testing available, the agency will have only limited means to monitor compliance. Without the ability to monitor compliance, the health of animals and the public may be put at risk.

7. Special Circumstances Relating to the Guideline of 5 CFR 1320.5

All recordkeeping requirements are consistent with 5 CFR 1320.5.

8. Efforts to Obtain Comments on the Information Collection Before Submission to OMB.

The center for Veterinary Medicine (CVM), published a 60 day notice in the **Federal Register** (attached), soliciting comments on the recordkeeping requirements placed on handlers of ruminant proteins, to ensure separation of mammalian protein from non mammalian protein intended for use in ruminant feed. No comments were received.

9. Explanation of Any Payment or Gift to Respondents.

This information collection does not provide for payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondent.

Confidentiality of information will be safeguarded within the provisions of FDA's public information regulations in 21 CFR Part 20,

11. Justification for Sensitive Questions.

This information collection does not involve any questions of a sensitive nature.

12. Estimates of Hour Burden Including Annualized Hourly Cost.

Firms (renderers, blenders, feed manufacturers and distributors) that handle animal protein products from both mammalian and non-mammalian sources, and intend to keep the products separate, have certain requirements related to their source of mammalian material, i.e., the need for separate facilities or clean out procedures and standard operating procedures (SOPs). Similar requirements also apply to firms that handle feeds containing animal protein products from both mammalian and non-mammalian sources.

The recordkeeping burden in the following table has been estimated using the typical average size firm that handles animal protein from both mammalian and non-mammalian sources, or feeds containing these products, which in both instances, are kept separate. Our estimate of the number of recordkeepers that separate mammalian and non-mammalian materials is derived from inspection data of firms handling animal protein for use in animal feed. The annualized hourly burden for recordkeeping under 21 CFR 589.2000 (e)(1)(iv) is estimated as follows:

Estimated Annual Recordkeeping Burden:

21 CFR Section	No. of Recordkeepers	Annual Frequency per response	Total Annual Records	Hours per Recordkeeper	Total Hours
589.2000(e)(1)(iv)	1030	1	1030	14	14420

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

13. Estimate of Other Total Cost Burden to Respondents and Record keepers

There are no additional costs associated with this collection of information.

14. Annualized Cost to the Federal Government.

Records would be inspected during the agency's normal course of business. Either during routine or for cause inspections. In addition some of these inspections would be carried out under contract or in partnership with state agencies.

Estimated total number of hours per federal inspection spent on reviewing records = 4 hours

Estimated number of federal inspections each year = 60 federal

Estimated number of hours for record review = 240 federal hours (60 inspections x 4 hours).

Estimated number of state inspection performed under contract to or in partnership with the federal government = 200-500

Estimated number of hours for federal coordination and instruction = 800 hours

Estimated total cost for review of records, coordination, and instruction = (1040 hours [800 = 240] x \$30/hour for review/coordination/instruction) = \$31,200 (hourly cost for review or instruction is equivalent to that of a base GS-13 salary.)

The above estimate is for additional inspections resulting from the proposed rule. FDA and the States currently visit 600 to 800 feed establishments a year to fulfill the requirements of various other compliance programs. We envision that during these visits, inspectors would check records for compliance with the proposed rule in addition to the primary purpose for the visit.

15. Explanation of Program Changes or Adjustments.

Our original estimate was that 2,000 firms would attempt to separate mammalian and non-mammalian tissue. Inspection data finds the total to be approximately 1,030.

16. Plans for Tabulation and Publication and Project Time Schedule.

Not applicable.

17. Explain the reasons that display of the expiration date for OMB approval of the information collection would be inappropriate.

Not applicable.