

Pet Event Tracking Network-State
Federal Cooperation to Prevent Spread of
Pet Food Related Diseases and Livestock Network
OMB Control No. 0910-0680
Supporting Statement

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 1002(b) of the FDA amendments of 2007 mandated that “not later than 1 year after the date of the enactment of this Act, the Secretary shall establish an early warning and surveillance system to identify adulteration of the pet food supply and outbreaks of illness associated with pet food.” This legislative action was taken in response to the 2007 outbreak that occurred in companion animals that was associated with the deliberate adulteration of pet food components, such as wheat gluten with melamine.

In part to fulfill this mandate, FDA formed the Partnership for Food Protection (PFP) with Federal, State and Local government partners to continue work started at the Gateway to Food Protection 50-State meeting held in August 2008 in St. Louis, Missouri. As part of the PFP, CVM was charged with facilitating the development of the Pet Event Tracking Network (PETNet). CVM assembled a PETNet working group composed of Federal and State government partners. The PETNet working group determined PETNet would be a secure information exchange network that would allow FDA and the appropriate Federal and State Agencies to share initial reports of food-borne disease outbreaks in pets.

PETNet was originally developed for pet animals only, but after its initial launch in 2011, there have been ongoing requests to expand the system to include livestock animals, aquaculture species, and horses. Such an early alert system does not currently exist to share information related to illness associated with consumption of adulterated food or product defects for these species. LivestockNet has been developed to serve as a similar early-alert system for feed-related illness and product defects associated with feed for livestock animals, aquaculture species, and horses.

LivestockNet and PETNet will be web-based portals with the same functionality, but the questions asked for each portal will be specific for each. Users of the individual portals are expected to be the same officials from Federal, State, and Territorial agencies. Because of the similarity of the portals and the intended audience for both, the two individual portals will be housed in an overall system titled the Animal Feed Network. PETNet and LivestockNet will be able to be accessed individually in the Animal Feed Network, once the user logs into the system.

Use of the Animal Feed Network, including the reporting of incidents, will continue to be voluntary. FDA and the PFP have designed the form itself to contain only the essential information necessary to alert Animal Feed Network members about animal feed- and pet food-related incidents.

This action also relies on 21 U.S.C. 342 and 343, the adulteration and misbranding sections of the FD&C act respectively.

This information collection is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

2. Purpose and Use of the Information Collection

The Animal Feed Network will allow FDA and its State partners to quickly and effectively exchange information about outbreaks of illness in companion animals and livestock associated with animal food. FDA has worked closely with its Federal and State partners to develop this initiative, and believes that it will serve an important function in protecting the public and animal health. The Animal Feed Network will be a secure, internet-based system accessed by the FDA, other Federal agencies, and State regulatory and public health officials that have authority over animal food. The Network will provide timely and relevant information about animal food-related incidents to FDA, the States, and other Federal Government agencies charged with protecting animal and public health.

3. Use of Improved Information Technology and Burden Reduction

The Animal Feed Network is an entirely electronic, internet-based system. Its members will make reports about animal food-related incidents in their jurisdiction and receive reports made by other members through a secure, internet website (www.animalfeednetwork.net). Use of the system is entirely voluntary. The system will make use of standardized electronic forms to collect and distribute basic information related to animal-food incidents. The system contains separate forms for PETNet and LivestockNet that were developed specifically for companion animals and livestock animals, respectively. The form contains drop down menu choices and free text entry fields. FDA estimates that 100% of the respondents will use electronic means to use this system.

4. Efforts to Avoid Duplication and Use of Similar Information

The information obtained from the participants is not currently available in real time in order to deal with pet food and livestock food incidents that occur across State lines and which could affect large numbers of animals. This system will allow integrated data from multiple sources to be shared in a timely and efficient manner; a goal, which has not been achieved prior to this program.

5. Impact on Small Businesses or Other Small Entities

This is an incident reporting network that does not directly affect small businesses to any degree more than large businesses. An indirect effect of this program would be to contain to a greater extent the occurrence of such outbreaks, which would protect consumers and animals and therefore, create more consumer confidence in the pet and livestock food supply.

6. Consequences of Creating the Information Less Frequently

The information cannot be collected less frequently because it is collected as an outbreak occurs. There is ongoing data collection. To collect this information less frequently would reduce the effectiveness and usability of the data sources.

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

In order to be useful, the information must be collected as incidents occur and on an ongoing basis. This would foster improved Federal-State cooperation and communication.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register on August 26, 2013 (78 FR 52774). Although the agency received four comments, none were responsive to the information collection elements solicited in the notice. Three comments, however, generally supported FDA's efforts to improve the safety of pet and livestock food.

9. Explanation of any Payment or Gift to Respondents

There are no gifts or payments to respondents.

10. Assurance of Confidentiality Provided to Respondents

The Animal Feed Network is comprised of Federal and State regulatory and public health officials (respondents) who will report information about animal food-related incidents in their jurisdiction by filling out a standardized electronic form. The form is housed on a secure internet site that is not available to the public, and only authorized members will be able to submit or receive reports. The standardized form has been designed to contain mostly questions with drop down answers, and will not contain any personal information such as the names or addresses of veterinarians, pet owners, or others involved in a pet or livestock food incident. The system is designed to automatically capture the name and contact information for the Animal Feed Network member (i.e. Federal or State government official) entering a report into the system so that other members can follow up with the reporter for further information or questions about the reported incident.

11. Justification of Sensitive Questions

FDA is not asking questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

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

Table 1.—Estimated Reporting Burden

21 U.S.C. Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
21 U.S.C. 342, 21 U.S.C. 343, Section 1002(b) of the FDA Amendments Act of 2007/PETNet	20	5	100	.25	25
Ibid./ LivestockNET portal	20	5	100	.25	25
Total Hours					50

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

FDA estimates that 20 members will report to the Animal Feed Network (i.e., fill out the PETNet or LivestockNET form to alert other members about a pet food- or animal feed-related incident, respectively) approximately 5 times per year for each portal. This estimate represents the maximum number of reports that FDA expects a member to submit in a year, and in many cases the number of reports submitted by a member will probably be less. FDA believes that, given the PETNet form has 15 items and the LivestockNet form has 19 items, with most being drop down fields and not all fields being required for submission, 15 minutes is a sufficient amount of time to complete the form. State regulatory officials responsible for animal feed and pet food already possess computer systems and have the internet access necessary to participate in the Animal Feed Network, and thus there are no capital expenditures associated with the reporting.

Regarding recordkeeping, State regulatory officials who report in the Animal Feed Network receive the reportable information from consumers in their States in the course of their customary and regular duties. Further, these individuals already maintain records of such consumer complaints in the course of their duties which are sufficient for the purposes of reporting in the PETNet and LivestockNet portals of the Animal Feed Network. Therefore, FDA believes that the proposed collection of information does not have additional recordkeeping requirements.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Veterinarian and Other Scientific and Technical State Specialists ¹	50	\$43.50	\$2175

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no other costs.

14. Annualized Cost to the Federal Government.

We estimate that the annual cost to government is approximately \$105,211. This reflects the cost of one FTE for a GS-14 Consumer Safety Officer to review and monitor submissions.

15. Explanation for Program Changes or Adjustments

Although the agency has seen an increase in usage for this voluntary collection since its implementation, upon reevaluating the collection we find that our initial numbers were too high. We attribute this to the absence of data upon which we could rely to make a more informed burden estimate upon commencement of the program. For this revision request, we were able to utilize reporting data from the past 3 years to provide a more accurate estimate, which has resulted in a burden reduction. Specifically, the number of annual responses has decreased by **300** and the annual hourly burden has decreased by **117**.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no such plans.

17. Reasons Display of OMB Expiration Date is Inappropriate

Display is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

¹ May 2009--Bureau of Labor Statistics, Occupational Employment and Wage Estimates for State Government. Veterinarians and Other Professional Scientific and Technical Services.