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GAO

United States
General Accounting Office
Washington, D.C. 20548

Resources, Community, and
Economic Development Division

B-249636



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August 21, 1992

The Honorable Barbara Boxer
House of Representatives

Dear Mrs. Boxer:

This letter responds to your request that we review the scientific adequacy of documentation compiled by the Food and Drug Administration (FDA) in support of its decision to (1) raise the amount of selenium permitted as an additive/supplement to animal feeds and (2) eliminate requirements for the analysis of each batch of selenium mixture (called premix) manufactured for use in animal feedstuffs.

Selenium is an essential nutrient for the normal growth and development of animals. However, selenium in greater than minute (trace) amounts is toxic to human and animal life. According to FDA, the minimum dietary requirement for selenium ranges from 0.1 to 0.5 parts per million (ppm), depending on animal species, age, and other factors. Although selenium is a natural element found all over the world, FDA estimates that about 70 percent of the basic feedstuffs grown domestically do not contain enough selenium to meet the nutritional needs of animals. FDA first approved the use of selenium in small amounts as an animal feed additive in 1974 in response to a feed industry petition. FDA also required industry to analyze each batch of selenium premix to ensure that established maximum allowable levels of selenium were not exceeded.

After issuing a final rule amending the selenium food additive regulation on April 6, 1987, FDA received numerous comments objecting to the increased levels of selenium allowable in animal feedstuffs. Commenters raised questions regarding the adequacy of the scientific data used to reach the decision and the potential harmful effect that increased levels of selenium might have on the environment when leached from animal wastes (manure and urine).

GAO/RCED-92-256R, Selenium in Animal Feeds

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In summary, several actions are under way to address the selenium issue. FDA has asked the Department of the Interior for its official position on the adequacy of scientific data FDA used in formulating the 1987 rule. FDA will also hold a public hearing on the selenium issue on August 25 and 26, 1992. In addition, the Environmental Protection Agency (EPA) is expected to respond soon to a request from the Chairman, Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, on the scientific adequacy of data used in FDA's 1987 decision.

As agreed with your office, we are providing information on the status of the selenium issue, including current actions to resolve it. This letter confirms our briefing to your office on July 20, 1992.

HISTORY OF THE 1987 SELENIUM AMENDMENT

In 1986 the American Feed Industry Association petitioned FDA to increase the amount of selenium allowable in animal feed for some species from 0.1 ppm to 0.3 ppm. The Association also asked that FDA eliminate the premix analysis requirement because, in the Association's opinion, quality control was ensured by the Current Good Manufacturing Practices (CGMP) standards already required of the industry and monitored by FDA. In accordance with requirements of the National Environmental Policy Act (NEPA) and FDA regulations, the Association submitted an Environmental Impact Assessment on its proposal to FDA. FDA evaluated and accepted the Association's assessment. In addition, using "worst-case" calculations to compensate for missing and incomplete data, FDA concluded that no significant environmental consequences would result from raising the allowable selenium supplement levels as proposed. FDA also agreed with the Association's position that CGMP standards could be relied on in lieu of testing each batch of selenium premix.

Notice of the Association's petition was published in the Federal Register on February 21, 1986 (51 FR 6321). FDA's final rule amending the selenium food additive regulation was published in the Federal Register on April 6, 1987 (52 FR 10887). The amended regulation allowed up to 0.3 ppm selenium as an additive to animal feed and eliminated the premix analysis requirement. According to FDA officials, the agency itself had also determined that a 0.3 ppm selenium supplement was needed to prevent selenium deficiency diseases in livestock, largely on the basis of

recommendations made by the National Research Council in a series of studies.¹ (The National Research Council is part of the National Academy of Sciences--a quasi-public scientific organization chartered by the Congress in 1863 as an official U.S. government adviser.) The 1987 rule currently regulates selenium supplements in animal feedstuffs.

Among the objections received by FDA on the final rule were concerns that FDA did not consider the ability of selenium to biologically concentrate, accumulate, and magnify in the environment and that the possible buildup from its continued use in animal feeds could impair aquatic ecosystems and endanger fish and wildlife. Some commenters requested a "stay" of the amended rule and/or a public hearing on their objections.

FDA provided a tentative response to the environmentally based objections on the final rule in the Federal Register on July 11, 1989 (54 FR 29019). In essence, FDA found that the comments received did not provide information that could be used to resolve scientific issues concerning the impact of selenium on the environment. FDA therefore extended the period for public comment to 60 days to request additional information on the biological accumulation of selenium from animal manure and the contribution of this source to selenium levels in the environment.

During the 60-day period, FDA received numerous comments from Members of Congress, scientists in federal and state agencies, conservation and environmental groups, and others. Among other things, these commenters said that the data used by the Association and FDA in making their assessments were inadequate and outdated. Individual scientists from Interior expressed concerns that the higher levels of selenium that would be leached into the environment from animal wastes might biologically accumulate in aquatic environments and result in toxicity to fish, wildlife, and humans through the food chain. Some commenters believed that an Environmental Impact Statement

¹Of the series, FDA officials cited as principal in importance Mineral Tolerance of Domestic Animals (Washington, D.C.: National Academy Press, 1980); Selenium in Nutrition (Washington, D.C.: National Academy Press, 1983); and Nutrient Requirements of Domestic Animals, Beef Cattle (Washington, D.C.: National Academy Press, 1984).

should be prepared using more current data, and public hearings were again called for to address the selenium issue.

CURRENT ACTIONS

In an April 15, 1992, letter, FDA asked Interior for an official position on the adequacy of the Finding of No Significant Impact that FDA had prepared for the 1987 amendments to its selenium additive regulation. In turn, Interior solicited input from seven of its bureaus and services regarding the issue. Interior officials told us that the input is now being reviewed and a combined departmental response is being prepared for release to FDA.

In addition, on June 26, 1992, FDA announced in the Federal Register (57 FR 28606) that it will hold a public hearing on the selenium issue. FDA's objectives in holding the hearing are to (1) identify issues of public concern, (2) obtain comments and analyses from other government agencies and scientists, and (3) identify a wider circle of resources (i.e., associations, institutions, individuals) that are interested in developing better data on the selenium biological/geological chemical cycle and the role of selenium supplements in the food of animals and humans. The hearing is scheduled to take place at 8:30 a.m. in the Jack Mesur Auditorium, Building 10, Clinical Center, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland, on August 25 and 26, 1992.

FDA believes that once it has received and evaluated information from Interior and the public hearing, it will be in a better position to address the environmental issues raised about selenium regulation. According to FDA, if evidence of significant environmental impact is presented, the agency may take one or more courses of action to minimize potential risk, including denying, in whole or in part, the food additive petition that prompted the 1987 selenium additive amendments.

According to FDA's Director, Division of Surveillance and Compliance, Center for Veterinary Medicine, it is FDA's responsibility to prepare an Environmental Impact Statement on the selenium supplementation of animal feeds, should one be needed. However, FDA does not support the preparation of an Environmental Impact Statement until better scientific data are available. The Director believes that the selenium issue may be resolved within a year if enough new scientific data are obtained as a result of the public

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hearing. However, if additional basic research is needed, it may take another 3 to 5 years before the selenium issue is settled. FDA believes that it would be potentially costly and beyond the scope of its statutory requirement for it to perform basic research on the selenium issue. At this point it is not clear who would be responsible for this additional research should it be needed.

In addition, on February 25, 1992, the Chairman of the Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, asked EPA to review the scientific adequacy of FDA's decision to increase the amount of selenium allowed in animal feed. Particular reference was made to the NEPA documentation submitted by the Association and FDA in support of the 1987 selenium amendments. The EPA official coordinating the work involved told us that EPA's response to the Chairman is imminent.

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As discussed with your office, because scientific staff at Interior and EPA are currently reviewing the scientific adequacy of NEPA documentation submitted in support of the 1987 selenium amendments, we do not believe that a separate evaluation of that documentation by GAO at this time would contribute further toward resolving the issue.

If you or your staff have any questions about this information, please call me at (202) 275-5138.

Sincerely yours,



John W. Harman
Director, Food and
Agriculture Issues

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