LETTER 16 - David Eisenberg

Response to Comment 16-1

Selenium (Se) is a naturally-occurring semi-metallic element that is both an essential nutrient for animals at relatively low levels and a potential environmental toxin at elevated levels. Selenium occurs in the environment in a variety of inorganic and organic forms (or species). Of the common inorganic forms, selenium oxide (SeO) is virtually insoluble in water while selenates and selenites are selenium salts that are soluble and are the typical forms found in water. Organic species of selenium include selenomethionine, which is incorporated into proteins. Volatile organic species of selenium include dimethylselenide, which is transpired by plants.

The potential toxicity of selenium to livestock has been recognized for many years. Elevated levels of selenium contained in forage crops has resulted in alkali disease and "blind staggers." Clinical signs of toxicity include lameness, sloughing of hooves, emaciation, and loss of hair. Selenium concentrations of 5 to 40 milligrams per kilogram (mg/kg) in dairy cattle can cause chronic toxicity. Acute toxicity can occur in young cattle when selenium concentrations exceed 10 mg selenium per kilogram of body weight.[3]

Although the toxic effect of selenium on livestock has concerned animal nutritionists for a long time, the dietary benefits of selenium were not recognized until the late 1950s when selenium became recognized as an essential micronutrient. Ruminant animals, such as dairy cows, can develop white muscle disease when deficient in selenium. This disease is manifested by leg weakness and stiffness and muscle tremors. Poor growth, unthriftiness, and diarrhea have been attributed to selenium deficiency. The best understood metabolic function of selenium is as a component of glutathione peroxidase, an enzyme that is important to the cellular antioxidant system.

Animal nutrition science has established selenium as an important dietary requirement for livestock. Selenium is one of over twenty micronutrients that are commonly recommended as necessary for proper dairy cattle health. In most areas of the United States and many parts of the world, the amount of selenium naturally contained in forage and other feedstock is less than the amount required for a healthy diet. Therefore, as with other important nutrients, selenium is commonly prescribed by nutritionists as a dietary supplement.

[3] National Research Council, 2001, Nutrient Requirements of Dairy Cattle, Seventh Revised Edition, 2001, prepared by the Subcommittee on Dairy Cattle Nutrition, Committee on Animal Nutrition, Board on Agricultural and Natural Resources, National Academy Press, pp. 141-143.

Although selenium is an essential nutrient, bioaccumulation of selenium in wildlife can result in significant environmental damage. The potential problems related to elevated levels of selenium in the environment were exemplified by conditions that developed at the Kesterson Reservoir in Merced County, California. Kesterson Reservoir was a series of twelve shallow evaporation ponds constructed between 1968 and 1975 to receive subsurface agricultural drainage water from the western San Joaquin Valley. The ponds were jointly operated by the U.S. Bureau of Reclamation and the U.S. Fish and Wildlife Service to provide wetland habitat while providing for disposal of highly saline drain water. The unanticipated result of this dual function was bioaccumulation of selenium in all trophic levels within the wetland habitat. Toxic levels of selenium were manifested in significant reproductive defects and high mortality rates in waterfowl. Following recognition of the selenium contamination problems, discharge of drainage water was terminated and the ponds were pumped dry in the late 1980s.

In recognition of the toxic properties of selenium, the use of selenium as a dietary supplement is controlled by regulations developed and enforced by the U.S. Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act. The initial food additive regulation for selenium was promulgated in 1974 and restricted its addition to 0.1 part per million (ppm) for chicken feed and 0.2 ppm for turkey feed. The regulation was amended in 1987 and the allowable supplementation of selenium for cattle, sheep, chickens, ducks, and swine was set at 0.3 ppm. In 1993, the FDA acted to stay the 1987 amendments citing that the potential environmental effects related to increasing the permissible selenium supplementation had not been fully evaluated. The FDA determined that, at that time, the available data on environmental impacts "would not be sufficient to permit an adequate environmental analysis, and that the information that is necessary to do an adequate environmental analysis is unavailable."[4]

The FDA found that inadequate information was available to accurately determine the concentration and forms of selenium in waste generated by animals fed supplemental selenium. In addition, insufficient data and methodologies were available to predict the environmental fate and transport of various forms of selenium under the wide range of "biogeochemical" conditions throughout the United States. In consideration of the uncertainties raised in the review of existing scientific data regarding the amounts of selenium in livestock excreta, the FDA evaluated whether it would be appropriate and meaningful to prepare an Environmental Impact Statement (EIS) in accordance with the goals and requirements of the National Environmental Quality Act (NEPA). In 1993, FDA concluded the following:

[4] Food and Drug Administration (FDA), 1993, Food additives permitted in feed and drinking water of animals; stay of the 1987 amendments; final rule. Federal Register, 58(175):47961-47973.

> "Preparation of an EIS without improved selenium environmental information would not be expected to yield improved decisionmaking, consistent with the National Environmental Protection Act. The information in the record demonstrates that using the current data base and making assumptions where data are missing leads to interpretations of potential environmental impact across the entire spectrum from no impacts expected to significant impacts expected. Consequently, FDA has determined that the preparation of an EIS would not be helpful at this time."

On the basis of this conclusion, the FDA decided to stay the 1987 amendments to 21 CFR 573.920, which would allow increases in the allowable selenium supplement for livestock and poultry. The allowable selenium supplement level for cattle was revised from 0.3 ppm to 0.1 ppm.

Subsequent to the FDA's stay of the decision to increase allowable dietary supplements of selenium from 0.1 to 0.3 ppm, various agricultural industry groups lobbied Congress to overturn the FDA's ruling. These groups argued that higher levels of selenium supplementation were critical for animal health and productivity. In 1994, the Council for Agricultural Science and Technology[5] submitted additional information regarding selenium generated by supplemented animals and its environmental fate. Following further consideration of the risks and benefits of selenium as an essential dietary supplement for domestic animals and the potential environmental risks associated with its use, the U.S. Congress passed legislation in 1994 that set allowable selenium supplementation at 0.3 ppm.

In the years following that legislation, considerable additional research has been conducted in California investigating the forms and environmental fate of selenium related to animal waste. In 1995, the University of California at Davis presented a symposium on selenium in the environment.[6] The symposium presented five technical papers and seventeen abstracts summarizing the results of investigations of the effects of selenium on the environment. With respect to selenium issues related to cattle, research presented at the symposium included:

[5] Council for Agricultural Science and Technology (CAST), 1994, *Risks and benefits of selenium in agriculture*, Issue Paper No. 3 Supplement, Council for Agricultural Science and Technology, Ames, Iowa, 35 p.

[6] University of California, 1995, Selenium in the Environment: Essential Nutrient, Potential Toxicant, Proceedings of a National Symposium, 68 p.

- Evaluation of analytical methodologies for determining forms of selenium in soil, water, and plants;[7]

- A general review of the geochemistry and biogeochemistry of selenium to its deficiency and toxicity in animals;[8]

- A "bench-test" evaluation of the mineralization and speciation of organic selenium compounds applied to soil from the Central Valley of California;[9]

- A "bench-test" evaluation of the yield and selenium concentration in forage crops fertilized with excreta from cattle supplemented with selenium and unsupplemented cattle;[10]

- A "bench-test" evaluation of the selenium speciation in plant residues with high selenium content (seleniferous) applied to Central Valley soils;[11]

- A field study of the effects of selenium supplementation on selenium blood levels in pastured beef cattle in Oregon and selenium levels in pasture soils;[12]

- A field study of selenium levels in surface water, algae, and fish samples collected from streams at upstream and downstream locations relative to four California beef

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[7] Palmer, I.S., 1995, Water, soil and plant selenium: analytical methodology, in Selenium in the Environment: Essential Nutrient, Potential Toxicant, Proceedings of a National Symposium, University of California-Davis, pp. 20-37.

[8] Meyer, R.D. and Burau, R.G., 1995, The geochemistry and biogeochmeisty of selenium to its deficiency and toxicity in animals, in Selenium in the Environment: Essential Nutrient, Potential Toxicant, Proceedings of a National Symposium, University of California-Davis, pp. 38-44.

[9] Martens, D.A. and Suarez, D.L., 1995, Mineralization and speciation of sulfur and selenoamino acids applied to soil, in Selenium in the Environment: Essential Nutrient, Potential Toxicant, Proceedings of a National Symposium, University of California-Davis, p. 45.

[10] Drake, D.J., Norman, B.B., and Carlson, H., 1995, Selenium content of plants grown in excreta from selenium supplemented and unsupplemented cattle, in Selenium in the Environment: Essential Nutrient, Potential Toxicant, Proceedings of a National Symposium, University of California-Davis, p. 49.

[11] Martens, D.A. and Suarez, D.L., 1995, Mineralization and Se speciation of seleniferous plant residues added to soil, in Selenium in the Environment: Essential Nutrient, Potential Toxicant, Proceedings of a National Symposium, University of California-Davis, p. 55.

[12] Hatheway, R.L. and Hill, D.R., 1995, Supplementation of selenium to beef cattle, in Selenium in the Environment: Essential Nutrient, Potential Toxicant, Proceedings of a National Symposium, University of California-Davis, p. 56.

cattle ranches where selenium-supplemented cattle were pastured for a minimum of three years.[13]

Some of the research reported at the symposium had been considered by the FDA in 1993 and refuted as being inadequate or inconclusive. Notably, adequacy of the field study conducted on the effects of pastured, selenium-supplemented beef cattle on aquatic ecosystems was challenged by the FDA. The FDA concluded that interpretations of the results of this study "to yield a general understanding of selenium dynamics in pasture settings is inappropriate, due to limited experimental design." Specifically, FDA found the study to be inadequate because of the manner of selenium supplementation, lack of data on the forms of selenium in the excreta and environmental samples, incomplete soil characterization, and the possibility that background selenium levels in the environment may have obscured selenium introductions from the cattle.

Continuing research is further evaluating the complex biogeochemistry of selenium in the environment. The University of California Cooperative Extension is completing a three-year field and laboratory study evaluating the effects of selenium supplementation to cattle on pasture crops. The study investigated three different forms of selenium supplementation (bolus, injection, and pasture treatment with seleniferous fertilizer). Total selenium concentrations in cattle blood, excreta, pasture soil, and pasture crops from the three variously supplemented cattle herds were compared to a control (unsupplemented) herd. Limited surface water runoff sampling was performed. However, recent research has not directly addressed all of the data deficiencies identified by the FDA in 1993. Specifically, data are not available to determine the distribution of forms and fate of selenium in aerobic agricultural soils, the selenium uptake rates for all common agricultural crops, or the forms of selenium in dairy cattle manure and fate of those forms in the environment.

Response to Comment 16-2

The commentor's estimates of the amount of selenium that may be released to the environment following implementation of the Element are noted for the record. The assumption presented in the comment that all of the estimated selenium contained in supplemented cattle feed would be "leached" during one heavy rainfall does not acknowledge scientific research that would support a substantial decrease in the estimate of available selenium. Although not fully understood at present, dairy cattle would metabolize a portion of the supplemented selenium that would be incorporated into milk and muscle tissue. Available research suggests that between 30 and 60 percent of dietary

[13] Norman, B., Nader, G., Oliver, M., Delmas, Drake, D., and George, H., 1995, Effects of selenium supplementation in cattle on aquatic ecosystems in Northern California, in Selenium in the Environment: Essential Nutrient, Potential Toxicant, Proceedings of a National Symposium, University of California-Davis, p. 59.

selenium is digested by ruminant animals.[14] Not all of the selenium contained in dairy cattle excreta would be present in soluble ("leachable") forms. Some of the selenium contained in manure and process water as fertilizer and irrigation supply would be taken up by agricultural crops. The preparers of the PEIR concede that insufficient data are available at this time to accurately estimate the amount of selenium that could be released in bioavailable forms after cattle digestion and agricultural crop uptake. However, the assumption that all supplemented selenium would be released is not supported by available scientific data.

The comment references potential releases of selenium to "lakes." Under the Element, there is no reason to assume that runoff from dairy operations would be released to lakes. **Policy DE 4.1b.C** of the Element requires dairy operators to prepare and implement an Irrigation Management Program, which ensures that irrigation water and runoff from fields at each dairy unit would not be allowed to migrate away from the project site or into surface water features.

Response to Comment 16-3

An accurate assessment of the fate of selenium contained in manure and process water cannot be made at this time. Following a thorough review of available data and research on the environmental fate of selenium contained in animal manure, the preparers of the PEIR conclude that the basis of the 1993 FDA determination that environmental effects of selenium cannot be determined remains unchanged. Substantial additional basic research is necessary before all aspects of selenium metabolism and fate in the environment can be fully understood. Section 15145 of the CEQA Guidelines provides guidance for the determination of the significance of a potential environmental impact when thorough investigation is unable to resolve an environmental issue. After careful review of available scientific information, the Kings County Planning Agency has determined that definitive understanding of all forms and transformation of selenium is not possible at present. A determination of the significance of potential adverse environmental effects associated with this nutrient would be speculative.

[14] NRC, 2001, Nutrient Requirements of Dairy Cattle, Seventh Revised Edition, 2001, prepared by the Subcommittee on Dairy Cattle Nutrition, Committee on Animal Nutrition, Board on Agricultural and Natural Resources, National Academy Press, p. 142.