FINAL ENVIRONMENTAL IMPACT STATEMENT

RULE MAKING

ON SELENIUM IN ANIMAL FEEDS

Bureau of Veterinary Medicine

Food and Drug Administration

Department of Health, Education and Welfare

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SECTION I

SUMMARY AND EVALUATION OF COMMENTS RECEIVED ON THE DRAFT ENVIRONMENTAL IMPACT STATEMENT

In the FEDERAL REGISTER of April 27, 1973 (38 FR 10458), the Commissioner of Food and Drugs published a notice of availability of the draft environmental impact statement (DEIS) issued by the Agency in reference to the proposed rule making on selenium in animal feeds. Copies of this statement were submitted to other Federal agencies and the Council on Environmental Quality pursuant to the provisions of the National Environmental Policy Act. All comments received have been reproduced and are presented in Appendix D. Although the official comment period closed on June 27, 1973, we have considered all comments received as of November 1, 1973, and discussed them in the final environmental impact statement.

A total of 27 comments from the public, industry, trade associations and Federal agencies was received concerning the draft environmental statement. Ten of these comments were from feed manufacturing and associated industries, eleven from other government agencies, two from trade associations, three from university scientists, and one from a private citizen.

The substantive issues that were raised by the comments have been summarized and are evaluated as follows:

1. The judicious monitoring of the proposed use of selenium was emphasized in several comments (Appendix D, Comments No. 3, 4b, 4c, 4e, 4g, 5 and 12). It was unclear as to why all animals and birds in all geographical locations must or should be treated alike and as to how the use of selenium

could be confined to proven incidences of deficiency demonstrated and defined by known clinical signs. Further, a question was raised in regard to the capability of the Food and Drug Administration (FDA) to provide the manpower necessary to monitor the proposed use of selenium.

The foregoing issues are closely allied to the comments that referred to the inadequacy of the section on feed monitoring. A more complete discussion was requested. One commentator described a prospective program for ensuring the safe use of selenium in animal feeds. This program included feed monitoring.

The FDA, upon careful consideration of these issues, concludes that Section 409 of the Federal Food, Drug, and Cosmetic Act provides the control necessary to assure the safe use of selenium in animal feeds. The factors that form the basis for this conclusion are discussed as follows.

Selenium deficiency results in a set of relatively non-specific symptoms in poultry and swine and as such a positive diagnosis would depend on a post-mortem examination by a veterinary pathology laboratory. Most producers could not recognize a selenium deficiency in their birds and flocks without this examination. In line with this, supplementation with selenium after the onset of the clinical symptoms will not recover the bulk of the economic losses caused by the disease.

With regard to the prevalence of selenium, it is well known that certain geographic areas of the U.S. produce feedstuffs that contain adequate quantities of selenium. These feedstuffs are not identified as to origin when they move through interstate commerce and, accordingly, end-point utilization may occur at a fair distance from the

production area. It has been estimated that, at most, 70 percent of swine and poultry feeds contain less than adequate quantities of selenium. The remaining 30 percent of the feeds, therefore, do not require selenium supplementation. The available data, however, do demonstrate that selenium supplementation of adequate feeds will not cause an animal or human health problem.

In reference to the control of selenium usage, it should be recognized that all feed additives are subject to Section 409 of the Federal Food, Drug, and Cosmetic Act. Many of these feed additives (vitamins, trace minerals and other nutrients) presently are listed as "generally recognized as safe" items. It is acknowledged that certain trace nutrients on the "gras list" are more toxic than selenium (when toxicity is expressed as a multiple of the amount required for optimum nutrition); nonetheless, all of these feed additives have enjoyed a long history of safe use. This history demonstrates that the feed industry is capable of producing a safe feed from a potentially toxic feed additive. To assist in this task, the FDA has imposed a variety of controls on the feed industry. Feed mills are registered with FDA. This registration ensures that the feed mill has the appropriate equipment, facilities and personnel which are required to prepare quality feeds. Feed mills are also subject to inspection by FDA. This inspection ensures adherence to the Good Manufacturing Practice regulations for both feeds and premixes. All records are examined during this inspection. In addition to control by FDA, feed mills are also subject to control by the respective state authorities. Whereas the degree of control varies from state to state, generally all feeds must

be registered with the state, all labels must be filed and reviewed, and feeds can be sampled and analyzed for nutrient content.

Finally, the amount of selenium in food is currently being determined by FDA as one facet of the Market Basket Survey. The USDA also plans to include selenium in its meat surveillance program.

Accordingly, the Commissioner concludes that the proposed rule making is adequate to ensure the safe use of selenium. Not all animals and birds are to be reared on selenium-supplemented feeds since at least 30 percent of these populations are already receiving a selenium-adequate diet. It is clear that confining the use of selenium to after the onset of clinical symptoms would obviate much of the expected benefit. The use of selenium should be confined only to those instances when a producer has experienced a history of selenium deficiency. This use history will permit the producer to prevent the disease in subsequent herds and flocks.

Monitoring the use of selenium by a program of frequent and extensive feed analysis is not a viable alternative. The work of Scott (1973) shows that feed analysis may or may not predict the occurrence of selenium deficiency. Further, the imposition of such analysis is quite expensive and may override any cost benefit which will result from the proposed use of selenium. It should be recalled, however, that supplementation of selenium-adequate feeds with selenium will not adversely affect animal or human health.

Finally, the use of selenium will be monitored as far as the selenium reaching the human consumer is concerned. Selenium has been included in

the FDA Market Basket Survey for the past two years. Data from this survey will provide background information upon which the effect of the proposed action on the selenium content of food can be assessed.

2. Comments were also received which alluded to the inadequacy of the section on human toxicity (Appendix D, Comment No. 4b, 4c, 4e and 5). As such, concern was expressed over the potential occupational health hazard to persons working in feedmills, the amount of selenium required to elicit a toxic response in humans, the amounts of selenium which were used in the carcinogenicity tests, and other factors related to the potential impact on humans. In general, more information related to human toxicity was requested. This section has been expanded accordingly (pages 30-35).

It should be emphasized that the effects of the proposed action on the human population can be estimated from the animal toxicity and tissue residue studies. In most animals, 3.0 ppm of dietary selenium approximates the minimum toxic dose. In rats, 2.0 ppm of dietary selenium produces liver cirrhosis. These selenium levels are much greater than those which occur in the tissues of animals reared on selenium-deficient/sufficient diets. Further, the logic developed in the DEIS was based on the fact that the amount of selenium in tissues from treated animals is similar to the amount in untreated animals that have been reared on diets adequate in selenium from natural sources. Since 30 percent of animal feeds are adequate in selenium, this extent of the human population has been exposed to an amount of selenium in tissues which will be permitted by the proposed order. This exposure has resulted in no known cases of toxicity in humans.

The feed industry is aware of the potential hazard caused by dusts and aerosols of potentially toxic feed ingredients. The precautions required are described in 21 CFR 133, the regulations concerning good manufacturing practices for feeds and premixes.

3. Further comments addressed the inadequacy of the sections concerning potential effects on aquatic biota, plant accumulators and wildlife (Appendix D, Comment No. 1, 2, 4d and 4g). These effects are to be examined in the light of the increased biological activity of sodium selenite or selenate.

The Commissioner concludes that these areas were not thoroughly discussed in the DEIS and as such the present statement has been expanded (Pages 35-37).

The DEIS statement in reference to the biological activity of selenites and selenates was limited to animals. Scott (1973) has shown that the biological availability of selenium in feedstuffs varies. Thus, the selenium in grains is 85 percent available, that in soybean meal is 65 percent available, and that in fish meal is 33 percent available. These data make it clear that feed analysis may or may not be an indicator of selenium status. These differing biological availabilities are no doubt due to the fact that inorganic selenium salts are partially metabolized to the selenium analogs of cystine and methionine. The analogs are incorporated into proteins which are differentially and incompletely digested. The biological availability of the various forms of selenium to all components of the life chain has not been determined. In this respect, information is not available to assess such effects on the soil microbes, plants, and predators.

4. An issue was raised in regard to the traditional patterns of manure disposal and the influence of these patterns on localized environmental impacts (Appendix D, Comment No. 4g).

The assumption that the traditional method of manure disposal involves application to the land is affirmed by Weeks et al. (1972). These authors indicate that the maximum feasible application rate is 20 tons/acre (fresh weight basis). This value corresponds to the 5 tons/acre assumed in the DEIS. The possibility is good that the manure will be composted prior to land disposal since the land is plowed usually in the fall or spring. The effects of this practice are discussed in the final impact statement (Pages 38-39).

5. Two commentators were concerned that there was no control over the amount of selenium in the premix and that the proposed regulation was vague in this area (Appendix D, Comment No. 4b and 12). Physical specifications for selenium compounds and premixes were also requested. The Agency agrees with these comments and the final order provides that premixes are to contain no more than 90.8 mg. of selenium per pound.

There is no question that adequate quality control is essential to the success of the proposed use of selenium. Such controls are now being applied by the feed industry to a variety of feed ingredients and additives. FDA is cognizant of the importance of these controls as evidenced by published regulations (21 CFR 133)--the Good Manufacturing Practice Regulations. It should also be remembered that the control of non-medicated feeds is under the aegis of the state feed control officials who are responsible for labeling, feed mill inspection and a variety of other

activities incumbent to the manufacture of quality, wholesome feed.

Notwithstanding the above, the FDA agrees that premix preparation will have to be done carefully. This situation is not unique to selenium since the feed industry already manufactures premixes to provide, for example, the following nutrients to broiler chickens:

Nutrient*	ppm in Feed
Vitamin K	.530
Biotin	.090
Vitamin B 12	.009
Folacin	.550
Iodine	.350

*(cited in Nutrient Requirements of Poultry, 1971)

These nutrient concentrations can be compared to the 0.1-0.2 ppm levels of selenium proposed by the current action.

The Commissioner does not consider it necessary to set physical specifications on the selenium compounds since selenium premixes can be prepared in a variety of ways (solid to solid dispersion, intermediate premixes, liquid to solid dispersion). In this regard, the feed manufacturer could select the technique which best fits his equipment and practice with proper precautions.

The Agency does not agree that this issue is important in assuring compliance to the proposed order. It is unclear, however, how a marker would improve the enforcement potential that now exists. All feed mills retain records of the contents of each batch of feed that is manufactured. These records are available for inspection by duly authorized agents of the Federal and state governments. Such examination will reveal if illegal feeds are being produced. This procedure has been effective in the past.

It must be emphasized that the proposed action is subjected to the full pre-clearance and enforcement requirements provided by Section 409 of the Federal Food, Drug, and Cosmetic Act. Furthermore, the labeling of all feeds must contain the following statement--"Caution: Follow label directions. The addition to feed of higher levels of this premix containing selenium is not permitted."

6. One commentator discussed the potential adverse effects of a local transient impact caused by accidents in the shipment of selenium premixes and cross-contamination of these shipments (Appendix D, Comment No. 12).

The Commissioner concludes that an accidental spill of a single ton of premix may have a deleterious effect, if it goes directly into the water supply. Such impacts were not considered in the DEIS since it is not possible to envision all of the kinds of accidents. Cross-contamination of premixes is unlikely since these are usually shipped in sealed multiwalled paper bags or cartons.

7. A commentator (Appendix D, Comment No. 4g) requested a comparison of the impacts of a single large application of selenium versus multiple small applications. The logic developed in the DEIS assumes that multiple small applications of selenium do not have as great an impact as an equal amount of selenium applied at one time. The information available does not permit verification of this assumption, but since selenium is a natural component of the environment, natural mechanisms probably exist for handling the substance in small quantities. A single large dose may exceed the natural adaptive mechanisms.

8. A commentator (Appendix D, Comment No. 8) sought to correct an error on page 26 of the DEIS concerning the liver selenium content of turkeys. This value is now presented on a fresh basis in accordance with the other tissue residue data that are presented (Page 33).

9. A request was made for the expansion of the proposed action to include selenium fortification of diets for all species of farm animals, birds, laboratory and zoo animals, and pets (Appendix D, Comment No. 4b).

It should be understood that the FDA can promulgate regulations for the safe use of food additives only after being petitioned for such use. The FDA has not been petitioned for the use of selenium in feeds for animals other than those described in the proposed action. It is understandable, however, that these other species of animals may also need selenium supplementation.

10. A commentator was concerned that the proposed action would constitute an abuse of our natural resources (Appendix D, Comment No. 14).

The Commissioner concludes that the proposed action will not result in an irretrievable commitment of this resource. Selenium is a by-product of the copper smelting industry and has limited use at the present time. Further, it is estimated that the proposed use of selenium will involve very small quantities (6,000 kg./year).

11. A commentator expressed concern that some of the terminology used in this DEIS would not be clearly understood by the general public. Accordingly, definitions of these terms have been incorporated in the text of the final statement (Appendix D, Comment No. 4d).

12. A recommendation (Appendix D, Comment No. 4d) was made to modify the format of the DEIS, including areas where there was a lack of information, so that the issues involved would be more clearly defined. The merit of this recommendation is recognized and the final statement, particularly Section IV, has been modified accordingly.

13. Several comments suggested editorial changes and offered opinion supporting the conclusion of the DEIS. (Appendix D, Comment No. 4a, 4b, 4c, 6, 7, 8, 9, 10, 11, 13, 15, 16, 17, 18, 19, 20, and 21.) The editorial suggestions requested a clarification of certain issues and the correction of grammatical and typographical errors. All suggestions have been considered and those deemed appropriate have been included in the final statement.

14. One commentator (Appendix D, Comment No. 5) requested the differentiation between a selenium-adequate diet and a fortified diet. Diets may contain adequate quantities of selenium from natural sources. These diets do not require supplementation with selenium. This subject is further considered on page 35.

FINAL ENVIRONMENTAL IMPACT STATEMENT

SECTION II

SUMMARY

This Final Environmental Impact Statement is prepared in compliance with the requirements of the National Environmental Policy Act. It concerns the proposal of the Food and Drug Administration made in response to a petition by the American Feed Manufacturers Association, Inc., to amend the Food Additive Regulations in accordance with the provisions of the Federal Food, Drug and Cosmetic Act to permit the safe use of selenium as a nutrient in the feed of chickens, turkeys and swine. The proposed rule making provides that selenium (as sodium selenite or selenate) may be added to the complete feeds of chickens and swine at a level not to exceed 0.1 ppm, and to the complete feed of turkeys at a level not to exceed 0.2 ppm.

The Draft Environmental Impact Statement was issued for comment by Federal and State government agencies and the public. A notice of availability of the Draft Statement was published in the FEDERAL REGISTER of April 27, 1973. Copies of the written comments received are included in Appendix D and a summary and evaluation of these comments has been provided in Section I.

Background and Description

Selenium is an essential trace nutrient for animals and probably for man which, like other trace nutrients, can be toxic if consumed in excessive amounts. The characteristic which distinguishes selenium from other trace nutrients is its relatively high degree of toxicity. For this reason, it is necessary to consider the effect of selenium supplementation not only on

the direct recipients (swine and poultry) but also on its ultimate consumer, the human population.

For many years there was concern over the toxic effects of selenium on animals; only more recently have the nutritional aspects of selenium become of interest. Objections to the concept of selenium as a nutrient were raised largely on the basis that some of the selenium-responsive diseases also responded to other dietary supplementation, notably vitamin E and cystine. Selenium is now accepted, after extensive research studies, as a necessity for the health and growth of large numbers of domestic animals and birds in widely diverse sections of the world.

These studies demonstrated that dietary supplementation with selenium is effective in preventing the clinical signs of a selenium deficiency in animals and birds.

Probable Impact on the Environment

A variety of beneficial effects would accrue from the implementation of the proposed action. The use of selenium would permit the more efficient production of food derived from the affected animals. Commensurate with this enhanced productivity would be the more efficient use of agronomic inputs (seed, fertilizer, land and labor). It is anticipated that the quality of the food so produced would also be improved.

Various toxic effects are noted when excessive quantities of selenium are ingested by livestock and poultry. When these animals are reared on diets containing greater than 3.0 ppm of selenium, loss of appetite, atrophy of the heart and cirrhosis of the liver can result. The proposed regulation

prescribes use levels of 0.1 or 0.2 ppm of selenium which are considerably below those required to elicit a toxic response.

The proposed use level of selenium in animals has been restricted to an amount which will not cause an increase in the levels of selenium in the food derived from the treated animals. The data demonstrate that the edible tissues of poultry and swine, when fed a diet fortified with selenium at the proposed levels, will contain no more selenium than tissues from animals that have been reared on a selenium-adequate diet. There is no evidence that these levels will be toxic to man.

The possible carcinogenicity of selenium and its salts has been thoroughly considered. The available evidence permits us to conclude that selenium at nutritionally required levels is not a carcinogen. The evidence is inconclusive that selenium at very high dietary levels is a carcinogen.

The impact on the natural environment (including physical and biological components) resulting from the addition of selenium to animal feeds will be restricted to small amounts of supplemental selenium excreted as wastes by the treated animals (no more than 6000 kg./year).

These wastes will be returned to the land surfaces. As such, the level of selenium added to the soil, leached into the surface water and/or absorbed by certain so-called selenium accumulator plant species will be minimal.

Special precautions should be taken in those instances where animal waste is stored in piles to insure that the higher selenium levels leached by rainfall under these circumstances will not have direct access to the water table or other aquatic sources.

Selenium is a natural component of the ecosphere, therefore, the synthetic source of the trace element may enter ecosystems in a manner similar to natural processes.

Adverse Environmental Impact Considerations

There are no known adverse environmental impacts which cannot be avoided by the proposed action if selenium is used under proper controls at the levels provided for in the proposed regulation. These proper controls are provided by the Federal Food, Drug, and Cosmetic Act (Sections 402 and 409) and the good manufacturing practice regulations (21 CFR 133) and are used by FDA to regulate all food additives. The sufficiency of these controls is addressed in Sections I and III.

Alternatives to the Proposed Action

There is no known economic alternative to meeting the selenium requirements of all animals and birds currently being reared on selenium-deficient diets in all geographical locations of the United States. The principal immediate advantage to be gained from the proposed action would be increased efficiency in producing foods of animal origin. The losses in animal husbandry production that are caused by selenium deficiency are difficult to estimate, but they are considered to be substantial. The regulations confine use of selenium to feeds which historically produce a selenium deficiency demonstrated and defined by known clinical signs. There are other alternatives for satisfying the animal's nutritional requirements for selenium. These include administering selenium (1) applied directly to the soil, (2) interregional feed blending, (3) corporeal injection, (4) addition to the animal's and bird's drinking water, and (5) feed monitoring. Alternatives three and four would require the use

and environmental distribution of essentially the same amount of selenium as demanded by feed administration. These were rejected, therefore, on grounds of not being economically feasible. Alternative number one required the use of much greater quantities of selenium than feed administration. This alternative was rejected because it may impose a greater potential for environmental degradation. Alternative number five was rejected due to excessive cost of implementation. Alternative number two was environmentally attractive since synthetic selenium compounds would not have to be used, but it was infeasible, costly, and thought to require excessive energy outputs.

Relationship Between Local Short-Term Uses of Man's Environment and the Maintenance and Enhancement of Long-Term Productivity

Since selenium may be added to the soil of selenium-deficient agronomic areas, long-term benefits may accrue from the addition of selenium to that soil. No long-term detrimental effects are anticipated.

Irreversible and Irretrievable Commitments of Resources Which Would be Involved in the Proposed Action Should It Be Implemented

Based on the low use level of this food additive, there would be little irretrievable commitment of a natural resource (selenium is a by-product of the copper smelting process). The used selenium will be distributed so as to add small amounts to the basal levels.

Evaluation of Substantive Issues Raised in the Comments on the Draft Environmental Impact Statement

The substantive issues were thoroughly considered and additional relevant information has been incorporated into the final statement.

Conclusions

In assessing and balancing the potential value of the addition of selenium to the feed of chickens, turkeys and swine against the possible environmental consequences of such addition, the FDA's overall judgment is that under quality control procedures selenium can be judiciously used in the production of food animals for the benefit of the consumer.

SECTION III

BACKGROUND AND DESCRIPTION

Selenium is an essential trace nutrient for animals and probably for man which, like other trace nutrients, can be toxic if consumed in excessive amounts. The characteristic which distinguishes selenium from other trace nutrients is its relatively high degree of toxicity and is cited as one of the few mineral elements absorbed by plants in sufficient concentrations to kill animals that eat the plants. For this reason it is necessary to consider the effect of selenium supplementation not only on the direct recipients (swine and poultry) but also on its ultimate consumer--the human population.

Distribution of Selenium

Selenium occurs in nature mostly as mixed sulfides of lead, copper, mercury and silver. A number of measurements of the total selenium content of soils was made in connection with studies of toxicity in the western United States during the period 1933 to 1949. These studies have been reviewed by Lakin (1961). Soils containing as much as 100 ppm of total selenium have developed from Cretaceous sedimentary rocks in the Northern Plains and along the eastern front of the Rocky Mountains. The concentration of selenium in these soils is highly variable; in a single field, soils containing more than 50 ppm of total selenium may be interspersed with soils containing less than 1 ppm.

The concentration of selenium in some seleniferous soils has been reduced both by leaching during the soil development processes and by irrigation water. Moxon et al. (1939) have estimated that over 80 percent

of the selenium originally present in some Cretaceous sediments in South Dakota has been removed from the upper part of the section during the development of a soil profile. Lakin (1961) presented evidence that selenium is being removed from some irrigated areas in drainage waters. Kubota et al. (1967) observed that forage growing on the alluvial bottomlands along the Missouri and Mississippi Rivers contained more selenium than did forage growing on the adjacent upland soils. This may be interpreted as evidence that the Missouri and Mississippi Rivers are transporting selenium toward the sea from the upper parts of their watersheds. Even though selenium is being removed from the surface layers of the seleniferous areas of the United States, it has not been established that this removal is resulting in a significant decrease in the areas that are potentially capable of producing plants containing toxic concentrations of selenium.

A unique feature of the distribution of selenium in plants in the United States is the occurrence of several broad areas where almost all the plants sampled contained low levels of selenium. These areas coincide with areas where selenium deficiency in livestock and poultry has been most noticeable (Figure 1). A major area of selenium-deficient soil includes central and southern Florida and the tidewater section of the south Atlantic coast. Here the soils were formed by recent marine and coastal deposits. These soil-forming materials were generally laid down long after the period of selenization of the Western Great Plains and the Rockies. The selenium content of the forages grown in these selenium-deficient areas varies from 0.01 to 0.10 ppm. Obviously, there are important differences in the concentrations of selenium in animal feeds produced in different areas. These are

demonstrated in the work of Bruins et al. (1966), in which a standard turkey diet prepared from materials produced in western Iowa was compared with a similar diet prepared from materials produced in Ohio and New York. The Iowa diet contained 0.37 ppm of selenium, and turkeys fed this diet showed no evidence of selenium deficiency. The Ohio-New York diet contained 0.08 ppm of selenium and turkeys fed this diet showed a high incidence of gizzard myopathy (a muscle disease).

The median concentration of selenium produced in areas considered having adequate soil selenium was 0.26 ppm. Presumably, the concentration of selenium in feed grains would show a similar distribution.

Role of Selenium in Nutrition

Selenium is an essential trace nutrient which is needed by poultry and livestock to permit normal growth and metabolism. Although it is present in a wide variety of feedstuffs, the levels that occur are often not sufficient to satisfy the animal's metabolic requirement. Animal nutrition problems now recognized to be due to selenium deficiency have been suggested for over 30 years. Recognized instances of selenium deficiency diseases have unquestionably increased, but these may be due to improved diagnosis. The insufficiency precipitates clinical signs of debilitation in a significant portion of our food-animal population. Estimates of economic losses caused by selenium deficiency in chickens, turkeys and swine are in the millions of dollars (see Appendix C).

Ample evidence is available to show that these losses could be prevented if selenium could be used to supplement poultry and swine diets. This evidence demonstrates that the proposed use of selenium is necessary and safe

both to the animals treated and to humans consuming the food derived from these animals.

New interest in the biological significance of selenium has developed in the last few years, although for many years there was concern over its toxic effects at high levels upon animals. Objections to the concept of selenium's essentiality as a nutrient continued to be raised, largely on the basis that some of the selenium-responsive diseases (diseases which can be prevented by selenium therapy) also responded to other dietary supplementation, notably vitamin E. In independent discoveries (Schwarz and Foltz, 1957; Patterson et al., 1957) selenium was identified as a third factor (vitamin E and cystine, a sulfur amino acid, had already been identified) active in preventing degeneration of the liver in rats and was shown to prevent exudative diathesis (a disease characterized by edema and subcutaneous capillary hemorrhages) in chicks fed torula yeast low in vitamin E. These discoveries led to investigations with other species of animals. All the early work with selenium was done with diets containing some selenium and substantial unsaturated fat, and most of the studies revealed a relationship between vitamin E and selenium. Recently, the use of synthetic amino acid diets extremely low in selenium with Japanese quail and chicks has shown that severe deficiency signs and death occur even in the presence of very high dietary levels of vitamin E (Thompson and Scott, 1969). Adding small quantities of selenium prevented all signs of deficiency.

Swine are also affected by a combined deficiency of vitamin E and selenium. When semipurified diets containing torula yeast and adequate levels of sulfur amino acids were fed to weanling pigs, the animals developed

liver necrosis (death of tissue) or hepatosis diaetetica (a diet-caused liver disorder) and eventually died unless the diet was supplemented with vitamin E or selenium (Eggert et al., 1957). In other studies, liver necrosis and degeneration of cardiac and skeletal muscle were observed in pigs fed a torula yeast diet that was deficient in vitamin E (Pellegrini, 1958). These deficiency signs were prevented by supplementing the diet with vitamin E or selenium, but not with cystine. Nutritional muscular dystrophy (a selenium responsive disease characterized by degeneration of the skeletal musculature) was also studied in pigs fed a diet of oats, barley, and cottonseed oil, all treated to reduce the vitamin E content (Orstadius et al., 1963). The presence of disease was determined by an elevated glutamic-oxaloacetic transaminase (an enzyme) content of the plasma. Either vitamin E or selenium inhibited elevation of this enzyme, but the best results were obtained with a combination of both nutrients, which suggested that vitamin E and selenium were acting synergistically (enhancing the effects of each other).

A combined deficiency of selenium and vitamin E in chicks results in exudative diathesis. This disease can be prevented by supplementing the diets with vitamin E or selenium. If amino acid diets very low in selenium are used, chicks show poor growth, poor feathering and fibrotic degeneration (the formation of fibrous tissue) of the pancreas (Thompson and Scott, 1970). Death usually occurs following markedly decreased absorption of lipids, including vitamin E. The pancreatic degeneration results in a decrease in pancreatic and intestinal lipase (an enzyme which catalyzes the hydrolysis of dietary lipids), which causes a failure to

digest fat. Under these conditions, bile flow diminishes markedly. In the absence of bile and monoglycerides in the intestinal lumen, there is a failure of lipid-bile and salt micelle formation (the process which facilitates the absorption of lipids), which in turn impairs the absorption of vitamin E.

Thompson and Scott (1968 a & b) showed that the addition to the basal diet of free fatty acids, monoglycerides, and bile salts improved the absorption of vitamin E and survival during the experimental period of 4 weeks. Their research demonstrated that this addition prevented exudative diathesis, but did not prevent the degenerative changes of the pancreas. The selenium requirement for prevention of pancreatic degeneration was found to depend on the vitamin E level in the diet. With very high dietary vitamin E levels (100 IU per kg.) as little as 0.01 mg. of selenium as sodium selenite per kg. of diet prevented pancreatic degeneration. However, when the vitamin E content of the diet was at more normal levels (10-15 IU per kg.), 0.02-0.04 mg. of selenium per kg. of diet was required. It was observed in these experiments that exudative diathesis did not occur as long as some vitamin E was being absorbed. Thus, either vitamin E or selenium in the diet will prevent exudative diathesis, but a moderate blood level of vitamin E also helps to preserve the selenium in the body tissues, thereby reducing the dietary level of selenium required to protect the pancreas. Vitamin E spares the selenium requirements and conversely selenium enhances absorption of alpha-tocopherol, thereby reducing the dietary requirement for vitamin E.

A diet low in sulfur amino acids and selenium results in myopathy (a muscle disease) in the chick (Calvert et al., 1962). White striations

are observed in the breast muscle. Adding methionine, cystine, or vitamin E prevents myopathy in chicks, but selenium is only partly effective (Nesheim and Scott, 1961). The effectiveness of methionine or cystine is not due to selenium contamination. Vitamin E and selenium appear to act synergistically in preventing this disease (Calvert et al., 1962). Combined low levels of these two nutrients prevent the condition, but the same level of either one will not prevent the disease.

It appears that between 0.05 and 0.08 mg. of selenium as sodium selenite is needed per kg. of diet to prevent exudative diathesis in chicks. The amount depends on the type of diet used and vitamin E level. Using a semipurified diet containing torula yeast, Nesheim and Scott (1958) observed that adding 0.08 mg. of selenium per kg. of diet prevented exudative diathesis in chicks. They also observed a growth response to selenium in the presence of a high level of vitamin E, providing the first evidence that selenium is required for maximum growth rate in chicks independent of vitamin E.

Field cases of exudative diathesis and myopathy in chicks have been seen in the United States. Several outbreaks of typical exudative diathesis have been observed in flocks of chickens in New Zealand (Hartley and Grant, 1961), and necropsy showed degeneration of the breast and, occasionally, degeneration of the gizzard musculature. White muscle disease in pullets 4 to 6 months old has also been observed in New Zealand in spite of widespread use of wheat-germ meal and synthetic vitamin E (Salisbury et al., 1962). These conditions have been prevented and controlled by adding selenium to the drinking water.

Manifestations of a combined vitamin E and selenium deficiency in turkey poults differ somewhat from those in chicks. Although a mild form of exudative diathesis has been reported in turkey poults (Creech et al., 1957; Rahman et al., 1960), the condition is not nearly as severe as that observed in chicks. The most characteristic sign of selenium deficiency in poults is a degeneration of the gizzard musculature.

White striation (streaking) in the breast musculature is also observed, but only 25-50 percent of the poults will have myopathy in that area whereas almost 100 percent have degeneration of the gizzard. Degeneration of heart muscle is also observed in turkey poults (Scott et al., 1967).

In contrast to the chicken, myopathy observed in the gizzard, heart, and breast of turkey poults is not influenced by the level of methionine or cystine in the diet, and these myopathies are prevented by selenium. Vitamin E deficiency can readily be produced in turkey breeder hens; no evidence has been obtained that selenium can substitute for the function of vitamin E in reproduction (Jensen, 1968).

Description of Rule Making

Accordingly, the Food and Drug Administration notice of rule making adds a new section to the Food Additive Regulations (21 CFR 121.325) which will provide for the safe use of selenium. The rule making provides as follows: The food additive selenium may be safely used in accordance with the following prescribed conditions:

(a) The additive is used in animal feed as a nutrient in the form of sodium selenite or sodium selenate.

(b) It is added to the complete feed of growing chickens up to 16 weeks of age and to the complete feed of swine at a level not to exceed 0.1 part per million of added selenium; it is added to the complete feed of turkeys at a level not to exceed 0.2 part per million of added selenium.

(c) The additive shall be incorporated into each ton of the complete feed of growing chickens up to 16 weeks of age and of swine by a premix containing no more than 90.8 milligrams of added selenium and weighing not less than 1 pound. The additive shall be incorporated into each ton of the complete feed of turkeys by a premix containing no more than 181.6 milligrams of added selenium and weighing not less than 2 pounds.

(d) The premix manufacturer shall analyze each production batch of selenium premix and shall establish by such analysis that the levels of selenium specified in paragraph (c) of this section are not exceeded.

(e) The label or labeling of any selenium premix shall bear adequate directions and cautions for use including this statement: "Caution: Follow label directions. The addition to feed of higher levels of this premix containing selenium is not permitted."

(f) Feeds containing added selenium may not be administered to hens laying eggs for human consumption.

The first provision states that selenium can only be used in animal feed to rectify a deficiency of this element. Selenium supplementation is expected to be limited to feeds which historically produce a deficiency but it will not be limited according to geographic area. Sodium selenite or selenate were selected since these salts provide a ready source of nutritionally available selenium.

The second provision specifies the levels of selenium that can be used. These levels were established by a comparison of the animal's needs to the amount of selenium that is available in the more common feedstuffs, and by an evaluation of residue data and both animal and human toxicity data.

The restriction imposed by provision (c) was incorporated in order to facilitate the preparation of feeds containing the regulated amount of selenium. This provision, by specifying an upper limit on the concentration of selenium in premixes, will require the use of highly diluted premixes.

Provision (d) requires that each production batch of selenium premix is to be analyzed for selenium content. This analysis will assure that selenium premixes contain the labeled amount of selenium and, in no case, will this amount exceed 90.8 mg of selenium per pound.

The application of a caution statement to the label as specified in provision (e) will ensure that feeds prepared from selenium premixes will be manufactured according to label directions.

Finally, the sixth provision is included since the Food and Drug Administration does not have information to show that selenium administration to laying hens is a safe practice.

Provisions of the rule making will become effective as indicated in the notice published in the Federal Register.

The rule making does not relate to any other proposal that is presently under consideration by the Food and Drug Administration.

SECTION IV

PROBABLE IMPACT ON THE ENVIRONMENT

Primary Environmental Impact

Primary environmental impacts can result from the direct application of foreign substances to the environment. In the case of selenium, which is widely distributed in nature and will be administered via the feed to animals at low levels, we would anticipate no primary environmental impact resulting from its use.

Secondary Environmental Impact

A variety of secondary environmental effects would occur. Beneficial impacts would accrue with regard to land use since selenium supplementation would permit the more efficient production of poultry and livestock. This enhanced productivity allows a more efficient utilization of the acreage allocated for food production and also of allied agricultural inputs (fertilizer, seed, pesticides and labor).

In order to determine the potential adverse environmental effects of the proposed action, the following factors were given consideration:

1. Toxicology

   a. Animal

Selenium in the form of sodium selenite (Na_2SeO_3) or sodium selenate (Na_2SeO_4) is highly toxic. Consumption of plant materials containing 400-800 ppm of selenium have been fatal to sheep, hogs, and calves. Chronic selenium toxicity in livestock occurs when animals consume seleniferous plants

containing 3-20 ppm of selenium over a prolonged period. Miller and Schoening (1938) reported that selenium as sodium selenite was toxic for swine when fed at the rate of 11.3 ppm.

In studying the effect of selenium as sodium selenite in the ration of poultry, Moxon (1937) found evidence of toxicity when hens were fed 26 ppm; pullets, 6.5 ppm; and growing chicks, 8 ppm. While many factors enter into selenium toxication, the following factors revealed by Muth and Binns (1964) appear to be the most important: (1) size and frequency of the doses; (2) characteristics of the compound; (3) presence of combining, reducing, diluting, or synergistic substances; (4) inherent susceptability of the animal; and (5) efficiency of elimination after absorption. The statement by Trelease and Beath (1949) that "It is not yet possible to state with any degree of accuracy what constitutes the minimum toxic dose of selenium in each of its forms for different kinds of livestock," is still a pertinent one. It is most difficult to state with any degree of accuracy what actually constitutes the minimum toxic dose of selenium in each of its numerous forms for different species of livestock or for man. The ratio between beneficial dose and toxic dose, based on Factor-3 selenium, is of the order of 1:100.

A variety of toxic effects are noted when excessive quantities of selenium are ingested by livestock and poultry. Generally, these animals will suffer from a loss of appetite, atrophy of the heart, cirrhosis of the liver and anemia. A more complete description of the toxic effects of selenium can be found in "Trace Elements in Human and Animal Nutrition," by E. J. Underwood (1971).

It has been well-documented that the minimum toxic level of selenium in poultry and swine feeds approximates 3.0 ppm. Feeds that have been supplemented with 0.1 or 0.2 ppm of selenium contain an amount of selenium which is well below that which is toxic to poultry and swine. Accordingly, such feeds are safe for poultry and swine.

b. Human

The addition of selenium to animal feed has been thoroughly considered because of the questions that have been raised concerning the possible carcinogenic (cancer causing) activity of selenium. Available animal data which have been extrapolated to effects on humans have been evaluated by the Food and Drug Administration and the National Cancer Institute. These data can be summarized as follows:

(1) Nelson et al. (1943)

Selenium was initially thought to be carcinogenic on the basis of studies performed by these workers. The studies were designed to compare the toxicity of graded levels of naturally occurring selenium with that caused by potassium ammonium sulfoselenide (Selocide--a systemic insecticide). Female rats were reared on a low protein diet (12 percent) which contained 5, 7 and 10 ppm of selenium from natural sources and 10 ppm of selenium from ammonium potassium sulfoselenide for a lifetime. Mortality was high and found to be approximately proportional to the level of dietary selenium. One hundred and twenty-six rats were divided into 7 groups of 18. Only 53 survived 18 months; 39 survived 24 months. Of the 53 rats that survived 18 months, 11 developed liver tumors and 4 developed advanced adenomatoid hyperplasia (benign tumor). None of the tumors metastasized. It is believed that the neoplastic lesions (new or abnormal growth) observed in this study were secondary to the cirrhosis promoted by the nutritionally inadequate diets that were used.

(2) Klug and Hendrick (1954)

Groups of 35 male rats were treated for a lifetime with up to 19 ppm of selenium derived from organic sources. The selenium treatments resulted in decreased life spans and liver damage. No liver tumors were evident.

(3) Volgarev and Tscherkes (1967)

Studies which appeared to confirm the results of Nelson et al. (1943) were conducted by these workers. These studies tested the effects of selenium (as sodium selenate) in male rats at levels ranging from 4.3 to 8.6 ppm. The diets used contained 12 percent protein. The first study resulted in tumor development in 14 of 40 animals. In the second, 5 of 40 animals developed tumors. In the third study involving 100 animals, no animals developed tumors. No control animals were used in these studies and it was subsequently discovered that the rats used in the first 2 studies were infested with a parasite which is known to induce tumors.

(4) Tinsley et al. (1967) and Harr et al. (1967)

These authors conducted an extensive study of chronic selenium toxicity in rats to determine whether excess selenium produces liver cancer. A total of 1,437 rats was used with 274 of this total serving as controls. Three diets were tested (12 percent casein, 22 percent casein, and a commercially available rat chow). Selenium treatments ranged from 0.5 to 16.0 ppm and N-2-fluorenyl-acetamide (a known carcinogen) was used as a positive control. Of the 1,126 animals that were autopsied, 63 neoplasms were found; 43 of these occurred in the 90 rats receiving N-2-fluorenyl-acetamide. The other 20 neoplasms were randomly distributed throughout the rats receiving the various experimental diets. No hepatic neoplasms

were found in the rats fed selenium.

(5) Schroeder and Mitchener (1971)

Male and female rats in groups of 50 were treated with sodium selenate and/or sodium selenite (3 ppm of selenium) via the drinking water. Because of the high toxicity of the sodium selenite treatment, the animals were switched from this treatment, after the first year, to sodium selenate at the same dose. All of the surviving rats were treated for 2 years. There were no tumors observed in the rats started on sodium selenite and switched to sodium selenate. For the groups treated with sodium selenate for the lifetime, however, it was claimed that a higher incidence of tumors were found. Critical analysis of these studies was not possible since the sodium selenate-treated rats lived longer than the control animals. Thus one could not attribute the tumors to sodium selenate or the increased life span.

(6) Schroeder and Mitchener (1972)

These same authors repeated the rat studies in mice. Here, treatment with 3 ppm of selenium via the drinking water did not have a significant effect on the incidence of spontaneous tumors.

These studies, examined in total, permit the conclusion that selenium at nutritionally required levels is not a carcinogen. Available evidence at higher levels is inconclusive.

Selenium at high dietary levels (above 2 ppm) is a proven hepatotoxic agent. Early studies at dietary levels of 5, 7 and 10 ppm showed liver damage and regeneration in rats and increased incidence of hepatoma in treated animals as compared with controls. Hepatoma did not occur in the absence of severe hepatotoxic phenomena. In more recent studies, hepatotoxicity

was observed in rats fed selenium at 2 ppm. At 16 ppm, more severe liver damage was observed but was not associated with hepatoma. No hepatotoxic effects were noted at 0.5 ppm or below.

Knowledge of selenium residue distribution and concentration levels in food animal tissues is important in order to assess the potential for human toxic effects. Limited data on the distribution of selenium in animals and birds have been available for some time as a result of analyses conducted in connection with studies of selenium toxicity and selenium deficiency. Moxon and Rhian (1943) reported 5.6 ppm of selenium in the liver and 3.0 ppm in the muscle of steers that had been maintained on seleniferous rangeland for 3 years. Maag and Glenn (1967) fed sodium selenite to steers until six out of eight animals died from selenium poisoning. The level fed was 12-24 mg./kg. of body weight per week. The selenium content of the muscles of these steers ranged from 0.10 to 0.73 ppm. The liver contained 5.0-12.3 ppm of selenium.

Useful reviews of levels of selenium that occur under normal physiological conditions have been provided by Ganther (1965) and by Hartley (1967). It has been shown that animals rapidly excrete much of the administered selenium.

Scott and Cantor (1971) have shown, using graded levels of sodium selenite in diets for chickens and turkeys, that the selenium content of blood, muscle, and liver tends to plateau as the selenium content of the diet is increased. After selenium had been added to the diet at the rate of 0.2 ppm, the selenium content of blood was 0.2 ppm in chicks and 0.12 ppm in turkey poults. The selenium content of the liver was somewhat higher--about 0.6-0.7 ppm for both chicks and poults. These selenium levels

are well within the range found in chickens and turkeys receiving normal rations. Levels of dietary selenium up to 0.67 ppm did not appreciably increase the selenium content of the blood, muscle, or liver of chicks or poults above the levels obtained with 0.2 ppm of dietary selenium in the form of sodium selenite.

The retention of dietary selenium and its distribution in various tissues of the animal have been studied intensively through the use of oral selenium. More recent studies utilizing lambs as test animals indicate that 25-75 percent of an oral dose of selenium is excreted within a few days after intake (Ehlig et al., 1967; Ewan et al., 1968 a and b). Ruminants tend to excrete more of the dietary selenium in the feces than do nonruminants. Animals that have been depleted of selenium retain a higher percentage of an oral dose of this element than do animals that have been on a selenium adequate diet before dosing. Only minor effects of vitamin E on retention and distribution of selenium have been noted.

Information is meager concerning the potential toxicity of selenium in human diets in the United States. Such information has been collected and summarized by Frost (1972), Trelease and Beath (1949), Rosenfeld and Beath (1964), Smith and Westfall (1937), Hadjimarkos (1965), and Williams et al. (1941). Thus, Smith and Westfall (1937) conducted a survey of the relationship between the selenium content of urine and of food in 14 rural families living in the seleniferous area of the U. S. (South Dakota and Nebraska). The selenium concentration in the urine of this group of families ranged from 0.20 to 1.98 ppm. Another survey (Sterner and Lidfeldt, 1941) involving the urine of 60 male industrial workers living in a "low" selenium area

(Rochester, New York) revealed that the urine selenium concentration varied from 0.001 to 0.025 ppm of selenium. The significance of these low levels of selenium excreted is difficult to assess. There is no evidence that any people in the U. S. are suffering from toxic levels of selenium in food. Several investigators have provided evidence that elevated dietary selenium levels may contribute to increases in dental caries (Hadjimarkos, 1965; Ludwig and Bibby, 1969: Buttner, 1963). Public Health officials have taken action on the bases of reports that selenium may contribute to dental caries, on reports that the element is a potential carcinogen, and that concentrations of selenium in water considered safe for man were found toxic for fish. Their action took the form of lowering the previously permitted level of selenium in water from 0.05 ppm to 0.01 ppm (Public Health Service Publication 956, 1962). The effects of the proposed action on this permissible selenium level in water are discussed (page 39-42).

It has been shown, however, that use of feeds containing selenium at certain low levels (in some cases including those levels set forth in the regulation) does not result in an increase to toxic levels in the selenium concentration of the edible products of chickens, turkeys, and swine (Tables 3-7). Thus, the animals tested absorbed dietary selenium in proportion to their physiological needs. Excesses are rapidly excreted.

c. Wildlife

The toxic effects of selenium on aquatic biota have been reviewed by Rosenfeld and Beath (1964). Freshwater catfish died within 48 hours after receiving intraperitoneal injections of 0.15 mg. or more of selenium as sodium selenite. Injections of 0.05 mg. of selenium resulted in death after 12 to 15 days. Edema and a disturbance in the hematopoetic system (blood forming)

were observed. Ten ppm of selenium in the water is lethal to carp in 25 days and mudsnails in 8 days. It is also acknowledged that 2.5 ppm of selenium in the water is toxic to Daphnia, a small test animal known to be highly susceptible to toxic substances.

Duck sickness was produced by the addition of 20 ppm of selenium to the drinking water. Many of the symptoms were identical with those of Clostridium botulism--type C.

2. Rate of uptake by the biota and potential for food chain concentration (biomagnification).

The fact that certain substances (particularly pesticides and radionuclides) become concentrated at the higher food chain levels has been well-documented. One study by Metcalf et al. (1971) utilizing a model ecosystem, has shown that radiolabeled DDT was accumulated in mosquito larvae, snails, and fish as DDE, DDD, and DDT, and concentrated from 10,000 to 100,000-fold.

In the case of selenium, it is well-known that certain native plants growing on seleniferous soils accumulate high concentrations of this substance (Rosenfeld and Beath, 1964). In certain locations, accumulator species containing over 1,000 ppm of selenium have been found growing alongside grasses containing less than 10 ppm (Table 10). These so-called selenium accumulator plants include 24 species and varieties of Astragalus (milk vetch); section Xylorhiza (woody aster) of Machaeranthera; section Oonopsis (goldenweed) of Haplopappus; and Stanleya (prince's plume). The accumulator plants generally grow in dry, nonagricultural areas, and range animals do not graze them unless forced to by a shortage of other feeds. The geographical distribution of certain species of Astragalus is presented in Table 9.

Information with regard to the wildlife which feed on selenium accumulator plants is unavailable. Since these are noxious weeds which contain high levels of selenium, it is unlikely that these plants would be preferred as a feed source for the indigenous fauna. Probably, the toxicity of selenium to wild herbivores would be of the same order of magnitude as that observed in domestic livestock and poultry. FDA can only speculate that predators will not be adversely affected.

There is a paucity of information on the potential concentration of selenium in aquatic food chains. However, studies by Sandholm et al. (1973) showed that the phytoplankton, Scenedesmus dimorphus actively concentrated radiolabeled selonomethionine, but neither actively nor passively concentrated inorganic selenite. It was concluded that common water plants do not accumulate large quantities of selenium from surrounding water. These authors also observed that zooplankton (primarily Daphnia pulex) absorbed selenium from selenite. Fish concentrated only a small amount of organic or inorganic selenium directly from water, but did concentrate it from food. Thus, biomagnification by flora and fauna is possible and should be considered in determining potential environmental impacts. With reference to the proposed action, however, the major concern is directed towards assessing the changes in biomagnification potential caused by the small increment of selenium that will be distributed into the environment. Provided this increment is small enough, currently operative natural biomagnification schemes would be unaltered.

3. Rate of input into the environment.

In order to determine whether or not probable secondary impacts will occur

it is necessary to estimate the rate of input of selenium into the environment. This estimate is based on an analysis which assumes that all of the selenium administered to the animals will be excreted. It further assumes that the excreta will be disposed of by soil application at the rate of 5 tons of waste dry matter per acre. This is the highest practical rate of application.

HYPOTHESIS 1. None of the selenium leaches from the soil.

The highest level of supplemental selenium permitted on a practical basis by this petition would be 0.2 ppm in turkey rations. If all of this were passed into the waste with 40 percent of the dietary matter excreted, the level of selenium in the waste from 0.2 ppm added selenium would be 0.5 ppm selenium on a dry weight basis. Converted to a ton basis, a ton of dry turkey waste would contain 0.4545 grams selenium from the added selenium. The application of 5 tons of dry turkey waste per acre would add only 2.27 grams selenium per acre.

In the normal farming practices, the waste would be worked into the top 6 inches of soil. The top 6 inches of soil per acre weighs 2,000,000 pounds (M. L. Jackson, 1958) or 909,000 kilograms. Therefore, a 2:27 grams increase in selenium per 909,000 kilograms is equivalent to an increase in selenium content of 0.0025 ppm from the 5 tons of turkey waste.

In general, farmers apply the waste to the soil at the time of plowing in either spring or fall. As such, as much as one year's production of waste may be stored in piles. It has been shown (Viets, 1972) that up to 10 percent of the mineral matter in feedlot waste can be leached by rainfall. As such, each 1,000 ton pile of waste would lose 45.45 grams of

selenium via the water runoff. If the selenium is absorbed by the surrounding one acre of soil, then the selenium concentration of this soil will increase by 0.05 ppm per year. This increase is negligible.

If, however, the selenium in the 1,000 ton pile of waste is totally leached by 24 inches of rainfall (2,467,051 kg.), then the water runoff would have a selenium concentration of 0.018 ppm. The contribution of this leached selenium to the concentration of selenium in the surface and subsurface streams is difficult to estimate since it would depend upon size, drainage area and rate of flow of these streams.

The regulation would provide for practical addition of up to 0.1 ppm added selenium for chicken and swine rations. This is 1/2 the amount used for turkeys. Therefore, 5 tons of dry waste from chickens and swine would supply 1.136 grams per acre or 0.0012 ppm. Single application of 900 grams selenium per acre from sodium selenite have been added without detrimental effects to sheep fed forages grown on the treated soil (in Selenium in Nutrition, 1971). Sheep are known to be among the most sensitive animals to selenium. Stated another way, the annual addition of 2.27 grams selenium per acre would require 396 years to equal the 900 grams per acre selenium addition referred to above, assuming that all the selenium is accumulated in the top 6 inches of soil.

Since soils in many areas of the U. S. are deficient in selenium, and since the waste is applied to the soil in the area in which the animals are grown, the effect, if any, of the addition of the small amounts of selenium would be beneficial to the animal consuming the forages and grains grown on these soils.

HYPOTHESIS 2. <u>All of the selenium leaches from the soil and finds its way into the waterways.</u>

The area of the U. S. which will require selenium supplementation due to deficient levels in grains and feedstuffs comprises the eastern U. S. and west coast area of California, Oregon and Washington (Figure 1). The eastern U. S. is defined as the area east of the western borders of the following States: Minnesota, Iowa, Missouri, Arkansas and Louisiana. Of the States in the above described deficient areas, California has the lowest mean annual rainfall of 24 inches (Miller, 1973). For the purposes of this discussion, we are also assuming the addition of 5 tons of dry manure per acre contributing the same levels of selenium per acre referred to above (i.e., 2.27 grams from turkey waste and 1.136 grams from chicken and swine waste). Twenty-four inches of rainfall would be equivalent to 2,467,051 kilograms water per acre. Therefore, if the amount of selenium added by 5 tons of dry turkey waste (2.27 grams) is assumed to be totally leached out of the soil by the 24 inches of rainfall (2,467,051 kilograms) this would give a selenium concentration of 0.00092 ppm in the water.

Using the same figures for chickens and swine, wastes from these species would contribute half the level of 0.00046 ppm selenium in the water.

There is an insufficient quantity of waste produced by all of the chickens, turkeys, and swine in the eastern U. S. and Pacific coast areas to apply 5 tons to each acre of land in farms. The total waste production in turkeys, chickens, and swine in the eastern U. S. and Pacific coast area is given in Table 1. The total waste produced annually would be 1,418,839 tons for turkeys and 22,793,205 tons of chickens and swine combined. If this were spread at a rate of 5 tons per acre, then the turkey waste would cover 283,768 acres or 0.055 percent of the land in

farms in the eastern U. S. and Pacific coast regions (509,815,551 acres) (U. S. Census of Agriculture, 1964). The number of acres to which chicken and swine waste could be added at the rate of 5 tons per acre is 4,448,641 acres or 0.8959 percent of the land in farms.

The animal population in the areas in which selenium supplementation is required is given by species in Table 2 with the level of selenium which would be consumed at the proposed added selenium levels of 0.2 ppm for turkeys and 0.1 ppm for chickens and swine. The combined total selenium consumption for all species grown in the eastern U. S. and Pacific coast areas is 5,815,780 grams. Assuming all of the animals in these areas were given supplemental selenium, this would be the total possible selenium which could be added back to the land through the wastes.

If the total amount of possible selenium present in the waste (5,815,780 grams) is spread over the entire land area in farms (509,815,551 acres) in the same area of the U. S., the amount of selenium added per acre per year should not exceed 0.0114 grams. This would add 0.000012 ppm selenium to the top 6 inches of soil.

The earth's crust is calculated to contain 0.09 ppm selenium (Mitchell, 1964). The addition of 0.000012 ppm selenium to the soil through the waste from the supplementation of poultry and swine rations would amount to only 0.0133 percent of the selenium present in the earth's crust for that area.

Soils in areas where selenium deficiency diseases occur are reported to contain 0.04 ppm selenium or less and areas of moderate selenium content where selenium deficiency diseases do not occur contain 0.5 ppm to 5.0 ppm

(Allaway, 1968). The addition of 0.000012 ppm selenium to soil containing low selenium levels (0.04 ppm) would only increase the selenium content 0.03 percent. Adding 0.000012 ppm to the soils containing the lower limit of selenium for moderate selenium content soils (0.5 ppm) would increase the selenium content 0.0024 percent.

The maximum effect on the water as a result of total leaching out of the selenium from the waste by an annual rainfall of 24 inches would be insignificant. We have used 24 inches rainfall because this is the lowest mean annual rainfall of any State (Figure 2) in which supplementation is necessary (Miller, 1973). Other States have higher annual rainfall. Using 2,457,051 kilograms water per acre from the 24 inches of rainfall and 0.0114 grams selenium added per acre on farmland, the water concentration of selenium would be 0.00000462 ppm. The average concentration of selenium for the waters of the entire area would be lower than this since the average rainfall is greater than 24 inches annually and would be further diluted with water from land which is not in farms.

The United States Public Health Service has established 0.01 ppm selenium as a safe upper limit for human water supplies (Public Health Service Publication 956). The selenium content of seawater has been calculated to be 0.00009 ppm based upon analytical results from the Atlantic, Pacific, and Antarctic Oceans, Long Island Sound and the Carribbean (Schutz and Turekian, 1965). This indicates that the maximum level of selenium leached out of the soil from returning waste containing added selenium from sodium selenite or sodium selenate would be insignificant. It would be safe for both humans and aquatic life even at the maximum possible levels.

Conclusion

Compounds of selenium are, without question, highly toxic. The amounts required to satisfy essential nutritional requirements are between one-tenth and one-hundredth the minimum toxic levels for animals. Their use as feed additives should be carefully controlled to prevent harm either to the animals or to prevent excess selenium deposition in edible tissues destined for human food. No adverse environmental effects are anticipated when animal waste containing selenium is applied to the soil at a rate of 5 tons or less per acre. Under these circumstances, the amount of selenium added to the soil is so small that it is unlikely that natural biomagnification schemes in terrestrial and aquatic ecosystems would be adversely affected. Special precautions should be taken in those instances where animal waste is stored in piles to ensure that selenium leached by rainfall will not have direct access to the water table or other aquatic sources. The proposed use of sodium selenite or sodium selenate would assure that the nutritional requirements of poultry and swine are satisfied and present no hazard of increased selenium levels in human food above that found in tissues of normal animals.

SECTION V

ADVERSE ENVIRONMENTAL IMPACT CONSIDERATIONS

Selenium is a natural component of the environment. In this regard, any adverse impact must be assessed in terms of the added burden the proposed use of selenium will place onto the ecosphere. Section IV demonstrates that this burden would be negligible and could be handled by acceptable safeguards.

Adverse environmental impact in the form of increased selenium levels in the soil and water supply may occur if animal feeds are over-formulated by the addition of excess selenium or addition of selenium to feeds high in selenium. However, the levels of selenium in animal tissues would most likely be unaffected by such over-formulation and excessive addition with the exception of possible increased levels in liver and kidney of treated animals (see Tables 6 and 7). At any rate, any such adverse environmental effects would not foreseeably compromise human safety. Animal safety would be unaffected under controlled conditions since the margin of safety is adequate under such conditions.

To control these potential adverse environmental effects, the regulation stipulates that no more than one pound of a premix containing a maximum of 90.8 mg of selenium per pound may be added to a ton of chicken or swine feed. At this rate, 30 pounds of this premix would have to be added to a ton of feed to reach a toxic selenium level, a practice which is not expected to occur.

million acres, this technique of selenium treatment would require the distribution of at least 7 million kilograms of selenium. The proposed dietary use of selenium would involve only approximately 6 thousand kilograms, therefore, from an environmental standpoint, the dietary use is more desirable. In addition, we have a regulatory concern with soil amendment via fertilization. At present this route of administration is impossible to control.

2. Interregional Feed Blending

It is known that certain areas of the country produce basal feedstuffs which contain quantities of selenium at or above the required levels. It may be possible to use these feedstuffs as selenium sources. We discounted this alternative since it is well known that selenium from natural sources is not as biologically available as that from sodium selenite or selenate. In this regard, a feedstuff may contain "adequate" levels of selenium, but it could produce a selenium deficiency. Also, there would be insufficient quantities of "high" selenium ingredients to adequately balance "low" selenium ingredients. Interregional feed blending suffers from the further disadvantage that the high selenium commodities would have to be segregated in the marketplace. This practice is currently not feasible. The cost of transporting bulky feed ingredients would be expensive and would offset much of the intended economic benefit. In addition, the transportation of grain would require a considerable increase in energy consumption.

3. Corporeal Injection

This process would involve injecting animals with therapeutic levels

SECTION VI

ALTERNATIVES TO THE PROPOSED ACTION

The alternative of not permitting the use of selenium would force livestock producers to rely on selenium obtained from natural sources. This alternative was rejected since natural sources (feedstuffs and drinking water) often contain less than the needed amount of selenium (Table 8).

The only method for mitigating a selenium deficiency in poultry and livestock requires the direct administration of selenium to the deficient animals. Two major problems are particularly pertinent in evaluating the feed route as a means of administering physiologically effective quantities of selenium. First, the amounts required are so small (less than 1 ppm in the diet dry matter) that there is a highly practical problem of adequate mixing with the large mass of feed material. Secondly, it may be difficult to avoid toxic levels of selenium by the addition of the nutrient to feeds under conditions currently applied in commercial agricultural practice. These problems should be considered in any program of direct addition of selenium to animal feed.

There are several ways in which direct selenium administration can be accomplished.

1. Soil Amendment

Selenium can be added to the soil on which our basic feedstuffs are grown. This practice has been successful in New Zealand where farmers have applied 14-28g of selenium (as sodium selenite) per acre. Since the selenium-deficient arable area of the U.S. encompasses in excess of 509

of selenium. Its disadvantages accrue from the fact that each animal would have to be handled at periodic intervals. The current high density livestock production practices make this a costly and undesirable alternative.

4. Drinking Water Administration

This alternative is a variant of the feed method. Essentially similar quantities of selenium would have to be used. We discounted this alternative since livestock producers, in general, lack the metering devices necessary to assure that the animal will consume the required selenium dosage. Further, since water consumption is highly variable and dependent on climatic conditions, we doubt if the selenium dosage could be controlled with any degree of assurance.

5. Feed Monitoring

This alternative would provide for the establishment of a program for monitoring the levels of selenium in the animal's diet through extensive and frequent chemical or physical analyses. Such a program does not exist, but analytical methods that would be required for it are available. There are several acceptable methods published in the Journal of the Association of Official Analytical Chemists (A.O.A.C.). Several new methods have been developed, including x-ray fluorescence spectrometry for the detection of potentially toxic levels of selenium and procedures for determining selenium in biological materials by neutron activation analysis.

Variations of this program would require individual feedmills to analyze either each ton of feed or each lot of feed ingredients prior to the addition of selenium. If each ton of feed were analyzed (analysis costs $15-20 per sample), the program would cost from 70-100 million dollars (49 million tons of feed affected), a sum which may exceed the potential benefit.

Conclusions

Of the six alternative methods proposed for satisfying the selenium requirements of swine and poultry, three (feed administration, corporeal injection, and drinking water administration) would involve the environmental distribution and use of about the same quantity of selenium. Rejection, therefore, of two of these alternatives (corporeal injection and drinking water administration) was based on feasibility and cost considerations. An additional alternative (feed monitoring) which could potentially limit selenium distribution was rejected for excessive costs. The alternative of soil amendment was rejected since its application would require the use of at least 1400 times more selenium than that required by feed administration. The alternative of interregional feed blending was attractive from an environmental viewpoint since no synthetic selenium salts would have to be distributed into the environment. It was thought, however, that the energy output required to accomplish the massive movement of feedstuffs coupled with cost and feasibility considerations would outweigh the proposed environmental benefits.

SECTION VII

RELATIONSHIP BETWEEN LOCAL SHORT-TERM USES OF MAN'S ENVIRONMENT AND THE MAINTENANCE AND ENHANCEMENT OF LONG-TERM PRODUCTIVITY

There would be no known long-term detrimental effects on the environment of supplementing animal rations with selenium due to the very low level of addition to the soil of selenium from manure. Assuming, as discussed in Section IV, the application of 0.000012 ppm annually, it would take:

A. 75 years to change the selenium content of the farmland in the affected area by 1% when soil contains 0.09 ppm selenium.

B. 33 years for a 1% change in low selenium soils containing 0.04 ppm.

C. 416 years for a 1% change in soils containing moderate selenium levels (0.5 ppm).

The long-term beneficial effects can be more readily postulated since the selenium will be added to rations in areas where soils are deficient. The addition of selenium to these soils would help to minimize soil depletion occurring through intensive farming and natural leaching of selenium from the soil. The incidence of diagnosis of selenium deficiency diseases has progressively increased in poultry and swine.

For the short term, the various beneficial effects would accrue by rectifying the selenium deficiency. No short-term compromise of man's environment is foreseen.

SECTION VIII

IRREVERSIBLE AND IRRETRIEVABLE COMMITMENTS OF RESOURCES WHICH WOULD BE INVOLVED IN THE PROPOSED ACTION SHOULD IT BE IMPLEMENTED

Based on the usage level of this feed additive, there would be no known irreversible or irretrievable commitment of natural resources.

Selenium is obtained from mined ore as a by-product of the copper smelting process. The use of selenium salts in animal feeds further distributes the selenium and eventually returns it to the earth's crust, as discussed in Section IV. The amount of selenium added to the soil (as animal waste) or to stream and ground water (as selenium is subsequently leached from the soil) would not exceed that of the natural selenium present in the soil or water of areas in the United States where selenium is present at normal levels.

SECTION IX

CONCLUSIONS

In assessing all of the available information, the FDA has arrived at the following conclusions:

1. Selenium is an essential trace nutrient which is needed by poultry and livestock to permit normal growth and metabolism.

2. Selenium in the form of sodium selenite or sodium selenate is highly toxic. Selenium compounds vary greatly with their chemical structure and nutritional status of the animal with regard to any toxic effect.

3. Data indicate that tissue levels of selenium will increase from a deficiency state when an animal receives additional selenium. The magnitude of the upper limits of such increases will be approximately that level found when an animal receives adequate selenium from natural sources. Such levels are construed to be safe. The only tissues that appear likely to consistently accumulate selenium are the kidney and liver and these are unlikely to constitute more than a very small part of the human diet. Based on these data no adverse effects on animal and human population are anticipated.

4. No adverse environmental effects are anticipated when animal waste containing selenium is applied to the soil at a rate of 5 tons per acre or less. Special precautions should be taken in those instances where animal waste is stored in piles to ensure that selenium leached by rainfall will not have direct access to the water table or other aquatic sources.

5. Various alternatives exist for providing selenium to animals when nutritional diseases are caused by selenium deficiency. The most

feasible alternative is feed administration to herds and flocks that have experienced a history of losses caused by selenium deficiency. Therefore, the proposed rule making provides for the direct addition of selenium to the feed of chickens, turkeys and swine when the loss history warrants such addition.

6. Under carefully controlled conditions, physiological levels of selenium can be administered effectively as an additive to feed. The FDA system for controlling food additives (feed mill inspections, feed sampling, and food analysis) and the required precautionary labeling should provide the necessary controls. Additionally, to preclude any possible environmental impact, appropriate quality control procedures should be followed when incorporating selenium into animal feeds in accordance with the proposed rule making order.

TABLE #1

Annual waste production in the Eastern U. S. 1/ and Pacific Coast areas by species:

SPECIES	LBS. FEED/ ANIMAL	# ANIMALS ANNUALLY	TOTAL POUNDS FEED CONSUMED	TOTAL LBS. DRY WASTE PRODUCED	TOTAL TONS WASTE ANNUALLY
		1,000's	1,000's	1,000's	
Turkey Growing 2a/	65	101,353	6,587,945	2,635,178	1,317,589
Turkey Breeder 2b/	150	3,375	506,250	202,500	101,250
Total Turkey Manure					1,418,839
Laying Hens 2c/	80	285,520	22,841,600	9,136,640	4,568,320
Pullet Replacements 2c/	15	285,520	4,282,800	1,713,120	856,560
Broiler Chickens 2d/	9.0	2,741,614	24,674,526	9,869,810	4,934,905
Swine Growing 2e/	600	80,695.4	48,417,240	19,366,896	9,683,448
Swine Breeders 2e/	2300	5,978.2	13,749,860	5,499,944	2,749,972
Total Chicken and Swine					22,793,205

1/ Includes all States east of the western borders of Minnesota, Arkansas and Louisiana and the States of California, Oregon and Washington.

2/ Based on data published by Crop Reporting Board, SRS USDA.
a) Turkeys crop for 1971, April 1972.
b) Total U. S. Turkey Breeders on farms, Dec. 1, 1971, Egg Ch cken and Turkey Report - Jan. 1972.
c) Average number of chicken hens on hand in 1971 - Feb. 1972 report.
d) Number of broilers reported for 1971, April 1972.
e) Number of pigs produced in 1971, Report - Dec. 1971.

SECTION X

APPENDICES

APPENDIX A

TABLES

TABLE #2

Annual consumption of added selenium at proposed added levels by species for the Eastern U. S. 1/ and Pacific Coast areas.

SPECIES	FEED CONSUMED PER ANIMAL	# ANIMALS IN AREA	SUPPLEMENTAL Se LEVEL	TOTAL SELENIUM CONSUMED
	lbs.	1000's	ppm	gm.
Turkey Growing 2/	65.0	101,353.0	0.20	597,982.7
Turkey Breeders 2/	150.0	3,375.0	0.20	45,967.5
Laying Hens 2/	80.0	285,520.0	0.10	1,036,437.6
Pullet Replacements 2/	15.0	285,520.0	0.10	194,439.1
Broiler Chickens 2/	9.0	2,741,614.0	0.10	1,118,578.5
Hogs, Growing 2/	600.0	80,695.4	0.10	2,198,131.8
Sows 2/	2,300.0	5,978.2	0.10	624,243.6
Total				5,815,780.8

1/ Includes all States east of the western borders of Minnesota, Iowa, Missouri, Arkansas, Louisiana, and the States of California, Oregon and Washington.

2/ See footnote (2/) Table 1.

TABLE #3

Effects of Selenium Supplementation on Tissue Selenium Levels in 20-week old Turkeys[1]

Tissue	Levels of Selenium in Tissue (ppm)		
	Basal	Basal + 0.1 ppm Se	Basal + 0.2 ppm Se
Breast Muscle	0.179 ± .009	0.168 ± .004	0.179 ± .008
Leg Muscle	0.198 ± .009	0.221 ± .005	0.219 ± .008
Liver	0.700 ± .021	0.671 ± .028	0.681 ± .024
Blood	0.181 ± .007	0.188 ± .006	0.196 ± .003

1. Scott, M. L. 1971. Data Submitted to FDA and Contained in MF 3433.

TABLE #4

Effects of Selenium Supplementation on
Tissue Selenium Levels in 14-week old Turkeys[1]

Tissue	Level of Selenium in Tissue (ppm)		
	Basal	Basal + 0.1 ppm Se	Basal + 0.2 ppm Se
Breast Muscle	0.219 ± .007	0.204 ± .013	0.197 ± .008
Leg Muscle	0.172 ± .007	0.172 ± .007	0.192 ± .007
Liver	0.615 ± .016	0.651 ± .035	0.641 ± .012
Blood	0.199 ± .012	0.184 ± .005	0.192 ± .003

1. Scott, M. L. 1971. Data Submitted to FDA and Contained in MF 3433.

TABLE #5

Effects of Selenium Supplementation on Tissue Selenium Levels in Broiler Chickens[1]

	Level of Selenium in Tissue (ppm)			
Tissue	Basal*	Basal + 0.1 ppm Se	Basal + 0.2 ppm Se	Basal + 0.4 ppm Se
Muscle	0.061	0.071	0.103	0.114
Liver	0.25	0.48	0.34	0.13
Kidney	0.39	0.34	0.80	0.56
Skin	0.09	0.13	0.16	0.13

*Low selenium basal (0.07 ppm).

1. Scott, M. L. 1970. Data Submitted to FDA and Contained in MF 3433.

TABLE #6

Effects of Selenium Supplementation on Tissue Selenium Levels in Chickens [1]

Tissue	Level of Selenium in Tissue (ppm)	
	Basal	Basal + 2.0 ppm Se
Thigh	0.44	0.44
Breast	0.40	0.42
Liver	0.80	1.03
Kidney	0.96	1.16
Heart	0.54	0.68

1. Olson, O. E. 1971. Data Submitted to FDA and Contained in MF 3433.

TABLE #7

Effects of Selenium Supplementation on Tissue Selenium Levels in Swine[1]

	Level of Selenium in Tissue (ppm)	
Tissue	Basal + 0.1 ppm Se	Basal + 1.0 ppm Se
Muscle	0.16	0.15
Heart	0.21	0.17
Liver	0.56	0.52

1. Olson, O. E. 1970. Data Submitted to FDA and Contained in MF 3433.

TABLE #8

Selenium Content of Corn in Midwestern States[1]

State	Number of Samples	Selenium in parts per million Low	High	Mean	Median
North Dakota	6	0.09	0.26	0.19	0.22
South Dakota	10	0.11	2.03	0.40	0.24
Nebraska	6	0.04	0.81	0.35	0.28
Kansas	1	---	0.99	---	---
Minnesota	22	0.02	0.29	0.09	0.06
Iowa	25	0.02	0.16	0.05	0.05
Missouri	4	0.02	0.09	0.05	0.05
Wisconsin	5	0.02	0.13	0.05	0.02
Illinois	31	0.02	0.15	0.05	0.04
Michigan	5	0.03	0.04	0.03	0.03
Indiana	20	0.01	0.15	0.04	0.04
Total	135	0.01	2.03	0.11	0.05

1. Patrias, G. and O. E. Olson. 1969. Selenium Contents of Samples of Corn from Midwestern States. Feedstuffs: October 25 Issue.

TABLE #9

The Geographic Distribution of Astragalus - A Selenium Accumulator Plant[1]

Species	Distribution
A. bisculatus	Montana, N. Dakota, S. Dakota, Idaho, Wyoming, Nebraska, Colorado, Oklahoma, Kansas, New Mexico
A. racemous Pursh	Montana, N. Dakota, S. Dakota, Wyoming, Nebraska, Colorado, Utah, Kansas, New Mexico, Oklahoma, Texas
A. osterhouti Jones	Colorado
A. argillosus	Utah, Arizona
A. gravi Parry	Wyoming, Montana
A. beathii Porter	Arizona

1. Rosenfeld, I. and O. A. Beath. 1964. Selenium: Geobotany, biochemistry, toxicity and nutrition. Academic Press, New York, page 62.

TABLE 10

The Selenium Content of Plants Grown on Seleniferous Soil[1]

Plant	Selenium Concentration (ppm)
Astragalus bisculatus	5,530
Stanleya pinnata	1,190
Astriplex nuttallii	300
Grasses	23

1. Rosenfeld, I. and O. A. Beath. 1964. Selenium: Geobotany, biochemistry, toxicity and nutrition. Academic Press, New York, page 91.

Table II

1969 POULTRY PRODUCTION

	Laying Hens[1/] Av. No. (000)	Broilers[1/] No. Produced (000)	Turkeys[1/] No. Produced (000)
Maine	5,831	72,900	14
New Hampshire	1,559	482	31
Vermont	588	18	8
Massachusetts	2,363	3,216	242
Connecticut	4,084	6,657	111
New York	10,487	2,438	412
New Jersey	4,139	950	111
Pennsylvania	14,720	48,998	1,925
Delaware	610	133,503	150
Maryland	1,600	174,274	95
Virginia	5,096	63,469	4,179
West Virginia	1,482	16,542	676
Ohio	9,468	10,051	3,919
Indiana	12,812	13,934	3,621
Illinois	8,232	----	671
Michigan	6,188	777	882
Wisconsin	5,109	15,183	3,166
Kentucky	3,121	7,190	57
Tennessee	5,464	46,132	14
North Carolina	15,342	280,637	9,408
South Carolina	5,078	24,219	2,536
Georgia	24,705	442,221	1,633
Florida	11,066	38,737	1,572
Idaho	830	7,936	
Washington	4,422	21,436	573
Oregon	2,305	14,700	1,800
California	37,740	76,757	15,080
TOTAL	204,441	1,523,357	52,886
United States	313,343	2,788,195	106,204
% of Birds in States Listed	65%	55%	50%

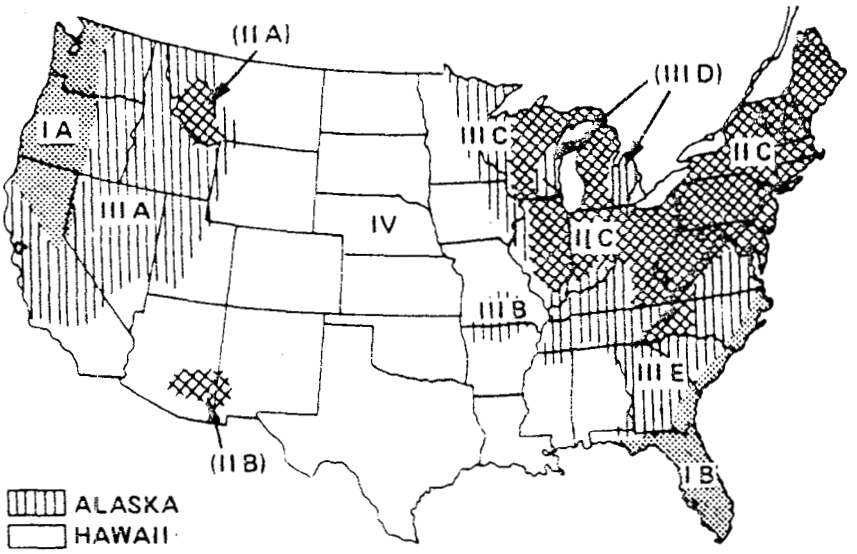
1/ Figures from USDA Agricultural Statistics 1970

APPENDIX B

FIGURES

AREA PATTERNS IN THE SELENIUM CONTENT OF PLANTS IN THE UNITED STATES

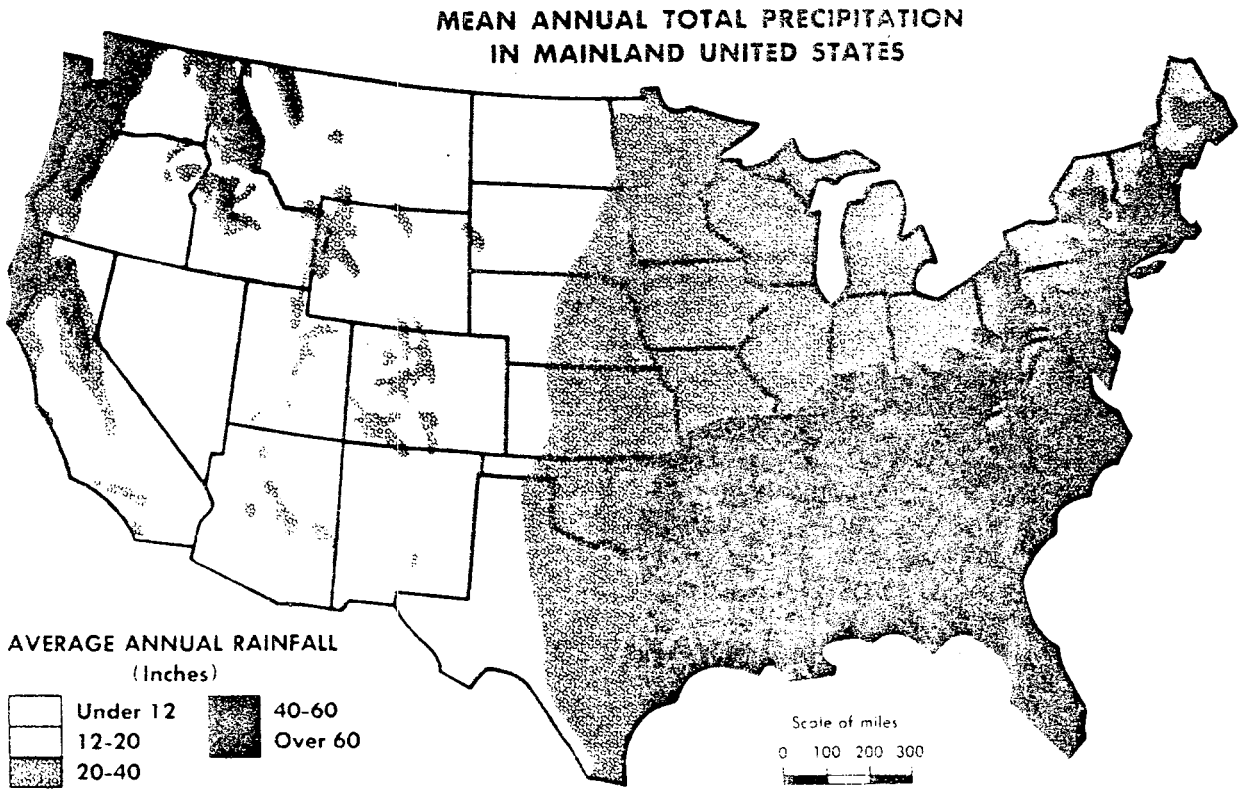
Figure 6 shows the concentrations of selenium in crops in different areas of the United States. A unique feature of the distribution of selenium in plants in the United States is the occurrence of several broad areas where almost all the plants sampled contained low levels



AREA	CROP	NO. OF SAMPLES	MEDIAN CONC.	FREQUENCY DISTRIBUTION (%) OF SAMPLES WITH Se CONCENTRATIONS (ppm) OF					
				0.01 to 0.05	0.05 to 0.10	0.10 to 0.50	0.50 to 1.0	1.0 to 5.0	5
I A	FORAGES	69	0.03	81	15	4	0	0	0
I B	FORAGES	26	0.02	89	11	0	0	0	0
II A	FORAGES	14	0.05	50	36	14	0	0	0
II B	FORAGES	11	0.05	36	45	19	0	0	0
II C	FORAGES	187	0.05	65	31	4	0	0	0
III A	FORAGES	261	0.09	20	31	43	4	2	0
III B	FORAGES	14	0.05	57	14	22	0	7	0
III C	FORAGES	39	0.09	20	41	26	13	0	0
III D	FORAGES	27	0.10	26	18	49	7	0	0
III E	FORAGES	79	0.06	50	23	22	5	0	0
IV	FORAGES	205	0.26	3	10	60	18	9	0
	WHEAT	856	—	—	9	—	22	30	34
	FEED GRAIN	262	—	—	33	—	22	38	7

FIGURE 6 Relative concentrations of selenium in crops from different areas of the United States. Data for wheat and feed grain are from U.S. Department of Agriculture Technical Bulletin 758 (1941). From Kubota *et al.* (1967).

FIGURE II


MEAN ANNUAL TOTAL PRECIPITATION
IN MAINLAND UNITED STATES
AVERAGE ANNUAL RAINFALL
(Inches)
Under 12
12-20
20-40
40-60
Over 60
Scale of miles
0 100 200 300

APPENDIX C

ECONOMIC IMPACT

APPENDIX C

ECONOMIC IMPACT

Agricultural statistics (USDA 1970) show approximately 65% of the laying hens, 55% of the broilers and 50% of the turkeys are produced in "selenium-deficient" States (Table 11). These percentages have been used in subsequent calculations to estimate numbers of birds affected by selenium-deficient diets.

Selenium deficiency has been diagnosed with increasing frequency in both chicken and turkey operations over the past five years. No natural feed ingredients have been found to contribute adequate levels of selenium to provide an economical solution to this nutrient deficiency which now has widespread geographic occurrence.

Selenium deficiency has been diagnosed in commercial poultry flocks in which the assayed selenium content of the ration was above the reported nutritional requirement. This indicates an accentuation of the requirement under stress conditions or perhaps low availability of the selenium in natural ingredients. It is believed that marginal levels of selenium in feeds cause impaired performance of many poultry flocks in which no visible symptoms are observed.

Economic losses to poultry producers attributed to lack of approval for addition of inorganic selenium to feeds may originate from:

1. Mortality, reduced weight gains, impaired feed conversion, loss of egg production and other losses affecting quality of the birds to be marketed.
2. Higher feed ingredient costs to increase natural selenium levels.

The following assumptions and estimates of economic losses represent an appraisal by the scientific staff of a national feed manufacturer of the economic impact of selenium deficiency on the chicken and turkey industries.

Turkeys

Assumptions: The following calculations are based on 57.5 million turkeys being produced in 1972 in selenium deficiency areas:

- 25% of turkeys are affected to the extent of showing 10% higher mortality to four weeks of age.
- 5% less grade A turkeys in affected flocks showing mortality.
- 50% of turkeys show impaired growth and feed conversion (5% on growth and 3% on feed conversion).
- Above losses in addition to increased ingredient costs of $1.00/ton in attempt to alleviate deficiencies.

Economic Losses

Mortality	: 0.25 x 57,500,000 x 0.10 = 1,437,500 mortalities @ $0.80/turkey =	$ 1,150,000
Reduced Grade	: 57,500,000 x 0.25 x 0.05 x 18 x $0.05 = (no. birds) (% affected) (% grade loss) (wt. birds) (loss/lb)	$ 646,875
Impaired Growth & Feed Conversion	: 57,500,000 x 0.50 x 18 (av. wt.) = 517,500,000 lbs. turkey produced 5% loss of weight = 0.05 x 517,500,000 = 25,875,000 @ 23 cents/lb. =	$ 5,951,250
	3% loss in feed conversion - 0.03 x 517,500,000 x 3.3 (av. feed conv.) = 51,232,500 lbs. feed @ 4 cents/lb. =	$ 2,049,300
Added Feed Cost	: 57,500,000 turkeys @ 60 lbs/bird = $\frac{3,450,000,000}{2,000}$ = 1,725,000 tons @ $1.00/ton =	$ 1,725,000
Total Annual Loss to Turkey Producers		$11,522,425

Broilers

Assumptions: The following calculations are based on 1.5 billion broilers being produced in 1972 in selenium deficient areas:

- 5% of broilers are affected to the extent of showing 3% higher mortality to four weeks of age.
- 25% of broilers show impaired growth and feed conversion (3% on growth and 2% on feed conversion).
- Above losses in addition to increased ingredient costs of $1.00/ton in attempt to alleviate deficiencies.

Economic Losses

Mortality	: 0.05 x 1,500,000,000 x 0.03 = 2,250,000 mortalities @ 0.30/bird =	$ 675,000
Impaired Growth & Feed Conversion	: 1,500,000,000 x 0.25 x 3.7 = 1,387,500,000 lbs. broiler meat	
	3% loss of weight - 0.03 x 1,387,500,000 = 41,625,000 @ 15 cents/lb. =	$ 6.243.750
	2% loss in feed conversion - 0.02 x 1,387,500,000 x 2.2 (av. fd. conv.) =	$ 2,747,250
Added Feed Cost	: 1.5 billion birds x 8 lbs/birds = 12,000,000,000 lbs. - 6,000,000 tons / 2,000 @ $1.00/ton	$ 6,000,000
Total Annual Loss to Broiler Producers		$15,666,000

Summary

An economic evaluation based on minimum estimates of the extent of selenium deficiency in poultry reveals that poultry producers are suffering from annual losses in excess of 27 million dollars. It is clear that the swine industry would have the same degree of loss. In this regard, selenium deficiency causes annual losses of about 55 million dollars.

APPENDIX D

SUBMITTED COMMENTS

APPENDIX D

SUBMITTED COMMENTS

List of Commentators

1. Environmental Protection Agency
2. Tennessee Valley Authority
3. United States Department of Agriculture
4. United States Department of Health, Education, and Welfare
   a. Assistant Regional Director for Health
   b. National Institutes of Health, Division of Research Services
   c. National Institutes of Health, Environmental Services Branch
   d. Office of the Secretary
   e. Region I - Boston, Social and Rehabilitation Service
   f. Region V - Chicago, Regional Engineer
   g. Social Security Administration
5. United States Department of the Interior
6. American Feed Manufacturers Association, Inc.
   1701 N. Ft. Myer Drive
   Arlington, Va. 22209
7. Central Soya
   Fort Wayne, Indiana 46802
8. Cornell University
   Ithaca, New York 14850
9. H. K. Webster Co., Inc.
   P. O. Box 8
   Lawrence, Massachusetts 01842
10. John W. Eshelman & Sons
    244 North Queen Street
    Lancaster, Pa. 17604

11. Michigan State University
East Lansing, Michigan 48823

12. Micro Tracers, Inc.
381 Eleventh Street
San Francisco, California 94103

13. Moorman Mfg. Co.
1000 North 30th Street
Quincy, Illinois 62301

14. Ms. Peggy Marine
4425 Van Buren
Riverside, California 92501

15. National Feed Ingredients Association
517 Merle Hay Tower
Des Moines, Iowa 50310

16. Ralston Purina Company
St. Louis, Missouri 63188

17. Smith-Douglass
Rural Route 1
Elgin, Illinois 60120

18. Southern States Cooperative, Inc.
P. O. Box 1656
Richmond, Virginia 23213

19. The Beacon Milling Company, Inc.
Cayuga, New York 13034

20. The University of Arizona
Tucson, Arizona 85721

21. Zip Feed Mills, Inc.
Sioux Falls, South Dakota 57102

Comment No. 1

ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

6 JUL 1973

OFFICE OF THE
ADMINISTRATOR

Hearing Clerk
Department of Health, Education
and Welfare
Room 6-88
5600 Fisher Lane
Rockville, Maryland 20852

Dear Sir:

The Environmental Protection Agency has reviewed the draft environmental impact statement for Rule Making on Selenium in Animal Feeds, including the proposed rule making, and our detailed comments are enclosed.

Our review indicates that the calculated selenium concentrations, as stated in the draft statement, and the conditions under which selenium will be used should have no immediate or long-term adverse impact on the environment.

In accordance with our responsibilities under Section 309 of the Clean Air Act to inform the public of our views on proposed Federal actions, we have designated this project an LO-2. A description of this rating system is enclosed for your information.

We will be pleased to discuss our comments with you or members of your office.

Sincerely yours,

Sheldon Meyers

Sheldon Meyers
Director
Office of Federal Activities

Enclosures

COMMENTS ON DRAFT ENVIRONMENTAL IMPACT STATEMENT

ON RULE MAKING ON SELENIUM IN ANIMAL FEEDS

GENERAL COMMENTS

Selenium is an essential trace nutrient for certain animals without which various deficiency diseases are known to develop. It can be toxic, however, if taken in excessive quantities.

The proposed rule has been formulated in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act and is an amendment to the Food Additive Regulations of the Food and Drug Administration. The rule proposes the addition of the 0.01 ppm of selenium in chicken and swine feed and 0.02 ppm in turkey feed. These levels are the minimum selenium requirements for these animals.

SPECIFIC COMMENTS

Air and Terrestrial Effects

Based on our review, we do not believe that the selenium concentrations as described in the draft statement will have any adverse effects on the air or terrestrial environments.

Aquatic Effects

Aside from an accidental spillage of selenium into a waterway at the point at which it is mixed with the feed or the spillage of the mixed feed into a waterway, the only foreseeable route whereby it can enter the aquatic environment is via animal excretion with eventual drainage into the waterways. According to the draft statement, the maximum predictable selenium concentration in surface runoff will be 0.00046 ppm from chicken and swine waste and 0.00092 ppm from turkey waste. Though not mentioned in the draft statement, these concentrations are considerably less than the 2.5 ppm selenium concentration in water which is toxic to Daphnia, a small test animal found in the aquatic food chain and known to be highly susceptible to toxic substances. Since no attempt is made in this draft statement to discuss the toxic effects of selenium on aquatic biota, the final statement would be strengthened by a discussion of these effects.

The United States Public Health Service has established 0.01 ppm selenium as the maximum safe concentration for human drinking water. The selenium concentrations in farmland runoff would not be expected therefore to endanger human water supplies.

Our review indicates that the selenium concentrations as described in this draft statement should not result in an immediate or long-term adverse impact on the aquatic environment.

U.S. Environmental Protection Agency Procedures for Classifying Federal Projects and Associated Draft Environmental Impact Statements

Environmental Impact of the Project

LO--Lack of Objections

EPA has no objections to the proposed project as described in the draft impact statement; or suggests only minor changes in the proposed project.

ER--Environmental Reservations

EPA has reservations concerning the environmental effects of certain aspects of the proposed project. EPA believes that further study of suggested alternatives or modifications is required and has asked the originating Federal agency to reassess these aspects.

EU--Environmentally Unsatisfactory

EPA believes that the proposed project is unsatisfactory because of its potentially harmful effect on the environment. Furthermore, the Agency believes that the potential safeguards which might be utilized may not adequately protect the environment from hazards arising from this project. The Agency recommends that alternatives to the project be analyzed further (including the possibility of no action at all).

Adequacy of the Impact Statement

Category 1--Adequate

The draft impact statement adequately sets forth the environmental impact of the proposed project as well as alternatives reasonably available to the project.

Category 2--Insufficient Information

EPA believes that the draft impact statement does not contain sufficient information to assess fully the environmental impact of the proposed project. However, from the information submitted, the Agency is able to make a preliminary determination of the impact on the environment. EPA has requested that the originator provide the information that was not included in the draft statement.

Category 3--Inadequate

EPA believes that the draft impact statements does not adequately assess the environmental impact of the proposed project, or that the statement inadequately analyzes reasonably available alternatives. The Agency has requested more information and analysis concerning the potential environmental hazards and has asked that substantial revision be made to the impact statement.

If a draft impact statement is assigned a Category 3, no rating will be made of the project, since a basis does not generally exist on which to make such a determination.

Comment No. 2

TENNESSEE VALLEY AUTHORITY
CHATTANOOGA, TENNESSEE
37401

TVA 40TH ANNIVERSARY OF PEOPLE IN PARTNERSHIP

August 21, 1973

Mr. Paul Cromwell, Acting Director
Office of Environmental Affairs
Department of Health, Education,
and Welfare
Washington, D. C. 20201

Dear Mr. Cromwell:

This is in response to your request during our telephone conversation of July 25, 1973, for specific TVA information regarding selenium toxicity. Unfortunately, we find that we have no new data or information of significance.

Although we expect you have a considerable bibliography on the subject of selenium toxicity, we have noted two recent publications on the subject that may be of interest. Abstracts of the two articles are enclosed.

Recently, TVA was fortunate to have some work on vanadium toxicity done by Dr. Eiichi Takahashi of Kyoto University. Dr. Takahashi is a recognized authority on selenium toxicity whom you might wish to contact as a resource. His address is:

Dr. Eiichi Takahashi
College of Agriculture
Faculty of Agricultural Chemistry
Kyoto University
Kyoto, Japan

We hope this information will be of assistance.

Sincerely yours,

Harry G. Moore, Jr., Ph. D.
Chief, Environmental Planning
and Assessment Staff

Enclosure

Reversal of Selenium Toxicity in Chicks by Mercury and Cadmium.
C. H. Hill, Department of Poultry Science, North Carolina State University, Raleigh, North Carolina 27607

Chicks fed selenium as SeO_2 in their diet at levels of 10, 20, and 40 ppm grew progressively more slowly than control chicks receiving the same feed without selenium. At 3 weeks of age, growth was negligible in those chicks receiving 40 ppm Se. Mercury as $HgCl_2$ at 500 ppm in this diet also decreased growth significantly. The combination of 40 ppm Se and 500 ppm Hg in the diet, however, resulted in very little growth retardation indicating that Hg counteracted Se toxicity. Further studies showed that this interaction occurred when mercury was present in equimolar amounts to selenium but the effect diminished when the molar ratio of mercury to selenium was less than 1. The effect of Hg on Se toxicity was shared by Cu and to some extent by Cd. A Hg-Se compound, probably $HgSeO_3$, was prepared and found to be relatively nontoxic when fed in amounts that supplied 10 and 20 ppm Se. This compound may form in the digestive tract or body of the chick, thereby greatly reducing the toxicity of Se.

Environmental Health Perspectives, June 1973. pp. 104-105.

Uptake of Selenium by Aquatic Organisms. Sandholm, M., H. E. Oksanen, and L. Pesonen, Department of Medicine, College of Veterinary Medicine, 00550 Helsinki 55, Finland

The Se content of aquatic organisms was lowest in aquatic plants, varying from 0.02 to 0.14 ppm (dry wt). Plankton samples contained from 1.1 to 2.4 ppm, fishes cultured in ponds 0.5 to 0.9 ppm, and fishes from natural environments 1.0 to 2.9 ppm.

The phytoplankter, Scenedesmus dimorphus, actively concentrated ^{75}Se-selenomethionine, but neither actively nor passively concentrated inorganic selenite. The zooplankton, consisting mostly of Daphnia pulex, absorbed ^{75}Se from selenite. In aquariums fish concentrated only a small amount of organic or inorganic Se directly from water, but did concentrate Se from food.

Limnology and Oceanography, May 1973. p. 496.

Comment No. 3

DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D. C. 20250

May 25, 1973

Dr. Kenneth E. Taylor
Director
Vffice of Environmental Quality
Public Health Service
Food and Drug Administration
Rockville, Maryland 20852

Dear Dr. Taylor:

We appreciate the opportunity to review the FDA draft environmental statement, Rule Making on Selenium in Animal Feeds. Comments prepared by reviewers in the Department are enclosed.

Sincerely,

T. C. BYERLY
Coordinator
Environmental Quality Activities

Enclosures

Comments Prepared by
Science and Education Staff

The draft environmental impact statement on rule making on selenium in animal feeds (FDA, April 19, 1973) is considered to be most complete and clearly supports the thesis that selenium can be judiciously used in the production of food animals for benefit to the consumer.

Selenium is known to be an essential dietary nutrient which is not supplied in sufficient quantities in a significant proportion of feeds for poultry and swine, so that additional supplementation is required for normal, efficient production. Provision of these small supplementary amounts can best be accomplished through the addition of biologically available selenium salts to the feed as has been requested. This, if done as proposed by FDA, is not considered to prevent any hazard to man or animals. On the contrary, this will make it possible to adequately meet the needs of this essential nutrient in an economical and safe manner.

The USDA not only strongly supports the environmental impact statement, but considers the proposed addition of selenium to these animal feeds to be most necessary for efficient production of swine and poultry products.

Comments
Prepared by
COOPERATIVE STATE RESEARCH SERVICE

The draft of the environmental impact statement has been reviewed by several specialists in CSRS. We are in general agreement with the intent and purpose of the statement and concur in the action taken by FDA. A few errors were noted in the document, but these do not change the basic conclusions. The document is not clear on whether supplementation would be permitted in areas where feed and forage contain adequate levels of selenium.

Dr. W. H. Allaway, Director of the Plant, Soil and Nutrition Laboratory, Ithaca, New York would be an excellent person to provide critical comments. Extensive studies on selenium have been made in that Laboratory.

MEMORANDUM

Comment No. 4b

DEPARTMENT OF HEALTH, EDUCATION, AND WELFA
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

TO : Chief, VRB, DRS

DATE: May 31, 1973

FROM : Nutritionist, VRB, DRS

SUBJECT: Comments Regarding FDA Impact Statement on Selenium in Animal Feeds

1. Nutritionists have recognized for several years that microconcentrations of dietary selenium are required by many species of farm animals in order to sustain normal body function. The toxic effects of selenium are also well documented. The magnitude of the difference between the required and toxic levels of selenium is similar to other dietary elements, but in the case of selenium the amount required to cause toxic effects is very small. Therefore, it is essential that regulations covering the use of selenium in animal feeds minimize the chance of an overdose due to errors in feed formulation. Item 3 of the proposed regulation (not less than one pound of premix per ton of feed) would not prevent such an error because there is no control over the amount of selenium in the premix.

2. The following considerations are offered for a program to ensure the incorporation of safe levels of selenium in animal feeds.

a. Place ceilings on the availability of selenium salts for livestock feeds.

b. Grant permits for approved companies to incorporate selenium in premixes and make selenium available to feed manufacturing companies only via premix. Permits would be granted to research institutions involved in selenium research to purchase and use the selenium salts.

c. Require that all feed manufacturers retain a representative sample from each batch of product supplemented with selenium. At the end of each quarter, a composite of these samples would be assayed for this element and reported to the FDA.

3. The sensitivity of sheep to selenium deficiency is cited several times throughout the impact statement, yet the proposed regulations do not allow for the dietary supplementation of selenium for this species. Consideration should be given to

Comment No. 4a

OPTIONAL FORM NO. 10
MAY 1962 EDITION
GSA FPMR (41 CFR) 101-11.6

UNITED STATES GOVERNMENT

Memorandum

TO : Mr. Paul Cromwell
Acting Chief Environmental Officer

DATE: June 6, 1973

FROM : Assistant Regional Director for Health

SUBJECT: Draft EIS #015-05-73
Rule Making on Selenium in Animal Feeds

No comment. We agree with the statement, conclusions and recommendations contained in the draft environmental impact statement.

Frederick H. Sillman, M.D.
Assistant Regional Director for Health

allow a maximum concentration of selenium fortification in sheep and cattle rations provided a program for adequate control similar to the one previously discussed is established.

4. Some data have indicated that laboratory and zoo animals may respond to dietary selenium fortification. Even though products from these animals do not directly enter the human food chain, there is a possibility that selenium residues in waste products from these animals could contribute to the total environmental selenium concentration. On this basis, at least, guidelines should be issued for the use of selenium fortification in rations for these animals.

5. Some statement regarding selenium fortification of pet foods should be included in the regulations.

6. In summary, the proposed regulations for selenium fortification of swine and poultry rations are valid. The impact statements appear to be quite correct. An improved program should be established to ensure against the over-fortification of this element. The regulations should be expanded to include (or exclude) selenium fortification of rations for all species of farm animals, birds, laboratory animals, zoo animals, and pets.

Joseph J. Knapka, Ph.D.

Comment No. 4c

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

TO : Director, Division of Research Services

DATE: June 4, 1973

FROM : Chief, Environmental Services Branch, DRS

SUBJECT: Comment--FDA Impact Statement on Selenium and Animal Feeds

1. The Environmental Services Branch has reviewed the subject impact statement. We concur with the assessment of the impact on the environment as stated. We are of the opinion that there will be no adverse impact in feeding the supplemental feed in the process outlined.

2. We wish to emphasize that there can be a hazard in preparation of the selenium mix at the mill where the feed is prepared. Our industrial hygienists indicate that the selenium must be added to the feed in a closed system whereby workers are not exposed in any manner to the selenium dust. We are not familiar with the pre-mix as formulated. Therefore, we would caution that the selenium be so compounded that it would not be a hazard to the person administering it to the poultry and animals.

Vinson R. Oviatt

Comment No. 4d

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY

TO : Dr. Kenneth Taylor
Agency Environmental Officer
FDA

DATE: JUN 28 1973

FROM : Acting Chief
Office of Environmental Affairs

SUBJECT: Draft Impact Statement on Selenium

I have attached the comments that I have received from sources within the Department and call your attention particularly to those developed by SSA, NIH and Region I (SRS).

In addition to those comments, I have the following comments:

1. The potential effects on wildlife are not discussed and this, in the absence of any real knowledge in this area, raises serious questions as to whether Food and Drug Administration should approve the use of selenium as an additive to animal feeds at this time. The most serious deficiency concerns the lack of discussion with respect to plant accumulators. If the toxicity level in some livestock can occur at 3 ppm (Page 23), some discussion should be provided concerning the level expected in plant accumulators in addition to the discussion of occurrence in soils. The draft should be amended to discuss:

   a. Plant species which are selenium accumulators should be identified (as suggested by SSA).

   b. Wildlife feeding on these plants should be identified, together with toxic levels for at least some of the species.

   c. Predators feeding on wildlife in (b) above should be identified, together with toxic levels (unless it can be shown that the levels in accumulators would be below that in selenium-rich areas).

   d. The same analysis should be performed for aquatic life which might be subject to higher concentrations of selenium through water run-off (including, particularly, predators).

2. The information presented on selenium content of plants (Page 46) is extremely limited.

   a. The number of samples is so small that it seems safe only to assume areas IA and IB have low concentrations of selenium.

   b. The samples apparently pertain only to wheat and other forages. Would other plants accumulate higher concentrations of selenium?

3. In the absence of hard data on toxicity levels in wildlife, it would seem reasonable to show (if possible) that, as a result of the action, the selenium level in accumulator plants in non-selenium areas would not exceed that in selenium-rich areas and that there are no wildlife species which are limited to selenium-deficient areas.

4. The use of selenium as an additive would also seem reasonable if it could be shown that the disposal of animal wastes is, by and large, subject to human control. This probably is not the case except in those instances where large producers (particularly of poultry) do control the disposal of wastes.

5. The final statement (or at least future FDA statements) should avoid the usage of terms which are not clearly understood by the general public unless a glossary is included. A partial list is included in Attachment #1.

6. A different format would more clearly define the issues involved, including those areas where there is a lack of information. A suggested outline is in Attachment #2.

Paul Cromwell

Comment No. 4e

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
SOCIAL AND REHABILITATION SERVICE
REGION I

MEMORANDUM

TO : Jack Costa
Deputy for State Programs

DATE: May 15, 1973

Our reference: SRS/ORC

FROM : Regional Medical Coordinator, SRS

SUBJECT: Your request for comments on "Draft Environmental Impact Statement Rule Making on Selenium in Animal Feeds."

1. This statement reveals a significant amount of consideration of studies on the effect of selenium on domestic animals and birds. Little information is available related to human subjects. We know it exists in the human body as a trace element. More exact knowledge of potential impact on human beings is highly desirable before any additives are authorized that will be in animal tissues destined for human consumption.

2. It is noted that the regulations confine "use of selenium to proven incidence of deficiency demonstrated and defined by known clinical signs." It is assumed that the regulatory agency would have the necessary man-power for judicious monitoring of the use of selenium in the interest of safe marketing.

3. Questions or comments for consideration in the interest of the consumer are posed in relation to the conclusions (pages 34-35).

4. Conclusion No. 3 - "The exact toxicity of selenium is unknown _____. Selenium in the form of sodium selenite or sodium selenate are highly toxic." The paragraph continues in stating that "Selenium compounds vary greatly with regard to any toxic effect." Would not this last statement apply as well to human consumers?

5. Conclusion No. 5 - The second sentence states, "The magnitude of the upper limits _____ appear to be safe in most edible tissues." What evidence is available to assure safety in edible tissues? This conclusion assumes that kidney and liver "are unlikely to constitute more than a very small part of the human diet." Should consumption of these organs carry a caution for those persons overly fond of kidney and liver? Also, what safe-guards would be available for persons who feed their house-hold pets significant quantities of these products?

6. Conclusion No. 6 - Should human beings be subjected to selenium "supplementation", when the effect of that supplementation is not known?

7. Appendix C, Economic Impact; The agricultural statistics (USDA 1970) are cited as "approximately 65% of the laying hens _____ are produced in 'seleium deficient' States." The statistics on the Economic Impact of adding selenium to feeds include "laying" hens. The regulations (4th provision) stipulate that "selenium must not be added to feeds intended for laying hens" since the safety of the practice is not known. It would appear then that the "layers" should not be included in the projected impact of adding selenium.

A. Bernice Clark, M.D.

Attachment

MEMORANDUM

Comment No. 4f

TO : Mitchell Cobey, Regional Environmental Officer DATE: May 17, 1973

DHEW-ORD-4

MAY 21 1973

RECEIVED

FROM : Regional Engineer

SUBJECT: Rule Making on Selenium in Animal Feeds
DRAFT ENVIRONMENTAL STATEMENT

1. The draft environmental impact statement for the proposed rule making on selenium in animal foods has been reviewed by this office.

2. This office does not have the special expertise to evaluate the environmental impact of the proposed rule making.

3. As far as our limited review capabilities can ascertain, the proposed rule making is not considered to be related to the architectural or engineering features of DHEW projects, existing or proposed.

Melvin H. Fisher, P.E.
Regional Engineer
Facilities Engineering
and Construction

Enclosure

Comment No. 4g

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
SOCIAL SECURITY ADMINISTRATION

TO : Paul Cromwell
Acting Chief Environmental Officer

DATE : May 22, 1973

REFER TO: OA:PR

FROM : Ronald Blavatt
SSA Environmental Officer

SUBJECT: Draft FDA-EIS on Rule Making on Selenium in Animal Feeds

After reviewing the draft EIS, I believe SSA should recommend that it be returned to the writer for modification before release for outside review.

The basic goal of ending selenium deficiencies in the diets of chickens, turkeys, and swine is clearly stated. Major alternatives to accomplish this are identified. The deficiencies in the EIS start at this point in the analysis. These deficiencies are enumerated below:

1. The discussion of feed monitoring, the fifth alternative, is completely inadequate. After stating that the technologies for this alternative exist, the EIS simply dismisses the alternative with a statement that no such monitoring program is in existence. (No selenium addition programs such as the FDA proposes is in existence either.) There is no discussion of how difficult or how expensive it would be to create a monitoring program or how effective it would be once in use.

2. Throughout the EIS, reference is made to the minor amount of selenium that would be added to the soil in the form of sodium selenite and selenate in comparison to natural levels of selenium. Yet, it is stated elsewhere in the EIS that sodium selenite and selenate are biologically more active than selenium. Does this increase biological activity affect the conclusion that the added sodium selenite and selenate are not significant in comparison to the natural soil levels of selenium? The EIS contains no discussion of this point.

3. The EIS assumes that excreta from feed lots will be tilled into the upper 6 inches of farm land at a maximum rate of 5 tons of dry waste per acre per year. How valid is this assumption? What is the possibility that the waste might

United States Department of the Interior

OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20240

In Reply Refer To:
FSF/SQ
ER-73/611

MAY 17 1973

Dear Dr. Taylor:

This is in response to your request of April 26 for review and comment on the proposed rule-making order on Selenium in Animal Feeds.

We do not believe that all questions have been addressed adequately. Elaboration in the indicated areas will, we feel, strengthen the statement.

Page 3. - Paragraph three.

The differentiation of a selenium-adequate diet and a fortified diet is not clear. Reference to tables #3 to #7 would be helpful.

Page 4. - Paragraph one.

It is not clear why all animals and birds in all geographical locations must or should be treated alike. There is an implication that other materials will suffice in some areas. This could be clarified.

Page 24. - Paragraph 3.

The levels at which these carinogenic studies were conducted should be included so that the reader may properly assess relevance of the results. If, indeed, there is some question concerning the results then the studies should be repeated prior to issuance to this order.

Page 25. - Human Toxicological Considerations.

This section is inadequate and contains information which is irrelevant. We fail to see the connection between exessive levels in steers and human toxicology since it is not proposed to add this substance to steer diets.

be placed in piles for long periods before final disposal or disposed of in manners other than even tilling into farm land? How would this affect the possibility of selenium uptake in nearby plants and animals?

4. The EIS notes that certain plant species are selenium accumulators and can be fatal to animals eating them. Nowhere are these accumulators identified. What is the incidence of accumulator plants in the proposed selenium addition areas? (Selenium addition is proposed for the area east of the Mississippi and west of the Rockies; in other words, in all of the United States except for the Plains States.) What animals eat the accumulator plants? Do humans?

5. Sheep are identified as being one of the animals most sensitive to selenium. The safety of the proposed level of selenium addition is forecast in part from the lack of harm to a band of sheep that grazed in an area with a large single application of selenium. Did this single grazing area have or not have accumulator plants that sheep might eat? No discussion. Does a single large application of selenium have the same biological impact as multiple small application repeated over many years? No discussion, but the assumption that repeated applications do not have a greater impact is fundamental to the reasoning in the EIS.

Ronald Blavatt

Comment No. 6

ORIGINAL

May 29, 1973

Hearing Clerk
Department of Health, Education & Welfare
Room 6-88
5600 Fisher's Lane
Rockville, Maryland 20852

Reference: Draft Environmental Impact Statement on Selenium in Animal Feeds dated April 19, 1973 - Notice of Availability Published in Federal Register April 27, 1973

Dear Sir,

As the petitioner for approval of selenium supplementation of animal feeds, and the national representative of manufacturers of animal feeds, this Association submits comments concerning the Draft Environmental Impact Statement on the proposed addition of selenium to animal feeds. Attention is called to our separate comments of May 29, 1973, filed with you on the proposed food additive regulation published in the Federal Register of April 27, 1973.

As expressed in our comments on the proposed food additive regulation, it is our belief preparation of an Environmental Impact Statement was not required. The Environmental Impact Analysis Report filed by us on July 26; 1972, clearly indicated a very minor, if any, impact on the environment from the proposed supplementation of animal feeds. If any impact could be discerned, it could only be construed as being beneficial in nature. The Report was filed voluntarily in response to a verbal suggestion prior to any effective regulations calling for such a report as a part of the petition. In addition to the foregoing, the requirement for an Environmental Impact Statement did not become effective until after the statutory time limit for processing our petition had expired. It certainly does not seem to be in order to impose a further delay, after some three years of review, by requiring the mechanics of draft and final Statements.

We hope the printing of a final Environmental Impact Statement can be expedited that an effective food additive regulation can be published at the earliest possible date. Losses in animal production and life have been and are continuing to occur due to selenium deficiencies. The regulation permitting supplementation of animal feeds to prevent these losses is urgently needed.

We recognize the good efforts of those charged with drafting the Impact Statement. We appreciate those efforts, the fact this was the first such Statement prepared by the Bureau of Veterinary Medicine, and that the time frame for its preparation was limited. Our comments are intended to be constructive and to insure the statement provides a balanced perspective. They are made in the sequence of the Draft Statement.

SECTION I - SUMMARY

Background and Description - The first paragraph may give the impression selenium is unique in being both essential and yet toxic if consumed in excessive amounts. Selenium is no different from other trace nutrients in this respect.

ARLINGTON, VA. 22209 • TELE: 703 / 524

There is no indication of the level at which human toxicity occurs. Reference is made to the existence of reports that selenium may contribute to dental caries, is a potential carcinogen and is toxic to fish. Elaboration and inclusion of numerical values would be helpful.

Sincerely yours,

Assistant Secretary of the Interior

Dr. Kenneth E. Taylor
Director
Office of Environmental Quality
Department of Health, Education, and Welfare
Food and Drug Administration
Rockville, Maryland 20852

Probable Impact on the Environment - The first sentence of the third paragraph ends with the word detriment. We believe impact is more appropriate. This paragraph would also benefit from the addition of the sentence: "In the major portions of the country where soils are deficient in selenium, any increases in soil content would be beneficial."

Alternatives to the Proposed Action - The first paragraph contains the sentence "The regulations confine use of selenium to proven incidence of deficiency demonstrated and defined by known clinical signs." The proposed addition of selenium to animal feeds is to prevent rather than treat deficiency. This sentence should be revised to read: "The proposed regulation provides for use of selenium in those amounts that have been demonstrated to be required for nutritional purposes."

Conclusions - The word normal should be inserted before the term quality control in this paragraph.

SECTION II - BACKGROUND AND DESCRIPTION - The word often should be added to the second sentence to read: "...the levels that occur are often not sufficient..." The word salvaged should be replaced with prevented in the first sentence of the second paragraph.

Action Description - Reference is made to our comments of May 29 on the proposed regulation. We believe this version of the regulation is preferable for the reasons stated.

SECTION III - PROBABLE IMPACT ON THE ENVIRONMENT

Selenium Distribution - This paragraph gives the impression that selenium concentrations in a wide variety of plants can be toxic. The plants should be identified as selenium accumulator type plants occurring in certain areas.

SECTION IV - ADVERSE ENVIRONMENTAL IMPACT CONSIDERATIONS - We question the statement "Adverse environmental impacts may occur..." if animal feeds are over-fortified with selenium. It is doubtful any such impact from an isolated instance could be measured or could be construed to be adverse. We suggest the following replacement paragraph:

> "Should animal feeds be oversupplemented with selenium or selenium supplementation be added to feeds high in natural selenium, there would be little if any impact on the environment. Human safety would not be compromised since the tissue levels of selenium would be unaffected with the exception of possible increased levels in liver and kidney of treated animals, (see Table 6 and 7). Likewise, animal safety would be unaffected since the margin of safety is adequate under controlled conditions."

A new third paragraph is also suggested:

> "The maximum supplementation of animal feeds is clearly stated as to species and amount. In addition, Section 3 of the proposed regulation stipulates that at least 1 pound of premix must be added to a ton of feed, an amount that is deemed adequate to insure good dispersion in the animal feed."

Attention is called to a unique and desirable characteristic of selenium from inorganic sources. Inorganic selenium is apparently more readily absorbed through the gut wall than is selenium from organic sources. Once absorbed, however, selenium from inorganic sources is more prone to be excreted than is selenium from organic sources. Selenium from plant and animal sources is more prone to deposition in the animal's tissues. This was graphically illustrated in the swine work from which Table #7 is drawn. There was no difference in tissue retention of selenium from diets fortified with either .1 or 1 ppm. selenium. A high natural diet containing almost exactly the same total selenium as the 1 ppm. fortified diet did result in higher tissue levels of selenium. Consequently, the addition of .1 or .2 ppm. selenium to a diet containing adequate levels of natural selenium will not result in any additional selenium in the edible tissues of the animal, with a possible exception of the liver and kidneys. Liver and kidneys make up only a very minor portion of the human diet.

SECTION V - OTHER ENVIRONMENTAL IMPACT CONSIDERATIONS

Toxic Effects of Selenium - The ratio between beneficial and toxic dose for selenium is no different than that for many nutritional elements. There is an apparent omission in the fourth sentence of the fourth paragraph (page 24). We believe it should read "...liver cirrhosis produced by a marked..." With respect to the last paragraph (page 25) we believe it should be indicated that selenium is a hepatotoxic agent at the levels indicated only on a continuous basis and that the species should be named. Toxic levels are normally higher than the 2 ppm. mentioned.

Human Toxicological Considerations - Attention is called to our earlier comments concerning the nature of inorganic versus organic forms of selenium. We agree that selenium content of animal tissues will plateau, that under normal conditions excesses of intake are rapidly excreted.

Conclusion - The first sentence gives the impression that selenium compounds are toxic period. This sentence should be revised to read: "Selenium in relatively large amounts can be highly toxic." We believe the minimum margin of safety is greater than the "one tenth" indicated in the second sentence. The third sentence should refer to feed rather than animal additives. The fourth sentence, making reference to 0.25 ppm., apparently is based on a proposal which has been dropped. This sentence should be revised to read: "The proposed use of selenium as an additive to the rations of growing chickens, swine, and turkeys specifies the maximum amount of selenium that may be added to the feeds for these species for nutritional purposes. These amounts are adequate to satisfy nutritional requirements and low enough to preclude any hazard of increased selenium levels in human food above that found in tissues of animals consuming diets adequate in selenium from natural sources."

SECTION VI - ALTERNATIVES TO THE PROPOSED ACTION - The second sentence of the first paragraph should read "...natural sources (feed stuffs and drinking water) more often than not contain less than the needed amount..." We question the fourth sentence of the second paragraph which states it may be difficult to avoid toxic levels by adding selenium to feeds under current conditions. The feed industry has long incorporated small amounts of other micro ingredients of both nutritional and drug nature - and done so in a very satisfactory manner. We do not believe there will

Point 6. - There is every reason to believe the supplementation of animal feeds with selenium which will produce a normal selenium content of foods of animal origin will benefit the human consumer. Some mention of this fact should be made under Point 6.

Point 7. - This paragraph gives the impression there are feasible alternatives to supplementing animal feeds. This is not the case. This paragraph should be revised to read as follows: "Various alternatives for providing needed supplemental selenium to animals to prevent nutritional deficiencies are not feasible when compared with supplementing animal feeds. The proposed regulation provides for the direct addition of selenium to the feed of chickens, turkeys, and swine under certain prescribed conditions."

Point 8. - This conclusion should be revised to read: "Under carefully controlled conditions, physiological levels of selenium can be administered effectively as an addition to feed. To preclude any possible environmental impact, appropriate quality control procedures should be followed when incorporating selenium into animal feeds in accordance with the proposed regulation."

As expressed in our separate comments filed on the proposed regulation, this Association and its members stand ready to aid the agency in any possible way with respect to publishing of a final Statement and an effective food additive regulation. Every week of delay causes more animal deaths and other economic losses which increase the cost of food to consumers. Thus we urge you to expedite this procedure as much as possible.

Yours truly,

Lee H. Boyd, Director
Feed Control and Nutrition

LHB:co

be any particular problems associated with supplementing feeds with the indicated amounts of selenium. Attention is called to the fact such supplementation has been carried out in this country for experimental purposes and is routinely carried out in certain foreign countries which have used selenium supplementation for a substantial period of time.

Interregional Feed Blending - We suggest the following revised paragraph:

"It is known that certain areas of the country produce feedstuffs which contain apparent adequate and superadequate quantities of selenium. Such feedstuffs could conceivably be used as selenium sources. This alternative must be discounted for several reasons. It is well known that selenium from natural sources is not as biologically available as that from sodium selenite or selenate. In this regard a feedstuff may contain 'adequate' levels of selenium, but still produce a selenium deficiency. Interregional feed blending suffers from the further disadvantage that the high selenium commodities would have to be segregated in the marketplace, which is not practically possible. The total cost of producing chickens, turkeys, and swine by transporting bulky feed ingredients from areas where selenium is adequate to areas which are selenium-deficient would increase the cost of poultry and pork to consumers. Last but not least, there are insufficient quantities of 'high' selenium ingredients to balance 'low' ingredients. Interregional feed blending is not a feasible alternative."

Corporeal Injection - The following addition to the third sentence should be made: "...high density livestock production practices with minimum labor inputs make this..."

Feed Monitoring - We believe this section is intended to suggest the possible alternative of analyzing all ingredients and supplementing feeds accordingly. This is definitely not a feasible alternative. The cost of such analyses, probably in the range of $15-20, is prohibitive. Laboratory facilities and personnel to perform the vast number of analyses that would be required are simply not available. The various reagents and power and the like required to perform the vast number of analyses contemplated would undoubtedly have a far greater impact on the environment and one of a detrimental nature - than the proposed supplementation of feeds. Most important of all, feed mills are not designed for the delay and warehousing that would be involved. Feed and food costs would increase.

SECTION IX - CONCLUSIONS

Point 2. - The word nutrition should be substituted for specific diseases.

Point 3. - The second sentence should be revised to read: "Selenium in the form of sodium selenite or sodium selenate is highly toxic at 50-100 fold the level needed for nutrition."

Point 5. - The second sentence should be revised to read: "The magnitude of the upper limits of such increases will be approximately that level found when an animal receives adequate selenium from natural sources. Such levels are construed to be safe."

CENTRAL SOYA Fort Wayne, Indiana 46802

May 31, 1973

Hearing Clerk
Department of Health, Education & Welfare
Room 6-88
5600 Fishers Lane
Rockville, Maryland 20852

Re: Draft Environmental Impact Statement - Rule Making on Selenium in Animal Feeds, dated April 19, 1973

Dear Sir:

Central Soya Company, Inc. is a producer of millions of pounds of poultry and turkeys and is a major manufacturer and supplier of swine feed in the United States. We therefore have a vital interest in the use of Selenium in animal feeds.

We concur with the contents of the Draft Environmental Impact Statement. We particularly concur with the position of the Food and Drug Administration that the alternatives (listed on Page 4) are not feasible. It is our understanding that the alternative of "Feed Monitoring", which is published in detail as Item 5, Page 31, implies that every batch of ingredients would be analyzed for natural Selenium content, the total natural Selenium content of the formulated feed determined and then Selenium addition permitted to the allowable levels. The economic burden of the assays would be so great as to more than offset the advantages of Selenium addition to animal feed. Further, it would not be a physically workable program since lots of individually-purchased ingredients eventually become co-mingled.

We do not know of any valid basis for denying the addition of Selenium to animal feed. It is an essential element for man and animal and is critically needed for the improvement of animal health, reduction of animal mortality and most important, more efficient food production.

Your consideration of our comments will be appreciated.

Sincerely,

Charles W. Klinger
Director of Regulatory Compliance

CWK/jk

New York State College of Agriculture and Life Sciences
a Statutory College of the State University
Cornell University

Department of Poultry Science
Rice Hall
Ithaca, New York 14850

June 22, 1973

Hearing Clerk
Department of Health,
Education & Welfare
Room 6-88
5600 Fishers Land
Rockville, MD 20852

Dear Sir:

Having conducted extensive research on the nutritional and metabolic needs for selenium, I am particularly gratified to read the "Draft environmental impact statement, Rule making on selenium in animal feeds," prepared by the Bureau of Veterinary Medicine, Food and Drug Administration, Department of Health Education & Welfare, which was issued April 19, 1973. This is an excellent review of the situation.

One small error in the "Draft" may be pointed out on page 26 where it is indicated in the tenth and eleventh lines that "selenium content of the liver was somewhat higher -- about 1.7 ppm for both chicks and poults". It should be pointed out that the approximate 1.7 ppm of selenium quoted was on the dry basis, whereas the blood data were given on the as is, wet basis. Itwould seem more appropriate to indicate the selenium levels on the wet tissue basis as is done in the "Draft" on pages 39, 40 and 41. Here it is shown that the addition of 0.2 ppm of selenium to the diet of turkeys does not increase the selenium level of the tissues at all in comparison with the levels present in the muscle, liver and blood of 14 or 20 week old turkeys or of broiler chickens at market age. The levels in the liver are only in the neighborhood of 0.6-0.7 ppm.

The action description proposed by the Food and Drug Administration in (21CFR 121.325) appears to be completely in line with the review and recommendations of the Subcommittee on Selenium, Committee on Animal Nutrition, National Research Council as published by the National Academy of Sciences in the booklet entitled, Selenium in Nutrition, 1971.

Since I have worked closely with the AFMA on this selenium problem, I have been sent a copy of the letter of May 29, 1973 from Lee H. Boyd, Director, Food Control and Nutrition, to your office pointing out a number of small changes which might improve the wording of the "Draft" for all concerned. For the most part, I am in agreement with the AFMA letter although I consider some of the points to be rather trivial.

As I indicated above, I feel that the proposed action is well thought out and well presented and I very strongly urge final approval of this action.

I realize that at present the Food and Drug Administration does not have sufficient research evidence to approve the use of added selenium in diets for breeding chickens and turkeys. We have obtained a good deal of information this year which is still unpublished showing that selenium is indeed required for egg production and particularly for normal hatchability. A level of approximately 0.1 ppm of selenium is needed in the breeding diet for adequate carryover for normal development of young chicks. We are obtaining information on the selenium content of eggs which indicates that this corresponds almost exactly with the level in the feed (i.e. a level of 0.15 ppm in the feed produces about 0.15 ppm of selenium in the egg). I am sure that when sufficient data of this type are accumulated the Food and Drug Administration will undoubtedly want to approve the use of selenium in breeding diets for chickens and turkeys.

Sincerely yours,

M. L. Scott
Professor of Animal Nutrition

MLS:mw

BLUE SEAL FEEDS

H. K. Webster Company, Inc.

P.O. BOX 8 LAWRENCE, MASSACHUSETTS 01842

SATELLITE FE

June 4, 1973

Hearing Clerk
Department of Health, Education & Welfare
Room 6-88
5600 Fisher's Lane
Rockville, Maryland 20852

#1 Reference: Draft Environmental Impact Statement on Selenium in Animal Feeds dated April 19, 1973 - Notice of Availability Published in Federal Register April 27, 1973

#2 Reference: Selenium in Animal Feed - Proposed Food Additive Regulation Published in the Federal Register of April 27, 1973, Pages 10458-60

Dear Sir:

We strongly support and endorse the comments of Lee H. Boyd of the AFMA, relative to the above references, in his letters of May 29.

Sincerely,

Marvin W. Colburn

Marvin W. Colburn, Ph. D.
Director of Livestock Nutrition

MWC/bc

Comment No. 10

JOHN W. Eshelman & SONS
ESTABLISHED 1842

Red Rose
ANIMAL FEEDS

June 8, 1973

Hearing Clerk
Department of Health, Education & Welfare
Room 6-88
5600 Fisher's Lane
Rockville, Maryland 20852

Dear Sir:

Re: Draft of Environmental Impact

The Draft of Environmental Impact prepared by the Bureau of Veterinary Medicine, C. D. Van Houweling, D.V.M., Director, provides excellent supportive data for Selenium addition to feed. We support and endorse comments made by American Feed Manufacturers Association and are providing additional comments.

The environmental impact from addition of Selenium to poultry and animal feeds will be minimal and beneficial since any Selenium excreted through manure of these animals will be returned to the soil in a soil deficient area. In fact, if all the Selenium added to the feed was eliminated in the manure and manure was returned to the land in maximum quantities, it would be impossible to re-build the soil to its original Selenium level through these means.

Section 6 indicates several alternatives in providing Selenium such as Soil Amendment, Interregional Feed Blending, Corporeal Injection, and Drinking Water Administration. None of these approach the practicality of administering Selenium to manufactured feed. The feed industry has experience in incorporating small amounts of vitamins, minerals and other compounds in feeds. Such feeds are constantly monitored by feed control officials. Procedures have been standardized for sampling and analysis of manufactured feeds. Adding Selenium through use of 1 lb. premix per ton of feed provides a practical means of supplying the essential mineral and greatly reduces the possibility of over-fortification.

Eshelman ANIMAL FEEDS SINCE 1842

MILLS: Lancaster, Pa. • York, Pa. • Circleville, O. • Tampa, Fla. • Sanford, N. C. • Chambles

Livestock losses continue each year due to lack of this needed nutrient. As a feed manufacturer familiar with the problems of Selenium deficiency in chickens, turkeys and swine, we hope the publishing of final Environmental Impact Statement (if necessary before Selenium regulations are implemented) can be expedited because animals continue to die from lack of Selenium.

Very truly yours,

JOHN W. ESHELMAN & SONS

E. I. Robertson, Ph.D.
Director of Nutrition

EIR:lew
cc: Lee H. Boyd

Comment No. 11

MICHIGAN STATE UNIVERSITY EAST LANSING · MICHIGAN 48823

DEPARTMENT OF ANIMAL HUSBANDRY · ANTHONY HALL

June 13, 1973

Hearing Clerk
Department of Health, Education and Welfare
Room 6-88
5600 Fisher's Lane
Rockville, Maryland 20852

Reference: Draft Environmental Impact Statement on Selenium in Animal Feeds dated April 19, 1973-Notice of Availability Published in Federal Register April 27, 1973

Dear Sir:

It is my belief that approval of selenium supplementation of swine and poultry diets will have no harmful effects upon the environment. As you may note in the enclosed reprint (Groce et al. J. Animal Sci. 32:905. 1971) in Table 6, supplementation of a corn-soybean meal diet with 0.1 ppm of selenium from sodium selenite resulted in only very small increases in fecal and urinary excretion as compared to the deficient basal diet. Such unavoidable losses would have a negligible influence on soil selenium levels when swine manures are applied to soil, and, depending on the physical character of the soil, available selenium levels may not increase at all.

Increases in available soil selenium levels in much of the United States would be beneficial to animals and humans consuming plant material growing on these deficient soils. However, it has been well established that direct soil fertilization with either inorganic selenium salts or selenium-containing manures is not an efficient way of providing animals with their selenium needs. Thus, it seems logical to add the required amount of selenium directly to animal diets.

Sincerely,

D. E. Ullrey
Professor

DEUdc

Enclosure

MICRO TRACERS, INC

381 Eleventh Street • San Francisco, California 94103 • (415) 626-3315

22 June 1973

Hearing Clerk
Department of Health, Education and Welfare
Room 6-88
5600 Fisher's Lane
Rockville, Maryland 20852

Re: I. Selenium in Animal Feed - Proposed Food Additive Regulation, Federal Register 27 April 1973.

II. Draft Environmental Impact Statement on Selenium in Animal Feeds, 19 April 1973 - Notice of Availability Published in Federal Register 27 April 1973.

Dear Sir:

We note that the proposed regulation responds to the food additive petition (MF3433V) filed by the American Feed Manufacturers' Association, Inc. in behalf of all feed manufacturers, Federal Register 17 June 1971.

A review of the proposed regulation and of the environmental impact study suggests that adequate quality control is essential to the program. Yet no guide lines are given for quality control other than the implied "good manufacturing practices."

We foresee three important problems and suggest a solution to minimize these problems.

I. Regarding dispersion of selenites

Since completed feeds will contain only circa 0.1 mg. sodium selenite or selenate per pound, it is essential that the selenium compound as used in making the premix be finely powdered. Even if it pass 200 mesh, we estimate that coefficients of variation (95% confidence) could be greater than ± 150% in unit rations given to chicks. This is a limitation imposed by the Poisson Distribution. It applies even though premixes, completed feeds, and feeding conditions are otherwise ideal.

Neither the proposed regulation nor the Environmental Impact Statement sets any physical specifications for the selenium compounds.

If these compounds are to be incorporated in premixes as fine powders, the premix manufacturer will face problems in the handling of extremely toxic dusts, in mechanical and electrostatic segregation of the active ingredient, and in possible contamination of other products.

II. Regarding prohibition of selenium in complete feeds of chickens above 16 weeks of age, and in feeds intended for laying hens.

Since there is no proposed method for distinguishing feeds with added selenium from other feeds, and since the "Marker" provision specified in Petition MF3433V has been deleted, we question how these prohibitions will be implemented by the industry, and how they will be enforced by regulatory agencies.

Enforcement potential is particularly important "since the Food and Drug Administration does not have information to show that selenium administration to laying hens is a safe practice." (Environmental Impact Statement, page 12.)

It is also important because the selenium content of eggs increases with the hens dietary intake of selenium, ranging between 0.12 ppm. selenium and 9.14 ppm. (Pages 20 and 46 of Selenium in Nutrition, National Academy of Science, 1971.)

And it is important too because there are reports that elevated dietary selenium may contribute to increases in dental caries (Environmental Impact Statement, page 27.)

III. Regarding impact upon the environment.

Though we accept the statistics given, we are impelled to point out they refer only to average effects; they give no consideration to local transient impact.

For example, a single ton of premix spilled into a 5,300,000 gallon pound (5 ft. X 375 ft. X 375 ft.) would contribute 0.01 ppm. selenium to the water, raising the selenium content on the average to a value higher than that permitted by regulatory agencies. Localized transient concentrations would of course be considerably higher at the spillage site.

As another example, minor premix residues in trucks or cars could contaminate subsequent shipments.

Would it not contribute to safety if such residues could be easily identified?

Now since the need for added selenium is well established, it is particularly important that the finalized regulation be effective and safe. Should anything go wrong, adverse public reaction

might induce withdrawal of the regulation, and make future group action petitions difficult. We need only recall the problems generated by DES and PCB, and the resulting public reaction.

We therefore suggest one answer to these problems of dispersion, of cross-contamination, and of offering enforcement potential in controlling the use of feeds with added selenium so that they are not fed to chickens above 16 weeks of age or to laying hens.

The "Marker" provision should be put back into the regulation, but sodium selenite itself should serve as the instrument of identification. This is in fact achieved by Microtracer RF-Se (Patent Pending), by adsorbing sodium selenite from solution onto a finely powdered vehicle such as Reduced Iron. This in effect increases the number of selenium-containing particles, and significantly relieves the Poisson limitation of dispersion.

Feeds with added selenium in this form can be easily distinguished from other feeds by the simple device of removing iron from the feed magnetically, and by testing it for adsorbed selenite - all a matter of seconds. Cost to the industry would be less than that of FD&C Red No. 2, the "Marker" originally proposed, and would be free from the stigma associated with that dye.

In short, we have raised three questions concerning the proposed regulation, and suggested an inclusive answer; namely, sodium selenite should be introduced into premixes in a form such as our Microtracer RF-Se, or equivalent. Microtracer RF-Se consists of Reduced Iron with 2.4% sodium selenite adsorbed from solution. Premixes formulated with 2.0% of this product when used at 1 lb. per ton completed feed will introduce 0.10 ppm. selenium to the feed as required by the proposed regulation. Such feeds could then be distinguished from other feeds, offering assurance potential that feeds with added selenium are used only as permitted by the regulation.

Sincerely,

MICRO TRACERS, INC.

Sylvan Eisenberg, President
SE:sc

Comment No. 13

Moorman Mfg. Co.

1000 NORTH 30TH STREET
QUINCY, ILLINOIS · 62301

June 26, 1973

Hearing Clerk
Department of Health, Education & Welfare
Room 6-88
5600 Fishers Lane
Rockville, Maryland 20852

Dear Sir:

Re: Draft Environmental Impact Statement on Selenium in Animal Feeds dated April 19, 1973 - Notice of Availability Published in Federal Register April 27, 1973

We are manufacturers of protein, vitamin, mineral concentrates as well as complete feeds for swine and poultry and therefore, are most interested in the supplementation of swine and poultry feeds with selenium.

We endorse the comments made by Mr. Lee H. Boyd, Director of Feed Control and Nutrition, of the American Feed Manufacturers Association, in his letter dated May 23, 1973, and respectfully request your consideration of the simple changes spelled out in his letter.

Sincerely,

MOORMAN MFG. CO.

R. A. Sturdy, D.V.M.
Director of Federal and State Relations

Comment No. 14

Dear Sir,

In reference to the proposed addition of selenium to feed, I am hoping very much that the TDR will not permit this.

Our environment is already choking with the foreign substances we have little by little introduced into her once balanced system. The ridiculous part being the way we carlessly incorporated these practices, so many of them being totally unnecessary.

If only we would work with nature and understand her, we would be saving ourselves the unforeseen headaches of the future.

We can not go on abusing our natural resources and using them without replacing and preserving, anymore than we can keep spending money in a savings account without foresight and not ending up broke.

It may take a little more effort but can be done, as I am proving to myself. We can produce abundant crops and productive animals without polluting our land

with chemicals and in- ③
dangering our health.
With cancer hitting
one in four and even rising don't you wonder
what the reason is? Maybe
the answer is not in a
cure but in it's prevention.

Peggy Marine

Comment No. 15

National Feed Ingredients Association

June 6, 1973

Hearing Clerk
Dept. of Health, Education & Welfare
Room 6-88
5600 Fishers Lane
Rockville, Maryland 20852

Dear Sir:

Re: Draft Environmental Impact Statement on Selenium in Animal Feeds - Dated April 19, 1973. Notice of publication (38FR10458)

The National Feed Ingredients Association, a national association representing both feed ingredient and mixed feed manufacturers, takes this opportunity to comment on the Draft Environmental Impact Statement on Selenium in Feeds.

We indorse the comments of the American Feed Manufacturers Association.

The impact statement seems, in general, to be a factual summary of the potential use of Selenium in feeds which is written with high degree of caution.

The corrections and revisions suggested by Mr. Boyd of A.F.M.A., if adopted, will provide considerably more precision and convey a more forthright impression to the readers of the statement of the actual case for Selenium in feeds.

Our Association, as manufacturers of ingredients and mixed feeds, believes strongly in the nutritional necessity of adding Selenium to animal feeds and is certain that the members of the industry can accomplish this safely and with benefit to all concerned.

We appreciate the opportunity to comment on this statement and offer the services of our Association if we can assist.

Sincerely,

NATIONAL FEED INGREDIENTS ASSN.

J. G. Pierce
Chairman,
Government Relations Committee

JGP:jm

517 MERLE HAY TOWER / MERLE HAY PLAZA / DES MOINES, IOWA 50310 / (515) 276-1706

Comment No. 16

Ralston Purina Company

June 26, 1973

Hearing Clerk
Department of Health, Education,
and Welfare
Room 6-88
5600 Fishers Lane
Rockville, Maryland 20852

Dear Sir:

Draft Environmental Impact Statement
On Selenium In Animal Feeds
Notice of Availability
FR April 27, 1973

Ralston Purina Company is a major manufacturer of animal feeds and is therefore interested in the proposed regulations to permit the use of selenium in animal feeds and the above referenced Environmental Impact Statement.

We are, in a separate communication, supporting the proposed regulation and urging its early adoption.

We agree with the Environmental Impact Analysis and the resulting Environmental Impact Statement indicating no significant effect upon the environment. It would seem, therefore, that the Environmental Impact Statement would be unnecessary.

Serious deficiencies of selenium continue to occur and are becoming more aggravated by the current problems of ingredient supply. Because of these deficiencies, the additional delays resulting from the writing and the review of the Environmental Impact Statements

are likely to have a greater effect upon the environment than will the supplementation of feeds with selenium.

If the Food and Drug Administration continues to believe that the Environmental Impact Statement is necessary, we urge the expedited approval of the final statement so that the regulation permitting the use of selenium in animal feeds may be finalized.

Cordially

H. Leroy Schilt, Director
Regulatory Compliance

kms

Comment No. 1/7

SMITH-DOUGLASS
Division of
BORDEN CHEMICAL, BORDEN INC

June 22, 1973

Hearing Clerk
Department of Health, Education & Welfare
Room 6-88
5600 Fisher's Lane
Rockville, Maryland

Reference: Draft Environmental Impact Statement on Selenium in Animal Feeds dated April 19, 1973 - Notice of Availability Published in Federal Registar April 27, 1973

Dear Sir:

As a corporation concerned both with animal and crop agriculture as well as food processing, we submit the following comments on the Environmental Impact Statement on Selenium in Animal Feeds. We also support the changes suggested by the American Feed Manufacturers Association in their letter of May 29, 1973.

We have read the Draft Environmental Impact Statement on the proposed addition of selenium to animal feeds. This statement represents a large amount of work and there is no doubt that the quantity of selenium added to the soils by the addition of selenium to feeds of poultry and swine will have little or no measurable affects on the selenium concentration in the soil and water. The quantities you have indicated are understood to be maximum since there will be some retention of selenium by deficient animals up to the levels provided by the selenium in feedstuffs,if these feedstuffs provide the selenium required by the animal. In addition the availability of the selenium excreted by the animals could take the form of iron salts or complexes in acid soils (Muth, Symposium Selenium in Biomedicine, AVI, 1967, page 274) and these have low solubility and low availability to animals.

Small amounts of selenium will be beneficial over the long range by replenishing the soil as normal leaching will no doubt continue to deplete our soil supplies.

We fully support the Environmental Impact Statement with the changes suggested by the American Feed Manufacturers Association and hope a final draft can be expedited along with the food additive regulation.

Very truly yours,

William J. Monson

William J. Monson, Ph.D.
Technical Director

Comment No. 18

Southern States Cooperative, INC.

GENERAL OFFICES—SEVENTH AND MAIN STREETS
POST OFFICE BOX 1656 — RICHMOND, VIRGINIA 23213

TELEPHONE 703-644-6061

June 19, 1973

Hearing Clerk
Department of Health, Education and Welfare
Room 6-88
5600 Fisher's Lane
Rockville, Maryland 20852

Dear Sir:

RE: Draft Environmental Impact Statement on
Selenium in Animal Feeds dated April 19, 1973

As a member of the American Feed Manufacturers Association, who is the petitioner for approval of selenium supplementation of animal feeds, we wish to express our support for the expediting of the preparation and publishing of the final Environmental Impact Statement on Selenium in Animal Feeds in order that effective Food Additive Regulations can be published. This hope was expressed on this subject in the AFMA letter to you on this subject dated May 29, 1973.

We are continually hearing of reports originating from veterinarians and pathologists indicating the acute need for selenium supplementation of chicken, turkey and swine feeds, however, this general need is well documented in Section II, Background and Description of the Draft Environmental Impact Statement.

Again in reference to the AFMA letter of May 29, 1973, we express our support of their comments, rewording, additions and revisions suggested for consideration in drafting of the final Environmental Impact Statement on Selenium in Animal Feeds. Continued delay in the feed use of selenium results in losses of animals and decreased production that adds to the cost of food to the American consumer.

Sincerely,

Wm. McAllister

Wm. McAllister, Manager
Quality Control
FEED DIVISION

WMcA:lww

Comment No. 19

BEACON FEEDS
THE BEACON MILLING COMPANY, INC.
Cayuga, New York 13034 315-253-7331

June 21, 1973

Hearing Clerk
Department of Health, Education and Welfare
Food and Drug Administration
Room 6-88
5600 Fisher's Lane
Rockville, Maryland 20852

Reference: Draft Environmental Impact Statement on Selenium in Animal Feeds dated April 19, 1973 - Notice of Availability Published in Federal Register April 27, 1973

Dear Sir:

The following comments are filed in quintuplicate in regard to Draft Environmental Impact Statement on Selenium in Animal Feeds dated April 19, 1973 with Notice of Availability Published in Federal Register April 27, 1973.

The Beacon Milling Co., Inc. as a regional manufacturer of animal feeds in Northeastern United States endorsed the comments of Mr. Lee H. Boyd, Director of Feed Control and Nutrition, AFMA, in his letter dated May 29, 1973. It should be emphasized that the Environmental Impact Analysis Report filed by AFMA dated July 26, 1972 indicated that the proposed supplementation of chicken, turkey and swine feeds would have only a "very minor, if any, impact on the environmental." Furthermore, it should be recognized that further unwarranted delay in proper wording of the Environmental Impact Statement for Selenium in Animal Feeds can result in reduced animal production necessary to provide proper food for the people of the United States and, as well as, exports to other people of the world.

The constructive comments made by Mr. Boyd in his letter dated May 29, 1973 are important in improving the clarity and meaning of the draft statement. In the Northeastern area of the United States, plant products are often deficient in selenium; therefore, animal wastes from properly supplemented feeds can be beneficial to the soil.

In Section II, it is definite from the research work that selenium is an essential nutrient. The purpose of the proposed selenium supplementation at the designated levels is to "prevent" deficiency rather than "salvage" losses.

In reference to Section IV, careful attention is suggested in following Mr. Boyd's recommended revision of wording for clarity. We highly endorse Mr. Boyd's suggested revised wording of Sections V, VI and IX.

THE UNIVERSITY OF ARIZONA
TUCSON, ARIZONA 85721

COLLEGE OF AGRICULTURE

DEPARTMENT OF ANIMAL SCIENCE
204 AGRICULTURAL SCIENCES BUILDING

June 20, 1973

Hearing Clerk
Department of Health, Education & Welfare
Room 6-88
5600 Fisher's Lane
Rockville, Maryland 20852

Dear Sir:

The only comment I have to make relative to this document are the many statements concerning toxicity of selenium. It would appear that these need modification. I cannot see how an essential nutrient at the required level can be highly toxic. I believe that the first sentence under "Conclusion" on page 27 is not in the proper place. This sentence should actually follow the second sentence. Even then, it should be modified. It appears that the conclusion is stressing the toxicity of selenium and not the nutrient requirement of low levels of selenium. There is no argument that selenium at high levels is toxic but then so are probably all of the trace minerals at high levels and many of the other nutrients such as vitamin D and vitamin A.

Sincerely yours,

William H. Hale

William H. Hale, Professor
Animal Science Department

WHH:de

Reference: Draft Environmental Impact Statement on Selenium in Animal Feeds dated April 19, 1973.

As regional animal feed manufacturers in the Northeastern United States where selenium deficiency can be a problem in chicken, turkey and swine feeds, we urge you to expedite any necessary procedures to get the final feed addition regulation on selenium in effect at the earliest possible date.

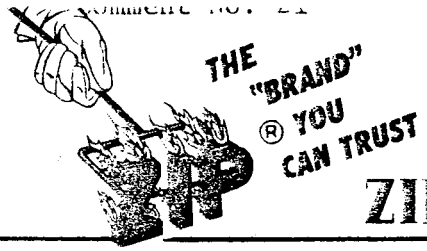
Sincerely yours

Olin A. Rowoth
Vice President, Director of
Research and Technical Services

OAR:lm

APPENDIX E

LIST OF REFERENCES



ZIP FEED MILLS, INC.

AREA CODE 605
PHONE 336-333

SIOUX FALLS • SOUTH DAKOTA 5710

June 7, 1973

Hearing Clerk
Department of Health, Education & Welfare
Room 6-88, 5600 Fishers Lane
Rockville, Maryland 20852

Reference: Draft Environmental Impact Statement on Selenium in Animal Feeds, dated April 19, 1973--Notice of Availability published in Federal Register April 27, 1973

Dear Sir:

ZIP Feed Mills, Inc., a regional feed manufacturer serving the states of North Dakota, South Dakota, Nebraska, Minnesota and Iowa, submits these comments concerning the Draft Environmental Impact Statement on the proposed addition of selenium to animal feeds.

We are hereby endorsing the comments as filed by the American Feed Manufacturers' Association as submitted by Lee H. Boyd, Director - Feed Control and Nutrition.

We urge you to publish the final statement as early as possible.

Sincerely yours,

ZIP FEED MILLS, INC.

Dean Radabaugh

Dean Radabaugh
Vice President - Nutrition

DR:dm
cc: Lee H. Boyd

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Table # 2

ANNUAL CONSUMPTION OF ADDED SELENIUM AT PROPOSED ADDED LEVELS BY SPECIES FOR THE EASTERN U. S.[1] AND PACIFIC COAST AREAS

Species	Feed Consumed Per Animal	Number of Animals In Area	Supplemental Se Level	Total Selenium Consumed
	lbs.	1000's	ppm	gm
Beef Cow Replacement	5,400	4,666	0.1	1,143,917
Beef Cows	6,120	22,009	0.1	6,115,157
Dairy Cow Replacement	5,400	3,555	0.1	871,544
Dairy Cows	8,640	9,690	0.1	3,800,961
Steers, 500 lbs. and over	5,400	8,414	0.1	2,062,776
Bulls, 500 lbs. and over	5,400	1,579	0.1	387,108
Steers, Heifers and Bulls under 500 lbs.	2,520	19,591	0.1	2,241,367
Stock Sheep	1,088	3,308	0.1	163,375
Lambs	1,316	592	0.1	35,358
Total	41,284	73,404		16,821,563

U.S. Metric Tons

1) Includes all states east of the western borders of Minnesota, Arkansas, Louisiana plus California and Oregon.

2) Based on data published in USDA Agricultural Statistics 1975.