Formal Recommendation From: The National Organic Standards Board (NOSB) To: The National Organic Program (NOP)

Date: October 24, 2024 Subject: DL-Methionine Annotation Change NOSB Chair: Kyla Smith

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: X Guidance Statement: Other:

Statement of the Recommendation:

NOSB recommends amending the annotation for DL-Methionine at 7 CFR 205.603(d)(1) as follows:

§ 205.603(d) As feed additives.

(1) DL-Methionine, DL-Methionine—hydroxy analog, and DL-Methionine—hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9)—for use only in organic poultry production. at the following pounds of synthetic 100 percent methionine per ton of feed in the diet, maximum rates as averaged per ton of feed over the life of the flock: Laying chickens—2 pounds; broiler chickens—2.5 pounds; turkeys and all other poultry—3 pounds.

Rationale Supporting Recommendation:

The rationale used to support this recommendation includes health impacts on organic poultry that the limits create, a lack of alignment between these limits and the standards of our major trading partners (Europe and Canada), and the lack of natural alternatives becoming realistic options for organic poultry farmers in the near future.

- 1. Avian health: Organic regulations at 7 CFR 205.238(a)(2) require that organic farmers provide livestock and poultry with "...a feed ration sufficient to meet nutritional requirements of the animal, including vitamins, minerals, proteins and or amino acids, fatty acids, energy sources, and fiber (ruminants)." When the regulations limit the amount of methionine a producer can add to their poultry rations it can create the situation where they are not able to provide their poultry with adequate amino acids or require them to over feed protein in order to meet minimum methionine requirements. Removing the limit on methionine will allow producers more flexibility in meeting the feed requirements in the organic regulations.
- 2. Trading partners: Europe and Canada both acknowledge that poultry need methionine beyond the amounts found in typical grain-based poultry diets. Europe allows for a certain percentage of non-organic feed ingredients to be used (e.g., corn gluten meal, which is high in methionine), and Canada allows for the inclusion of synthetic methionine and lysine when natural occurring sources are not adequate to meet poultry diets. Neither place any arbitrary limits on the inclusion rate of methionine specifically, and removing the restriction in the annotation will better align with standards of our trading partners.
- 3. Failure to accelerate natural alternatives: Much of the rationale previous boards used to justify arbitrary limits on methionine inclusion were based on the concept that restricting methionine would incentivize the development of natural alternatives. Based on public feedback, the best option currently is the use of insect meals to supplement methionine in poultry diets. However, because of organic feed requirements, insects must be certified organic in order to be fed to organic poultry, there are no certified organic insect producers currently, and there are no livestock production standards related to insects that are nearing completion. NOSB concludes

that the restrictions on methionine have not succeeded in accelerating the development and widespread adoption of natural alternative sources of methionine, and the time has come to remove the restrictions.

NOSB Vote:

Motion to amend the annotation of DL-Methionine at §205.603(d)(1) as follows:

(1) DL-Methionine, DL-Methionine—hydroxy analog, and DL-Methionine—hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9)—for use only in organic poultry production at the following pounds of synthetic 100 percent methionine per ton of feed in the diet, maximum rates as averaged per ton of feed over the life of the flock: Laying chickens—2 pounds; broiler chickens—2.5 pounds; turkeys and all other poultry—3 pounds.

Motion by: Nate Lewis Seconded by: Kim Huseman Yes: 14 No: 0 Abstain: 0 Recuse: 0 Absent: 1

Motion Passed

National Organic Standards Board Livestock Subcommittee Proposal DL-Methionine, DL-Methionine - hydroxy analog, DL-Methionine - Hydroxy analog calcium Annotation Change August 6, 2024

Summary of NOSB Activity:

Methionine is an essential sulfur-containing amino acid used in organic poultry rations. It was first allowed in organic poultry rations when its National List reference became effective on November 3, 2003. Since that time, methionine garnered scrutiny through NOSB reviews, petitions to amend annotations, and stakeholder comments. A full documentation of its NOSB and regulatory history can be found in the <u>Petitioned Substances Index</u>. Methionine is undergoing its five-year sunset review, and the Livestock Subcommittee (LS) is not recommending its removal, however, the LS is scrutinizing the current annotation and evaluating whether the impacts of this annotation on organic poultry flocks align with organic principles and the goals of encouraging natural alternatives.

Summary of Review:

At NOSB's Spring 2024 meeting in Milwaukee, WI, a majority of public commenters expressed the opinion that methionine remained necessary in organic poultry production and that natural alternatives were still not ready to replace methionine. A small minority of commenters recommended removal from the National List. The NOSB also posed the following question to stakeholders:

"Is the current restriction on methionine in organic poultry diets necessary? What would the impact be on poultry nutrition and feed formulations if methionine was allowed without any restrictions?"

LS has discussed the merits of the current listing, and the comments from the Spring meeting, and we are proposing to amend the annotation for methionine to eliminate the inclusion limits based on poultry breed.

Effects of Current Annotation:

The current annotation on DL-methionine limits inclusion rates of the substance to 2 pounds per ton (2lbs/ton) of feed for laying hens, 2.5 pounds per ton (2.5lbs/ton) of feed for broiler chickens, and 3 pounds per ton (3lbs/ton) of feed for turkeys and all other poultry. The annotation also allows for this inclusion limit to be averaged over the lifetime of the flock, so that producers can feed more than the limit when necessary at certain times of the birds' lifecycles provided they are balanced with less than the limit at other times during the lifecycle. The goal of this "averaging" is to honor the caps on inclusion rate while recognizing that poultry need different amounts of methionine based on phase of life.

Requiring organic poultry producers to limit the amount of methionine in organic rations has a number of impacts:

1. Increased reliance on soybean meal and high protein levels. Since the limits on methionine in the current annotation are still below widely accepted minimum poultry nutrition requirements, organic producers must make up for that deficiency by increasing the amount of feed ingredients known to be high in methionine, like soybean meal. Impacts of this practice can include feeding crude protein at higher than ideal levels which can, in turn, increase ammonia concentrations in poultry housing and create manure management challenges.

- 2. Higher mortality and morbidity. Since the numerical limits for methionine are less than what poultry need for adequate nutrition, organic poultry feeds are often deficient in these essential amino acids. Acute methionine deficiency expresses itself in poultry with nervousness, feather picking, cannibalism, and sudden death. These symptoms are relieved, somewhat, by allowing producers to average methionine rates over the lifetime of the flock, but this approach is not always attainable to producers who have less visibility into their feed ration formulas. In addition, even with the ability to average over the lifetime of the flock, rations for broilers and turkeys for meat are often providing less methionine than is recommended by poultry nutritionists, which can impact these animals' muscle, organ, and feather development. Any impacts to these critical bodily systems in poultry can have negative affects on health and make poultry more susceptible to disease.
- 3. Lower production. A number of commenters at our Spring 2024 meeting noted that the limit on methionine can reduce productivity of laying hens by as much as 10%. NOSB concurs with poultry nutritionists who do not consider methionine to be a growth promoter or production stimulator, so we conclude that reduced production resulting from limiting methionine is likely due to inadequate nutrition. Eliminating limits on methionine would allow for more balanced nutrition, and poultry thriving on balanced rations will likely support increased productivity.

Allowing producers to average methionine inclusion rates over the lifetime of the flock eases the health impacts of strict methionine limits somewhat for some producers. A bird's metabolic demand for methionine ebbs and flows over its lifetime, and the current annotation recognizes this reality and provides a mechanism to accommodate it. Some producers can utilize this regulatory flexibility and are "making it work" for their flocks. Other producers, however, who do not have full control over each specific poultry ration throughout the lifetime of the flock may not be able to increase methionine when it is needed due to recordkeeping burdens or simply not knowing how much methionine is included in their purchased feed. One certifier commenting in the spring indicated that requiring producers to produce records to average methionine over the lifetime of the flock was burdensome to producers and inspectors.

Rationale for Removing Methionine Restrictions:

LS is proposing to amend the annotation for methionine to remove the inclusion rate limits. These limits can prevent producers from providing adequate nutrition to their flocks which has serious health impacts on organic poultry, does not align with our largest trading partners, Canada and the EU, and does not appear to have hastened the development of natural alternatives.

Health Impacts

The organic regulations require that organic producers provide livestock and poultry with "...a feed ration sufficient to meet nutritional requirements of the animal, including vitamins, minerals, proteins and or amino acids, fatty acids, energy sources, and fiber (ruminants)." [7 CFR 205.238(a)(2)].

It is clear to the LS based on public comments that the limits to methionine in the current annotation, even if allowed to be averaged over the lifetime of the flock, needlessly hamper organic producers' ability to meet this requirement of the organic regulation. Since most of the avian health impacts of a methionine deficient diet can be prevented with an adequate ration and a widespread acceptance that organic regulations should convey a baseline animal welfare guarantee, LS is prioritizing bird health in our recommendation to remove the inclusion rate limits on methionine.

International Regulation Harmonization

LS recognizes that Canada's organic regulations allow synthetic forms of both methionine and lysine for monogastric livestock (poultry, swine) when natural forms of amino acids derived through fermentation or organic sources (like fishmeal, insect meal, or brewer's yeast) do not meet amino acid requirements to produce a balanced feed.

We also acknowledge that while the European organic regulations specifically prohibit synthetic amino acids, their feed formulation regulation allows for a certain amount of non-organic feed to be included. Many rations compliant with EU organic regulations will rely on highly processed feed ingredients (like corn gluten meal) to supply the required amount of methionine necessary for proper bird health. These ingredients are typically not available to organic producers certified to the USDA standards because they require processing aids like strong synthetic acids that are not allowed in organic processing.

Both Canada and the EU recognize that methionine is essential in poultry production and allow producers the flexibility they need to feed their flocks balanced rations that promote healthy flocks. Eliminating the limits on methionine in organic poultry production certified under USDA organic regulations would align more with our trading partners, and as natural alternatives become more available, future boards could consider an approach similar to Canada's, which applies commercial availability as an incentive to choose natural substances, but ultimately allows farmers to provide balanced feeds when necessary.

Natural Alternatives

One of the justifications for limiting the amount of methionine in organic poultry rations is the assumption that the limitation itself would hasten the pace of development and adoption of a natural alternative to synthetic methionine. Methionine was first added to the National List in 2003, and since that time it has been annotated with either an expiration date or an arbitrary inclusion limit in organic poultry rations.

Over this period, the organic industry has explored various methionine alternatives; none of which have developed into feed ingredients that are widely available to producers, adequately address methionine needs in poultry rations, are acceptable feed ingredients to consumers, and are defined by the Association of American Feed Control Officials (AAFCO).

There appears to be promise in a number of methionine alternatives including insects, fish, and fermentation products, but none are ready for widespread adoption and scaling necessary for acceptance by producers. It does not appear as though the pressure put on the industry by either an expiration date annotation or a step-down limit on methionine inclusion in feed has had much effect on the pace at which the natural alternatives are developed.

As we recognize that limits on methionine do have negative effects on poultry health, we must question whether the limits are justified and effective in achieving the goal of moving towards organic and natural methionine alternatives.

Conclusion:

The Livestock Subcommittee is proposing to remove the annotation for DL-Methionine because these limits have a negative impact on organic poultry health. We understand the preference by many stakeholders to prioritize organic and natural alternatives to synthetic amino acids, however, we are not comfortable prioritizing this preference over bird health.

We also understand that annotations, making it harder to rely on a particular substance, can push producers to innovate and adopt alternatives, but it does not appear that annotations have significantly hastened the pace of alternative development in the case of methionine. Nor does it appear that a natural alternative is going to be available imminently to replace synthetic methionine. Therefore, we propose removing the annotation for methionine, thereby removing the limitation of methionine in organic poultry rations.

Subcommittee Vote:

Motion to amend the annotation of DL-Methionine on the National List at 7 CFR 205.603(d)(1) as follows:

§ 205.603(d) As feed additives.

(1) DL-Methionine, DL-Methionine—hydroxy analog, and DL-Methionine—hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9)—for use only in organic poultry production at the following pounds of synthetic 100 percent methionine per ton of feed in the diet, maximum rates as averaged per ton of feed over the life of the flock: Laying chickens—2 pounds; broiler chickens—2.5 pounds; turkeys and all other poultry—3 pounds.

Motion by: Nate Lewis Seconded by: Kim Huseman Yes: 4 No: 0 Abstain: 0 Recuse: 0 Absent: 1