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Docket ID # AMS-NOP-18-0071-0001

Re. LS: Sunset §603

These comments to the National Organic Standards Board (NOSB) on its Spring 2019 agenda are submitted on behalf of Beyond Pesticides. Founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers, and farmworkers, Beyond Pesticides advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and the world.

Parasiticides

205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

(18) Parasiticides—Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.

(i) Fenbendazole (CAS #43210-67-9)— milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

(ii) Moxidectin (CAS #113507-06-5)— milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

The above listing, as given in the NOSB published materials, provides conflicting information about withholding periods for milk. The shorter periods were recently approved by the NOSB, along with a definition of a parasite emergency. Unfortunately, although the withholding periods have been shortened in the regulation, the definition and clarification of an emergency have not been

added. We cannot support the relisting of the parasiticides without having the definition and clarification added to the regulations.

Fenbedazole was originally listed to allow ivermectin and perhaps moxidectin to be removed from the National List. Ivermectin has now been removed, based on its toxicity to dung beetles. The impacts of ivermectin have been more extensively studied than other anthelmintics, but a recent review finds moxidectin to have much less, if any, impact on dung beetles than ivermectin.¹ Fenbedazole had little, if any, effect on dung insects in one study,² but has negative impacts on aquatic insects.³

Conclusion

Although moxidectin and fenbedazole have fewer known adverse effects than ivermectin, the definition and clarification of “emergency” approved by the NOSB must be added to the regulations. We regard the listing with shorter withholding periods in the absence of the NOSB-recommended definition to be a violation of OFPA §6517(d)(2), which prohibits USDA from adding uses of synthetics “other than those exemptions contained in the Proposed National List or Proposed Amendments to the National List.”

Atropine

205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

(3) Atropine (CAS #-51-55-8) - federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian; and

(ii) A meat withdrawal period of at least 56 days after administering to livestock intended for slaughter; and a milk discard period of at least 12 days after administering to dairy animals.

Conclusion

Beyond Pesticides supports the relisting of atropine due to its essentiality as an antidote for organophosphate poisoning and usefulness as an antispasmodic. The TR describes it as a benign treatment without a holistic or natural alternative. The withdrawal periods of 56 days and 12 days are twice the listed Food Animal Residue Avoidance Databank (FARAD) Withdrawal Interval (WDI).

¹ Jacobs, C.T. and Scholtz, C.H., 2015. A review on the effect of macrocyclic lactones on dung-dwelling insects: Toxicity of macrocyclic lactones to dung beetles. *Onderstepoort Journal of Veterinary Research*, 82(1), pp.01-08.

² Strong, L., Wall, R., Woolford, A. and Djeddour, D., 1996. The effect of faecally excreted ivermectin and fenbedazole on the insect colonisation of cattle dung following the oral administration of sustained-release boluses. *Veterinary parasitology*, 62(3-4), pp.253-266.

³ Park, K., Bang, H.W., Park, J. and Kwak, I.S., 2009. Ecotoxicological multilevel-evaluation of the effects of fenbedazole exposure to *Chironomus riparius* larvae. *Chemosphere*, 77(3), pp.359-367. Wagil, M., Białk-Bielińska, A., Puckowski, A., Wychodnik, K., Maszkowska, J., Mulkiwicz, E., Kumirska, J., Stepnowski, P. and Stolte, S., 2015. Toxicity of anthelmintic drugs (fenbedazole and flubendazole) to aquatic organisms. *Environmental Science and Pollution Research*, 22(4), pp.2566-2573.

Hydrogen peroxide

205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(13) Hydrogen peroxide

Hydrogen peroxide is relatively nontoxic in low concentrations, though it is a powerful oxidizer and may damage soil biota. Repeated exposure to vapor is harmful. It breaks down quickly to oxygen and water, and therefore does not have a residual effect.

Conclusion

Beyond Pesticides supports the relisting of hydrogen peroxide as a safer alternative to chlorine-based and other toxic sanitizers.

Magnesium sulfate

205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(16) Magnesium sulfate

Conclusion

Magnesium sulfate has a number of veterinary uses. We look forward to seeing the response of livestock producers to the LS question regarding the need for the material.

Peracetic acid

205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(19) Peroxyacetic/Peracetic acid is a solution in equilibrium of hydrogen peroxide and acetic acid.

Peracetic acid is a stronger oxidizer than chlorine dioxide and sodium hypochlorite, but weaker than ozone. It is more persistent and has higher residual activity than chlorine-based disinfectants, but its degradation products are less hazardous. Peracetic acid is an irritant of the skin, eyes, mucous membranes, and respiratory tract, but does not harm aquatic life or form carcinogenic and mutagenic compounds in breaking down like chlorine.

Conclusion

Beyond Pesticides supports the relisting of peracetic acid because of its usefulness as a replacement for chlorine compounds, wider range of usefulness, and innocuous degradation products.

Xylazine

205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(23) Xylazine (CAS #-7361-61-7)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:
(i) Use by or on the lawful written order of a licensed veterinarian;
(ii) The existence of an emergency; and

(iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

Xylazine is used in conjunction with tolazoline. Xylazine is used as a sedative, analgesic (pain killer) and muscle relaxant in veterinary medicine. Tolazoline is used to reverse the effects of xylazine.

Xylazine interacts with other tranquilizers, analgesics, and anesthetics.⁴ It impairs the effectiveness of anticonvulsants.⁵ Tolazoline has a number of interactions with other drugs.⁶ A metabolite of xylazine, 2,6-xylidine, is genotoxic and carcinogenic.⁷ “Numerous pharmacological side-effects of xylazine have been observed in treated animals, including mydriasis, impairment of thermo-regulatory control, various effects on the cardiovascular system, acid-base balance and respiration, hyperglycaemia, and haematological and gastrointestinal effects. Cattle and sheep are approximately 10 times more sensitive to xylazine than horses, dogs and cats.”⁸

According to the TAP review, “There are in fact, many alternative *practices* available for many uses of xylazine.”⁹

It appears that FDA does not permit the use of xylazine in food-producing animals, and the NOP cannot overrule FDA’s ruling.¹⁰ The transcripts¹¹ indicate that the NOSB was under the impression that xylazine could be used as an “off-label use.” FDA says, “The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) permits veterinarians to prescribe extralabel uses of certain approved new animal drugs and approved human drugs for animals under certain conditions.”¹² However, in this case, the FDA specifically said it is not to be used in food-producing animals.

FDA regulations state:

21 CFR §530.21 Prohibitions for food-producing animals.

(a) FDA may prohibit the extralabel use of an approved new animal or human drug or class of drugs in food-producing animals if FDA determines that:

(1) An acceptable analytical method needs to be established and such method has not been established or cannot be established; or

(2) The extralabel use of the drug or class of drugs presents a risk to the public health.

⁴ http://www.ccac.ca/en/_training/niaut/vivaria/analgesia/xylazine.

⁵ Właż, P., & Roliński, Z. (1996). Xylazine impairs the anticonvulsant activity of conventional antiepileptic drugs in mice. *Journal of Veterinary Medicine Series A*, 43(1-10), 495-500.

⁶ TAP, p.36.

⁷ TAP, p. 12.

⁸ TAP, p. 25.

⁹ TAP, p. 42.

¹⁰ FDA regulations at 21 CFR 522.2662(d)(2)(iii) and 21 CFR 522.2662(d)(3)(iii). OFPA §6519(c)(6)(B).

¹¹ Transcript of September 2002 meeting, pages 568-578.

¹²

(b) A prohibition may be a general ban on the extralabel use of the drug or class of drugs or may be limited to a specific species, indication, dosage form, route of administration, or combination of factors.

According to the TAP review, “The FDA has approved xylazine hydrochloride for use as a veterinary anesthetic, and tolazoline hydrochloride as a reverser of xylazine, but in both cases, use of these medications in ‘food-producing animals’ is specifically unapproved.” The FDA regulations state,

21 CFR §522.2662 (iii) *Limitations*. Do not use in domestic food-producing animals. Do not use in Cervidae less than 15 days before or during the hunting season.

The 2019 Technical Review also points to these restrictions.

An off-label use may be allowable in the absence of a specific prohibition, but since FDA does explicitly prohibit the use of xylazine in food-producing animals, it should be delisted. Since tolazoline is limited to use as an antidote to xylazine, it should also be removed from the National List.

In the past, the relisting of xylazine and tolazoline has been supported as critically-needed materials for the humane restraint and sedation of large animals for farmers and veterinarians to do commonly carried out surgical procedures. The function is mainly sedative but also has some anesthetic properties. Its use by livestock veterinarians is widespread for many procedures so that animals will not inflict injury to the humans working with them.

Conclusion

The FDA’s regulations are confusing, given the fact that in spite of what appears to be explicit language in FDA regulations prohibiting the use of xylazine in food animals, it nevertheless appears to be in common use in certain situations, with FDA’s blessing. In conversations with livestock producers and veterinarians, we have heard comments ranging from, “Its use is solely for the convenience of the human treating the animal,” to “I don’t like using it, but there have been cases –like sewing up a gash in a bull’s face– that I wouldn’t have been able to treat without it.”

AMDUCA puts a lot of responsibility on the shoulders of the veterinarian, even with the FARAD database as support. In this case, it also puts that responsibility on the shoulders of the NOSB. And it raises more general issues for the NOSB and NOP. Should off-label uses –that are not supported by regulation based on accepted scientific research– be allowed in organic production? If they are allowed, how is the public supposed to interpret that allowance as protecting organic integrity? If such uses are not allowed, does it put animals at risk? Since FDA does not force testing as entry to the marketplace, how can the NOSB and NOP ensure that animal drugs allowed under AMDUCA meet safety standards for drug use and the more stringent standards of OFPA? These questions do not necessarily need to be answered during the sunset of xylazine, but they should be acknowledged by the LS as valid concerns and put on the subcommittee’s agenda as a discussion document.

Iodine

205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

(14) Iodine

205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable

(3) Iodine

Iodine is frequently formulated as iodophors—with surfactants or complexing agents. Iodophors containing nonylphenols (NPs) and nonylphenol ethoxylates (NPEs) are strong endocrine disruptors with impacts on many species, including gender changes. Breakdown of certain NPEs may lead to toxic effects in treated livestock and applicators. Organic alternatives include ethanol or essential oils for some uses. Other natural alternatives identified by the TR include udder washes containing essential oils, vinegar, natural acids, nisin for teat dips, and natural ethanol. Other substitutes include chlorhexidine, alcohols, hydrogen peroxide, essential oils, and other chlorine materials. EPA has approved the following for use in Design for the Environment disinfectant products: citric acid, hydrogen peroxide, l-lactic acid, ethanol, and isopropanol. Some disinfectant TRs identify some alternative practices for some uses—steam sterilization and UV radiation. The iodine TR says, “The risk of mastitis incidents is significantly reduced when producers maintain a clean and dry environment for the animals. Frequently changing the animal’s bedding material and/or using inorganic bedding (i.e., sand) may also reduce environmental contamination with these bacteria. In addition, providing a healthy, balanced diet to the animal and ensuring the cleanliness of milking implements are important steps for maintaining health udders.”

Although the option for the NOSB to add annotations was unilaterally removed by the NOP, at sunset, we believe this is an example of where it is important to add an annotation to prohibit the use of nonylphenol ethoxylates (NPE) forms of iodophors in organic production; NPEs are suspected endocrine disruptors and proven aquatic toxins. NPEs were banned in Europe ten years ago (in all products) and China has banned dairy product imports with NPE residues above 10 ppb. There are many commercially available non-NPE iodine-based disinfectants and teat dips that can be used instead.

Conclusion

The iodine listings should not permit iodophors containing alkylphenols or alkylphenol ethoxylates. (APs and APEs are the general classes that include NPs and NPEs.) They should be annotated “without alkylphenols or alkylphenol ethoxylates.” I

Methionine

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.

The exemption for synthetic methionine should be phased out. The phase out requires that an expiration date be added to the listing.

History of Methionine in Organic Production

The first review of synthetic methionine by the NOSB began in 1999, as a result of a petition requesting to add it to the National List for poultry. A technical advisory panel (TAP) analysis of methionine was considered by the board in 2001, when the NOSB recommended listing it. Synthetic methionine was added to § 205.603 of the National List on October 31, 2003, to allow its use as a synthetic substance for use in organic poultry production until October 21, 2005 (68 FR 61987).

The listing continued the use through October 21, 2008 (70 FR 61217), and again through October 1, 2010 (73 FR 54057), based on NOSB recommendations in March 2005 and May 2008. The NOSB considered information about natural sources in 2005 and 2008 and expressed a strong preference for use of natural sources. However, the board believed that none of the then-available natural sources were sufficiently available and concluded that eliminating the exemption for the allowance for synthetic methionine would disrupt the well-established organic poultry market, and cause substantial economic harm to organic poultry producers. The NOSB and stakeholders supported continued research and development of organic and natural sources of methionine.

On July 31, 2009, the Methionine Task Force (MTF), which is comprised of organic poultry producers, submitted a new petition requesting to extend the allowance for synthetic methionine for five years until October 2014. In addition, the MTF proposed that the total amount of synthetic MET in the diet remain below the following levels, calculated as the average pounds of 100% synthetic MET per ton of feed over the life of the bird:

Laying chickens—4 pounds; broiler chickens— 5 pounds; and, turkey and all other poultry—6 pounds.

In response to the petition and public comments, the NOSB issued two recommendations on April 29, 2010. These recommendations stated a need for the continued allowance of synthetic methionine and the intent to decrease the amount of synthetic methionine allowed in organic poultry production, while encouraging development of natural alternatives. One recommendation proposed to allow synthetic MET in organic poultry production until October 1, 2012, at the following maximum levels per ton of feed:

Laying chickens—4 pounds; broiler chickens—5 pounds; and turkey and all other poultry—6 pounds.

The NOP codified this recommendation through a National List amendment published as an interim rule in the Federal Register on August 24, 2010 (75 FR 51919), and a final rule on March 14, 2011 (76 FR 13501).

The second NOSB recommendation from April 2010 proposed reduced maximum levels of synthetic methionine after October 1, 2015. The NOSB recommended that the annotation for synthetic MET be revised to read:

For use only in organic poultry after October 1, 2012, at the following maximum levels per ton: laying and broiler chickens—2 pounds per ton; turkeys and all other poultry—3 pounds per ton.

The NOP issued a proposed rule in the Federal Register to amend the National List to reflect the 2010 recommendation on February 6, 2012 followed by a final rule published in the Federal Register on September 19, 2012:

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 maximum levels of synthetic methionine per ton of feed: Laying and broiler chickens—2 pounds; turkeys and all other poultry—3 pounds.

The amended listing removed the expiration date of 2012 and subjected the revised listing of synthetic methionine to sunset review within five years. Synthetic methionine for the step-down for laying and broiler chickens – 2 pounds; turkeys and all other poultry – 3 pounds.

At the spring 2014 meeting in San Antonio, the NOSB was prohibited by NOP from taking up the question of whether an expiration date should be added to the methionine listing. Despite challenges from NOSB members, NOP determined that the attachment of an expiration date annotation on a new listing for methionine was a substantive change to the motion and untimely. When the issue was sent back to the subcommittee, it was with the suggestion that the issue of the expiration date could be separated from the issue of the methionine rates. In fact, it is apparent from the majority proposal and Livestock Subcommittee minutes that the subcommittee did not give any consideration to an expiration date.

The NOSB passed a recommendation at the Spring 2015 meeting that was put into regulation as:

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.

In the final rule this time around ([83 FR 66572](#), published 12/27/2018), AMS rejected the expiration date that we proposed in comments, saying,

One opposing comment recommended that the final rule add an expiration date to the annotation. AMS has considered the totality of comments received and reviewed the historical use and effectiveness of expiration dates for this substance. In previous rulemaking, AMS amended section 205.603 of the National List to allow methionine in organic poultry production with established expiration dates included in the annotation for the substance (October 31, 2003, 68 FR 61987; October 21, 2005, 70 FR 61217; August 24, 2010, 73 FR 54057; March 14, 2011, 75 FR 51919). Expiration dates were included in previous rulemaking in order to emphasize the need to develop alternatives

to synthetic methionine that are more compatible with organic production practice standards. AMS subsequently published additional rulemaking that removed the previously established expiration dates from the methionine annotation on September 19, 2012 (77 FR 57985). AMS has determined that the use of expiration dates did not result in the development of effective alternatives to synthetic methionine for use by organic poultry producers. Furthermore, establishing a phase-out in the absence of an effective alternative to methionine would result in a significant reduction in organic poultry and egg production. AMS has determined that the use of synthetic methionine is still essential for organic poultry production. Consequently, this final rule does not include a phase-out of methionine.

This justification does not take into account the step-down nature of the repeated expiration dates, which go back to the original NOSB recommendation. Nor does it acknowledge recent research on natural sources. Nor does it acknowledge the intention of the NOSB as stated in the resolution below.

At the Spring 2015 meeting, the NOSB also voted unanimously to adopt the following resolution, which was understood to keep the methionine issue on the LS work agenda:

The National Organic Standards Board is committed to the phase-out of synthetic methionine for organic poultry production, and encourages aggressive industry and independent research on natural alternative sources of methionine, breeding poultry that perform well on less methionine, and management practices for improved poultry animal welfare.

At the Fall 2015 meeting, synthetic methionine was relisted in a sunset vote. It never appeared on the LS work agenda after that. In the Spring 2016 and Spring 2017, the Organic Poultry Task Force, which would have been a venue for discussion of a systems approach to discuss methionine, was put on hold “until the OLPP final rule is published.” The OLPP final rule was published January 19, 2017, with a number of delays in implementation, and finally withdrawn March 13, 2013. The NOSB has, each Fall, beginning 2016, established as a research priority “evaluation of methionine in context of a systems approach in organic poultry production.”

The current listing is based on inadequate support for a regulatory decision that reverses a previous NOSB decision to phase out methionine and incentivize alternative approaches to managing poultry.

[The Livestock Subcommittee majority has not responded to the NOSB.](#)

At the spring 2014 meeting in San Antonio, the NOSB was prohibited by NOP from taking up the question of whether an expiration date should be added to the methionine listing. Despite challenges from NOSB members, NOP determined that the attachment of an expiration date annotation on a new listing for methionine was a substantive change to the motion and untimely. When the issue was sent back to the subcommittee, it was with the suggestion that the issue of the expiration date could be separated from the issue of the methionine rates. In

fact, it is apparent from the majority proposal and Livestock Subcommittee minutes that the subcommittee did not give any consideration to an expiration date.

The listing of synthetic methionine must be considered in the context of an organic management system.

The “need” for synthetic methionine is a result of choices regarding management of organic poultry flocks in this country –choices regarding breeds, stocking rates (both density and group size), and outdoor access. Increasingly, consumers are turning to eggs and meat produced in pastured poultry systems, which require fewer synthetic inputs. In the time since the last consideration of synthetic methionine by the NOSB, there have been advances in the use of insects –specifically black soldier fly larvae—as a source of natural methionine.¹³ However, organic poultry producers and the NOSB should not limit their consideration to one source.

Synthetic methionine is not necessary for animal welfare.

The claim has been made that the use of synthetic methionine is essential for the welfare of poultry. This claim is not supported with established measures of animal welfare and data separating the impact of synthetic methionine from that of management choices. It is not supported by the research results reported by the Methionine Task Force (MTF) in its 2009 petition.¹⁴ The European Union does not allow the use of synthetic methionine in organic poultry,¹⁵ but does require more space per bird, fewer birds per house, and more access to the outdoors.¹⁶ Significantly, the EU also requires that poultry be of slow-growing breeds or be slaughtered at an older age. The contribution of all these factors to the welfare of poultry has been documented.

¹³ For example, Al-Qazzaz, M.F.A., Ismail, D., Akit, H. and Idris, L.H., 2016. Effect of using insect larvae meal as a complete protein source on quality and productivity characteristics of laying hens. *Revista Brasileira de Zootecnia*, 45(9), pp.518-523. <https://www.morningagclips.com/black-soldier-fly-larvae-earns-fda-recommendation/>.

¹⁴ Petition for Amending the National List of the USDA’s National Organic Program: DL- Methionine, ML- Methionine Hydroxy analog, and DL-Methionine-hydroxy analog calcium-for use only in organic poultry production submitted by the Methionine Task Force. July 31, 2009. Pp. 17-18.

<http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5084508&acct=nopgeninfo>

¹⁵ “[G]rowth promoters and synthetic amino-acids shall not be used.” Council Regulation (EC) No 834/2007, consolidated. p. 20. <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02007R0834-20130701&qid=1416479300107&from=EN>; EU organic livestock summary

http://ec.europa.eu/agriculture/organic/eu-policy/eu-rules-on-production/livestock/index_en.htm.

¹⁶ EC regulation No. 889-2008, Article 12.

Studies show that reduced stocking rates (both density and group size),¹⁷ outdoor access,¹⁸ and slower-growing birds (who use the outdoors more effectively),¹⁹ but not synthetic methionine and cystine²⁰ have a positive impact on the welfare of poultry.

The 2015 recommendation says, “[T]here emerged a trend that flocks on the lower rates of MET had an increased tendency to demonstrate more stress related issues, including feather pecking and cannibalism. In discussion with stakeholders who provided input, the availability of outdoor access did not seem to have a significant impact on this trend.” No peer-reviewed research has been presented to support this opinion. From the citations above, it appears likely that any failure of outdoor access to alleviate feather-pecking and cannibalism, as observed by these unnamed observers, is due partly to the fast-growth breeds, which do not use the outdoors as well as the slow-growth breeds used in EU organic production. The American Pastured Poultry Association states, “There is a simple test to ensure that stocking densities are correct. If debeaking or beak trimming is required to keep the flock from pecking each other, then the stocking density is too high and, consequently, the animal welfare is too low. One common cause of pecking is caused by environmental stressors, such as crowding.”²¹ The relationship between lack of synthetic methionine and feather-pecking is not supported by research.

Questions the NOSB Must Ask

In its examination of the role of synthetic methionine in an organic poultry production system, the following questions must be addressed:

1. How do methionine requirements vary with species and with breeds within species?
2. How much methionine is provided by pasture under optimum conditions?
3. Can poultry pasture be improved to provide more sources of methionine (e.g., more insects)?

¹⁷ de Jong I, Berg C., Butterworth A., Estevéz I., 2012. Scientific report updating the EFSA opinions on the welfare of broilers and broiler breeders. Supporting Publications 2012:EN-295. [116pp.]. Available online: www.efsa.europa.eu/publications Beloor, J., Kang, H. K., Kim, Y. J., Subramani, V. K., Jang, I. S., Sohn, S. H., & Moon, Y. S. (2010). The effect of stocking density on stress related genes and telomeric length in broiler chickens. *Asian-Aust. J. Anim. Sci*, 23(4), 437-443. Buijs, S., Keeling, L., Rettenbacher, S., Van Poucke, E., & Tuytens, F. A. M. (2009). Stocking density effects on broiler welfare: Identifying sensitive ranges for different indicators. *Poultry Science*, 88(8), 1536-1543.

¹⁸ Mahboub, H. D. H., Müller, J., & Von Borell, E. (2004). Outdoor use, tonic immobility, heterophil/lymphocyte ratio and feather condition in free-range laying hens of different genotype. *British Poultry Science*, 45(6), 738-744. Knierim, U. (2006). Animal welfare aspects of outdoor runs for laying hens: a review. *NJAS-Wageningen Journal of Life Sciences*, 54(2), 133-145. Bestman, M. W. P., & Wagenaar, J. P. (2003). Farm level factors associated with feather pecking in organic laying hens. *Livestock Production Science*, 80(1), 133-140.

¹⁹ Sossidou, E. N., Dal Bosco, A., Elson, H. A., & Fontes, C. M. G. A. (2011). Pasture-based systems for poultry production: implications and perspectives. *World's Poultry Science Journal*, 67(01), 47-58.

²⁰ Kjær, J. B., & Sørensen, P. (2002). Feather pecking and cannibalism in free-range laying hens as affected by genotype, dietary level of methionine+ cystine, light intensity during rearing and age at first access to the range area. *Applied Animal Behaviour Science*, 76(1), 21-39.

²¹ APPPA Comments on National Organic Program: Organic Livestock and Poultry Practices, July 12, 2017. <https://apppa.org/news/5020618>.

4. Can natural sources of methionine be combined to provide methionine that is missing from pasture?
5. Are there particular conditions –e.g., seasons or temperature ranges— under which poultry pasture cannot be sufficiently improved and natural sources of methionine are inadequate to produce specific breeds/species?

These questions are pertinent to the question of whether organic systems require synthetic methionine, that is, whether it is “necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products.” If poultry producers can choose breeds, pasture systems, and natural sources of methionine that can provide for the needs of the birds, then there is no need for synthetic methionine. If an organic management system can provide for the needs of the birds without adding synthetic methionine when temperatures are suitable for the birds to be on pasture, then an annotation can limit the use to those situations when pasture is not possible. Thus, questions surrounding the use of synthetic methionine are tightly linked to other issues of animal welfare that USDA has refused to address in regulations.

Other Comments

Synthetic methionine is hormonally active.

Dr. Walter Goldstein of the Mandaamin Institute submitted to the NOSB evidence that synthetic methionine “up-regulates production of growth hormone insulin-like growth factor I (IGF-1).”²² Dr. Goldstein documents with citations from peer-reviewed studies the following facts with regard to the endocrine effects of methionine. Synthetic methionine strongly increased growth and food consumption while depressing thyroid hormone production (T3).²³ Methionine stimulates production of plasma IGF-1 and associated genes.²⁴ A study examining RNA expression of both IGF-1 and growth hormone receptor concluded that the general mechanism by which methionine stimulates growth is by stimulating synthesis and release of the growth factor.²⁵ IGF-1 also seems to regulate egg production, and synthetic methionine increases IGF-1 production.²⁶ Human athletes who consciously consume methionine-rich diets to stimulate the production of IGF-1 to build their bodies suffer long-term problems with performance, lowered longevity and greater risk of cancer.²⁷ Thus, there is an analogy to

²² Walter Goldstein, letter to National Organic Standards Board dated November 26, 2014. Pp. 5-6.

²³ Carew, L.B., J.P. McMurtry, F.A. Alster. 2003. Effects of methionine deficiencies on plasma levels of thyroid hormones, insulin like growth factors-I and II, liver and body weights, and feed intake in growing chickens. *Poultry Science* 82:1932-1938.

²⁴ Wen, C., P. Wu, Y. Chen, T. Wang, Y. Zhou. 2013. Methionine improves the performance and breast muscle growth of broilers with lower hatching weight by altering the expression of genes associated with the insulin-like growth factor-I signalling pathway. *British Journal of Nutrition*.

²⁵ Del Vesco, A.P., E. Gasparino, A.R. Oliveira Neto, S.E.F. Gulmaraes, S.M.M. Marcato, and D.M. Voltolini. 2013. Dietary methionine effects on IGF-1 and GHR mRNA expression in broilers. *Genetics and Molecular Research* 12(4):6414-6423.

²⁶ Kim, M.H., D.S. Seo, Y. Ko. 2004. Relationship between egg productivity and insulin-like growth factor-1 genotypes in Korean native Ogol chickens. *Poultry Science* 83:1203-1208.

²⁷ Stoppani, J. 2012. Insane Growth Factors.: nutrition strategies to supersize your physique. <http://www.bodybuilding.com/fun/insane-growth-factors-nutrition-to-supersize-your-physique.html> Scarth, J.P.

recombinant bovine growth hormone (rBGH, also known as bovine somatotropin (BST)), which upregulates production of IGF-1, and IGF-1 prevents death of milk producing cells in the udder, thereby increasing milk production. The evidence shows that methionine is not only an amino acid building-block for protein, but also an inducer of a powerful growth hormone.”

To put the hormone discussion into a broader context, it helps to look at research on methionine in other animals. Aside from poultry, studies have shown that methionine upregulates IGF-1 and/or reduces the lifespan in fruit flies,²⁸ pigs,²⁹ mice,³⁰ rats,³¹ and rabbits.³² Recently, growth hormone signaling has been shown to be essential to the negative effect of methionine on lifespan.³³ This research has promoted enough interest in the gerontology field

2006. Modulation of the growth hormone insulin like growth factor (GH-IGF) axis by pharmaceutical, nutraceutical and environmental xenobiotics: an emerging role for xenobiotic-metabolizing enzymes and the transcription factors regulating their expression. A review. *Xenobiotica* 36(2-3):119-218.

²⁸ Troen, A. M., French, E. E., Roberts, J. F., Selhub, J., Ordovas, J. M., Parnell, L. D., & Lai, C.-Q. (2007). Lifespan modification by glucose and methionine in *Drosophila melanogaster* fed a chemically defined diet. *Age*, 29(1), 29–39. doi:10.1007/s11357-006-9018-4. “Dietary methionine was related to lifespan by **an inverse U-shaped curve.**” [Strongly indicative of a hormonal effect.] “The reference concentration of 0.135% methionine yielded the longest lived flies. Restricting methionine intake to one third this amount (0.045%) decreased mean lifespan by 1.95%, top quartile lifespan by 2.53% and median lifespan by 4.0%, with no effect on the bottom quartile. Increasing methionine intake to three times this amount (0.405%) was more harmful, limiting maximal lifespan by 2.33% compared to the reference diet and curtailing longevity across all ages. High methionine decreased maximum lifespan by only 2.33%, however it decreased mean lifespan by 9.55% from 71.72 to 64.87 days, compared to flies fed the reference diet. Furthermore, high methionine decreased lifespan by 8.86% for flies in the top quartile, 9.33% for flies with median lifespan and by 10.29% for flies in the bottom quartile. All changes were statistically significant.”

²⁹ Stubbs AK, Wheelhouse NM, Lomax MA, Hazlerigg DG. Nutrient-hormone interaction in the ovine liver: methionine supply selectively modulates growth hormone-induced IGF-I gene expression. *J Endocrinol*. 2002;174:335–341. “These results indicate that methionine is the key limiting amino acid involved in the modulation of IGF-I expression in the ovine liver. This nutrient-hormone interaction is a highly selective phenomenon, occurring against a background of modest effects on general protein synthetic control.”

³⁰ Miller, R. A., Buehner, G., Chang, Y., Harper, J. M., Sigler, R., & Smith-Wheelock, M. (2005). Methionine-deficient diet extends mouse lifespan, slows immune and lens aging, alters glucose, T4, IGF-I and insulin levels, and increases hepatocyte MIF levels and stress resistance. *Aging cell*, 4(3), 119-125. “Mice in the Meth-R group are significantly lower in serum IGF-I, and thyroxine (T4) levels. Serum insulin is approximately 25% of controls, and fasting glucose is reduced by about 50%. Differences between groups are significant at $P < 0.01$ for all four measures.”

³¹ Orentreich N, Matias JR, DeFelice A, Zimmerman JA. Low methionine ingestion by rats extends life span. *J Nutr*. 1993;123:269–274. Caro, P., Gómez, J., López-Torres, M., Sánchez, I., Naudí, A., Jove, M., ... & Barja, G. (2008). Forty percent and eighty percent methionine restriction decrease mitochondrial ROS generation and oxidative stress in rat liver. *Biogerontology*, 9(3), 183-196. “The results show that 40% isocaloric MetR [methionine restriction] is enough to decrease ROS [reactive oxygen species] production and oxidative stress in rat liver. This suggests that the lowered intake of methionine is responsible for the decrease in oxidative stress observed in DR [dietary restriction].”

³² Zhang and Li, 2010: *Effect of dietary methionine on growth performance and insulin-like growth factor-I mRNA expression of growing meat rabbits.*

³³ Brown-Borg, H. M., Rakoczy, S. G., Wonderlich, J. A., Rojanathammanee, L., Kopchick, J. J., Armstrong, V., & Raasakka, D. (2014). Growth hormone signaling is necessary for lifespan extension by dietary methionine. *Aging cell*, 13(6), 1019-1027.

to inspire a mini-symposium devoted to the connection between methionine intake and aging.³⁴

All of this research shows that methionine acts as a growth promoter above and beyond its role as a protein building block. It shows that methionine has an inverted-U dose-response curve typical of hormonally-active chemicals. To speak of methionine “deficiency” in this context is misleading. The “deficiency” can only be measured against some norm or goal. If the goal is long life and freedom from oxidative stress, then the norm is different from that defined by a goal of maximum growth. A level that is “excessive” with respect to one norm may be “adequate” with respect to the other. Regardless of the goal, manipulating methionine in the diet through additions of synthetic methionine is, as Dr. Goldstein points out, effectively using a synthetic growth promoter and is comparable to the use of rBGH to enhance milk production.

In a letter submitted to the LS in response to Dr. Goldstein, Dr. Jacquie Jacob dismissed most of the studies cited by Dr. Goldstein because they “compared diets deficient or adequate in methionine levels.” In this case “deficient” and “adequate” are measured against a norm of growth promotion. When taken in the broader context, however, that terminology becomes misleading. Whether or not it makes sense within the context of nonorganic, chemical-intensive agriculture, it does not make sense within the organic context, which does not permit the use of synthetic growth promoters. Within the organic context, the norm must be growth achievable through natural means, using management practices consistent with organic principles.

In view of these facts, it would be wise to take into consideration the prohibition in OFPA against the use of growth promoters and hormones in livestock,³⁵ as well as the strong consumer reaction against rBGH/BST use in dairy cows.

The claim that “Overall usage of MET will likely be lowered” is not supported by research or proposed feeding schedules.

The MTF has not provided feeding schedules to show how the methionine will be used over the life of the bird in a way that averages out to the numbers in the new regulation. There is one respect, however, in which the overall usage of methionine will certainly be raised under the new rule –that is because the cap on methionine in feed for broilers will be raised from **2.0** pounds per ton to an average of **2.5** pounds per ton. Furthermore, there are a number of assumptions that must be made in calculating the overall usage under an averaging system – the total feed consumption per bird at each lifestage, for how many lifestages rations will be developed, and how much synthetic methionine will be provided in each. Since the later life stages –at least for broilers—require less methionine, but consume more food, the amount of synthetic methionine in the starter ration can be quite high –perhaps as much as 2-4 times the

³⁴ Ables, G. P., Brown-Borg, H. M., Buffenstein, R., Church, C. D., Elshorbagy, A. K., Gladyshev, V. N., ... Orentreich, N. (2014). The First International Mini-Symposium on Methionine Restriction and Lifespan. *Frontiers in Genetics*, 5, 122. doi:10.3389/fgene.2014.00122.

³⁵ §6509(c)(3).

limit of 2.5 pounds per ton. For the sake of transparency, the MTF and the LS should supply some examples showing how the rations will be balanced over the lifetime of the birds.³⁶

Reversal of the Principle of Continuous Improvement

In past decisions, the NOSB was very clear that, consistent with the principle of continuous improvement, it wants to institute a step-down process, which it did using expiration dates. The expiration dates sent an important message that the board is serious about moving away from this allowed material. Logistically, it allowed the NOSB to accomplish the step down by changing allowed rates of methionine in the absence of the ability to annotate at sunset. The move back to a sunset came after the NOSB policy change allowed annotations at sunset. The current regulation reverses a previous board decision without presenting substantive new scientific information that reviews a variety of approaches to poultry management and other feed sources that are scientifically verifiable. In doing so, it approves a petition that had been previously turned down, without substantive new information. As NOP has stated on numerous occasions to the NOSB, reversing a previous board decision requires new information that is based in science. Individual testimonials are not sufficient basis for a reversal.

An expiration date is needed.

If, as the 2015 recommendation states, the NOSB is committed to a phase-out of synthetic methionine, then it is essential that an expiration date be attached. The expiration date is the only way to incentivize alternative practices and products. Otherwise, the process under the NOP-mandated sunset process assumes continued use unless a decisive 2/3's vote of the board removes the materials from the National List. Without an expiration date under the new sunset policy, it would require a petition to effect the changes required by a step-down. Therefore, we suggest that the listing be changed to read:

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% Methionine per ton of feed in the diet, averaged over the life of the flock: Laying and broiler chickens – 2 pounds; Turkeys and all other poultry – 3 pounds. Until December 31, 2022.

Conclusion

The will of past boards cannot be effected without an expiration date. Sunset gives the NOSB the opportunity to reconsider the past decision and reinstitute a process of continuous improvement. Beyond Pesticides urges the NOSB to delist synthetic methionine or add an expiration date to force serious reconsideration.

³⁶ For example, assuming a growing (days 22-38) ration with 0.06% MET and a finishing (days 38-54) ration of 0.03% MET would allow the starter ration (days 1-21) to be as high as 0.55% (11 pounds per ton.) This assumes a feed intake as recommended by the NRC and life stage divisions for fast-growing broilers as cited in an example in Fanatico, A., 2010. Organic Poultry Production: Providing Adequate Methionine, p. 14.

Trace minerals

205.603(d) As feed additives

(2) Trace minerals, used for enrichment or fortification when FDA approved.

Conclusion

Organic production should not be dependent on synthetic nutrients. While we realize that the variability in forage and feeds may occasionally lead to a need for supplementation, the existing annotation is not restrictive enough to prevent reliance on synthetic materials. Therefore, we recommend adding the annotation, “when forage and available natural feeds are poor quality.”

Vitamins

205.603(d) As feed additives

(3) Vitamins, used for enrichment or fortification when FDA approved.

Synthetic inputs may be needed to respond to unusual conditions or fine tune the system, but in organic production, they cannot be routine. The blanket listing of all synthetic vitamins is not justified. The 1995 NOSB recommendation on vitamins saw a limited use of synthetic vitamins, to be reviewed within two years. Livestock producers were “to decrease or eliminate use of feed additives when possible.”

The table below summarizes information about natural sources of vitamins available to different species of livestock, taken from the 2015 technical review,³⁷ except that food sources of vitamin B6 were omitted in the TR –see note below table. F = forage; F/W = forage, but late winter may present shortages requiring supplementation; N = natural feed sources available; R = produced in rumen; S = produced by sunlight on exposed skin, but may be inadequate in winter.

Vitamin	Cattle	Sheep	Swine	Poultry
A	F/W	F/W	F/W	F/W
C	F/W	F/W	N	N
D	S/W, F/W	S/W, F/W	S/W, F/W	F/W
B1	R	R	N	N
B2	R	R	N	N
B3	R	R	N	N
B5	R	R	N	N
B6	R	R	N*	N*
B7	R	R	N	N
Inositol (B8)	R	R	N	N
B9	R	R	N	N

³⁷ 2015 Technical Review of Vitamins for Livestock, lines 1142-1201.

B12 Choline (B4) E K	R	R	N	N
	R	R	N	N
	F/W, N	F/W, N	N	N
	R	R	N	N

*Vitamin B6 sources: meats, rice bran, molasses, potatoes, wheat germ, pistachio nuts, cottonseed, brown rice, amaranth grain, chickpeas, sesame seeds, beans, sunflower seeds, barley malt flour, soy flour, corn, Japanese chestnuts, whey protein powder.³⁸

From the table above, we conclude that livestock feed should rarely need supplementation with synthetic vitamins, and then the only synthetic vitamins that may be needed are vitamins A, C, and D.

Conclusion

The listing for vitamins should be replaced with one for vitamins A, C, and D because the need for synthetic forms of others is not supported:

205.603(d) As feed additives

(3) Vitamins A, C, and D, used for enrichment or fortification when forage is not available and available natural feeds are of poor quality.

Thank you for your consideration of these comments.

Sincerely,



Terry Shistar, Ph.D.
Board of Directors

³⁸ USDA National Nutrient Database for Standard Reference, Release 27, listing for Vitamin B6.
<https://ods.od.nih.gov/pubs/usdandb/VitaminB6-Content.pdf>.