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

Date: October 24, 2024
Subject: Potassium phosphate(s) - petitioned
NOSB Chair: Kyla Smith

The NOSB hereby recommends to the NOP the following:
None

Statement of the Recommendation:

The NOSB does not support:

- removing the restriction that potassium phosphate can only be used in products labeled 'made with organic ingredients'
- changing "potassium phosphate" to "potassium phosphates," which would allow new types of potassium phosphate (*e.g.,* diphosphates and triphosphates) in organic food products

Rationale Supporting Recommendation:

1. FDA's designation of Generally Regarded as Safe (GRAS) applies only to dipotassium phosphate, with no other potassium phosphate salts deemed GRAS.

2. Many materials already on the National List are available for the uses mentioned in the petition.

3. The NOSB finds that the body of research finding no health impacts is not sufficiently robust and is still outweighed by vast amount of the research that finds negative health impacts of phosphorous. Thus, the health concerns raised in the 2016 NOSB Discussion Document remain relevant.

NOSB Vote:

Classification Motion:
Potassium phosphate has already been classified as synthetic.

National List Motion:
Motion to remove the annotation restricting the use of potassium phosphate to 'made with organic ingredients' and to add an "s" to phosphate at 205.605(b)
Motion by: Carolyn Dimitri
Seconded by: Jerry D'Amore
Yes: 0 No: 14 Abstain: 0 Recuse: 0 Absent: 1

Motion Failed

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Potassium Phosphate(s)
August 9 2024

Summary of Petition [link]:

Potassium phosphate is currently allowed on the National List of Allowed and Prohibited Substances (the National List) portion of the USDA organic regulations in 7 CFR 205.605(b)(28) with the following annotation: *For use only in agricultural products labeled "made with organic (specific ingredients or food group(s)),"* prohibited in agricultural products labeled "organic."

The petitioner asks: (1) to remove the restriction that potassium phosphate can only be used in products labeled 'made with organic ingredients' and (2) to change "potassium phosphate" to "potassium phosphates," which would allow new types of potassium phosphate (*e.g.,* diphosphates and triphosphates) in organic food products

The petitioner states the current views on phosphates are outdated. This petition argues that removing the restriction on use would:

1. Make it possible for potassium phosphate(s) to replace sodium phosphate in organic food, thereby lowering sodium content of processed foods. This is in response to FDA's proposed rule to permit the replacement of salt completely or partially with potassium phosphate.
2. Align organic with the Food Safety and Inspection Service (FSIS) "safe and suitable" use of potassium phosphates for meat and poultry products.
3. Not have a negative impact on human health, as newly published research suggests.

Context:

The Organic Foods Production Act of 1990 (OFPA) (7 U.S.C. chapter 94) establishes criteria [in §§6518(m)(1) – (7)] the Board must consider when evaluating a substance for inclusion on the National List. Section 6518(m)(6), specifically, requires the Board to consider the availability of alternative practices and substances. Several potential alternative substances allowed for use in organic handling are identified in Table 1, shown as Appendix 1.

Furthermore, in addition to the review criteria in §6518(m), §6517(c)(1)(A) prohibits allowing substances in organic production that are harmful to human health. One method for evaluating substances against this requirement is to check if the U.S. Food and Drug Administration (FDA) determined the substance is "generally recognized as safe" for human consumption, also referred to as GRAS (21 CFR part 182).[1] One form of potassium phosphate, dipotassium phosphate, is listed in FDA regulations as GRAS (21 CFR 182.6285); other forms of potassium phosphate may be allowed as food additives. There were no GRAS Notices found for potassium phosphate, but a GRAS Notice was found for a related substance, sodium potassium hexametaphosphate (GRN No. 316).[2] Reports were found for potassium phosphate monobasic, potassium phosphate dibasic, and potassium phosphate tribasic in the GRAS Substances Database (SCOGS).[3]

[1] Generally Recognized as Safe (GRAS). *FDA*. www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras.
[2] GRAS Notices. *FDA*. https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices.
[3] SCOGS Reports. *FDA*. https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=SCOGS.

Summary of Review and Discussion:

This substance has been examined multiple times by the NOSB, as it is already on the National List for use, albeit in a restricted fashion. A 2016 discussion document, titled "Cumulative impact of phosphates in organic food" discussed phosphates in general. A 2016 Technical Report provided current information on phosphates. The NOSB voted to leave potassium phosphate on the list, with the annotation, in 2021.

Given that the substance has already been classified and is already on the list, the NOSB's response to the petition focuses only on the request to change the annotation and to change the listing to potassium phosphates. We first examine whether there are sufficient changes in the scientific evidence since the 2016 discussion document.

New scientific research

The petitioner's addendum dated May 2024 included a peer reviewed journal article reporting research that was funded by the petitioner; furthermore, the following disclosure is included on the publication:

> We acknowledge the support and coordination of Berit Dockter; Scientific and Regulatory Affairs Manager of the International Food Additives Council on managing project details.

Fulgoni, K., Fulgoni III, V.L. and Wallace, T.C., 2022. Association of total, added, and natural phosphorus intakes with biomarkers of health Status and mortality in healthy adults in the United States. Nutrients, 14(9), p.1738.

In this paper, Fulgoni et al. attempt to separate health impacts of natural and added phosphorous using The Center for Disease Control's National Health and Nutrition Examination Survey (NHANES) data in tandem with industry supplied data on phosphorous content of foods. The authors refer to the current understanding of phosphorous: "*Elevated serum phosphate levels, otherwise known as hyperphosphatemia, have been associated with changes in health status, of note detrimental effects on cardiovascular and renal health." (quote from abstract).* Their work has two results relevant to this petition: (1) no 'meaningful' association between phosphorous and mortality was identified and (2) naturally occurring phosphorous intake was found to be negatively associated with the risk of increased blood pressure.

The Subcommittee discussion centered on the following:

1. FDA's designation of GRAS applies only to dipotassium phosphate, with no other potassium phosphate salts deemed GRAS.

2. As shown in Appendix A, many materials already on the National List are available for the uses mentioned in the petition.

3. The findings of the search of the peer reviewed literature targeted recent publications (see Appendix B for select list). The literature search revealed that the health concerns remain unchanged. The publications we identified mentioned: the likelihood that dietary exposure to phosphates is underestimated; the typical person is exposed to more than twice the recommended amount; and impacts on brain, cardiovascular, kidneys, bone health, and overall

mortality. Thus, the bulk of the evidence still points to health concerns about dietary exposure to phosphate(s) in general.

4. The paper submitted by the petitioner – funded and managed by the petitioner – appears to be the lone paper we were able to locate that finds no significant relationship between phosphorous intake and negative health outcomes (including the papers that cite this work).

5. The subcommittee finds that the body of research finding no health impacts is not sufficiently robust and is still outweighed by the vast amount of the research that finds negative health impacts of phosphorous. Thus, the health concerns raised in the 2016 NOSB Discussion Document remain relevant.

Classification Motion:
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National List Motion:
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Motion by: Carolyn Dimitri
Seconded by: Jerry D'Amore
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Appendix A: Other products on the National List that are alternatives to potassium phosphate, by use

Table 1: Potassium phosphate alternatives on the National List. Organized by potassium phosphate petitioned functions.

Potassium phosphate petitioned use	National List (7 CFR 205.605 and/or 205.606) alternative substance
As a **pH buffer**, to adjust the pH	Calcium chloride[4] Calcium citrate[5] Calcium hydroxide[6] Citric acid[5] Glucono delta-lactone[7] Lactic acid[4,5] Phosphoric acid[6] Potassium carbonate[6] Potassium chloride[6] Potassium citrate[5] Potassium hydroxide[7] Potassium lactate[7] Sodium citrate[5] Sodium hydroxide[8] Sodium lactate[7] Sodium phosphates[9] Tartaric acid[4]
In processed cheese products, both for pH buffering and also to interact with milk proteins to promote emulsification (**emulsifier**)	Agar-agar[7] Alginates[6] Calcium citrate[5] Carrageenan[7] Gellan gum[6] Glycerides[6] Lecithin[6] Magnesium stearate[6] Phosphoric acid[6] Potassium citrate[5] Sodium acid pyrophosphate[5] Sodium citrate[5] Sodium phosphates[9] Tamarind seed gum[6] Tartaric acid[7] Tragacanth gum[6] Xanthan gum[6]

[4] Chen, B.Y., A.S. Grandison, and M.J. Lewis. "Comparison of Heat Stability of Goat Milk Subjected to Ultra-High Temperature and in-Container Sterilization." *Journal of Dairy Science*. 95, no. 3 (March 1, 2012): 1057–63. https://doi.org/10.3168/jds.2011-4367.
[5] Spring 2024 Handling Sunset Review, www.ams.usda.gov/sites/default/files/media/HS2026SunsetRvwMtg1RqstPublicCmmnt2024.pdf
[6] Fall 2023 Handling Sunset Review, www.ams.usda.gov/sites/default/files/media/HS2025SunsetRvwMtg2_0.pdf
[7] Fall 2021 Handling Sunset Review, www.ams.usda.gov/sites/default/files/media/HS2023SunsetRvwFinalRec.pdf
[8] Fall 2020 Handling Sunset Review, www.ams.usda.gov/sites/default/files/media/HS2022SunsetRecs_webpost.pdf
[9] Fall 2022 Handling Sunset Review, www.ams.usda.gov/sites/default/files/media/HS2024SunsetRvwFinalReviews.pdf

Potassium phosphate petitioned use	National List (7 CFR 205.605 and/or 205.606) alternative substance
In casein-based coffee creamers, to stabilize the protein layer and thus prevent syneresis and curdling of the protein when added to hot, acidic coffee or tea (use a **gelling agent** to prevent syneresis)	Agar-agar[7] Calcium carbonate[6] Carob bean gum[6] Carrageenan[7] Gelatin[5] Guar gum[6] Gum arabic[6] Locust bean gum[6] Tamarind seed gum[6] Gellan gum[6] Pectin[9]
As a nutrient and buffer in fermentation operations (**ferment**)	Calcium carbonate[7] Magnesium sulfate[5] Microorganisms[5] Potassium citrate[5] Sodium hydroxide[7] Yeast[5]
As a **sequestrant** in meat and poultry products to decrease the amount of cooked-out juices (**chelate**)	Calcium citrate[5] Calcium phosphate (monobasic)[8] Citric acid[5,8] Glucono delta-lactone[7] Potassium citrate[5] Sodium acid pyrophosphate[5] Sodium phosphates[9] Tartaric acid[7]
As a **mineral** supplement in foods and beverages to provide **potassium** fortification	Potassium carbonate[6] Potassium chloride[6] Potassium citrate Potassium hydroxide[5,7] Potassium iodide[5] Tartaric acid (to make potassium salts)[7]
As a partial substitute for sodium chloride or in combination with sodium phosphates to reduce sodium content in food products (**sodium** or **salt**)	Calcium phosphate (monobasic and dibasic)[8] Potassium carbonate[6] Potassium chloride[6] Potassium citrate[5]

Potassium phosphate petitioned use	National List (7 CFR 205.605 and/or 205.606) alternative substance
In ice cream and frozen desserts as a protein **stabilizer** (**stabilization**) [and/or] To promote heat stability (acting as a **chaperone**) for whey proteins during thermal processing to prevent destabilization during processing and aggregation of the protein (**stability, stabilization,** or **stabilizer** in dairy)	Alginates[6] Calcium carbonate[6] Carob bean gum[6] Enzymes[5] Gellan gum[6] Glycerides[6] Guar gum[6] Gum arabic[6] Locust bean gum[6] Potassium acid tartrate[9] Potassium chloride[6] Sodium acid pyrophosphate[5] Sodium carbonate[9] Sodium citrate[5] Sodium phosphates[9] Tamarind seed gum[6] Xanthan gum[6]
To promote **stabilization** for Indirect Ultra High Temperature (UHT) pasteurized dairy products.	Calcium phosphate[8]
Aid **emulsification** in Indirect UHT pasteurized dairy products.	Lecithin[6]
Assists in **removing excess calcium** and/or **adjust the pH** in Indirect UHT pasteurized dairy products.[4,10]	Calcium citrate[5] Potassium citrate[5] Sodium citrate[5]
To promote **stabilization of proteins** and **prevent product separation** in Indirect UHT pasteurized dairy products.	Sodium phosphates[9]

Appendix B: Select readings identified in literature search

Bird, R.P. and Eskin, N.M., 2021. The emerging role of phosphorus in human health. In *Advances in food and Nutrition Research* (Vol. 96, pp. 27-88). Academic Press.

- The intake of phosphorus by the general population world-wide is almost double the amount required to maintain health. This increase is attributed to the incorporation of phosphate containing food additives in processed foods purchased by consumers. The role of phosphorus and its polymers in the renal and cardiovascular system as well as on brain health appear to be important and promising future research directions.

[10] *UHT milk is heated to high temperatures to destroy pathogens, which allows this milk to be shelf-stable without refrigeration. However, there can be some unwanted effects in UHT milk that results from this heat. One type of unwanted effect is sediment formation from calcium ions. Stabilizing salts, like potassium phosphate, are added to remove calcium ions from UHT milk.*

Brown, R.B., Bigelow, P., Dubin, J.A. and Mielke, J.G., 2023. High dietary phosphorus is associated with increased breast cancer risk in a US Cohort of middle-aged women. *Nutrients*, *15*(17), p.3735.

Calvo, M.S. and Uribarri, J., 2017. Phosphorus in the modern food supply: underestimation of exposure. *Clinical aspects of natural and added phosphorus in foods*, pp.47-76.

- Problematic for chronic kidney disease

Chazelas, E., Deschasaux, M., Srour, B., Kesse-Guyot, E., Julia, C., Alles, B., Druesne-Pecollo, N., Galan, P., Hercberg, S., Latino-Martel, P. and Esseddik, Y., 2020. Food additives: distribution and co-occurrence in 126,000 food products of the French market. *Scientific reports*, *10*(1), p.3980.

- Describes phosphates as having suspected health effects

Deng, C.Y., Ke, X.P. and Guo, X.G., 2024. Dietary calcium, phosphorus, and potassium intake associated with erectile dysfunction in the National Health and Nutrition Examination Survey (NHANES) 2001 to 2004. *Plos one*, *19*(2), p.e0297129.

Ma, J., Li, P., Jiang, Y., Yang, X., Luo, Y., Tao, L., Guo, X. and Gao, B., 2024. The Association between Dietary Nutrient Intake and Acceleration of Aging: Evidence from NHANES. *Nutrients*, *16*(11), p.1635.

Rubio-Aliaga, I. and Krapf, R., 2022. Phosphate intake, hyperphosphatemia, and kidney function. *Pflügers Archiv-European Journal of Physiology*, *474*(8), pp.935-947.

- High dietary phosphate intake and hyperphosphatemia are progression factors for declining kidney function and are associated with higher cardiovascular disease and mortality risk. This is best established for pre-existing chronic kidney disease, but epidemiological and experimental data strongly suggest that this holds true for subjects with normal renal function as well.
- An important proportion of the population is consuming regularly twice the amount of phosphate recommended. Studies indicate that this high phosphate consumption may lead to higher incidence of kidney disease and associated risks such as cardiovascular disease and bone disorders and a higher mortality rate.