National Organic Standards Board
Handling Subcommittee
Cumulative impact of phosphates in organic processed foods
Discussion Document
August 16, 2016

I INTRODUCTION

Recent research indicates that phosphate intake has increased dramatically in the general population due to widespread use of phosphate food additives in processed foods in the United States. Consumers may be unaware of phosphorous levels when reading labels on products because phosphorous may not be disclosed on the nutrition panel. Phosphorous is an essential nutrient and deficiency is extremely rare. However, high levels of phosphates can result in a range of human health problems.

Outside the US and Canada, the only phosphate additive allowed in organic processed food is monocalcium phosphate, and only as a leavening agent.

During Sunset Review in 2015 the Handling subcommittee received public comment which included new research indicating potential serious human health impacts from the cumulative effects of phosphates which are added to processed foods. The NOSB evaluated the substances according to the criteria in OFPA, especially with regards Criteria 4, 6, and 7, and with reference to CFR 205.600(b) especially with regard 3 and 4. There was inadequate data to implicate any single phosphate, or any individual food item, as an isolated risk factor and thus the NOSB did not recommend that any of the phosphates be removed from the National List at Sunset. However the cumulative impact of these ingredients or processing aids remains an issue which merits further Discussion.

This Discussion Document outlines the issues and seeks public comment to determine the range of use of phosphates in organic processed foods, the extent to which they are really necessary, and to seek additional new medical and nutrition research on the human health impacts of these additives and their cumulative impact.

If public comment and associated research finding indicate need for further action, the NOSB may recommend increased restrictions through annotations or removal of phosphate food additives.

II BACKGROUND

In 2015, during its Review of Sunset 2017 materials, the NOSB received public comment, based on recent scientific research, raising concerns about the cumulative negative impact of phosphate food additives.

In July 2015, because several of the phosphates on the National List had not been fully reviewed in formal Technical Reports (TR), the NOSB requested a comprehensive TR to cover all the Phosphates, with particular emphasis on cumulative health impacts. The NOSB received this Technical Evaluation Report (TR) in February 2016. This TR did not include Tetrasodium pyrophosphate because a 2002 TR was already available and the material had been voted to be removed from the national list in April 2015.

The February 2016 TR presented a range of issues of concern which are further discussed below. However, at its October 2015 meeting in Stowe Vermont, while acknowledging the cumulative negative health impacts of phosphates, the NOSB voted to continue to list the phosphate materials as there was insufficient research to indicate that the tiny amounts of any one phosphate additive alone, as an isolated risk factor,

was sufficient to suggest removal from the List. The NOSB members and public comment indicated need for further discussion of this issue.

III RELEVANT AREAS OF THE RULE

Phosphate salts are allowed under the National Organic Program (NOP) Regulations at:

> 7 CFR 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."
>
> The following nonagricultural substances may be used as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" only in accordance with any restrictions specified in this section.
>
> 205.605(b) Synthetics allowed:
>
> **Calcium phosphate** (monobasic, dibasic, and tribasic).
>
> **Potassium phosphate**- for use only in agricultural products labeled "made with organic (specific ingredients or food group(s)," prohibited in agricultural products labeled "organic".
>
> **Sodium acid pyrophosphate** (CAS # 7758-16-9) –for use only as a leavening agent.
>
> **Sodium phosphates** – for use only in dairy foods.
>
> **Tetrasodium pyrophosphates** – (CAS # 7722-88-5) for use only in meat analog products. (This material was recommended by the NOSB, April 2015, for Removal from the National List and is presently in rulemaking).

The Organic Foods Production Act (OFPA) requires that the NOSB evaluate each substance according to 7 criteria as specified in 7 USC Section 6518(m) of the Act. The criteria of particular relevance to this discussion are:

(4) The effect of the substance on Human Health, and
(6) The alternatives to using the substance in terms of practices or other available materials and
(7) Compatibility with a system of sustainable agriculture.

In addition, CFR Section 205.600 (b) requires that any synthetic substance used as a processing aid or adjuvant will be evaluated against 6 additional criteria, where criteria 3, 4, 5, and 6 are particularly relevant to this discussion:

(1) The substance cannot be produced from a natural source and there are no organic substitutes;
(2) The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling;
(3) The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations;
(4) The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing except where the replacement of nutrients is required by law;

(5) The substance is listed as generally recognized as safe (GRAS) by Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; and
(6) The substance is essential for the handling of organically produced agricultural products.

IV DISCUSSION

1). Technical Reports:

It is clear that the NOSB has expressed concern about the health impacts of phosphates for a number of years, and requested several Technical Reports (TR), Technical Evaluation Reports (TR), and Technical Advisory Panel Reports (TAP). These reports have consistently included concerns for human health. The following TR and TAP are incorporated by reference herewith:

Calcium phosphate: TAP 1995 and TR Phosphates Feb 10, 2016;
Potassium phosphate: TAP 1995 and Phosphates TR Feb 10, 2016;
Sodium acid pyrophosphate: Sodium phosphates TAP Sept. 21, 2001, and SAP TR Sept 17, 2010 for rejected petition for expanded use in 2010, and Phosphates TR Feb 10, 2016;
Sodium phosphates: TAP Sept 21, 2001 and TR Phosphates Feb 10, 2016;
Tetrasodium pyrophosphate: TAP July 29, 2002; Limited scope TR June 9, 2014;

Note: These substances are also bioavailable sources of the nutrients calcium, phosphorus, potassium and sodium, and all but one are allowed by FDA as nutrient supplements in foods. However, their use as nutrient sources in foods labeled as organic is the subject of a separate Technical Report for Nutrient Vitamins and Minerals in 2015.

2). Uses of phosphate additives in processed products:

Phosphates are common additives found in many processed foods to increase shelf life, thicken, aid in gelling, stabilize, texturize, pH buffer, leavening etc. In recent years, as production of processed organic foods has increased, processors who typically produce non-organic foods, simply used some of the same additives as they expanded their production into organic. The result is widespread use of phosphate additives in organic processed foods.

(a) Phosphates in Organic foods

A survey and sampling of grocery stores in the Cleveland, Ohio area found that 44% of the best-selling grocery items contained phosphorus additives. The additives were particularly common in prepared frozen foods (72%), dry food mixes (70%), packaged meat (65%), bread and baked goods (57%), soup (54%), and yogurt (51%) categories.

Some companies produce the same or essentially the same organic product both with and without added phosphates. For example : Kraft Macaroni & Cheese Dinner™ is “organic” with added phosphate, and Kraft Organic Cheddar Macaroni & Cheese Dinner™ is produced without added phosphate.

Phosphorus additive-containing foods averaged 67 mg phosphorus per 100 g more than matched non-additive containing foods. Sample meals comprised mostly of phosphorus additive-containing foods had 736 mg more phosphorus per day compared to meals consisting only of additive-free foods. Phosphorus additive-free meals cost an average of $2.00 more per day (Leon, Sullivan, and Sehgal 2013) (TR 2016 lines 678-687)

Due to the present annotations on phosphate use in organic foods, it would be expected that basing a diet on organic foods would reduce the phosphorus intake. De Lorenzo et al. (2010) compared those

who ate an "Italian Mediterranean Organic Diet" to participants who followed a similar diet with phosphate additives and found reduced serum homocysteine and phosphorus levels, reduced microalbuminuria, and reduced cardiovascular disease risk in healthy individuals and in those with Chronic Kidney Disease (CKD). The results of this European trial cannot be extrapolated to the U.S. without some reservations. The EU organic regulations allow addition of only one phosphate, monocalcium phosphate, which can only be used as a leavening agent, whereas USDA organic regulations allow sodium pyrophosphate for this purpose and several other phosphates for other uses. These differences could be important, since Karp et al. (Karp, Ekholm, Kemi, Itkonen, et al. 2012) found that the conventional cereal product with the highest total phosphate content (216 mg/100 g), all of which was digestible, was industrial muffins that contained sodium acid pyrophosphate as the leavening agent. (TR 2016, 665-676)

(b) Specific phosphates and their uses.

Calcium phosphate *(monobasic, dibasic, and tribasic).*

Calcium phosphates are used in conventional foods as leavening agents, dough strengtheners and conditioners, nutrients, malting or fermenting aids and yeast foods (all three forms); the monobasic form is used as a buffer, firming agent and sequestrant; tribasic is used as an anticaking agent or free-flow agent, buffer or pH control agent, thickener or stabilizer. The NOP regulations at 7 CFR 205.605(b) do not impose additional restrictions on the use of calcium phosphates in processed organic foods. Tricalcium phosphate is commonly used in organic non-dairy beverages (soy 'milk', almond 'milk', orange juice, etc.) to provide the nutrients calcium and phosphorus. Dicalcium phosphate is the inert diluent and carrier for Vitamin B12 in fortified organic foods. Monocalcium phosphate is used as a component of chemical leavening agents ("baking powder"). Tricalcium phosphate is commonly used in non-dairy beverages as a source of calcium since these beverages displace cows' milk from the diet. Organic orange juice that is calcium-fortified contains tricalcium phosphate. Some organic yogurts and some non-dairy yogurt-like foods also contain tricalcium phosphate. Without this calcium fortification, these non-dairy beverages would be practically devoid of calcium.

Potassium phosphate*- for use only in agricultural products labeled "made with organic (specific ingredients or food group(s)," prohibited in agricultural products labeled "organic".*

Potassium phosphate is used as a pH control agent in milk products, as a nutrient supplement, sequestrant and emulsifier, a malting or fermentation aid, and a stabilizer and thickener. Dipotassium phosphate is the only form of potassium phosphate cited by FDA for use in pasteurized process cheese (21 CFR 133.169) and pasteurized process cheese food (21 CFR 133.173).

Sodium acid pyrophosphate *(CAS # 7758-16-9) –for use only as a leavening agent.*

Sodium acid pyrophosphate is used in conventional foods as a chemical leavening agent in baked goods; a sequestrant (chelating agent) to maintain the appearance of cooked and uncooked fruits and vegetables, particularly processed potatoes; an emulsifying agent and stabilizer in cheeses and related products; an inhibitor of struvite1 formation in canned tuna; and a curing accelerator in processed meat and poultry products.

Sodium phosphates *– for use only in dairy foods.*

Sodium phosphates are used in conventional foods as pH control agents and buffers, sequestrants, texturizers and nutrients. Monobasic sodium phosphate is used as an acidulant. Some organic products containing cheddar cheese, such as cheese crackers or macaroni and cheese, may contain organic cheddar cheese with added sodium phosphate.

Tetrasodium pyrophosphates *– (CAS # 7722-88-5) for use only in meat analog products*
Tetrasodium pyrophosphate (TSPP) is used as a synthetic food additive in the manufacture of meat substitutes (analogs) serving a number of purposes that compensate for insufficient gelling requirements. The effects of TSPP are to improve texture, adjust pH, act as a pH buffer, and reduce cooking loss. This material has been recommended for Removal from the National List

3). Approved Legal Uses of the Substance:
Each of the phosphate salts listed in the NOP regulations at 7 CFR 205.605(b) is identified by FDA in 21 CFR 182 as "Generally Recognized As Safe" (GRAS) for use in food for the various purposes shown below in Table 4 of the TR 2016. The only potassium phosphate salt that is the subject of a GRAS citation as a food ingredient is dipotassium phosphate. Nevertheless, monopotassium phosphate is permitted in frozen eggs (21 CFR 160.110(b)), and all of the potassium phosphates (mono-, di- and tripotassium) are GRAS for incidental food use in adhesives in articles intended for use in packaging, transporting or holding food (21 CFR 175.105). The USDA Food Safety Inspection Service (FSIS) permits both monopotassium phosphate and dipotassium phosphate in certain meat- and poultry-containing products (9 CFR 318.7 and 9 CFR 424.21).

FDA permits addition of sodium phosphates by name as an optional ingredient in several classes of dairy foods: pasteurized process cheese (21 CFR 133.169); pasteurized process cheese food (21 CFR 133.173); pasteurized process cheese spread (21 CFR 133.179); ice cream and frozen custard (21 CFR 135.110); and frozen eggs (21 CFR 160.110). The generic optional ingredient designation "stabilizer," which frequently is sodium or potassium phosphate, is permitted in a variety of dairy foods, such as acidified milk (21 CFR 131 131.111), cultured milk (21 CFR 131.112), evaporated milk (21 CFR 131.130), heavy cream (21 CFR 131.150), light cream (21 CFR 131.155), light whipping cream (21 CFR 131.157), eggnog (21 CFR 131.170), yogurt (21 133 CFR 131.200), and cream cheese (21 CFR 133.133).

Because most dairy foods naturally contain substantial amounts of both sodium and phosphorus from the milk, the small incremental amount of sodium and phosphorus contributed by a sodium phosphate stabilizer may exempt sodium phosphate from the requirement to be declared as an ingredient on the label. This practice is allowed by FDA at 21 CFR 101.100(a)(3)(ii)(b). The only FDA-regulated foods where this exemption from labeling is not permissible are hypoallergenic foods (21 CFR 105.62) and infant foods (21 CFR 105.65).

FSIS also requires labeling of all food additives for meat products. Thus, the absence of sodium phosphate from the ingredient declaration of an FDA-regulated food does not necessarily mean that this substance has not been added to the food.
FSIS regulates meat- and poultry-containing foods and is responsible for determining the suitability of FDA-approved substances in meat and poultry products. FSIS lists allowed food ingredients at 9 CFR 318.7 and 9 CFR 424.31. Phosphates, including sodium acid phosphates, trisodium phosphate, and mono- and dipotassium phosphates, are allowed at 9 CFR 319.180 in a variety of prepared meat-containing foods, particularly cooked sausage, which includes frankfurter, frank, hotdog, weiner, vienna sausage, bologna, knockwurst and similar products.

The NOP regulations at 7 CFR 205.605(b) restrict the use of sodium phosphates to organic dairy products only, so added phosphates are not permitted in prepared organic meat products .

4). International:
The Canadian Organic Standards align with the NOP regulations with regard to phosphates and the restrictions on their use. In contrast, the CODEX Guidelines, the European Regulation, the Japanese

Agricultural Standard and the IFOAM norms only allow monocalcium phosphate and only for use as a leavening agent.

5). Nutritional Value of Food (TR 2016 lines 346-405):

An important nutritional consideration of a diet is its calcium-to-phosphorus (Ca:P) ratio. During periods of rapid skeletal growth, such as in infancy, the dietary calcium-to- phosphorus ratio should not fall below 1.0. The FDA infant formula regulation (21 CFR 107.100(e)) requires a Ca:P ratio not less than 1.0 and not more than 2.0. In later life, calcium metabolism is closely regulated by Vitamin D metabolites, particularly calcitriol. High levels of blood phosphorus suppress the formation of calcitriol (Institute of Medicine 1997). The dangers of too much dietary phosphate include excessive bone loss and other effects.

The nutrient phosphorus is not subject to mandatory listing in the Nutrition Facts of a food label (21 CFR 101.9(c)(8)(ii)), and the ingredient declaration may not declare an added phosphate if exempted by 21 CFR 101.100(a)(3)(ii)(b). Consequently, 'silent' addition of phosphates as functional additives can alter the Ca:P ratio of food, and thus the diet, without the consumer being aware of the fact.

Sodium and potassium are two electrolyte minerals essential to life. Sodium and potassium interact nutritionally. Potassium salts are more expensive than their sodium counterparts, and potassium has a greater molecular weight than sodium, so a greater weight of potassium salts must be added. For these reasons, sodium phosphates are used far more frequently than are potassium phosphates in any application where the two are functionally interchangeable. However, since our diets in general provide much less potassium than is advised and much more sodium than is advised, using the potassium salt would be nutritionally advantageous. Note that sodium chloride (table salt) is the primary source of sodium in the diet and a much greater contributor of sodium to the American diet than the sodium phosphates (Institute of Medicine 2005).

6). Effects on Human Health: (see TR 2016 lines 438-687 and citations)

Phosphorus interacts with other mineral elements, particularly calcium, magnesium and potassium, in bone formation, kidney function, and other physiological processes. Understanding this interaction is important for understanding the effects of phosphates on human health and nutrition. The Ca:P ratio of a diet is important. The relation of these two well-known minerals to the lesser studied mineral magnesium is also important. Sodium also interacts with these mineral nutrients, particularly potassium.

The National Health and Nutrition Examination Survey (NHANES) is a program of studies designed to continuously assess the health and nutritional status of adults and children in the United States. The survey is unique in that it combines interviews and physical examinations and provides a correlation of nutrient intakes with health as well as socioeconomic status. The NHANES data provides a foundation base but it is understood that total phosphorus intake may be much higher.

The NHANES data on phosphorus, sodium, calcium and magnesium, and potassium intakes for adult American (~20 to ~50 years of age), compared to the dietary reference intakes for these nutrients, indicate the following for phosphorus:

Phosphorus: The Estimated Average Requirement (EAR) for adult men and women is 580 mg per day. The Recommended Dietary Allowance (RDA) is 700 mg per day and the Tolerable Upper Intake Level (UL) is 4000 mg per day (Institute of Medicine 1997). Mean daily intakes were reported as 1701 mg for men (243% of the RDA) and 1179 mg for women (168% of the RDA). The average intake of women in the lowest quartile of phosphorus intakes was reported as 671 mg per day, 15% greater than the EAR (Lee and Cho 2015). (TER, 2016, 464-469)

An analysis of NHANES data found that, after adjusting for demographics, cardiovascular risk factors, kidney function, and energy intake, a higher phosphorus intake was associated with higher all-cause mortality in individuals who consumed more than 1400 mg/day, but at intake levels less than 1400 mg/day, there was no association (Chang et al. 2014). Analysis of the NHANES data for individuals with moderate chronic kidney disease ("CKD") found that high dietary phosphorus intakes were not associated with increased mortality in moderate CKD (Murtaugh et al. 2012). A higher phosphorus intake was associated with higher calcium intake and was positively associated with bone mineral content in female teenagers, and it was also positively associated with bone mineral content and bone mineral density, as well as reduced risk of osteoporosis, in adults over 20 years of age (Lee and 490 Cho 2015). (TER 2016, 480-490)

7). Health effects of phosphorus provided by phosphate additives versus natural phosphorus in foods.

Elevated serum phosphate is a risk factor for certain diseases and disease outcomes. In healthy individuals, higher serum phosphate levels have been associated with greater risk for end-stage renal disease and mortality (Sim et al. 2013; Dominguez et al. 2013), abnormally low blood circulation (Meng et al. 2010), abnormally high arterial stiffness (Ix et al. 2009; Kendrick et al. 2010), increased risk of cardiovascular disease (Dhingra et al. 2007) and twice the risk of developing heart failure (Dhingra et al. 2010). Higher levels of serum phosphorus have also been shown to predict coronary artery disease development and progression (Tuttle and Short 2009).

Sodium and potassium phosphates and sodium acid pyrophosphate are very soluble in water. Consequently, the phosphorus in these additives, commonly referred to as "additive phosphorus," is immediately and completely bioavailable upon consumption. In contrast, the phosphorus naturally present in most foods ("food phosphorous") is much less available, in part due to the physical structure of the food and also because digestion of phosphate complexes may be required before the phosphorus can be absorbed.

The digestibility of phosphorus in various foods has been estimated by in vitro studies (Karp, Ekholm, Kemi, Hirvonen, et al. 2012; Karp, Ekholm, Kemi, Itkonen, et al. 2012). Only 6% of the phosphorus in sesame seeds with intact hulls was found to be digestible. In legumes, where much of the phosphorus is present as phytate, the average in vitro phosphorus digestibility was 38%. In contrast, the "additive phosphorus" in cola drinks and beer was 87-100% digestible. In cereal products the highest total phosphorus content and digestibility were found in industrial muffins containing "additive phosphorus" in the form of sodium pyrophosphate as a leavening agent.

8). Summary:

- The American diet provides very large amounts of phosphorus and sodium.
- The published phosphorus content is not based on analysis, so the amount of phosphorus consumed is understated.
- Half of the adult American population consumes less than the Estimated Average Requirement, EAR of magnesium and essentially no one nowadays consumes the Adequate Intake, AI of potassium.
- A substantial proportion of Americans, almost 40%, consume less than the EAR of calcium (Fulgoni et al. 2011).
- The major mineral content of the adult American diet is severely imbalanced.
- It is difficult to fully asses the health impacts of phosphate additives in processed organic foods, in part because scientific research typically focuses on one aspect of one material at a time. This allows the specific question posed in the research to be answered, but rarely allows for an understanding of the synergistic effects or cumulative impacts over time. A comprehensive meta-analysis may provide greater insight.

- Consumers typically do not calculate the total intake of every material as they eat their standard diet, both organic and conventional, processed or unprocessed, and often take additional mineral or nutritional supplements.
- The phosphate in phosphate additives is highly bioavailable and more potent for increasing blood phosphate levels than natural phosphate from food.
- High blood phosphate levels are associated with kidney and vascular disease.
- A sufficiently high intake of calcium appears to counteract some of the ill effects of excess dietary phosphorus but leads to an increased requirement for magnesium.

V REQUEST FOR PUBLIC COMMENT

The NOSB recognizes that although no single phosphate can be implicated as an isolated risk factor, it is clear that there are health implications from cumulative impact of phosphate additives in processed organic foods.
Please provide answers to the following questions:

1. If some brands of organic processed dairy products can be produced without use of phosphates, why not all of them? What are the alternatives?
2. If European, Japanese, CODEX and IFOAM standards limit phosphates to only monocalcium phosphate – only as a leavening agent, why are all the other phosphates necessary in U.S organic food processing?
3. Should phosphate food additives in processed organic foods be phased out, and if so should just some of them be phased out or should it be allowed in only some products?

Vote in Subcommittee

Motion to accept the discussion document on phosphates as written
Motion by: Jean Richardson
Seconded by: Ashley Swaffar
Yes: 7 No: 0 Recuse: 0 Absent: 1 Abstain: 0