

**Suggested Regulatory Changes to Comply with Harvey v. Johanns
Submitted to the USDA from members of the
National Organic Standards Board
(Please Note that entire NOSB has not yet voted on this document)**

Introduction:

On January 26, 2005, the United States Court of Appeals for the First Circuit issued its decision in the case of Harvey v. Veneman, Docket No. 04-1379 (1st Cir. 2005), *amended at*, 396 F.3d 28 (1st Cir. 2005). In the decision, the Court held that existing regulations found at 7 C.F.R. Part 205 were inconsistent with the Organic Foods Production Act (OFPA). In handing down its decision, the US Court of Appeals ruled in favor of three of the nine issues Harvey raised concerning technical inconsistencies between the national organic standards implemented in October 2002, and OFPA of 1990. In its ruling the court called for the following changes to the NOP regulations.

- 1) For multi-ingredient products labeled as "Organic" OFPA bars synthetic substances. NOP regulations have allowed synthetics to be used in these organic processed foods on a limited basis after strict review for placement to the national list of approved synthetics.
- 2) NOP regulations have allowed whole dairy herds transitioning to organic production to feed up to 20 percent non-organic feed for the first nine months. However because OFPA required all organic dairy animals to receive organic feed 12 months prior to the sale of milk, or milk products, this provision no longer can be followed.
- 3) For multi-ingredient products labeled as "Organic" (at least 95% organic ingredients) agricultural products not available commercially as organic must have individual reviews and appear on the National List in order to be used in the 5 percent not required to be organic.

Potential Adverse Effect of the June 2005 Court Ruling

The June 2005 court ruling impacts three parts of the federal rules.

- First, it effectively blocks today's use in organic products of small amounts (up to 5%) of synthetic substances like baking powder (ammonium bicarbonate), low-methoxy pectin, ascorbic acid, vitamins and minerals, etc. in processed food products labeled as "organic" that may bear the USDA's organic seal.
- Second, it requires the rules relied upon by dairy farms to transition to organic management practices to be revised, making the change to organic more costly after the ruling.
- Third, it disallows the procedures implemented by the Secretary's organic certifying agents throughout the country for recognizing the commercial unavailability of organic agricultural products and ingredients.

The USDA was ordered to revise the rules by June 4, 2006. The organic industry has until June 9, 2007, to continue to sell products which meet pre-Harvey requirements. Due to crop cycles and the lead time necessary to address existing and new product formulation and labeling requirements that must precede marketing organic products to consumers, the businesses that produce and market many of America's organic farm products that today carry the USDA's organic seal may drop product lines, or re-formulate, or re-label them without the USDA seal. The loss of the USDA organic seal may devastate or confuse the organic marketplace.

Suggestion:

Under the Court's decision, many organic industry markets may be affected, including agricultural suppliers, farmers, shippers and handlers, ingredient suppliers, importers, exporters, manufacturers and processors, certifiers, retailers, and consumers. The NOSB trusts that the

NOP will take this into full consideration but would like to urge the NOP to seek to minimize the disruption to the industry as this ruling is implemented. In the short term, uncertainty in the marketplace will slow or stop new investments. Reduced visibility and reduced availability means reduced growth overall. Less growth means less opportunity for every business involved in the business of producing or selling organic agricultural products, or that provides service to those businesses. In the end, less land converted to organic agriculture means a less sustainable environment for everyone.

Members of the National Organic Standards Board propose a number of regulatory proposals designed to ensure the long-term integrity of the organic label, to create an equitable and consistent standard, and to bring the current National Organic Program regulations into compliance with the Court's ruling. Ultimately one of the most important factors to the ruling will be the need to give the organic industry the proper and fair grace period to deal with any possible changes, as ordered by the court.

I. Dairy Animal Conversion

In Harvey, the Court found that the existing regulation at 7 C.F.R. §205.236(a)(2)(i) is inconsistent with OFPA because §6509(e)(2) requires that all dairy animals and herds undergoing transition into organic production must be under a single type of organic handling for a consistent period of twelve months prior to the sale of any dairy product as "organic." 396 F.3d at 43. There are several aspects of the Harvey ruling that affirm the Secretary's discretion to implement the regulatory changes necessary to conform with the Court's opinion.

First, in its ruling the Court held that the OFPA does not define "handled organically" as the term "handled" is used in §6509(e)(2). 396 F.3d at 44. The Court further stated that the Secretary filled this gap in definition through implementation of 7 C.F.R. §205.237(a). 396 F.3d at 44. Through this reasoning, the Court has implicitly recognized the Secretary's authority and discretion to issue regulations that inform and define the term "handling" as found at §6509(e)(2). The Court also noted that as "fairly construed" 7 C.F.R. §205.237(a) requires 100% organic feed. 396 F.3d at 44. The use of this "fair construction" analysis concerning the meaning of §205.237(a) further indicates that Court was focused on analyzing the reasonable interpretation of the regulatory requirement created by the Secretary using his discretion and not on the text of §6509(e)(2) of the OFPA.

Second, the Court's interpretation of §205.237(a) further suggests that the Secretary possesses the necessary authority to make regulatory changes to the existing dairy provisions. The Court held that its construction of §205.237(a) was consistent with the intent of Senate report which stated "Livestock must be fed 100 percent organically grown feed." 396 F.3d at 43, n. 7 quoting S. Rep 101-357, 1990 U.S.C.C.A.N. 4656, 5222 (emphasis added). The brief analysis of legislative history is again used to interpret the regulation that was implemented under the Secretary's discretion and not specifically the plain meaning of §6509(e)(2). Further, the report language used by the Court refers to the animal production practices of the Senate's bill and not the final version of the OFPA. The Senate's language was replaced in conference by legislation adopted by the House of Representatives. See H. Conf. Rep. 101-916, 1990 U.S.C.C.A.N. 5699, 5702. Further, the conference report directed the Secretary to develop regulations regarding livestock standards in addition to those specified in the act. Id. In sum, if the Court has found that "handled" was not defined for purposes of §6509(e)(2) and Congress specifically directed the Secretary to adopt regulations to fill in any legislative gaps in the Act's livestock section, then it is clear that the requirements as implemented in §205.237(a) are within the discretion of the agency granted by Congress.

Additionally, it must be noted that the Senate's use of the term "grown" is not synonymous with the term "produced." The OFPA recognizes this semantic distinction by defining producer as a person "who engages in the business of growing or producing food or feed." 7 U.S.C. §6502(18) (emphasis added). This differentiation in terms is a further indication

that the Senate, reasonably construed, was most concerned that the feed for dairy animals be grown under consistent organic management practices and not necessarily the end product of a full three-year conversion.

Third, the Court indicates that its ruling was more focused upon the lack of a twelve month consistency in the existing regulations. The Court states that even if the meaning of "handled organically" remained unclear, that is regardless of use of §205.237(a) to fill in the gap, the existing dairy regulations at §205.236(a) were illegal because the regulations must contain a full, twelve month transition process. See 396 F.3d at 44.

Upon plaintiff's motion, the Court struck down the allowance of 20% non-organic feed during the first 9 months of conversion. The Court was silent on 205.236(a)(2)(i), which allows the feeding of feed that is "either organic or raised from land included in the organic system plan and managed in compliance with organic crop requirements." This provision was not ordered vacated by the Court.

In sum, the Court's ruling in Harvey concerning dairy conversion contains three major points: (1) the Secretary has discretion as to the meaning of "handled organically" for purposes of implementing §6509(e)(2); (2) any regulatory exercise of that discretion must be "fairly construed" within the context of the legislative history of the OFPA; and (3) all dairy herds or animals converting organic production under §6509(e)(2) must be managed consistent with a 12-month conversion.

Consistent with the decision, members of the NOSB request USDA to take the following actions:

(1) Amend §205.2 to include the following definition:

Organic feed. Feed that is produced and handled in accordance with this chapter including feed that has been raised from land included in an organic system plan and managed in compliance with organic crop requirements for at least two continuous years and used for the purpose of converting a dairy herd to organic production on land that is the subject of that organic system plan.

(2) Amend §205.236(a) to read:

§ 205.236 Origin of livestock.

(a) Livestock products that are to be sold, labeled, or represented as organic must be from livestock under continuous organic management from the last third of gestation or hatching: Except, That:

(2) Dairy animals. Milk or milk products must be from animals that have been fed organic feed and under continuous organic management beginning no later than 4-year twelve months prior to the production of the milk or milk products that are to be sold, labeled, or represented as organic. ~~Except, That, when an entire, distinct herd is converted to organic production, the producer may:~~

~~(i) For the first 9 months of the year, provide a minimum of 80-percent feed that is either organic or raised from land included in the organic system plan and managed in compliance with organic crop requirements; and~~

~~(ii) Provide feed in compliance with § 205.237 for the final 3 months.~~

~~(iii) Once an entire, distinct herd has been converted to organic production, all dairy animals shall be under organic management from the last third of gestation.~~

(3) Dairy Animals. Once a certified operation's dairy herd has been converted to organic production, all dairy animals on that operation, including purchased replacement animals, shall be under organic management from the last third of gestation.

~~(3)~~(4) Breeder stock. Livestock used as breeder stock may be brought from a non-organic operation onto an organic operation at any time: Provided, That, if such livestock are gestating and the offspring are to be raised as organic livestock, the breeder stock must be brought onto the facility no later than the last third of gestation.

The proposed amendment is consistent with the ruling in Harvey because it utilizes the discretion given to the Secretary to fill in the gap as to what “organically handled” means under §6509(e)(2). The amendments would clarify the definition of organic feed for all purposes including dairy herd conversion in the context of a mixed crop and livestock organic system plan. The language is also a fair construction of the Senate’s legislative intent. Under the proposed regulations, 100% of feed administered to dairy cows in transition to organic would be feed grown using organic production practices.

Additionally, the new regulatory definition of “organic feed” would ensure that dairy herd animals are converted to organic production under a standard that is consistent over a 12 month period similar to that for single replacement animals.

Finally, it would provide relief for dairy farmers from having to make a four year transition, three in converting land so pasture and crops would qualify as organic feed, then another 12 months so the animals could be fed certified organic feed for the required time. A four-year transition requirement penalizes dairy producers unfairly when a three-year transition is allowed for crop production. The proposed amendments would resolve this inequity. The proposed rule would limit the application of 7 U.S.C. §6509(e)(2) to the transition to organic production for dairy farmers, and would require that all dairy animals be raised organically from the last third of gestation after a certified producer’s dairy herd has completed the three-year transition to organic production.

If adopted these amendments would mean that a conventional dairy farm can transition to organic production over a three-year time period. For the last year, the entire herd, including young stock, must be fed feeds that are either certified organic or raised from land included in the organic system plan and managed in compliance with organic crop requirements.¹ The entire herd must otherwise be under full organic management for the final twelve months. All dairy replacement animals, both farm raised and purchased, must be under organic management from the last third of gestation once the operation is certified organic.

I. Proposed Amendments to 7 C.F.R. §205.605 Concerning Synthetic Substances

In Harvey, the First Circuit held that the existing regulations found at 7 C.F.R. §205.600(b) and §205.605(b) violated the scope of the Secretary’s authority granted under §6510(a)(1) and §6517(c)(1)(B) of the OFPA because the regulations allowed synthetic substances and ingredients to be used in the processing and post-harvest handling of products labeled as “organic” or “100% organic.” 396 F.3d at 38-40. The district court’s final judgment further elaborated that the two regulations exceeded the Secretary’s authority to the extent that they permitted the addition of synthetic ingredients and processing aids in the handling and processing of products which contain a minimum of 95% organic content and which were eligible

¹ 205.236(a)(2)(i) allows the feeding of feed that is “either organic or raised from land included in the organic system plan and managed in compliance with organic crop requirements.” This provision was not ordered vacated by the Court. In fact, the Court was silent on the allowance. The Court struck down the allowance of 20% non-organic feed during the first 9 months of conversion.

to bear the USDA organic seal. Harvey v. Johanns, Civ. No. 02-216 (D. Me. June 9, 2005), Consent Final J. Order at 3.

The Court made two additional findings that clarified the scope of its ruling. First, the Court found that the “ban on the addition of synthetic substances in handling applies only to those products labeled ‘organic’ or ‘100% organic.’ The statute does not prohibit the addition of synthetic substances to foods labeled ‘made with organic [ingredients],’ provided the other requirements of the Act are met.” 396 F.3d at 39, n.2.

Second, the Court acknowledged that the prohibition on synthetic substances in handling did not alter the limited exemption to the prohibition as provided by §6519(f), which states that the OFPA is not to be interpreted so as to alter the Secretary’s (or the Secretary of Health and Human Services and Administrator of the Environmental Protection Agency) from the authority provided under other statutes. Id. at 40, n.5. The district court’s final judgment also recognized that the prohibition on synthetic ingredients and processing aids did not apply to those authorized by §6519(f) or §6510(a)(7). Harvey v. Johanns, Civ. No. 02-216 (D. Me. June 9, 2005), Consent Final J. Order at 3.

Accordingly, the existing regulations found at 7 C.F.R. §205.600(b) and §205.605(b) need to be amended to come into compliance with the strictures of the Court’s ruling.

Members of the NOSB request the Secretary to make the following changes to existing §205.605 (additions underlined and deletions struck out):

§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 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.

(a). Nonsynthetics allowed in or on products labeled “organic” or “made with organic (specified ingredients or food group(s)).”

Nutrient vitamins and minerals, nonsynthetic forms, when fortification is required by law.

[Maintain the rest of existing 205.605(a) unchanged]

(b). Synthetics allowed for use in or on products labeled “organic” or “made with organic (specified ingredients or food group(s)).”

1. For use as sanitizers, disinfectants or cleaning agents, as needed for food safety:

Chlorine materials (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).—~~disinfecting and sanitizing food contact surfaces, Except~~. That, residual chlorine levels in the water *in direct crop or food contact* shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

Hydrogen peroxide

Ozone

Peracetic acid

Phosphoric acid—cleaning of food-contact surfaces and equipment only

2. Nutrient vitamins and minerals and required by law.

(b) (c) Synthetics allowed in or on products labeled "made with organic (specified ingredients or food groups)":

Alginates.

Ammonium bicarbonate—for use only as a leavening agent.

Ammonium carbonate—for use only as a leavening agent.

Ascorbic acid.

Calcium citrate.

Calcium hydroxide.

Calcium phosphates (monobasic, dibasic, and tribasic).

Carbon dioxide.

Cellulose—for use in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid.

~~Chlorine materials—disinfecting and sanitizing food-contact surfaces, Except, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).~~

Ethylene—allowed for post-harvest ripening of tropical fruit and degreening of citrus.

Ferrous sulfate—for iron enrichment or fortification of foods when required by regulation or recommended (independent organization).

Glycerides (mono and di)—for use only in drum drying of food.

Glycerin—produced by hydrolysis of fats and oils.

~~Hydrogen peroxide—~~

Lecithin—bleached

~~Magnesium carbonate—for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic."~~

Magnesium chloride—derived from sea water.

~~Magnesium stearate—for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic."~~

Nutrient vitamins and minerals, in accordance with 21 C.F.R. §104.20, Nutritional Quality Guidelines For Foods.

~~Ozone—~~

Pectin (low-methoxy)

~~Phosphoric acid—cleaning of food-contact surfaces and equipment only.~~

Potassium acid tartrate.

Potassium tartrate made from tartaric acid.

Potassium carbonate

Potassium citrate

Potassium hydroxide —prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches during the Individually Quick Frozen (IQF) production process.

~~Potassium iodide —for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic."~~

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

Silicon dioxide.

Sodium citrate.
Sodium hydroxide — prohibited for use in lye peeling of fruits and vegetables.
Sodium phosphates — for use only in dairy foods.
Sulfur dioxide — for use only in wine labeled “made with organic grapes,”
 Provided, That, total sulfite concentration does not exceed 100 ppm.
Tartaric acid.
Tocopherols — derived from vegetable oil when rosemary extracts are not a
 suitable alternative.
Xanthan gum

(e) (d)-(z) [Reserved]

(A). Proposed Conforming Language Changes to §205.605(a).

Currently, the title of §205.605 is inaccurate in that it describes all items that follow as “ingredients.” The NOSB has previously recommended that the term “ingredients” be struck to reflect the inclusion of processing aids as well as ingredients on this list of substances that are approved for use in handling of organic food products. See NOSB, Meeting Minutes, June 6-7, 2001, available at www.ams.usda.gov/nosb/archives/minutes/June01/mins.html. Such an amendment would be consistent with the Court’s ruling in Harvey that cited that the OFPA requirements under §6517(c) established exemptions for the broader term of nonorganic “substances,” not ingredients, on the National List. See 396 F.3d at 39 (stating “Prong (B) . . . specifically requires that substances used in handling be nonsynthetic.”)(emphasis added).

Similarly, the proposed amended §205.605(a) has been re-titled to make it clear in this section that non-synthetics are allowed in products labeled “organic” and “made with organic (specified) ingredients.”

(B). Proposed Amendment to §205.605(b) - Sanitizers, Disinfectants or Cleaning Agents.

Consistent with the ruling in Harvey, §205.605(b) should be amended to include a limited number of synthetics allowed for both “organic” and “made with organic” labeling categories. This includes a proposed list of synthetic sanitizers, disinfectants or cleaning agents as needed for food safety. The authority for inclusion of these synthetics in or on products labeled “organic” is consistent with the Court’s recognition of the Secretary’s authority pursuant to §6519(f) and §6510(a)(7). See 396 F.3d at 40, n.5.

Under section 402(a)(4) of the Federal Food Drug and Cosmetic Act (FFDCA) food will be deemed adulterated “if it has been prepared, packed, or held under unsanitary conditions.” 21 U.S.C. §342(a)(4). In order to ensure that prepared or packaged products are not deemed adulterated, handlers must act in a manner consistent with FDA regulations that establish good manufacturing practices.

In passing the OFPA, Congress was clear that organic handling practices were not exempted from meeting existing good manufacturing requirements. For example, the Senate stated:

The Committee notes that nothing in this title exempts organically produced food from other food laws. Organically produced food must, like all other food products, meet certain grading, quality, and food safety standards. S. Rep. 101-357, 1990 U.S.C.C.A.N. 4943, 4947 (emphasis added).

Consistent with this legislative intent and the Court’s recognition that §6519(f) anticipates some synthetics in handling may be required by other laws, the new proposed §205.605(b) includes sanitizers and cleaning agents that are considered essential for food safety purposes

and which have been recommended by the NOSB for inclusion on the National List. The substances on the proposed list have already been reviewed and recommended by the NOSB, pursuant to the National List process, as compatible with organic handling.

More specifically, the NOSB has reviewed and recommended inclusion of a number of substances for use in sanitation. The existing National List at §205.605(b) includes chlorine products, hydrogen peroxide, ozone, and phosphoric acid for sanitation purposes. The chlorine listing is consistent with the OFPA as stated in §6510(a)(7) that requires that all handlers use water that conforms to all requirements of the Safe Drinking Water Act. The NOSB also determined that peracetic acid should be included for this purpose. *See* NOSB, Meeting Minutes, November 15-17, 2000, at www.ams.usda.gov/nosb/archives/minutes/Nov00/mins.html. The NOSB has additionally recommended that the chlorine annotation be corrected to make it clear that chlorine products are permitted in water that is in food contact, provided the restrictions on use are met. *See* NOSB, Meeting Summary, May 13-14, 2003, available at www.ams.usda.gov/nosb/May03Summary/May03Summary.html. The current language of the chlorine annotation implies that chlorine may only be used for disinfecting food contact surfaces.

Finally, it should also be noted that in *Harvey*, the plaintiff dropped his challenge with regard to synthetics listed at §205.605(b)(9) and (22) (chlorine and phosphoric acid) “because they are not added ingredients, but materials used for cleaning food contact surfaces and equipment.” Pls.’ Br. at 36. The Court in *Harvey* recognized and stated that its ruling did not prejudice Harvey’s concessions or the general principle of 20 (sic) U.S.C. §6519(f). *See* 396 F.3d 40, n.5 (correct citation is 7 U.S.C. §6519(f)).

Members of the NOSB, consistent with previous positions adopted by the Board, request that the Secretary issue a Guidance Statement regarding the status of cleaners and disinfectants that do not appear on the National List. The clarification should direct accredited certifying agents and certified handlers that cleansers and disinfectants that do not have food contact (e.g. used to clean equipment and utensils), do not leave residues, and are used subject to rinse or other intervening event, and do not leave residues, are permitted.

(c). Proposed Amendment to §205.605(b) - Nutrients Required By Law.

Members of the NOSB request providing an additional section to list “Nutrients required by law.” The section would provide for the limited use of synthetic substances in or on “organic” products consistent with §6519(f). The proposal does not delineate the specific synthetics to be listed under the proposed section as such a list may change over time due to FDA actions. The Secretary should issue a Guidance Statement to provide processors, certifiers and consumers with the current information as to the number and identity of nutrients that are required by law (such as in the case of infant formula and reduced fat or nonfat milk products).

(d). Proposed Additional Conforming Language Changes for §205.605.

Finally, members of the NOSB request that the title of existing §205.605(b) be changed to *§ 205.605(c) Synthetics allowed in or on products labeled “made with organic (specified ingredients or food groups).”* As the Court specifically clarified, synthetics on the current §205.605(b) list may be permitted in or on products labeled as “made with organic (specified ingredients or food groups).” 396 F.3d at 39, n.2. Consistent with the ruling and proposed regulatory amendments, annotations that previously limited certain synthetics in this list previously to use in the “made with organic” category should be struck as redundant. Similarly, the cleaners and sanitizers should be moved to the proposed amended §205.605(b).

III. Synthetics Used in Processing: Technical Reviews Needed

In addition to the previous proposed regulatory changes, members of the NOSB believe that certain substances currently listed at §205.605(b) deserves review and reconsideration as to

availability of non-synthetic sources. Should petitions be submitted and non-synthetic sources for each of the listed substances be determined to exist, the substances would be added to existing §205.605(a).

The particular substances that should be subjected to review include:

Ascorbic acid (vitamin C) – sources derived from citrus and other natural plant sources may be available.

Carbon dioxide – NOSB voted in 1995 that both synthetic and non-synthetic forms are permitted, however only synthetic carbon dioxide appears on the National List. Sources may now be available of natural forms, including as a byproduct of ethanol generation. Could also be listed as allowed in organic crop production as an insecticide under 7 C.F.R. § 205.601(e).

Lecithin, bleached – The unbleached form is considered agricultural and permitted. A petition has already been filed to state that organic unbleached forms are available. A review is needed to determine if the bleached form is needed, if it is in fact synthetic, or if other forms are sufficient for organic and “made with organic” uses.

Magnesium chloride – Technical Advisory Panel reviews conducted for NOSB in 1995 and 1999 identified different processes for manufacture. The brine process (involves recovery from natural brines or seawater, then evaporation and crystallization) was considered nonsynthetic by all reviewers in 1999.

Potassium acid tartrate - is obtained as a byproduct of wine manufacture. Fermentation is considered a natural process

Nutrient vitamins and minerals (natural forms) - Certain vitamins and minerals may be available in natural form, such as potassium iodide from brine and vitamin E from plant sources.

Silicon dioxide – There may be nonsynthetic forms available for some purposes (steamed sand). There are many related forms and a review to identify the exact nomenclature would be useful to identify synthetic forms permitted in “made with organic” labeled products.

Tocopherols – Certain sources may be natural, obtained by vacuum steam distillation of edible vegetable oil products.

IV. Proposed Amendment to Evaluation Criteria for Allowed Synthetics on the National List

In Harvey, the Court agreed with the plaintiff that the existing criteria for synthetic processing aids or adjuvants found at 7 C.F.R. §205.600 could not be used to identify synthetic substances for use in products labeled “organic.” 396 F.3d at 39. However, the criteria retain their relevance and usefulness for purposes of reviewing ingredients and processing aids used in “made w/organic” products, as well as for the review of non-synthetic substances petitioned for use in or on “organic” foods.

The criteria were originally developed by the NOSB in February 1999 to aid in review of processing materials because such materials were not well addressed by the OFPA criteria found in §6518(m), and, as such should be retained. USDA has recognized the criteria as an interpretation of the general criteria for synthetic processing aids and adjuvants under the OFPA and as complimentary to existing FDA regulations related to food additives. 65 Fed. Reg. 80612/2 (Dec. 21, 2000).

Non-synthetic substances used as food ingredients or processing aids should also be evaluated under these criteria because they are non-organic substances that must be reviewed for use in “organic” and “made with organic” products and the criteria explicitly address food

processing issues. In practice, the NOSB has been using these criteria to review non-synthetic substances since the criteria were recommended in 1999.

Members of the NOSB request the following changes be made to §205.600 to reflect the existing regulation's application subsequent to the Harvey ruling:

§205.600 Evaluation criteria for allowed and prohibited substances, methods, and ingredients.

The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List:

(a) Synthetic and nonsynthetic substances considered for inclusion on or deletion from the National List of allowed and prohibited substances will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

(b) In addition to the criteria set forth in the Act, any synthetic substance used as a processing aid or ~~adjuvant ingredient~~ in foods labeled "made with organic (specified ingredients or food groups)" will be evaluated against the following criteria:

- (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.

(c) Nonsynthetics used in organic processing will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518) as well as criteria of 205.600(b).

V. Proposed Amendments Related to Commercial Availability

In Harvey, the Court did not allow the existing language of §205.606 to be read broadly so as to provide for the use of any non-organic ingredients in "organic" products simply because such ingredients were not commercially available in organic form. Specifically, the Court found that §6517 and §6518 of the OFPA require that all specific exemptions to the Act's ban on non-organic substances need to complete the National List process. 396 F.3d at 35. The Court further directed that the regulation needs to be brought into conformity with the National List process through an acceptance of USDA's concession that "the list of the five products in 205.606 is a part of the National List and that provision. . . should be interpreted as a further limitation on the addition of non-organic ingredients to the National List." Id. at 35. The district court reiterated these findings in its final order. Harvey v. Johanns, Civ. No. 02-216 (D. Me. June 9, 2005), Consent Final J. Order at 2.

Members of the NOSB request the USDA to make the following amendments to the existing regulations to ensure implementation consistent with the Court's ruling:

§205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

The following nonorganically produced agricultural products 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.

~~Any nonorganically produced agricultural product may be used in accordance with the restrictions specified in this section and when the accredited certifying agent determines that the product is not commercially available in organic form.~~

- (a) Cornstarch (native).
- (b) Gums—water extracted only (arabic, guar, locust bean, carob bean).
- (c) Kelp—for use only as a thickener and dietary supplement.
- (d) Lecithin—unbleached.
- (e) Pectin (high-methoxy).

§ 205.301 Product composition.

~~(b) Products sold, labeled, or represented as "organic." A raw or processed agricultural product sold, labeled, or represented as "organic" must contain (by weight or fluid volume, excluding water and salt) not less than 95 percent organically produced raw or processed agricultural products. Any remaining product ingredients must be organically produced, unless not commercially available in organic form pursuant to 205.606, or must be nonagricultural substances pursuant to 205.605, or nonorganically produced agricultural products produced consistent with the National List in subpart G of this part. If labeled as organically produced, such product must be labeled pursuant to § 205.303.~~

The title of §205.606 should be adjusted to indicate that this section applies only to the non-organic agricultural products used in products labeled "organic." "Made with organic" products may contain up to 30% non-organic agricultural and synthetic ingredients, provided they follow the requirements of §205.301(c), which does not require that the non-organic ingredients appear on the National List.

In addition, conformance with the Court's finding that §205.606 is an extension of the National List process will require new procedures on behalf of NOSB and NOP. For instance, a new petition notice will need to be issued, criteria for commercial availability developed, templates for appropriate technical advisory panel (TAP) reviews developed and NOSB review procedures established.

VI. Establish Options for "Made With Organic" Label Claims

As a result of the Harvey decision concerning synthetic substances in handling, certain products produced using all organic ingredients yet requiring the use of synthetic processing aids will be mandated to be labeled as "made with organic (specified ingredients)." In a few cases, the result will present awkward labels. For example, sugar processing requires the use of the synthetic calcium hydroxide as a clarification aid. This could create the redundant and confusing label "Sugar, made with organic sugar."

In the second count of Harvey, the Court recognized that the USDA has discretion to implement regulatory requirements for products that may be labeled "made with organic

(specified ingredient)” so long as such requirements are reasonably designed to ensure consistent standards. 396 F.3d at 38. In order to avoid confusing labeling such “Sugar, made with organic sugar,” flexibility should be granted to provide more understandable descriptions such as “Sugar, made from organic cane” or “sugar from organically grown cane.” The regulatory changes provided below would provide consumers with clearer and more accurate labels and maintain incentives for growers and handlers to continue organic production.

§ 205.304 Products labeled “made with organic (specified ingredients or food group(s))”

(a) Agricultural products in packages described in 205.301(c) may display on the principle display panel, information panel, and any other panel an don any labeling or market information concerning the product:

(1) the statement:

(iii) “(specified product) made from organic (source),” or “(specified product) from organically grown/ organic (source):” Provided, That, the statement does not list more than one source; and

(iv) (iii) Which appears in letters that do not exceed one-half the size on the largest type size on the panel and which appears in its entirety in the same type, size, style, and color without highlighting.

(2) The percentage of organic ingredients in the product. The size of the percentage statement must not exceed one-half the size of the largest type size on the panel on which the statement is displayed and must appear in its entirety in the same type size, style and color without highlighting. For products containing over 95% organic ingredients but ineligible for “organic” or “100% organic” label claim, the percentage claim may state “over 95%”.

Members of the NOSB also request issuance of a Guidance Statement clarifying that §205.301(c) allows the use of “made with organic” products as ingredients in other “made with organic” products, provided that only the weight or fluid volume of the organic ingredients in the “made with organic” ingredient are counted in the calculation of percentage of organic ingredients in the finished product. Such guidance is necessary to clarify that ingredients, such as sugar, that are produced using synthetic substances, are allowed to be used in products that are labeled “made with organic.” While such ingredients cannot be identified as “organic” on the ingredient panel, their organic content can be calculated in the percentage verified by the certifying agent when approving an operation’s organic system plan.

Respectfully submitted,

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