Comments of Consumers Union To
The National Organic Standards Board

Docket No. AMS-NOP-14-0006

April 8, 2014

Ms. Michelle Arsenault, Special Assistant
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave, SW.
Washington, DC 20250

Thank you for the opportunity to submit comments on proposals and discussion documents posted for the Spring 2014 meeting of the National Organic Standards Board. Consumers Union submitted extensive comments on October 1, 2013 on many of the proposals and discussion documents — please refer to those comments. In this comment, we reiterate and summarize the points that we believe to be very important to consumers, and that we wish to emphasize.

These comments were prepared by Consumers Reports' Food Safety and Sustainability Center. Consumer Reports is the world's largest independent product-testing organization. Using its more than 50 labs, auto test center, and survey research center, the nonprofit rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 8 million subscribers to its magazine, Website and other publications. Its advocacy division, Consumers Union, works for health reform, food and product safety, financial reform, and other consumer issues in Washington, D.C., the states, and in the marketplace.

Conflict of Interest

We are very concerned with the direction that the USDA appears to be moving in regarding the NOSB's conflict of interest policy. We submitted a comprehensive comment on this topic in October 2013, yet it appears that the USDAhas not considered the concerns we raised and is moving ahead with a different approach from the one we proposed.

Given its importance to the integrity of the process, we urge the Board and the NOP to read our comment on COI in its entirety. Below are some highlights from our comment:

NOSB members are <u>not</u> representatives We are especially concerned with the USDA's assertion that NOSB members are "representatives." The first line of the National Organic Program Memo on Conflict of Interest from March 2013 states: "NOSB members (you) are classified as representatives under the Federal Advisory Committee Act (FACA)."

It is unclear why the USDA considers NOSB members to be "representatives" based on FACA. *Neither OFPA nor the Federal Advisory Committee Act (FACA) refers to NOSB members as "representatives" or suggests their primary interest is in representing a particular interest group. In fact, FACA never uses the term "representative" to refer to advisory committee members. Both OFPA and FACA clearly suggest that NOSB members are* ***advisors***.

The rationale behind OFPA's creation of different NOSB member categories was not to create "representatives" but rather to bring stakeholders together, with various expertise from different sectors, into a deliberative process to assist and advise the Secretary with the implementation of OFPA.

It is unreasonable to expect Board members to speak and vote on behalf of entire groups, like "farmers" and "handlers." It is an oversimplification of the complexity that exists that we believe the Secretary must consider. Public comment often shows this complexity; and there have been plenty of votes where one group of farmers urged Board members to vote one way when other farmers urged the Board to vote another way.

If the NOP's COI policy becomes official, NOSB members will no longer be expected to vote objectively on materials petitions - determining objectively whether a material meets OFPA criteria - and therefore protect organic integrity, but will be expected to serve narrow interests regardless of whether OFPA criteria are met and organic integrity is preserved. The organic industry depends on consumer trust in the integrity of the label, and we cannot allow this USDA policy to become official.

Defining Conflict of Interest We are less concerned with *who* determines the conflict of interest than with *how* conflict of interest is defined and how recusals are determined. Who makes the decision is less important than that the declaration be made in a transparent manner and that the decision be based on clear, ethically sound standards that were openly and publicly discussed and developed.

A "conflict of interest" occurs when a primary interest is unduly influenced by a secondary interest. In order to determine what constitutes a "conflict," it is necessary to first define the primary interest - it must be clearly articulated and agreed upon.

We believe that NOSB members' primary interest is written in the Organic Foods Production Act of 1990 (OFPA): "to assist in the development of standards for substances to be used organic production and to advise the Secretary on any other aspects of the implementation of this chapter (Section 6518(a))" and OFPA's purpose includes "to assure consumers that organically produced products meet a consistent standard (Section 6501(2))."

Transparent Process We believe that a set of criteria for determining recusals due to a conflict of interest must be developed in a transparent manner, involving both the NOSB and the public. The development of clear criteria should go through the formal NOSB and NOP rulemaking process, including a public comment period for both the NOSB recommendation and the NOP proposed rule. We oppose the current process as it is unfolding, where the USDA appears to be adopting a new policy without public input or participation, and with their own interpretation of FACA.

The organic industry's continued growth and success depends on consumer trust in the integrity of the label. We would like to see a strong conflict of interest policy based on sound standards that will assure consumers of the integrity of the organic program and label.

Again, we urge the USDA and NOSB to read our full comment on Conflict of Interest in its entirety.

Ancillary Substances / Other ingredients

We are concerned with the approach that the NOSB seems to be taking regarding "other ingredients." We have submitted a separate comment on this issue on April 8, 2014. Please refer to our full comment.

In summary, the National List is for single substances, not formulated multi-ingredient products. We believe all non-organic ingredients and substances used in organic production must be on the National List.

We urge the NOSB revisit its Spring 2013 recommendation on ancillary substances. If an organic handler believes that a material on the National List cannot be sourced without a particular synthetic and unapproved "other ingredient," then that ingredient should be petitioned to be added to the National List with an annotation restricting its use to the materials for which it is needed.

Aquaculture

Consumers Union urges the Board to reject the four Livestock Subcommittee (LS) proposals for organic aquaculture materials until standards for organic aquaculture have been created.

We are also remain concerned with the previous Board recommendations regarding aquaculture, and strongly urge the Board to reconsider certain recommendations. We believe that open ocean systems should be prohibited, wild-caught fish meal and fish oil should be prohibited, 100% organic feed should be required, and carnivorous and migratory fish should not be produced in "organic" aquaculture systems.

Methionine

Consumers Union opposes the recommendation, since it does not appear to be moving producers away from synthetic methionine use; rather, it allows the maximum levels to be higher than what they currently are in certain situations.

We oppose the continued use of synthetic methionine in poultry feed. Synthetic methionine is a poster child for how Sunset is not working as designed - and that was before the National Organic Program's change to the Sunset process on Monday, September 16, 2013.

The industry has lost opportunities to replace synthetic methionine with natural alternatives because of the multiple continued extensions allowing the use of the synthetic version. There are few incentives to finding natural alternatives when a material is granted endless extensions and therefore remains on the National List.

Streptomycin

We urge the Board to reject the petition to extend streptomycin's expiration date to October 2017. We agree with the Crops Subcommittee's Minority Opinion and request that the Board vote to keep the existing October 2014 expiration date.

Consumers have come to expect that organic foods are produced without the use of antibiotics. Organic is widely marketed as "no antibiotics," which has become a consumer expectation. Other segments of the organic market, like organic meat, cheese and milk, have set and met this expectation, and so have organic fruit growers including nectarine and peach growers. Organic apple and pear trees treated with antibiotics simply do not meet consumer expectations.

In September 2013, the Centers for Disease Control and Prevention released a report that notes that 23,000 human deaths could be attributed to the development of antibiotic resistance from overuse of antibiotics, including in agricultural settings. At Consumers Union, we urge you to prioritize the continued effectiveness of streptomycin to save human lives.

Confidential Business Information

We support the proposal to remove the provision for Confidential Business Information in material petitions.

We believe that the NOSB can only make informed decisions about whether a petitioned material meets the criteria for inclusion on the National List of Approved and Prohibited Substances if all information about the material is made public.

Research Priorities

One of the Materials Subcommittee's (MS) requests for research involves "consumer demand." The MS writes that "research into the relationship of consumer buying habits and their beliefs about them would be helpful."

For more than a decade, Consumers Union has provided credible survey information about consumer sentiment, based on nationally representative consumer survey data, on important issues to the NOSB, and will continue to do so.

Surveys are developed by the National Research Center, a research arm of Consumer Reports' National Testing and Research Center in Yonkers, N.Y.. The National Research Center is comprised of highly trained social scientists and conducts more than 200 qualitative and quantitative projects annually, surveying consumers about a wide range of topics. The surveys we conduct for the NOSB on consumer sentiment use national probability samples to accurately represent the entire U.S. population.

Like the rest of Consumer Reports, the National Research Center is free of corporate influence and advertising. Surveys are never commissioned or financed by industry. Rather, these surveys are designed by survey scientists to gather unbiased, objective information from consumers.

Ammonium Hydroxide

Consumers Union urges the Board to reject the petition to add ammonium hydroxide as a boiler water additive to the National List.

Ammonium hydroxide is a toxic synthetic substance that is hazardous to human health and the environment. It does not appear to be essential to organic handling, as numerous alternatives to preventing corrosion and "acid attack" exist; these alternatives have been used by organic processors for years.

We also disagree with each of the three arguments supporting the addition of ammonium hydroxide to the National List made by the petitioner in the Petition Justification Statement. The petitioner is not being forthright when arguing that ammonium hydroxide will replace the three volatile amines currently on the National List. The allowed synthetic volatile amines are restricted to use as a "boiler water additive for package sterilization." The FDA does not allow these three volatile amines for milk pasteurization. Ammonium hydroxide is petitioned for all boiler water additive uses, including milk pasteurization which would bring ammonium hydroxide in direct contact with organic milk.

Glycerin

Consumers Union supports the petition to remove glycerin from the National List 205.605(b). When companies develop organic alternatives to the non-organic or synthetic materials on the National List, their commitment to developing organic versions should be rewarded with a removal of the material from the National List.

Gellan gum

Consumers Union is concerned with the possible use of excluded methods and "other ingredients" to manufacture the ingredient gellan gum, and urges careful review by the Board to ensure that the gellan gum currently used in organic foods is fully compliant with all

requirements in the organic law and regulations. If excluded methods are found to be used anywhere in the process, we would oppose relisting gellan gum.

PGME

Consumers Union believes that PGME needs to be petitioned, reviewed and approved before it can be allowed in organic feed production. According to the Technical Evaluation Report (TR), PGME is synthesized from butanol, propylene oxide and ethylene oxide. It is a synthetic made from toxic starting materials, and should be prohibited in organic production unless added to the National List.

We disagree with the Handling Subcommittee's suggestion that it should be removed from the agenda because "when used as a boiler additive, PGME is not required to be on the National List because it has no contact with organic products." Organic certification is systems-based, and all synthetic inputs used in the process, from field to fork, regardless of "contact with organic products" or residues in the final product, must be approved for use.

We agree with the Handling Subcommittee that PGME may not be appropriate for 205.605, but suggest that the petitioner be instructed to petition PGME for 605.603 - "Synthetic substances allowed for use in organic livestock production," since it would be used as a boiler water additive only for the production of livestock feed. It may be necessary to create a new subsection under 603, since currently no category exists for "feed processing aids."

Tragacanth gum

Consumers Union supports the sunset of tragacanth gum. Under the new sunset policy, we urge the Handling Subcommittee to draft a proposal to remove tragacanth gum from the National List.

In the original petition to add tragacanth gum to the National List, the petitioner wrote that tragacanth gum and gum arabic are nearly identical. An organic version of gum arabic is now available. We support the development of organic alternatives to materials on the National List, and the removal of tragacanth from the National would reward and further encourage the development of organic alternatives.

Sunset

Although it is not an NOSB agenda item, we wish to comment again on the September 2013 decision by the USDA to change the process for relisting materials on the National List (Sunset). No public comment period was provided for the changes to this policy, which had been in place since 2005. We object to both the process and the substance of the policy change. We remain seriously concerned about this.

Under OFPA and prior to the NOP's September 16, 2013 announcement, there was a controlled process for listing materials on the National List. Otherwise prohibited materials received exemptions for a five-year period, in order to encourage the development of natural (or organic) alternatives. The exemptions were required by law to expire, known as "sunset," unless they

were reinstated by a two-thirds "decisive" majority vote of the National Organic Standards Board (NOSB) and include a public review. This is no longer the case.

In light of this recent policy change, we urge extra caution by NOSB members during materials review. Any material approved for listing on the National List is much more likely to remain on the National List in perpetuity, since the new policy requires a two-third vote to remove, rather than a two-thirds vote to relist, and only after the Subcommittee votes to propose a removal.

We are especially concerned that the NOP's new policy charges subcommittees with the task of proposing to remove a material from the National List. If a subcommittee decides not to propose a material's removal, the full NOSB does not have the opportunity to vote during the sunset process. Had oxytetracycline been a sunset vote (rather than a petition to extend an expiration date), this means that the full Board would not have voted on its removal, since the Crops Subcommittee voted by a one-vote margin against the immediate phase-out of oxytetracycline. Any time a Subcommittee determines that the material should be relisted, there will be no proposal to remove and therefore no opportunity for the full Board to review and vote.

We believe that the USDA's decision minimizes all incentives for creating organic, natural alternative ingredients and lowers the standard for what consumers can expect behind the organic label. Allowing the USDA to automatically relist materials without the recommendation of the NOSB erodes the Board's legal authority over materials decisions, a key to consumer trust in the organic label. The fact that the agency made this decision without any public input only adds to the violation felt by watchdog groups and consumers alike.

Potentially allowing an indefinite listing of non-natural ingredients and requiring a super-majority vote to retire a substance after five years undermines the spirit of the law for how materials head into "sunset" or retirement. It is unfair to producers trying to produce a truly organic product and it is unfair to consumers trying to make meaningful purchasing decisions. Simply put, this lowers the bar for much of the organic market. We believe the USDA must reverse course and we intend to mount a fierce campaign to hold the agency accountable to the millions of Americans who expect more from the government—and the organic label.

Sincerely,

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Comments of Consumers Union To
The National Organic Standards Board
On
Handling Subcommittee / Ancillary Substances

Docket No. AMS-NOP-14-0006

April 8, 2014

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1400 Independence Ave, SW.
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Thank you for the opportunity to submit comments to the National Organic Standards Board. The Spring 2014 agenda includes an update on "ancillary substances," but no discussion document is posted. Without a discussion document to comment on, we wish to comment on the recommendation that the NOSB approved at the Spring 2013 meeting in Portland, Oregon.

This is an ongoing issue that affects many materials currently on the National List, as well as all future petitioned materials, and is of critical importance to ensuring the integrity of the organic label and meeting consumer expectations.

These comments were prepared by Consumers Reports' Food Safety and Sustainability Center. Consumer Reports is the world's largest independent product-testing organization. Using its more than 50 labs, auto test center, and survey research center, the nonprofit rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 8 million subscribers to its magazine, Website and other publications. Its advocacy division, Consumers Union, works for health reform, food and product safety, financial reform, and other consumer issues in Washington, D.C., the states, and in the marketplace.

Background

The Organic Foods Production Act of 1990 (OFPA) requires that all ingredients in certified organic foods must either be produced in accordance with the federal organic standards or must appear on the National List of Approved and Prohibited Substances.

SEC. 2111. [7 U.S.C. 6510] HANDLING.

(a) IN GENERAL.—For a handling operation to be certified under this title, each person on such handling operation shall not, with respect to any agricultural product covered by this title—
(1) add any synthetic ingredient not appearing on the National List during the processing or any postharvest handling

OFPA does not distinguish between "ingredients" and "other ingredients" or "ancillary ingredients." Quite simply: any synthetic ingredient not appearing on the National List shall not be added to organic products during processing or any post harvest handling.

OFPA also specifies that the National List "shall contain an itemization, by specific use or application, of each synthetic substance permitted" (Sec. 2118 [7 USC 6517]).

The National List is for single substances, not formulated multi-ingredient products. All non-organic ingredients and substances used in organic production must be on the National List.

This was affirmed by the USDA National Organic Program in a Notice published in the Federal Register on January 18, 2007: "only single substances may be petitioned for evaluation; formulated products cannot appear on the National List."

Yet some of the materials appearing on the National List are standardized, preserved, sweetened, stabilized or otherwise mixed with ingredients that are not organic and do not appear on the National List. While these unapproved "other ingredients" are disclosed to the organic handlers when they purchase the ingredients, they can and would end up in organic food. Because of FDA labeling laws, these "other ingredients" are disclosed to the organic handlers, but are not included on the ingredients list of the final product, and therefore are not disclosed to the consumer.

Consumers look to the organic label for assurance that the contain no artificial ingredients that have not been approved. This expectation is rooted in organic law and regulations, which clearly state that organic handlers must not add any non-organic agricultural products or synthetic ingredients not appearing on the National List to organic foods.

The materials review process by the National Organic Standards Board should ensure that *all* ingredients are reviewed for human health and environmental impacts, and are approved by a 2/3 majority vote for use in organic foods before they are added.

The issue has not been resolved

In a 2011 Memo to the NOSB, NOP made the following request:

> The NOP is requesting that the NOSB develop a policy on "other ingredients" in § 205.605 substances that is comparable to the comprehensive policy for crop and

> livestock materials. From this point forward, NOP is requesting that NOSB consider the presence of any "other ingredients" as part of its processes. As substances on the National List come up for sunset review, or as new petitions are considered, NOP requests that NOSB clarify whether any restrictions are warranted for "other ingredients" in § 205.605 substances. Any third-party technical report that NOP provides will include information on any "other ingredients" commonly found in the substance under review.
>
> NOP is requesting that NOSB specify any allowed "other ingredients" in the background section of its recommendations for substances recommended for listing on § 205.605, so that these allowances are clear to the organic trade, certifying agents, and NOP. Any "other ingredients" not listed on § 205.605 or not referenced in the background section of the recommendation, would not be allowed in formulations of substances on § 205.605 that are used in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

At the Spring 2013 meeting in Portland, Oregon, in an attempt to resolve this issue, the NOSB debated and voted on a recommendation. During the discussion, Miles McEvoy, the National Organic Program's administrator, again urged the NOSB to work within the legal requirements.

Mr. McEvoy told the Board in clear terms:

> "Any input in a processed organic product has to be either an organic agricultural ingredient or it has to be on the National List. Right."

The NOSB's final recommendation, adopted at the Spring 2013 meeting, does not ensure that every ingredient in organic foods are either produced organically or on the National List. The NOSB's recommendation states:

> The NOSB intends to review ancillary substances found in substances on and petitioned for the National List in accordance with OFPA criteria. **Comprehensive review, however, does not require these substances to be individually listed on the National List.** The Board intends to follow the request by NOP to consider ancillary ingredients contained in substances as they come up for review or as new petitions are considered. A procedure is presented to carry out this review that includes identification of ancillary substances, Technical Review support, NOSB checklist revisions, and process for annotation or guidance implementation of the policy. [Emphasis added]

Concerns

All synthetic ingredients should and must be on the National List. We are concerned that the recommendation does not take seriously the requirement in OFPA and the assertion by the NOP

that all non-organic and synthetic ingredients should be on the National List before they may be used in organic foods.

We disagree with the NOSB's Spring 2013 "Rationale Supporting Recommendation":

> The NOP requested clarification on this issue in a memorandum to the NOSB in November of 2011. OFPA and the Rule are not very specific regarding this subject and a policy and procedure is needed because the reviews of handling materials have been inconsistent with regard to ancillary substances. The recommendation adopted unanimously is consistent with OFPA by calling for review to OFPA criteria. It is consistent with what some ACAs are doing now, and makes it clearer what petitioners and NOSB member should expect for future ingredient reviews.

We do not agree with the statement "OFPA and the Rule are not very specific regarding this subject." We believe that OFPA is very clear when it states that organic handlers shall not *add any synthetic ingredient not appearing on the National List during the processing or any postharvest handling.* Handlers can see the "other ingredients" in the materials they use to process organic foods. If there are "other ingredients" that do not appear on the National List in the formulated ingredient, OFPA would not allow handlers to add these to organic foods.

No discussion of "other ingredients" in Sunset Review. We have not seen any discussion of "other ingredients" in the materials that are up for sunset review. In the NOSB Handling Subcommittee document titled "Sunset 2015 Review List - Request for Public Comment Handling Substances," there is no mention of "other ingredients." The Handling Subcommittee makes several requests for public input, but none of the requests are for information regarding "other ingredients."

At the very least, the NOSB should request information about "other ingredients" from handlers and manufacturers. For example, we have identified several "other ingredients" used in the production in gellan gum that should be brought to the attention of the NOSB during the sunset review process. Yet **no** request for such information was made by the Handling Subcommittee.

Responsibility for sharing "other ingredients" does not lie with the public and technical reviewers. In the Spring 2013 NOSB recommendation on "other ingredients," the NOSB proposes this as a first step: "NOSB identifies "ancillary substances" as disclosed in the petition and previous Technical Reports, and through the public comment process." In Step 3, the recommendation proposes that "TR identifies commonly used ancillary substances and describes them."

We do not believe it should be the responsibility of the technical reviewers or the public to identify "other ingredients." Identifying the "other ingredients" is practically impossible since manufacturers withhold this information from the public as Confidential Business Information.

Even many GRAS Notices to the FDA do not give any information regarding manufacturing processes and other ingredients used. It should be the responsibility of manufacturers, and organic handlers who use the materials, to be transparent and share this information with the public.

Many of the ingredients currently on the National List were approved without the NOSB's knowledge regarding "other ingredients" that are used. Manufacturers withheld that information as "Confidential Business Information."

For this reason, we support the proposal by the Materials Subcommittee (MS) on "Confidential Business Information in Petitions." We agree with the MS that "the importance of transparency of the petition process, the right of the public to fully know the materials included in or on certified organic products, and the potential for an untenable administrative burden of management of CBI precludes the provision of CBI in materials petitions."
We urge the NOSB to adopt the Materials Subcommittee proposal to revise the Material Petition process to eliminate the provision for Confidential Business Information.

If manufacturers and handlers want to continue using the substances, then it is their responsibility to share openly with the organic community which "other ingredients" are used.

Proposed procedure for NOSB review is inadequate. We also are concerned with the inclusion of Step 4: "All ingredients must meet Baseline Criteria." The baseline criteria are that any "other ingredient" must be Generally Recognized as Safe (GRAS). GRAS designation is essentially meaningless. Manufacturers determine on their own whether their product should be "Generally Recognized as Safe," and the FDA conducts no safety testing or review of its own. Substances that are GRAS include propylparaben (184.1670), propane (184.1655), high fructose corn syrup (184.1866); surely we would not want to see these ingredients used in organic foods.

Policy should be strengthened to preserve organic integrity

We urge the NOSB revisit this recommendation. If an organic handler believes that a material on the National List cannot be sourced without a particular synthetic and unapproved "other ingredient," then that ingredient should be petitioned to be added to the National List with an annotation restricting its use to the materials for which it is needed.

This approach:

1. Respects OFPA and the requirement for *all ingredients* to be organic or on the National List.

2. Is in line with OFPA's specification that substances on the National List shall be listed "by specific use or application." The NOSB can recommend that a synthetic ingredient be approved only for the particular ingredient for which its use is petitioned.

3. Addresses the difficulties raised by the fact that other ingredients may vary from manufacturer to manufacturer. If a particular manufacturer, or an organic handler who uses the ingredient, knows that a particular "other ingredient" is used and believes its use is necessary, that particular ingredient can be petitioned by the manufacturer or organic handler.

4. Increases transparency by requiring handlers and manufacturers to disclose the unapproved "other ingredients" that are used.

5. Preserves consumer trust in the organic label and the process. The public has a right to know *all* ingredients used in the production of organic foods.

Conclusion

We urge the Board to revisit the recommendation and strengthen it, clarifying that only single substances may appear on the National List and that all ingredients added to organic foods should be either organic or on the National List.

Any ingredients considered essential as components of materials on the National List should be petitioned for that particular purpose, with an annotation specifying the approved use.

Sincerely,

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Comments of Consumers Union To
The National Organic Standards Board
On
Livestock Subcommittee
Proposal: Aquaculture (chlorine, tocopherols, vitamins and trace minerals)

Docket No. AMS-NOP-13-0049

October 1, 2013

Ms. Michelle Arsenault, Special Assistant
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Thank you for the opportunity to submit comments to the National Organic Standards Board on the Livestock Subcommittee's four proposals on aquaculture materials: chlorine, tocopherols, vitamins and trace minerals.

These comments were prepared by Consumers Reports' Food Safety and Sustainability Center. Consumer Reports is the world's largest independent product-testing organization. Using its more than 50 labs, auto test center, and survey research center, the nonprofit rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 8 million subscribers to its magazine, Website and other publications. Its advocacy division, Consumers Union, works for health reform, food and product safety, financial reform, and other consumer issues in Washington, D.C., the states, and in the marketplace.

Summary

Consumers Union urges the Board to reject the four Livestock Subcommittee (LS) proposals for organic aquaculture materials until standards for organic aquaculture have been created.

We are especially concerned that the Board is unable to adequately review these petitioned materials to OFPA criteria, since it is has not been determined which aquaculture systems will be allowed. Some of these petitioned materials may be compatible with organic principles when used in one type of system - like land-based closed systems where interaction with the environment and marine ecosystems can be controlled - but incompatible when used in others -

like open ocean systems where the material would be in direct contact with the surrounding marine ecosystem.

It is also not possible for the Board to determine the essentiality of a material until there are standards specifying which systems are allowed and which fish species will be raised under the organic standards. A material may be essential in one type of system but not in another - for example, tocopherols are unlikely to be essential for the production of certain herbivorous fish species since they are petitioned as preservatives for fish meal and fish oil. Given that three of the petitions are for nutrient supplementation of fish feed, it is difficult to determine essentiality before the Board knows which fish species' nutritional needs must be considered. Until the Board and the public have a clear understanding which systems will be allowed in organic aquaculture, we believe it is not possible to make an informed decision.

We also believe that the petitions and the Technical Reports (TR) for these materials should be written with a specific system, or systems, in mind. For example, the TRs are not able to adequately address the potential environmental impact of these materials if it is unknown which systems would be allowed.

For these reasons, we urge the Board to reject the petitioned materials.

We are also concerned with the previous Board recommendations regarding aquaculture, and strongly urge the Board to reconsider certain recommendations:

Prohibit Open Ocean Systems

We are concerned that open ocean aquaculture is incompatible with organic principles. In 2007, a coalition of more than 40 organic farmers, consumer advocates, animal welfare, conservation groups and even celebrity chefs joined forces to call on the USDA to ensure that the organic label does not include carnivorous fish and open ocean systems. These organizations included the Center for Food Safety, the Humane Society of the United States, Greenpeace USA, Sierra Club Canada, Trout Unlimited, Food and Water Watch, Pure Salmon Campaign and Consumers Union.

Open ocean systems are potentially damaging to the marine ecosystem by creating water pollution from fish waste, excess feed and dead fish.

Escapes from open ocean systems may cause genetic disruption of wild fish when they interbreed with or overtake wild fish populations.

Farming certain fish, like salmon, at high stocking densities in open net cages creates a breeding ground for bacterial and viral diseases as well as parasites, which can readily transfer to and from wild fish by tidal flow and escapes. An October 2006 study published in the National Academy of Sciences showed sea lice infections on salmon farms in British Columbia can kill up to 95 percent of young wild salmon as they migrate out to sea past salmon farms. The Norwegian Directorate for Nature Management has estimated that in some areas, 90 percent of the outgoing juvenile, wild salmon run carries lethal lice levels.

It is also still unclear whether open ocean systems can function long-term without the drugs, including antibiotics and parasiticides, that are currently used in conventional aquaculture.

The State of Alaska prohibited open ocean finfish farming in 1990, to protect the health of its native marine ecosystem and the fishing industry that depends on it. The Alaska state legislature opposes open ocean aquaculture for finfish and predatory shellfish.[1]

Given these concerns, we urge the Board to reconsider previous decisions and prohibit all open ocean systems.

Prohibit wild-caught fish meal and fish oil

We support the arguments by the Center for Food Safety and Food and Water Watch to prohibit the use of wild-caught fish meal and fish oil in organic aquaculture.

Require 100% organic feed

Like other animals raised for food, organic fish should be given 100% organic feed. This would exclude the use of wild-caught fish meal and fish oil. We are concerned with the safety of wild-caught fish, which is exposed to oceanic pollutants, including methyl mercury and radiation, which cannot be controlled. Those pollutants concentrate as they move up the food chain, and with consumers at the top of the chain, we believe that carnivorous farmed fish should not carry the organic label.

Prohibit carnivorous fish

Carnivorous fish like salmon and cod require other fish as food. A farmed salmon diet relies heavily on wild fish, which should never be certified organic. They also place pressure on wild fish for feed. It currently takes three pounds of wild fish to produce one pound of farmed salmon, not exactly an ecologically efficient system. And, this "fish chow" exposes farmed salmon to a variety of toxins such as PCBs and dioxins.

Prohibit organic salmon and other migratory fish

We are concerned that salmon farming interferes with the animals' natural behavior. Salmon are migratory fish, and cannot exhibit this instinctive natural behavior when they are confined. Salmon farming, or farming any other migratory fish, is not compatible with organic principles and should not be allowed.

The National Organic Standards Board should not succumb to the pressures of big business and should focus on maintaining the integrity of the organic label. If the USDA allows for open net systems, then it will be selling the organic label down the river.

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[1] http://www.legis.state.ak.us/basis/get_bill_text.asp?hsid=HJR015C&session=24

Conclusion

The NOSB should reject all petitions related to aquaculture until standards are in place. Without knowing which systems will be allowed under the organic standards, it is not possible for the NOSB to determine whether the materials comply with OFPA criteria.

Consumers Union
Nonprofit Publisher of Consumer Reports

Comments of Consumers Union To
The National Organic Standards Board
On
Livestock Subcommittee
Proposal: Methionine

Docket No. AMS-NOP-13-0049

October 1, 2013

Ms. Michelle Arsenault, Special Assistant
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave, SW.
Washington, DC 20250

Thank you for the opportunity to submit comments to the National Organic Standards Board on the Livestock Subcommittee's proposal on Methionine in Organic Poultry Feed.

These comments were prepared by Consumers Reports' Food Safety and Sustainability Center. Consumer Reports is the world's largest independent product-testing organization. Using its more than 50 labs, auto test center, and survey research center, the nonprofit rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 8 million subscribers to its magazine, Website and other publications. Its advocacy division, Consumers Union, works for health reform, food and product safety, financial reform, and other consumer issues in Washington, D.C., the states, and in the marketplace.

The Livestock Committee proposes to change the annotation of the methionine listing, from a maximum level to an average level of synthetic methionine in organic poultry feed. This would allow producers to increase the allowed levels above the current maximum levels at certain stages in the lives of laying hen chicks (when they first "come into production").

Consumers Union opposes the recommendation, since it does not appear to be moving producers away from synthetic methionine use; rather, it allows the maximum levels to be higher than what they currently are in certain situations.

Consumers Union opposes the continued use of synthetic methionine in poultry feed. Synthetic methionine is a poster child for how Sunset is not working as designed - and that was before the National Organic Program's change to the Sunset process on Monday, September 16, 2013. The industry has lost opportunities to replace synthetic methionine with natural alternatives because

of the multiple continued extensions allowing the use of the synthetic version. There are few incentives to finding natural alternatives when a material is granted endless extensions and therefore remains on the National List.

It is interesting to note the sense of urgency to finding natural alternatives in the 2005 petition for an extension, and compare it with the current petition's language:

From the 2005 petition: "The intent of the NOSB was clear; Synthetic Methionine was not to be on the National List with the same status as other materials subject to renewal every five years. Nor was their intent to start a process that would damage or destroy the organic poultry industry. The intent with this material was to send a message that hard fast research would be required to find alternative feedstuffs and breeds. To source and develop the production of those alternatives and to seamlessly if not painlessly wean the US organic poultry industry from this last essential amino acid before the sunset."

The language sending a strong message that synthetic methionine will be phased out is no longer present in the current petition: "While expressing a strong preference for supplementation with allowable natural sources of MET, the NOSB concluded that terminating the allowance for synthetic MET would disrupt the well-established organic poultry market, and cause substantial economic harm to organic poultry producers. The NOSB and stakeholders agreed that the organic feed sector would continue to research and develop sufficient supplies of allowable organic and natural sources."

What happened in the eight years between the 2005 petition and the 2012 petition? Researchers responded with "hard fast research," but the industry did not step up to the plate to either create the demand for these products or support the research. No organic alternatives are commercially available today.

For example, at the Spring 2010 NOSB meeting in Woodland, California, the NOSB heard from Walter Goldstein, whose high-methionine corn did not come to commercial viability in part because there was no research funding available for a product for which there was no demand. As long as synthetic methionine is on the National List and appears to be on the National List to stay, it is will be nearly impossible to fund the research necessary to develop alternatives.

When materials like synthetic methionine do not sunset, and receive continued extensions, it sends a clear message to the marketplace that there is no real need to develop an alternative. It has become clear over the years that as long as synthetic methionine remains on the National List, organic alternatives will not be developed. And without organic alternatives, synthetic methionine remains on the National List to "avoid substantial economic harm to organic poultry producers." It's a cycle that can only be broken by continuing the process of winding down the allowed use of synthetic methionine. This proposal does the opposite by allowing higher levels of synthetic methionine in poultry feed at certain stages of production.

We are also concerned that the use of synthetic methionine enables a model of poultry production that is incompatible with the organic standards and with consumer expectations. Specifically,

chickens without access to the outdoors are also deprived of access to worms, insects and other natural sources of methionine that increases their need for synthetic methionine.

Finally, it appears that changing the annotation would reset the sunset clock, adding another year to the exemption, which we oppose.

We urge the NOSB to reject the proposal to change the annotation for synthetic methionine.

Comments of Consumers Union To
The National Organic Standards Board
On
Crops Subcommittee
Proposal: Streptomycin

Docket No. AMS-NOP-13-0049

October 1, 2013

Ms. Michelle Arsenault, Special Assistant
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Thank you for the opportunity to submit comments to the National Organic Standards Board on the Crops Subcommittee's proposal on an extension for the use of Streptomycin in organic apple and pear production.

These comments were prepared by Consumers Reports' Food Safety and Sustainability Center. Consumer Reports is the world's largest independent product-testing organization. Using its more than 50 labs, auto test center, and survey research center, the nonprofit rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 8 million subscribers to its magazine, Website and other publications. Its advocacy division, Consumers Union, works for health reform, food and product safety, financial reform, and other consumer issues in Washington, D.C., the states, and in the marketplace.

Summary

Consumers Union urges the Board to reject the petition to extend streptomycin's expiration date to October 2017. We agree with the Crops Subcommittee's Minority Opinion and request that the Board vote to keep the existing October 2014 expiration date.

We understand that the oxytetracycline vote at the Spring 2013 meeting was an extremely difficult decision for Board members. We realize that the vote on streptomycin will be no less difficult.

Consumers have come to expect that organic foods do not contain antibiotics. Organic is widely marketed as "no antibiotics," which has become a consumer expectation. Other segments of the

organic market, like organic meat, cheese and milk, have set and met this expectation, and so have organic fruit growers including nectarine and peach growers. Organic apples and pears treated with antibiotics simply do not meet consumer expectations.

Just a weeks ago, in September 2013, the Centers for Disease Control and Prevention released a report that notes that 23,000 human deaths could be attributed to the development of antibiotic resistance from overuse of antibiotics, including in agricultural settings. When the medical community urges the preservation of human medicine that is crucial for saving human lives, it eclipses other stakeholder interests. At Consumers Union, we urge you to prioritize the continued effectiveness of streptomycin to save human lives over the continued use of streptomycin to save trees.

Preserving antibiotics to save human lives

Consumers have benefited greatly from the commitment of organic orchardists who farm without toxic pesticides and offer a safe, sustainably grown alternative to conventional apples and pears. Streptomycin has been a tool in their toolbox for many years, and we understand the challenges farmers would face without the ability to use this drug. However, it is also important to note that fire blight resistance to streptomycin is widespread, and growers in many regions are already unable to turn to streptomycin to treat fire blight infections.

We must weigh the potential effect on orchards against the interests of the medical community and the public at large. The loss of an orchard to fire blight is indeed devastating, and should not be downplayed. But when we weigh this against the potential negative effect on humans and animals from infections with pathogens that have developed resistance to streptomycin and other antibiotics, we must place a higher value on human life than on tree life.

A Centers for Disease Control and Prevention (CDC) report released a few weeks ago estimates that every year, more than two million people in the United States get infections that are resistant to antibiotics and at least 23,000 people die as a result.[2] Antibiotic resistance is a serious threat to public health, and must be addressed at once.

According to Steve Solomon, M.D., Director of CDC's Office of Antimicrobial Resistance, "Every time antibiotics are used in any setting, bacteria evolve by developing resistance. This process can happen with alarming speed. These drugs are a precious, limited resource - the more we use antibiotics today, the less likely we are to have effective antibiotics tomorrow."[3] Please note that Dr. Solomon said the threat to developing resistance exists when antibiotics are used ***in any setting*** -- organic orchards are not exempt.

We do not agree with the assertion by the Majority on the Crops Subcommittee that there is no evidence that resistance to streptomycin, as a result of its use in orchards, spreads to human

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[2] Centers for Disease Control and Prevention. Press release. Untreatable: Report by CDC details today's drug-resistant health threats. September 16, 2013. Available online: http://www.cdc.gov/media/releases/2013/p0916-untreatable.html. Last accessed on September 22, 2013.

[3] Ibid

pathogens. This opinion defies the basic tenets of bacterial biology. The use of antibiotics in the environment puts selective pressure on the bacteria in the environment to develop resistance to these drugs. Once resistant bacteria develop in the environment they can easily be spread to humans by a variety of pathways. Even if these bacteria themselves do not cause harm they have the ability to spread their resistant genes to other potentially more harmful bacteria. Tracing resistant genes from specific orchards to specific humans would be almost impossible to study, however this doesn't mean it can't occur.

At the Spring 2013 meeting, the NOSB heard from Dr. Glenn Morris, Professor of Medicine and Director of the Emerging Pathogens Institute at the University of Florida. Dr. Morris said: "the transfer of resistant gene strains from the environmental sources to humans and human microbial flora is well-documented. It definitely happens." He testified on tetracycline and said: "every time you're using tetracycline you are presenting an opportunity for the development of new resistance genes and/or the amplification of resistance genes and potential to transfer those into humans." The same would apply to streptomycin. He closed his testimony: "What the models say is a very, very rare event is enough to have significant impact in terms of long-term risk within human populations."

The development of antibiotic resistance due to the use of antibiotics outside medical settings, or its overuse within medical settings, is now well established and accepted in the medical community.[4] Using antibiotics in the environment increases the risk of the development of the bacteria that are resistant to these medications. This is a risk that we should not take, given the human lives that depend on the continued effectiveness of streptomycin, which is considered "critically important" by the World Health Organization.[5]

According to CDC Director Tom Frieden, M.D., M.P.H.: "Antibiotic resistance is rising for many different pathogens that are threats to health. If we don't act now, our medicine cabinet will be empty and we won't have the antibiotics we need to save lives."[6]

With the CDC Director imploring an immediate end to the use of antibiotics outside medical settings, we urge the Board to phase out the use of streptomycin as soon as possible, and keep the October 2014 expiration date.

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[4] See Centers for Disease Control and Prevention. Antibiotic resistance threats in the United States, 2013. Available online at http://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf. Last accessed on September 23, 2013.
See also World Health Organization. Antimicrobial resistance. Fact Sheet #194. Updated May 2013. Available online at http://www.who.int/mediacentre/factsheets/fs194/en/. Last accessed on September 23, 2013.

[5] World Health Organization. Critically Important Antimicrobials for Human Medicine: Categorization for the development of risk management strategies to contain antimicrobial resistance due to non-human antimicrobial use. Report of the Second WHO Expert Meeting. Copenhangen, 29-31 May 2007. Available online at http://www.who.int/foodborne_disease/resistance/antimicrobials_human.pdf. Last accessed on September 23, 2013.

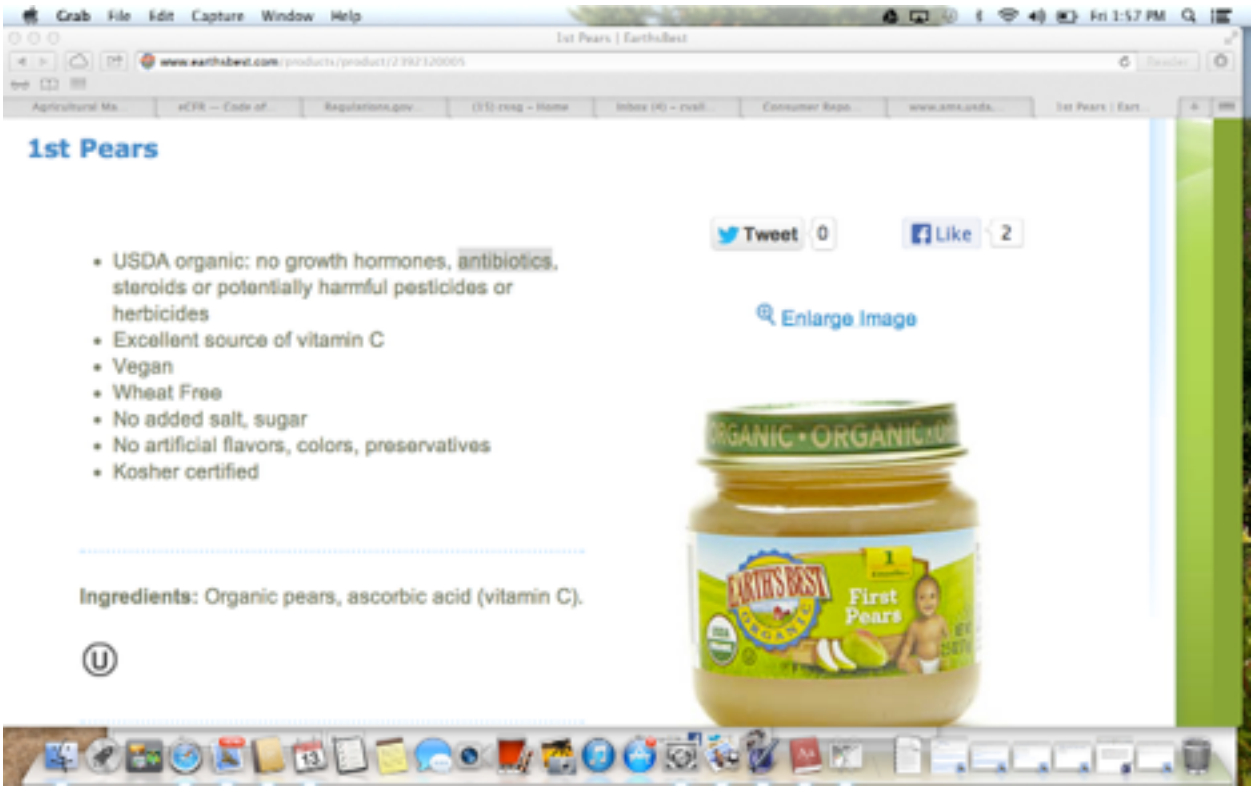
[6] Ibid

Consumer Expectations

The potential loss of a critically important human medicine is the primary reason for Consumers Union's opposition to the petition for an extension. We are also concerned with the effect that a continuation of the use of an antibiotic in organic agriculture would have on consumer confidence in organics.

One of the strengths of the organic label is the assurance to consumers that a wide range of inputs that pose a threat to the environment or human health are not used - and this includes the prohibition against the use of antibiotics. The assertion that antibiotics are not used in organics is prevalent on marketing materials, packages, advertisements, etc. It is central to the messaging that benefits the entire organic industry: "organic means no antibiotics."

This claim is even found on marketing materials accompanying products that contain only organic apples and pears:



Consumers Union believes in the importance of "organic" remaining a credible, commercially viable model of how sustainable agriculture practices can succeed in the market. The goal of the OFPA was to apply consistency to the organic label. The selective use of antibiotics in one segment of the organic market but prohibited use in another (which is the one typically marketed to consumers) is not consistent and consumers have not been adequately informed about these practices—like other practices that go unlabeled, like ammonia in pink slime, the public does not know. We believe the continued use of antibiotics for one segment of the organic market over another is not in line with the OFPA or market standards and will undermine consumer confidence in the organic label in general.

The honesty and added value that organic conveys is constantly under scrutiny and comparison in the marketplace. As the market grows, so does the scrutiny. When the value is compromised, so is consumer trust.

Conclusion

Consumers Union urges the Board to reject the petition for an extension to the phase out of streptomycin for organic apple and pear production.

Comments of Consumers Union To
The National Organic Standards Board
On
Materials Subcommittee
Proposal: Update of Petition & Technical Review Process

Docket No. AMS-NOP-13-0049

October 1, 2013

Ms. Michelle Arsenault, Special Assistant
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Thank you for the opportunity to submit comments to the National Organic Standards Board on the Materials Subcommittee's proposal on Update of Petition & Technical Review Process.

These comments were prepared by Consumers Reports' Food Safety and Sustainability Center. Consumer Reports is the world's largest independent product-testing organization. Using its more than 50 labs, auto test center, and survey research center, the nonprofit rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 8 million subscribers to its magazine, Website and other publications. Its advocacy division, Consumers Union, works for health reform, food and product safety, financial reform, and other consumer issues in Washington, D.C., the states, and in the marketplace.

Confidential Business Information

Consumers Union supports the proposal to remove Confidential Business Information from the petition process. Please see our separate comment on the Confidential Business Information proposal.

Petitions to Remove

We urge the Board to reconsider some of the proposed language changes in the Policy and Procedures Manual (PPM) that appear to make it more difficult to file a complete petition to remove a material.

The proposal suggests adding language that would require petitions to remove to "[make] sure to cover all uses of the listed substance" and would require listing alternatives to the petitioned material as well as "their [the alternative's] availability and applicability to all situations where the substance is used."

First, it is important to consider that petitions to remove may be filed for various reasons. The most common reason, so far, has been due to the development of an organic version. But another reason, which was likely not considered when this language chance was proposed, is the advancement of scientific knowledge regarding human health or environmental concerns with the material.

We believe that it would be inappropriate to require a full list of uses and alternatives in a petition to remove if the petition is based on human health or environmental concerns. Such petitions must focus on the scientific data raising those concerns, not on whether all uses will be covered by suitable alternatives. We are concerned that the proposed language could lead to a Subcommittee's decision to send a petition to remove a dangerous or harmful material back to the petitioner for incompleteness, when data regarding uses and alternatives is missing.

If the petition to remove is based on the development of an organic alternative, and it is therefore the essentiality criterion that is no longer met, then we believe it is reasonable for the NOSB to request information regarding essentiality - all uses and alternatives - to be included in the petition to remove. However, we still caution against adding this proposed language regarding uses and alternatives because it could delay the process. We would rather see the question of "all uses and alternatives" discussed during the public comment period - industry participants who believe their use will not be covered by the organic alternative will have ample opportunity to express their concerns during the public comment period.

Comments of Consumers Union To
The National Organic Standards Board
On
Materials Subcommittee
Proposal: Confidential Business Information in Petitions

Docket No. AMS-NOP-13-0049

October 1, 2013

Ms. Michelle Arsenault, Special Assistant
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Thank you for the opportunity to submit comments to the National Organic Standards Board on the Materials Subcommittee's proposal on Confidential Business Information in Petitions.

These comments were prepared by Consumers Reports' Food Safety and Sustainability Center. Consumer Reports is the world's largest independent product-testing organization. Using its more than 50 labs, auto test center, and survey research center, the nonprofit rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 8 million subscribers to its magazine, Website and other publications. Its advocacy division, Consumers Union, works for health reform, food and product safety, financial reform, and other consumer issues in Washington, D.C., the states, and in the marketplace.

Consumers Union supports the proposal to remove the provision for Confidential Business Information in material petitions.

We believe that the NOSB can only make informed decisions about whether a petitioned material meets the criteria for inclusion on the National List of Approved and Prohibited Substances if all information about the material is made public.

One of the strengths of the organic label is that it offers consumers an alternative to the conventional food supply, where food processors routinely add ingredients that have not been sufficiently reviewed for safety. For example, a report by Pew Health Group researchers found: "Overall, FDA's changes have moved away from public scrutiny and, in the case of its voluntary GRAS notification program, away from independent safety review by the agency.

The cumulative result is that there are an estimated 6204 current affirmative safety decisions which allow for more than an estimated 10000 substances to be used in food. More than half of the safety decisions are not made by FDA or EPA." The report also found that an estimated 1000 manufacturer safety decisions are never reported to FDA or the public.[7]

Organics is an alternative to this system, where every non-organic or synthetic food additive is reviewed for safety before it is allowed. Such careful review can only happen when all information about the material is made known to the public, otherwise, a safety decision by the NOSB based on a petition with CBI is essentially no different than a safety decision by the manufacturer. Removal of CBI is therefore a critical improvement to organic integrity.

Misleading choices

When farmers and consumers do not know what is in their food, feed and even farming materials, it can lead to misinformed and misleading choices. The majority of consumers want to know how their food is produced, and this is especially true for organic consumers who are willing to pay a premium. For organic consumers, transparency is a must.

One example that illustrates the necessity for eliminating the Confidential Business Information provision is the frequent redaction of information regarding fermentation media. In many cases, fermentation media contain corn byproducts, which are likely produced from genetically engineered corn. Consumers expect "organic" to mean "non-GMO" because organic is both regulated and marketed as such. When fermentation media or other processing aids to produce ingredients on the National List are GMO, that's a problem. Such information should be available, especially to the NOSB during the decision making process, and should never be considered Confidential Business Information. When consumers don't know whether an ingredient was produced using GMO fermentation media, it leads to misinformed decisions in the marketplace (consumers think they're buying non-GMO when they buy organic, when in fact they're not) that threaten consumer trust in the integrity of the organic label.

Sunset

We urge the Board to determine how it will handle sunset reviews of materials whose petitions contained CBI. One example, relevant today, is the petition for gellan gum, which had the entire manufacturing process redacted as CBI.

We suggest that the Board include language in the Policy and Procedures Manual (PPM) clarifying that any material up for sunset review must have a complete petition, without missing information that was redacted as CBI. If a material was approved when information was missing from the petition, the Board must request this missing information from the petitioner before a sunset decision can be made. If the petitioner is unwilling or unable to provide the missing information, the NOSB should reject the relisting of the material.

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[7] Neltner, T. G., Kulkarni, N. R., Alger, H. M., Maffini, M. V., Bongard, E. D., Fortin, N. D. and Olson, E. D. (2011),Navigating the U.S. Food Additive Regulatory Program. *Comprehensive Reviews in Food Science and Food Safety* 10: 342–368

Consumers Union
Nonprofit Publisher of Consumer Reports

Comments of Consumers Union To
The National Organic Standards Board
On
Materials Subcommittee
Proposal: Research Priorities for 2013

Docket No. AMS-NOP-13-0049

October 1, 2013

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Thank you for the opportunity to submit comments to the National Organic Standards Board on the Materials Subcommittee's proposal on Research Priorities for 2013.

These comments were prepared by Consumers Reports' Food Safety and Sustainability Center. Consumer Reports is the world's largest independent product-testing organization. Using its more than 50 labs, auto test center, and survey research center, the nonprofit rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 8 million subscribers to its magazine, Website and other publications. Its advocacy division, Consumers Union, works for health reform, food and product safety, financial reform, and other consumer issues in Washington, D.C., the states, and in the marketplace.

One of the Materials Subcommittee's (MS) requests for research involves "consumer demand." The MS writes that "research into the relationship of consumer buying habits and their beliefs about them would be helpful."

Consumers Union has provided credible information about consumer sentiment, based on consumer survey data, on important issues to the NOSB for more than a decade.

In its request for research, the MS mentions that "this issue has come up with regard to fortification by synthetic nutrients in infant formula and other processed food" and "oxytetracycline."

Consumers who buy organic apples do not necessarily approve of the use of antibiotics. As shown by the results of a Consumer Reports' consumer survey data presented to the Board in April 2013, consumers either think antibiotics are prohibited or they do not know that antibiotics

are used. Their purchasing decisions - “consumer demand” - therefore does not reflect consumer expectations.

Consumers who buy organic formula, milk or processed foods with synthetic nutrients do not necessarily approve of the synthetic nature of the nutrients - they are likely to be unaware that organic foods allow the addition of synthetic nutrients. Even if they are aware the nutrients are synthetic, they likely prefer natural versions over synthetic. Results from a consumer survey by PCC Natural Markets in 2011 showed a clear preference for natural or organic additives over synthetic ones. The survey also showed that for non-synthetic nutrients, like DHA algal oil, consumers may be unaware that various non-organic processing aids, methods and “other ingredients” are allowed to produce the additive. Consumers’ purchasing decisions therefore do not necessarily reflect their approval of the additives; rather, their purchasing decisions are likely based on erroneous beliefs regarding the organic standards - about what is allowed and what isn’t.

The MS has requested additional research on the interaction between consumer demand and consumer expectations. Consumer Reports will conduct this research. The National Research Center is a research arm of Consumer Reports' National Testing and Research Center in Yonkers, N.Y. and is comprised of highly trained social scientists, using state-of-the art techniques to survey more than 1 million consumers each year for their feedback on a broad range of experiences with products, services, and health care.

Using scientifically valid research methods, the National Research Center surveys consumers about a wide range of topics. The Center’s annual research calendar includes more than 200 qualitative and quantitative projects. The National Research Center conducts many of its surveys by selecting a random sample from the approximately 8 million readers who subscribe to Consumer Reports and/or to ConsumerReports.org, but also conducts many surveys using national probability samples to accurately represent the entire U.S. population.

Like the rest of Consumer Reports, the National Research Center is free of corporate influence and advertising. Surveys are never commissioned or financed by industry. Rather, these surveys are designed to gather unbiased, objective information from consumers.

We are happy to learn about the specific needs of the board regarding consumer attitudes and behaviors to help inform our survey work.

Comments of Consumers Union To
The National Organic Standards Board
On
Policy Development Subcommittee
Proposal: PPM Updates - Conflict of Interest

Docket No. AMS-NOP-13-0049

October 1, 2013

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Thank you for the opportunity to submit comments to the National Organic Standards Board on the Policy Development Subcommittee's proposal on PPM Updates - Conflict of Interest.

These comments were prepared by Consumers Reports' Food Safety and Sustainability Center. Consumer Reports is the world's largest independent product-testing organization. Using its more than 50 labs, auto test center, and survey research center, the nonprofit rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 8 million subscribers to its magazine, Website and other publications. Its advocacy division, Consumers Union, works for health reform, food and product safety, financial reform, and other consumer issues in Washington, D.C., the states, and in the marketplace.

Summary

In order to maintain organic integrity and continued consumer trust in the organic label, Consumers Union urges the National Organic Program (NOP) and the NOSB to collaborate on a sound definition of conflict of interest for NOSB members and a clear set of standards for determining recusals during materials votes.

We are less concerned with *who* determines the conflict of interest than with *how* conflict of interest is defined and how recusals are determined. Who makes the decision is less important than that the declaration be made in a transparent manner and that the decision be based on clear, ethically sound standards that were openly and publicly discussed and developed.

A “conflict of interest” occurs when a primary interest is unduly influenced by a secondary interest. In order to determine what constitutes a “conflict,” it is necessary to first define the primary interest - it must be clearly articulated and agreed upon.

We believe that NOSB members’ primary interest is written in the Organic Foods Production Act of 1990 (OFPA): “to assist in the development of standards for substances to be used organic production and to advise the Secretary on any other aspects of the implementation of this chapter (Section 6518(a))” and OFPA’s purpose includes “to assure consumers that organically produced products meet a consistent standard (Section 6501(2)).”

Neither OFPA nor the Federal Advisory Committee Act (FACA) refers to NOSB members as “representatives” or suggests their primary interest is in representing a particular interest group. In fact, the FACA never uses the term “representative” to refer to advisory committee members. Both the OFPA and the FACA clearly suggest that NOSB members are advisors.

Yet the Policy Development Subcommittee (PDS) proposal on Conflict of Interest would adopt the National Organic Program Memo on Conflict of Interest from March 2013 (hereafter referred to as “the NOP Memo”), which attempts to redefine NOSB member’s primary interest as representing interest groups.

This PDS proposal also suggests changing the “Duty of Loyalty” of Board members from requiring them to “exercise their power in the interest of the organic community and the public at large” to “exercise their power in the interest of the group she/he represents.”

The PDS proposal could turn NOSB members from advisors into lobbyists.

Consumers Union urges the Board to reject the PDS proposal. NOSB members cannot act in accordance with OFPA and assure consumers that organically produced products meet a consistent standard when a *bona fide* assessment of materials petitions is inhibited by an unclear and inadequate conflict of interest policy. When Board members vote on materials petitions when they have a conflict of interest, it results in National List decisions that no longer assure consumers of the integrity of the organic label.

We believe that a set of criteria for determining recusals due to a conflict of interest must be developed in a transparent manner, involving both the NOSB and the public. The development of clear criteria should go through the formal NOSB and NOP rulemaking process, including a public comment period for both the NOSB recommendation and the NOP proposed rule. We oppose the current process as it is unfolding, where the NOP writes a Memo and the PDS proposes that the NOSB adopt this Memo as official policy.

We urge the NOSB to reject the PDS proposal and to continue the discussion by agreeing to define NOSB members “primary interest” and “secondary interest,” which is necessary before conflict of interests standards can be developed.

The organic industry's continued growth and success depends on consumer trust in the integrity of the label. We would like to see a strong conflict of interest policy based on sound standards that will assure consumers of the integrity of the organic program and label.

Definition of Conflict of Interest

The NOSB should strive for the highest ethical standards. Currently, neither the NOP Memo nor the PDS proposal adequately address conflict of interest guidelines, and the proposed guidelines pale in comparison to every other set of conflict of interest guidelines we reviewed.

Both documents are missing even a basic definition of "conflict of interest." When we reviewed various conflict of interest definitions and standards, including from different government agencies and advisory committees, we found the discussion of conflict of interest by the Institute of Medicine to be most helpful as a starting point for the NOSB.

Before we discuss the IOM document and its relevance to developing standards for the NOSB, we urge the Board and NOP to consider the conflict of interest policy that Consumers Union has adopted to preserve our organization's impartiality and integrity.

Consumers Union Conflict of Interest Policy

Consumers Union's policy for its directors is perhaps most applicable to the discussion for a conflict of interest policy for the NOSB:

> Section 1: Compliance with Conflict of Interest Policy
>
> "Consumers Union's most valuable asset is its reputation for independence, impartiality, integrity and expertise. Consumers Union must avoid conflicts of interest, or even the appearance of such conflicts. When conducting Consumers Union's business, directors and employees are expected to act with professional and personal integrity in the best interests of the organization, and to refrain from actions that benefit or enrich themselves, family members and close associates as determined in accordance with applicable law and Consumers Union's Conflict of Interest Policy.
>
> Section 2: "No director shall have the right to vote on any proposal that he/she be paid compensation by Consumers Union, or on any contract, grant or other matter between Consumers Union and the director, between Consumer Union and a family member, or between Consumers Union and any other corporation, firm, association or other entity in which the director has any personal interest, direct or indirect or serves as a director or officer."[8]

Using FACA Conflict of Interest Guidelines

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[8] http://www.consumerreports.org/cro/about-us/by-laws/index.htm

In reviewing various conflict of interest guidelines, we reviewed FACA standards. In the NOP Memo, the NOP suggests that FACA rules are applicable to the NOSB. We do not, however, consider these guidelines to be appropriate for developing NOSB standards. We found the most compelling reason for developing standards stronger than FACA's in the FDA's discussion of "Policies and Procedures for Handling Conflicts of Interest with FDA Advisory Committee Members, Consultants, and Experts."

The FDA writes that "advisory committees convened under the Federal Advisory Committee Act (FACA) warrant a different approach than the standard conflict of interest treatment in 18 USC 208." It is worth noting the final reason why the FDA believes it to be acceptable to adopt a less stringent set of standards for FACA committees: "Finally, the recommendations of an advisory committee are not, in themselves, binding. Advisory committee recommendations are "presented publicly to another government official who can judge independently the degree to which recommendations" might be influenced by the personal interest of the members."

Note that the FDA believes a less stringent conflict of interest approach is warranted because FACA committee recommendations "are not binding." This is a crucial difference between standard FACA committees and the NOSB: the NOSB has statutory authority over the National List and its decisions *are* binding. We believe this crucial difference warrants a set of standards for determining conflict of interest that is different and stronger than conflict of interest standards adopted for the FACA boards whose decisions do not have statutory authority.

Discussion of conflict of interest by IOM

The Institute of Medicine issued a report in 2009 titled "Conflict of Interest in Medical Research, Education and Practice."[9] We found the discussion and definitions to be helpful. Recognizing that it is crucial to define "conflict of interest" before a serious discussion on the topic can begin, we urge the NOP and NOSB to consider the definition offered by the IOM:

A conflict of interest is a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.

This definition differs substantially from the implied definition in the NOP Memo (no actual definition was offered in the NOP Memo). The NOP Memo appeared to disregard conflicts of interest altogether, considering only the "appearance" of conflict. The NOP Memo states: "Interests create appearance problems, often referred to as conflicts of interest..."

We are concerned that the NOP considers conflicts of interest to be merely a problem of "appearance" and does not seem to recognize that actual conflicts exist. While appearance may be a problem, it comes secondary. The first and primary concern is *actual* conflict of interest: when a secondary interest unduly interferes with a Board member's primary interest. We believe there should be a discussion of what constitutes a Board member's primary interest and what

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[9] http://www.iom.edu/Reports/2009/Conflict-of-Interest-in-Medical-Research-Education-and-Practice.aspx

constitutes a conflict, but such discussion must be based on the understanding that conflict of interest is a serious ethical consideration, not a mere problem of "appearance."

The IOM takes conflict of interest seriously for the following reason:

"Whatever the primary interests are, the point of regulating conflicts of interest is to try to ensure that secondary interests do not subvert physicians' and researchers' decisions and actions regarding those primary interests and do not undermine trust in their clinical or scientific judgment."

Determining Conflict of Interest for NOSB

Primary Interest

The IOM writes: "The primary interest that conflict of interest policies seek to protect varies according to the purpose of a professional activity." It is important for the NOSB, NOP and the public to discuss, in an open forum, what constitutes the primary interest of NOSB members.

We urge the NOP and the NOSB to consider the primary interest of NOSB members as articulated in OFPA:

"The Secretary shall establish a National Organic Standards Board ... to assist in the development of standards for substances to be used organic production and to advise the Secretary on any other aspects of the implementation of this chapter (Section 6518(a))."

Advising the Secretary on the implementation of this chapter includes consideration of OFPA's purpose:

(1) to establish national standards governing the marketing of certain agricultural products as organically produced products;
(2) to assure consumers that organically produced products meet a consistent standard; and
(3) to facilitate interstate commerce in fresh and processed food that is organically produced.

We believe this to be NOSB members' primary interest: to advise and assist the Secretary with the organic standards, to assure consumers that organic foods meet a consistent standard - based on OFPA criteria - and to successfully market organic products - which means assuring the integrity of the label to consumers, upon which the market's growth and success depends.

We are concerned that the PDS proposal seeks to change the definition of NOSB members' primary interest. We strongly object to the deletion of the phrase, "a Board member's loyalty is to the organic community and the public at large" in the PPM and the proposal that it be replaced with the following line: "The Duty of Loyalty requires Board members to exercise their power in the interest of the group she/he represents (e.g., "we farmers/growers believe...") As such, each NOSB members are not expected to provide independent expert advice, BUT rather advice based on the interests of the group serves (sic)."

This phrase - "a Board member's duty of loyalty is to the organic community and the public at large" - is a crucial reminder to Board members that the growth and success of the organic industry cannot be attributed to any single stakeholder group in the organic community.

It serves as a crucial reminder to Board members that the organic community shares a common goal: to develop and grow an alternative, safe, and sustainable food system. Farmers, handlers, retailers, certifiers and consumers must work together to achieve this goal - remembering always that we do not operate in a vacuum. Above all, continued consumer trust in the organic label is crucial to the continued growth of the organic market.

We urge Board members to recognize that changing the definition of "Duty of Loyalty" essentially changes the determination of what constitutes a Board member's primary interest. Consumers Union believes that the primary interest of NOSB members is to uphold organic integrity which will ensure the continued growth and success of the organic market.

NOSB Members are not "representatives"

The rationale behind OFPA's creation of different NOSB member categories was not to create "representatives" - such language does not appear in OFPA - but rather to bring stakeholders together, with various expertise from different sectors, into a deliberative process to assist the Secretary with the implementation of OFPA. OFPA does not refer to Board members as "representatives," but simply requires that NOSB members in various seats fulfill certain basic criteria - for example, "four shall be individuals who own or operate an organic farming operation."

We therefore strongly disagree with the NOP Memo's attempt to redefine NOSB members as "representatives." The NOP writes: "NOSB members (you) are classified as representatives under the Federal Advisory Committee Act (FACA)").

The FACA mentions the word "representatives" only in the context of "House of Representatives" and "the Comptroller General or the United States, or one of his authorized representatives." The term "representatives" to refer to FACA members appears nowhere in the FACA. Members of advisory committees are referred to as "members" or "individuals."

We cannot make this point clearly enough: the term "representatives" is used in neither the Organic Foods Production Act nor the Federal Advisory Committee Act. The OFPA requires NOSB members to "assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of this chapter" (OFPA Section 6518(a)). The NOSB members' primary interest is in carrying out these responsibilities, not to "represent" their interest group.

More importantly, nowhere in OFPA does it say that NOSB members should vote to advance the interests of those they "represent" - the word "represent" or "representative," or "stakeholder" appears nowhere in OFPA. In fact, OFPA never even uses the terms "farmers," "retailers" or "handlers" to refer to NOSB members, but rather describes NOSB members as owning or operating farms, retail establishments or handling operations. This should make it clear that the

purpose of diversity of NOSB "seats" is to ensure a diversity of voices on the NOSB, rather than to create "representatives" who vote with only their narrowly defined interest groups in mind.

We also believe it is unreasonable to expect Board members to speak and vote on behalf of entire groups, like "farmers" and "handlers." There have been plenty of votes where one group of farmers urged Board members to vote one way when other farmers urged the Board to vote another way. The recent vote on tetracycline is an example: NOSB members who own or operate an organic farm heard from farmers both urging them to accept and to reject the petition. Likewise, handlers often disagree on whether a particular ingredient should be approved, with some handlers prioritizing organic integrity and consumer trust in the organic label while other handlers, eager to create "mirror-image" products, urge its approval. Since such situations are inevitable, it is especially important to retain the language that a Board member's Duty of Loyalty is to the "organic community and the public at large."

By redefining NOSB members as "representatives" of interest groups rather than advisors to the Secretary charged with ensuring the implementation of OFPA, the NOP is attempting to redefine NOSB members' primary interest.

If the NOSB accepts this proposal and implements the NOP Memo as official policy, NOSB members will no longer be expected to vote objectively on materials petitions - determining objectively whether a material meets OFPA criteria - and therefore protect organic integrity, but will be expected to serve narrow interests regardless of whether OFPA criteria are met and organic integrity is preserved. The organic industry depends on consumer trust in the integrity of the label, and we cannot allow this NOP Memo to become official policy.

Secondary Interest

The IOM writes: "The second main element of a conflict of interest is the secondary interest. Secondary interests may include not only financial gain but also the desire for professional advancement, recognition for personal achievement, and favors to friends and family or to students and colleagues. Conflict of interest policies typically and reasonably focus on financial gain and financial relationships. The reason is not that financial gains are necessarily more corrupting than the other interests but that they are relatively more objective, fungible, and quantifiable."

It is important to note here that secondary interests are not restricted to financial gain. The overarching question is whether a secondary interest unduly influences a Board member and interferes with the primary interest. In the case of NOSB members, a secondary interest may be the impulse to please or side with an employer. For example, if a Board member's employer and/or colleague advocates publicly for the approval of a certain material, it is unreasonable to expect that Board member to vote against his/her employer's position. The conflict of interest guidelines must take into consideration such situations and not restrict the definition of "secondary interest" to personal financial gain.

Conflict of Interest

The discussion regarding conflict of interest must begin with a discussion of primary and secondary interests. A conflict arises when a secondary interest unduly influences the ability to carry out the primary interest. Therefore, the determination of what constitutes a conflict for NOSB members is contingent on how NOSB member's primary and secondary interests are defined. As noted by the IOM:

"What counts as undue is a matter of judgment and depends on the context. It is not a numerical probability but a judgment in a particular situation about whether a risk is undue or inappropriate."

What constitutes an "undue" or "inappropriate" conflict for NOSB members should be discussed and determined in a public forum. Currently, the NOP's determination of a conflict is remarkably inconsistent with any other guidelines or standards we reviewed. For example, the NOP Memo states:

"Example #1: If more than one company uses Substance X, in addition to the NOSB member's company, "then there is no disproportionate benefit, nor the potential for an unfair competitive advantage. This is an acceptable interest, where the NOSB member is free to represent the interest of his or her group."

The NOP proposes that a conflict of interest exists for Board members in the for-profit sector if only one company uses the substance, such as if the company holds an exclusive license - an unlikely scenario.

We disagree with this interpretation of conflict of interest. A conflict of interest exists if a Board member's primary interest is unduly influenced by a secondary interest. If the primary interest is to uphold organic integrity and vote objectively on a petition according to OFPA criteria, the objectivity of a Board member on a specific materials vote would remain impaired even if another company also stands to profit from the outcome of the vote. Yet under the NOP's interpretation, two conflicts of interest cancel each other out.

When discussing conflict of interest for consultants and experts on advisory committees, the FDA clearly states that conflicts of interest are "not contingent and dependent on other events."[10] The FDA based this assessment on the Office of Government Ethics' regulations implementing the Ethics Reform Act, which make clear that a financial interest is not contingent on others having a financial interest as well.

Section 120 of the Food and Drug Modernization Act of 1997 states that members of advisory committees "may not vote on any matter regarding the clinical investigation or approval for marketing of a drug or biologic if the member or the member's immediate family could gain

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[10] "*Direct and Predictable Effect*, Under 18 U.S.C. 208, a conflict of interest arises when the employee participates in an official matter and there is a direct and predictable link between the matters in which the Federal employee participates and the employee's financial interests. **The link cannot be contingent and dependent on other events.**"From "Policies and Procedures for Handling Conflicts of Interest with FDA Advisory Committee Members, Consultants, and Experts."

financially from the committee's recommendations." The conflict of interest policy does not state that the advisory committee member may vote if another company stands to gain as well - again, two conflicts of interest do not cancel each other out.

Furthermore, the FDA makes clear that multiple conflicts of interest may exist. Note the use of the plural in the following discussion on conflict of interest for advisory committee members: "If the meeting or assignment involves a particular matter involving specific parties, all entities with a financial interest in the meeting or assignment are identified to the extent feasible. For a meeting or assignment related to a product approval, the entities with a financial interest may include the sponsor and firms who will manufacture or market (1) the product being reviewed, (2) products that would be used in conjunction with the one being reviewed, and (3) products that would compete with the one being reviewed." The FDA considers two or more individuals with a conflict of interest to be exactly that: two or more individuals with a conflict.

Disclosure

Public disclosure of a potential conflict of interest is key to maintaining the integrity of the NOSB process and therefore the integrity and consumer trust in the organic label.

The PDS states under **Section V**, Recommendation: "While NOSB members may share whatever information they wish with other Board members and the public, this level of disclosure is voluntary. For both legal and ethical reasons, the NOP respects the privacy of its volunteers, and does not require full disclosure of the nature of conflicts of interest to parties outside the NOP."

Like other FACA meetings, conflicts about upcoming discussion and voting items should be disclosed and recusals should be publicly stated.

Further discussion

We also urge the NOP and NOSB to consider the following:

Social science research on conflict of interest

The IOM report includes a review of research studies aimed at determining the impact of conflicts of interest: "research shows that when individuals stand to gain by reaching a particular conclusion, they tend to unconsciously and unintentionally weigh evidence in a biased fashion that favors that conclusion."[11] These studies are cited in Appendix C of the IOP report, and we urge the NOP and NOSB to review and consider them during the development of conflict of interest criteria.

Require disclosure from petitioners

[11] IOM page 358

Another way to determine whether conflicts of interest exist would be to require petitioners to disclose financial relationships to Board members in their petition.

Require conflict of interest disclosure from TR contractors

While we urge the rejection of this PDS proposal, we do agree with Recommendation #6: "All technical reviews should disclose the names and address of all authors on the first page of the TR below the TR title."

Consumers Union supports this proposal and requests that the names of all researchers, consultants and sub-contractors who assisted with the TR's development be listed as well. We also request that TR authors be required to disclose any conflicts, and sign a Conflict of Interest statement. We suggest adding this language to the Update of Petition and Technical Review Process proposal.

Conclusion

Consumers Union urges the Board to reject the PDS proposal. The NOP and NOBS should collaborate on a clear and sound set of standards for determining conflict of interest. If the Board accepts the PDS proposal, it would adopt the conflict of interest criteria in the NOP Memo, which would redefine NOSB members as no longer acting in the interest of the organic community and upholding OFPA and organic integrity, but as "representatives" who should "articulate the viewpoints and interests of their particular interest group."

The development of conflict of interest standards should happen in a transparent and open manner, and should go through the NOSB and NOP rulemaking process allowing for adequate public participation. The integrity of this process depends on first defining "conflict of interest" (when a primary interest is unduly influenced by a secondary interest) and agreeing upon what constitutes the NOSB members' primary interest.

We are very concerned that this proposal would allow the NOP to redefine NOSB members' primary interest as "representatives" of a "particular interest group." NOSB members' primary interest must remain as it is written in the law: to assist and advise the Secretary on a law that seeks to "govern the marketing" of organic products and "assure consumers that organically produced products meet a consistent standard." Their primary interest should be to uphold the integrity of the organic label and to vote objectively and in accordance to OFPA criteria on materials petitions.

We urge the Board to develop sound conflict of interest standards, and to reject the PDS proposal which would bring this important discussion to an end by adopting the inadequate NOP standards which essentially could turn NOSB members from advisors into lobbyists.

Comments of Consumers Union To
The National Organic Standards Board
On
Handling Subcommittee
Proposal: Ammonium Hydroxide

Docket No. AMS-NOP-13-0049

October 1, 2013

Ms. Michelle Arsenault, Special Assistant
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Thank you for the opportunity to submit comments to the National Organic Standards Board on the Handling Subcommittee's proposal on ammonium hydroxide as a permitted boiler water additive.

These comments were prepared by Consumers Reports' Food Safety and Sustainability Center. Consumer Reports is the world's largest independent product-testing organization. Using its more than 50 labs, auto test center, and survey research center, the nonprofit rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 8 million subscribers to its magazine, Website and other publications. Its advocacy division, Consumers Union, works for health reform, food and product safety, financial reform, and other consumer issues in Washington, D.C., the states, and in the marketplace.

Summary

Consumers Union urges the Board to reject the petition to add ammonium hydroxide as a boiler water additive to the National List.

Ammonium hydroxide is a toxic synthetic substance that is hazardous to human health and the environment. It does not appear to be essential to organic handling, as numerous alternatives to preventing corrosion and "acid attack" exist; these alternatives have been used by organic processors for years.

We also disagree with each of the three arguments supporting the addition of ammonium hydroxide to the National List made by the petitioner in the Petition Justification Statement. The petitioner is not being forthright when arguing that ammonium hydroxide will replace the three volatile amines currently on the National List. The allowed synthetic volatile amines are restricted to use as a "boiler water additive for package sterilization." The FDA does not allow these three volatile amines for milk pasteurization. Ammonium hydroxide is petitioned for all boiler water additive uses, including milk pasteurization which would bring ammonium hydroxide in direct contact with organic milk.

We also disagree with the petitioner that adding ammonium hydroxide to the National List will "harmonize" US regulations, since the Pasteurized Milk Ordinance, FDA regulations for boiler water additives and USDA regulations all currently do **not** list ammonium hydroxide as an allowed water boiler additive. We also disagree that US regulations should be "uniform," since consumers expect the organic standards to go above and beyond all other US regulations regarding food safety and sustainability.

Finally, we disagree with the petitioner that ammonium hydroxide should be added to the National List because it is a "less unnatural" alternative to volatile amines. The petition is for the synthetic version, petitioned for addition to 205.605(b) - synthetics allowed. Since ammonium occurs in nature, as the petitioner points out, the NOSB must consider the natural version of ammonium hydroxide (ammonium hydroxide is simply "ammonia in water" or "ammoniated water") as a natural alternative to the synthetic version that is petitioned.

Evaluation criteria for inclusion on the National List

7 CFR 205.600(b)(1): "The substance cannot be produced from a natural source and there are no organic substitutes"

It appears that there are numerous alternatives to the use of ammonium hydroxide as a boiler water additive in organic processing. These are listed in the petition and currently used by processors.

7 CFR 205.600(b)(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"

The designation of ammonium hydroxide as a "hazardous substance" by the Environmental Protection Agency is based on the toxicity of the substance, especially to aquatic life.[12] The petitioner includes a statement[13] he made in 2001 that the TAP reviewers' determination that ammonium hydroxide is "toxic" should be "construed as 'personal opinions' rather than 'technical comments.'"

The Environmental Protection Agency (EPA) regulations list ammonium hydroxide in several places as a "hazardous substance." Under 40 CFR 302.4, regulations for the Comprehensive

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[12] Material Data Safety Sheet for Ammonium Hydroxide.

[13] Petition, page 10

Environmental Response, Compensation and Liability Act (CERCLA), ammonium hydroxide is included in the "list of hazardous substances and reportable quantities." Ammonium hydroxide also appears under 40 CFR 116, which designates hazardous materials under the Federal Water Pollution Control Act ("Clean Water Act").

Based on the EPA's designation of ammonium hydroxide as a "hazardous material," we disagree with the petitioner that the characterization of ammonium hydroxide as "toxic" is a matter of "personal opinion."

7 CFR 205.600(b)(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;"

The petitioner writes that the breakdown product of ammonium hydroxide, when used as a boiler water additive, is ammonium carbonate, which is non-toxic. But the organic regulations require not only the breakdown product, but the product itself, to not have an adverse effect on human health. The regulations also do not specify that the only humans of concern are consumers; "human health" includes the health of workers in the food industry as well.

When the product itself and its effects on the health of workers are considered, ammonium hydroxide fails the criterion under 205.600(b)(3). According to the Material Safety Data Sheet (MSDS) for WET-1133,[14] a boiler water additive made from ammonium hydroxide for use in dairy processing plants, the material is hazardous to human health:

- "Skin: Severe burns to skin. Flush skin with water for at least 15 minutes. If irritation persists, get medical attention."

- "Eyes: Severe burn to eyes. Immediate flush eyes with water for 15 minutes. Get medical attention immediately."

- "Inhalation: Remove to fresh air"

- "Ingestion: Do not induce vomiting. Dilute by giving large amount of water. Get immediate medical attention"

Please note that this MSDS was for ammonium hydroxide at concentrations that would be used in a dairy processing plant, rather than at high concentrations. Workers in organic dairy processing plants would be exposed to ammonium hydroxide at these levels - risking their health and safety to process organic foods. The MSDS for ammonium hydroxide includes many additional health effects, including "death."[15]

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[14] See Appendix E of the Ammonium Hydroxide petition

[15] Ammonium Hydroxide Material Safety Data Sheet.

The 2001 TAP review for ammonium hydroxide stated: "exposure to humans and other mammals by ammonium hydroxide is a serious toxicological concern."[16]

7 CFR 205.600(b)(6): The substance is essential for the handling of organically produced agricultural products.

Handlers processing organic products have managed without the use of ammonium hydroxide for years. Processors in certain areas of the country do not encounter "acid attack" or corrosion in the condensate lines, since the hardness of the water supply is not a problem. Other processors use water softeners, reverse osmosis or management practices that make the use of ammonium hydroxide in organic processing unnecessary and therefore not essential to organic handling.

Petition Justification Statement

We disagree with each of the three arguments presented in the Petition Justification Statement.

1. Ammonium Hydroxide is not a replacement for volatile amines

The petitioner states that the approval of ammonium hydroxide would "permit avoidance of synthetic volatile amines by concerned processors." The petitioner suggests that the allowance of ammonium hydroxide would replace three synthetic volatile amines, cyclohexylamine, diethylaminoethanol and octadecylamine, which are currently on the National List.

First, the petitioner states on page 12 of the petition: "the Organic regulation currently allows use of cyclohexylamine, diethylaminoethanol and octadecylamine as boiler water additives and thus in culinary steam." **This is incorrect.** The use of the three volatile amines in organics is restricted through an annotation - they are permitted only "as a boiler water additive for package sterilization," and therefore their broad use in culinary steam is prohibited. The use of these three volatile amines is also prohibited in milk pasteurization by FDA regulations. The suggested annotation for ammonium hydroxide is "as a boiler water additive," which would include uses involving culinary steam and milk pasteurization.

The petitioner writes: "Ammonium hydroxide passes into steam as ammonia to neutralize carbon dioxide in steam, forming ammonium carbonate when the steam condenses to water and preventing "acid attack." We disagree. It is not certain that all the ammonium hydroxide immediately forms ammonium carbonate and that no ammonium hydroxide remains. There are also other substances in boiler water, other than carbon dioxide, which the ammonium hydroxide may react with. Since we do not know how ammonium hydroxide reacts with these other materials, we cannot assume that the only byproduct is ammonium carbonate or that no ammonium hydroxide remains.

Second, the addition of ammonium hydroxide to the National List would not be accompanied by an automatic removal of the three volatile amines from the National List. Petitions to remove and

[16] TAP 2001 Ammonium Hydroxide. Page 5

add materials to the National List are not *quid pro quo* deals. When a material is added to the National List, another does not automatically come off.

And with the recent change to the Sunset Provision process, which has made the removal of a material from the National List more difficult, we caution the Board against approving a new material based on the assumption that it will lead to the removal of materials that are already on the National List. It is important again to note that the petitioner requests the use of ammonium hydroxide for all boiler water uses. The petitioner uses the inclusion of the three volatile amines on the National List as a justification for adding ammonium hydroxide, but proposes listing ammonium hydroxide for uses that go beyond those of the three volatile amines.

2. Allowing ammonium hydroxide would not "harmonize" various regulations

The petitioner also includes "create consistency and uniformity with other US regulations" in the Petition Justification Statement. The petitioner writes: "Allowing ammonium hydroxide as a boiler water additive will begin to harmonize the Organic regulation with FDA, PMO, and USDA regulations." We disagree both with the accuracy of the statement as well as with the intent.

First, there already exists considerable inconsistency among the Pasteurizing Milk Ordinance (PMO), FDA and USDA regulations regarding the use of ammonium hydroxide as a boiler water additive. Adding ammonium hydroxide to the National List will make the inconsistency worse, by allowing a synthetic in organics that is not allowed in conventional dairy processing according to several US regulations.

A review of various regulations reveals the existing inconsistency:

- FDA regulations list ammonium hydroxide as a "direct food substance affirmed as generally recognized as safe." 21 CFR 184.1139 lists ammonium hydroxide and includes, "as a boiler water additive complying with §173.310 of this chapter." But §173.310 does **not** list ammonium hydroxide among a list of permitted boiler water additives.

- The petitioner writes that "The Pasteurized Milk Ordinance (PMO) requires that in culinary steam 'only compounds complying with 21 CFR 173.310 may be used to prevent corrosion and scale in boilers, or to facilitate sludge removal.'" What the petitioner fails to mention is that 21 CFR 173.310 does **not** list ammonium hydroxide as a permitted boiler water additives.

- USDA regulations for "General Specifications for Dairy Plants Approved for USDA Inspection and Grading Service" state at 7 CFR 58.127(d) that "Culinary steam used in direct contact with milk or dairy products shall be free from harmful substances or extraneous material and **only those boiler water additives that meet the requirements of 21 CFR 173.310 shall be used** (emphasis added)." Again, the petitioner fails to mention that ammonium hydroxide is not listed under 21 CFR 173.310 as a permitted water boiler additive, and 21 CFR 173.310 does not mention that additives other than those listed are allowed.

The various regulations are therefore far from uniform, and even suggest that ammonium hydroxide is currently not allowed in conventional processing either. Adding ammonium hydroxide to the National List would do little to create uniformity; in fact, it would worsen the inconsistency by allowing in organic dairy processing a material that several US standards prohibit even in conventional dairy processing

Second, we disagree that uniformity in US regulations is a goal that the organic regulations should address. In fact, we firmly believe the opposite: the organic regulations should go above and beyond all other US food-related regulations in terms of assuring safety and sustainability. In fact, we would argue that the organic regulations should strive to continue providing an alternative to the regulations that address the conventional food supply, and inconsistency in the regulations is a therefore an expected and desirable byproduct of strong organic standards.

If organic regulations are uniform with "other US regulations," as the petitioner suggests, then organics will no longer be the alternative for consumers who seek stronger oversight and higher standards for the foods they purchase.

3. Ammonium Hydroxide is not "less unnatural"

The petitioner also suggests that ammonium hydroxide is "less unnatural." The petitioner writes in the third section of the Petition Justification Statement: "Unlike these three volatile amines, the ammonium ion is found in nature." Ammonium is indeed found in nature, as is arsenic, mercury and formaldehyde. Moreover, the petition is for *synthetic* ammonium hydroxide to be added to §205.605(b) - synthetics allowed. Ammonium hydroxide is produced commercially in ways that render it a synthetic, using natural gas as a fuel source.[17]

And if ammonium is found in nature, then the answer to the question in the NOSB Evaluation Criteria checklist, "Section 2, question 5. Is there a natural source of the substance? [§ 205.600(b)(1)]" should be "yes." If a natural alternative exists, and organic processors wish to use ammonium hydroxide, they should be encouraged to explore natural versions of ammonium hydroxide.

Petitioner's Reliance on GRAS

The petitioner also relies heavily, throughout the petition, on the GRAS status of ammonium hydroxide to bolster the argument that ammonium hydroxide is safe and "not toxic." We have several concerns with this approach.

First, it should be well-accepted by now within the organic community that the FDA GRAS system is broken. The Pew Health Group analyzed the FDA GRAS system, and concluded: "Overall, FDA's changes have moved away from public scrutiny and, in the case of its voluntary GRAS notification program, away from independent safety review by the agency." The Pew researchers found that more than half of an estimated 6204 affirmative safety decisions were made not by the FDA or the EPA, but rather by the manufacturer of the substance. Of these

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[17] TAP 2001 Ammonium Hydroxide. Page 5

roughly 3000 self-determined "safety" determinations, an estimated 1000 decisions are never even reported to the FDA or the public.[18]

Extensive media coverage of the FDA's broken system presumably brings consumers to organics as an alternative to the conventional food system, where every non-organic or synthetic food additive *is* reviewed for safety. We caution the NOSB against using a material's GRAS status in their safety determination - GRAS status means little, if anything, and consumers rely on the NOSB to perform its own careful safety review.

Potential PR Disaster for Organics - "Organic Pink Slime?"

As pointed out in the petition, ammonium hydroxide and ammonia gas is used in the conventional beef processing industry to make "lean finely textured beef," which became known in the popular press as "pink slime." Pink slime has been overwhelmingly rejected by consumers. An online petition against the use of "pink slime" in school lunches gathered more than a quarter million signatures.

Yet to convince the NOSB of the safety of ammonium hydroxide and "pink slime," the petitioner cited only one source: the website of a non-profit advocacy group that has since taken the article off its website. The petitioner provided no other evidence that either pink slime is safe or that it is accepted by consumers.

Imagine if synthetic ammonium hydroxide - the same substance used to treat pink slime - suddenly becomes allowed in organic milk processing. Imagine a material with a Material Safety Data Sheet urging workers to avoid contact with skin and eyes because it will cause "severe burns to skin" and "severe burns to eyes" - allowed in organic milk processing?

Conclusion

Ammonium hydroxide fails all criteria for inclusion on the National List. We urge the NOSB to reject the petition for ammonium hydroxide.

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[18] Neltner, T. G., Kulkarni, N. R., Alger, H. M., Maffini, M. V., Bongard, E. D., Fortin, N. D. and Olson, E. D. (2011) Navigating the U.S. Food Additive Regulatory Program. *Comprehensive Reviews in Food Science and Food Safety* 10: 342–368

Comments of Consumers Union To
The National Organic Standards Board
On
Handling Subcommittee
Proposal: Glycerin

Docket No. AMS-NOP-13-0049

October 1, 2013

Ms. Michelle Arsenault, Special Assistant
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Thank you for the opportunity to submit comments to the National Organic Standards Board on the Handling Subcommittee's proposal on removing glycerin from the National List.

These comments were prepared by Consumers Reports' Food Safety and Sustainability Center. Consumer Reports is the world's largest independent product-testing organization. Using its more than 50 labs, auto test center, and survey research center, the nonprofit rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 8 million subscribers to its magazine, Website and other publications. Its advocacy division, Consumers Union, works for health reform, food and product safety, financial reform, and other consumer issues in Washington, D.C., the states, and in the marketplace.

Consumers Union supports the petition to remove glycerin from the National List 205.605(b).

When companies develop organic alternatives to the non-organic or synthetic materials on the National List, their commitment to developing organic versions should be rewarded with a removal of the material from the National List.

Removal from the National List will send a positive message to the industry and will provide an incentive to continue innovation and development of organic alternatives.

We are pleased to see that the Handling Subcommittee has voted unanimously to support the removal of glycerin from the National List, and urge the full Board to accept the petition for removal.

Consumers Union
Nonprofit Publisher of Consumer Reports

Comments of Consumers Union To
The National Organic Standards Board
On
Handling Subcommittee
Sunset Review: Gellan Gum

Docket No. AMS-NOP-13-0049

October 1, 2013

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Thank you for the opportunity to submit comments to the National Organic Standards Board on the Handling Subcommittee's request for comments on gellan gum, which is up for sunset review.

These comments were prepared by Consumers Reports' Food Safety and Sustainability Center. Consumer Reports is the world's largest independent product-testing organization. Using its more than 50 labs, auto test center, and survey research center, the nonprofit rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 8 million subscribers to its magazine, Website and other publications. Its advocacy division, Consumers Union, works for health reform, food and product safety, financial reform, and other consumer issues in Washington, D.C., the states, and in the marketplace.

Summary

Consumers Union is concerned with the possible use of excluded methods and "other ingredients" to manufacture the ingredient gellan gum, and urges careful review by the Board to ensure that the gellan gum currently used in organic foods is fully compliant with all requirements in the organic law and regulations. If excluded methods are found to be used anywhere in the process, we would oppose relisting gellan gum.

Background

Gellan gum is produced by microbial fermentation of *Sphingomonas elodea*, which was discovered by a Merck scientist in 1977.[19] Merck deposited the new species with the American Type Culture Collection in November 1978, and it was given Accession No. 31461. It is now known in the scientific literature as *Sphingomonas paucimobilis* ATCC 31461. The microorganism was patented in 1982[20] by Merck, which developed gellan gum commercially under its CP Kelco division. It was first used in food in Japan in 1988.[21]

Merck sold CP Kelco to Monsanto in 1995, which in turn sold the company in 2000 to its current owner, Huber Company.

CP Kelco petitioned gellan gum for inclusion on the National List in 2004. A Technical Review (TR) was developed by ICF International and submitted to the NOSB in February 2006.

In CP Kelco's petition, the entire section 5, "Sources and Detailed Description of Manufacturing Procedures" is redacted as Confidential Business Information (CBI). The TR provided little information regarding the manufacturing process, and provided no information regarding processing aids other than the mention of isopropyl alcohol as a solvent. It appears the Board did not have any of this information prior to their two votes on gellan gum. The first vote, at the March 2007 NOSB meeting, resulted in the rejection of the petition.[22]

CP Kelco then enlisted the services of William J. Friedman of the law firm Covington and Burling in an apparent attempt reverse the decision. Friedman wrote a letter on April 19, 2007 to the National Organic Program on behalf of CP Kelco, attempting to convince the NOP that a 6-4 with one abstention was a supermajority and that the motion passed. He wrote a second letter in May 2007 to request a "stay of final determination on Gellan Gum pending reconsideration by NOSB." Friedman argued that "The result of the vote strongly suggests board members may have voted under the misperception that a negative vote was a vote to evaluate whether the material was properly classified by the petitioner, the TAP reviewers and the handling committee." Friedman then suggested that "the NOP exercise its authority under 7 USC 6517 to stay the final disposition on the petition on gellan gum pending a reconsideration by the NOSB at its next meeting."

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[19] ATCC 31461. Available online at http://www.atcc.org/products/all/31461.aspx. Last accessed on September 25, 2013.

[20] Food Polysacchardes and their applications. edited by Alistair M. Stephen, Glyn O. Phillips and Peter Williams. CRC Press, Taylor and Francis Group. Published in 2006. Chapter "Bacterial Polysaccharides by VJ Morris. page 424.

[21] Food Polysacchardes and their applications. edited by Alistair M. Stephen, Glyn O. Phillips and Peter Williams. CRC Press, Taylor and Francis Group. Published in 2006. Chapter "Bacterial Polysaccharides by VJ Morris. page 424.

[22] NOSB Transcript Spring 2007 Day 3 page 292.

It is clear from the transcript that there was no confusion - the four board members who voted against gellan gum would not have been confused, as Friedman suggested to the NOP. Prior to the vote, the Board Chair stated: "Can you restate the motion, Julie, at this point?" Board member Ms. Weisman then stated: "The motion is for the listing of gellan gum on 205.605B."

Yet the NOP agreed with Friedman and put Gellan Gum back on the agenda for the Fall 2007 meeting for reconsideration. The Board voted 13-2 to reconsider the motion and then voted 15-0 to list Gellan Gum on the National List.

Concerns

1. Other ingredients and processing aids

The 2006 TR mentions only one processing aid - isopropyl alcohol - and no other ingredients or processing aids.

Several articles in the scientific literature mention experimentation with various processing aids to optimize gellan gum production. One article discusses the use of various nonionic surfactants to optimize gellan gum production from the bacterial cultures. The study found "Triton X-100" to maximize gellan yield.[23] Triton X-100 (CAS # 9002-93-1) is a surfactant trademarked by Dow Chemical Company and it is also known as 4-(1,1,3,3-Tetramethylbutyl)phenyl-polyethylene glycol or Polyethylene glycol tert-octylphenyl ether.

Since OFPA prohibits such ingredients and processing aids in organic food production, but the current *modus operandi* has been to allow any ingredient or processing aid in the production of materials on the National List, we urge the NOSB to address this issue. We believe the possible use of "Triton X-100" is a perfect example of why the NOSB and NOP should clarify to certifiers that OFPA criteria apply to all ingredients, and that "ingredients of ingredients" are not exempt.

2. Excluded methods

The 2006 TR by ICF International never addresses the question of excluded methods. Two issues must be considered: the use of excluded methods to "improve" the productivity of the bacterium, and the use of genetically engineered crops in the fermentation media, which includes corn steep liquor.

A. Excluded methods to "improve" the productivity of the bacterium

It is likely that scientists are using excluded methods to "improve" the productivity of the bacterium in an effort to increase gellan gum yields. It is unclear whether genetically engineered varieties are used for commercial gellan gum production, but several articles in scientific journals

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[23] Arockiasamy S and Banik RM (2008) Optimization of gellan gum production by Sphingomonas paucimobilis ATCC 31461 with nonionic surfactants using central composite design. Journal of Bioscience and Bioengineering 105(3): 204-10. Available online: http://www.ncbi.nlm.nih.gov/pubmed/18397769.

suggest that the Board should consider the possibility and ensure that gellan gum from non-GE strains remains available.

Excerpts from a 2000 study published in the journal *Applied and Environmental Microbiology*[24] are worth quoting in their entirety, as it suggests that scientists were actively seeking to use excluded methods, including recombinant DNA technology, to "improve" the bacterium used for commercial gellan gum production:

"The industrial strain Sphingomonas paucimobilis ATCC 31461 (formerly Pseudomonas elodea) synthesizes in high yields from different carbon sources and from cheese whey a new gelling agent, gellan gum. The commercial utility of gellan has been a stimulus for the study of its biosynthesis.

The cloning and functional analysis of genes essential for gellan synthesis are indispensable in attempting the genetic and environmental manipulation of its biosynthetic pathway in order to develop new polysaccharides with distinct structural and physical properties.

The objective of the present work was to identify the PGM gene from S. paucimobilis ATCC 31461 (pgmG gene) to be used as a target in the metabolic engineering of the gellan pathway.

The next step in this work will be the characterization of gellan gum biosynthesis after pgmG disruption in S. paucimobilis ATCC 31461, whether the gene is nonessential and the respective deletion mutant can be obtained, or in recombinant strains in which the expression of this gene is increased."

A 2002 study in the *Journal of Industrial Microbiology and Biotechnology* states: "Many Gram-negative bacteria synthesize and excrete extracellular polysaccharides (EPS), which may have diverse biological roles, as virulence factors in plant and animal pathogens, signalling molecules in bacteria-plant interaction and contributing to cell protection from environmental aggression. **Some of these EPS are potential or accepted products of biotechnology. This is the case of the commercial gelling agent gellan, produced by large-scale submerged fermentation of Sphingomonas paucimobilis ATCC 31461** with a typical yield of gellan from glucose of 40-50%. It has approval in the US and EU for food use as a gelling, stabilizing and suspending agent, either alone or in combination with other hydrocolloids"(emphasis added).[25]

A 2007 article in the journal *Food Technology and Biotechnology* states: "The most exciting prospects for gellan modification and increasing production yield are found in genetic engineering" but the article also suggests that "a better knowledge of the poorly understood steps

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[24] Videira PA, Cortes LL et al (2000) Identification of the pgmG Gene, Encoding a bifunctional protein with phosphoglucomutase and phosphomannomutase activities, in the gellan gum-producing strain Sphingomonas paucimobilis ATCC 31461. *Applied Environmental Microbiology* 66(5)" 2252-2258 Available online: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC101485/. Last accessed on September 25, 2013.

[25] Sa-Correia I, Fialho AM, Videira P et al (2002) Gellan gum biosynthesis in Sphingomonas paucimobilis ATCC 31461: Genes, enzymes and exopolysaccharide production engineering. *Journal of Industrial Microbiology and Biotechnology* 29:170-179.

and of the regulations and bottlenecks of the pathway is crucial for the eventual success of the metabolic engineering of gellan production."[26]

A 2011 study in the *Journal of Applied Microbiology* found VHb gene expression led to "enhanced cell growth" of the Sphingomonas elodea bacterium and a 20% improvement in gellan production.[27] What is VHb? Another study, in the *Journal of Biological Chemistry,* explains: "It has been demonstrated through genetic engineering that the intracellular expression of VHb in various heterologous hosts often results in the enhancement of cell density, oxidative metabolism, engineered product formation, and bioremediation, especially under oxygen-limiting conditions."[28]

B. Excluded methods in the fermentation process

According to the 1982 patent for the bacterium *Sphingomonas elodea*, the organism is fermented in a medium containing "the usual media," which may include: "corn steep liquor, glucose, fructose, maltose, soybean meal, cottonseed flour."[29] In commercial production today, these fermentation media would likely be sourced from organisms produced using excluded methods.

A more recent discussion of the fermentation media in the journal *Applied Environmental Microbiology* states:

"According to previous studies, *S. paucimobilis* ATCC 31461 can utilize glucose as well as other carbon sources, including corn syrup, lactose, and cheese whey, to synthesize gellan gum, while mutant strains of *S. paucimobilis* ATCC 31461 can utilize glucose, corn syrup, and soybean pomace to produce gellan gum. Organic nitrogen sources, such as urea, peptone, and soybean pomace, and inorganic nitrogen sources, such as NaNO3, NH4NO3, and NH4Cl, also support gellan gum production by *S. paucimobilis*."[30]

We urge the NOSB to verify that gellan gum currently used in organic foods is fermented in non-GE media, and that such non-GE sources of gellan gum are available, before relisting the material on the National List.

3. Human Health and Safety

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[26] Bajaj IB, Survase SA, Saudagar PS et al (2007) Gellan Gum: Fermentative Production, Downstream Processing and Applications. Food Technology and Biotechnology 45(5): 341-354.

[27] Wu, X.C., Chen, Y.M., Li, Y.D., Li, O., Zhu, L., Qian, C.D., Tao, X.L. and Teng, Y. (2011) Constitutive expression of *Vitreoscilla* haemoglobin in *Sphingomonas elodea* to improve gellan gum production. *Journal of Applied Microbiology* 110: 422–430.

[28] Ramandeep, Hwang KW, Raje M et al (2001) Vitreoscilla Hemoglobin intracellular localization and binding to membranes. *The Journal of Biological Chemistry* 276: 24781-24789. Available online: http://www.jbc.org/content/276/27/24781.abstract

[29] US Patent 4,326,053

[30] Wang X, Ping X, Yuan Y et al 2006 Modeling for gellan gum production by Sphingomonas paucimobilis ATCC 31461 in a simplified medium. Applied Environmental Microbiology 75(2): 3367-3374.

The 2006 TR lists only one study for safety and tolerance with humans, and it had 5 male and 5 female volunteers. The study found changes in fecal bile acid from consumption of gellan gum.[31] The scientific literature to date shows that only one tolerance study with humans has been conducted. We are concerned that only one human tolerance study has been conducted for a food ingredient that is entirely new to the human food system, from a fermented bacterium that was only recently discovered.

Animal studies support the need for further research and testing. In the World Health Organization/Food and Agriculture Organization Joint Expert Committee on Food Additives (JECFA) review in 1990, the following excerpts are worth noting:

- Male and female Sprague-Dawley rats (20/sex/group) were fed dietary levels of Gellan Gum ranging from 0-6% for 13 weeks. Although the **animals on this study experienced symptoms of a sialodacryoadenitis viral infection**, all animals survived treatment and there were no adverse effects associated with the feeding of gellan gum (emphasis added).[32]

- Survival of male treated rats was poor when compared to controls whereas female treated rats exhibited better survival than their concurrent controls."[33]

These animal studies were not made readily available to the NOSB in 2007. The 2006 TR did not review any animal safety studies, and the NOSB did not discuss any safety concerns during the Spring or Fall 2007 meeting.

We encourage the NOSB to practice the Precautionary Principle and demand more safety and tolerance studies before allowing a material on the National List. In the case of gellan gum, which has been listed, we urge removal of the material until more data is available.

Conflict of interest

We identified gellan gum as an ingredient in organic almond milk by Whole Foods Market's 365 brand. We believe Board member Joe Dickson, who is an employee of Whole Foods Market, should declare his conflict of interest and recuse himself.

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[31] World Health Organization and Food and Agriculture Organization Joint Expert Committee on Food Additives. 1990 Review of Gellan Gum. Available online at http://www.inchem.org/documents/jecfa/jecmono/v28je17.htm. Last accessed on September 21, 2013.

[32] ibid

[33] http://www.inchem.org/documents/jecfa/jecmono/v28je17.htm. Section (2.2.3.2)

Consumers Union
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Comments of Consumers Union To
The National Organic Standards Board
On
Handling Subcommittee
Discussion Document: PGME

Docket No. AMS-NOP-13-0049

October 1, 2013

Ms. Michelle Arsenault, Special Assistant
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave, SW.
Washington, DC 20250

Thank you for the opportunity to submit comments to the National Organic Standards Board on the Handling Subcommittee's discussion document on PGME.

These comments were prepared by Consumers Reports' Food Safety and Sustainability Center. Consumer Reports is the world's largest independent product-testing organization. Using its more than 50 labs, auto test center, and survey research center, the nonprofit rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 8 million subscribers to its magazine, Website and other publications. Its advocacy division, Consumers Union, works for health reform, food and product safety, financial reform, and other consumer issues in Washington, D.C., the states, and in the marketplace.

The Handling Subcommittee requests feedback from the public on whether to remove PGME from the agenda. The Handling Subcommittee is considering sending a request to the NOP to notify the petitioner that PGME is not eligible for petition to 205.605(b) because it is not used in direct contact with organic foods.

Consumers Union believes that PGME needs to be petitioned, reviewed and approved before it can be allowed in organic feed production. According to the Technical Evaluation Report (TR), PGME is synthesized from butanol, propylene oxide and ethylene oxide. It is a synthetic made from toxic starting materials, and should be prohibited in organic production unless added to the National List.

We disagree with the Handling Subcommittee's suggestion that it should be removed from the agenda because "when used as a boiler additive, PGME is not required to be on the National List

because it has no contact with organic products." Organic certification is systems-based, and all synthetic inputs used in the process, from field to fork, regardless of "contact with organic products" or residues in the final product, must be approved for use.

We agree with the Handling Subcommittee that PGME may not be appropriate for 205.605, but suggest that the petitioner be instructed to petition PGME for 605.603 - "Synthetic substances allowed for use in organic livestock production," since it would be used as a boiler water additive only for the production of livestock feed. It may be necessary to create a new subsection under 603, since currently no category exists for "feed processing aids."

Comments of Consumers Union To
The National Organic Standards Board
Handling Subcommittee
Sunset Review: Tragacanth Gum

Docket No. AMS-NOP-13-0049

October 1, 2013

Ms. Michelle Arsenault, Special Assistant
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1400 Independence Ave, SW.
Washington, DC 20250

Thank you for the opportunity to submit comments to the National Organic Standards Board on the Handling Subcommittee's request for comments on tragacanth gum, which is up for sunset review.

These comments were prepared by Consumers Reports' Food Safety and Sustainability Center. Consumer Reports is the world's largest independent product-testing organization. Using its more than 50 labs, auto test center, and survey research center, the nonprofit rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 8 million subscribers to its magazine, Website and other publications. Its advocacy division, Consumers Union, works for health reform, food and product safety, financial reform, and other consumer issues in Washington, D.C., the states, and in the marketplace.

Summary

Consumers Union supports the sunset of tragacanth gum. Under the new sunset policy, we urge the Handling Subcommittee to draft a proposal to remove tragacanth gum from the National List.

In the original petition to add tragacanth gum to the National List, the petitioner wrote that tragacanth gum and gum arabic are nearly identical. An organic version of gum arabic is now available. We support the development of organic alternatives to materials on the National List, and the removal of tragacanth from the National would reward and further encourage the development of organic alternatives.

Background

Tragacanth gum is a gum made from small shrubs that grow in the highlands and deserts of the Middle East. The majority of tragacanth gum on the world market is exported by Iran, which supplies the highest quality gum. Turkey is the second largest producer, followed by Afghanistan and Syria (as of 2003).[34]

Consumers Union supports sunset of tragacanth gum

While an organic version of tragacanth gum has not been developed, there has been an organic version of a gum that is very similar to tragacanth: gum arabic. In the original petition to add tragacanth to the National List, the petitioner wrote: "One of the attached abstracts is from *Applied Microbiology and Biotechnology* which clearly states that from growth, to harvesting, to processing, to functionality, the two gums (Arabic and Tragacanth) are almost the same."[35]

At least one supplier of organic gum arabic has been identified: TIC Gums.[36] The Sunset provision in OFPA aims to encourage suppliers to develop organic versions, especially of materials on 606. Since the petitioner of tragacanth stated that tragacanth and arabic are "almost the same," including in "functionality," we urge the NOSB to remove tragacanth from 606 and thereby reward the development of certified organic gum arabic.

Human Health Concerns

Since no TR was performed for this material (which is not unusual for 606 materials), we would like to share some of the concerns that we identified in the scientific literature regarding tragacanth gum.

Allergies: Several articles, as well as the World Health Organization/Food and Agriculture Organization Joint Expert Committee on Food Additives, raise the concern that tragacanth may trigger severe allergic reactions in sensitive individuals.[37] While we do not believe that allergenicity in itself is a reason to prohibit an agricultural product from organic products - we certainly wouldn't want to see a prohibition against organic peanut butter because some individuals are allergic to peanuts - we do believe that the Board should consider the

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[34] Verbeken D, Dierckx S and Dewettinck K (2003) Exudate gums: occurrence, production and applications. *Applied Microbiology and Biotechnology* 63: 10-21

[35] Petition to add Tragacanth Gum to the National List. August 31, 2007.

[36] Available from TIC Gums. See online: http://www.ticgums.com/products.html?page=shop.product_details&flypage=flypage.tpl&product_id=128&category_id=40

[37] Gelfand 1943 in JECFA Food Additives Series No. 5 (1973). Available online at: http://www.inchem.org/documents/jecfa/jecmono/v05je59.htm

appropriateness of including obscure ingredients that some people may not be aware they are allergic to.[38]

Toxicological Safety Concerns: An article in *Applied Microbiology and Biotechnology* mentioned that the supply of tragacanth gum has dwindled over the years, citing "serious doubts about the toxicological safety of the gum, which led to concerns about its use in the food industry" as one of the reasons.[39]

We located the articles that raised these concerns. In a mice study, the scientists found: "Single or small numbers of tiny nodules were observed on the luminal surface of the forestomach in 4 males of the 5.0% group, 2 males of the 2.5% group, and 1 male each from the 1.25 and 0.625% groups. Histopathologically, they were diagnosed as squamous-cell hyperplasia."

In a follow up study, squamous-cell hyperplasias in 2 out of 10 mice found at 24 weeks had disappeared by 48 weeks. The scientists concluded that "the oral toxicity of tragacanth gum to B6C3F1 mice [was] negligible."[40] Unfortunately, no other scientists appear to have followed up on these initial findings.

Another study which administered tragacanth gum at dietary levels of 0%, 1.25% and 5% in B6C3F1 mice found that the mean body weights of females in the 5% and 1.25% groups were lower than those controls after 11 and 16 weeks, respectively. A detailed histopathology revealed the development of squamous cell hyperplasias, papillomas and one carcinoma in the forestomach. The scientists performing this study were the same that performed the previous study, and they did not follow up on this study either, nor did other teams of scientists.[41]

We bring these studies to your attention but urge the Board to sunset tragacanth for the reason that an organic alternative with similar functionalities - certified organic gum arabic - now exists.

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[38] Taylor SL and Hefle SL (2001) Ingredient and labeling issues associated with allergenic foods. *Allergy* 56(67): 64-9.

[39] Verbeken D, Dierckx S and Dewettinck K (2003) Exudate gums: occurrence, production and applications. *Applied Microbiology and Biotechnology* 63: 10-21. Page 15

[40] Hagiwara A, Tanaka H, Tiwawech D et al (1991) Oral toxicity study of tragacanth gum in B6C3F1 mice: development of squamous-cell hyperplasia in the forestomach and its reversibility. *Journal of Toxicology and Environmental Health* 34(2): 207-18.

[41] Hagiwara A, Boonyaphiphat P, Kawabe M et al (1992) Lack of carcinogenicity of tragacanth gum in B6C3F1 mice. *Food and Chemical Toxicology* 30(8): 673-9.

Consumers Union
Nonprofit Publisher of Consumer Reports

Comments of Consumers Union To
The National Organic Standards Board
On
Sunset

Docket No. AMS-NOP-13-0049

October 1, 2013

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Consumers Union wishes to comment on the recent decision by the USDA to change the process for relisting materials on the National List (Sunset). No public comment period was provided for the changes to this policy, which had been in place since 2005. We object to both the process and the substance of the policy change.

Under OFPA and prior to the NOP's September 16, 2013 announcement, there was a controlled process for listing materials on the National List. Otherwise prohibited materials received exemptions for a five-year period, in order to encourage the development of natural (or organic) alternatives. The exemptions were required by law to expire, known as "sunset," unless they were reinstated by a two-thirds "decisive" majority vote of the National Organic Standards Board (NOSB) and include a public review. This is no longer the case.

In light of this recent policy change, we urge extra caution by NOSB members during materials review. Any material approved for listing on the National List is much more likely to remain on the National List in perpetuity, since the new policy requires a two-third vote to remove, rather than a two-thirds vote to relist, and only after the Subcommittee votes to propose a removal.

We are especially concerned that the NOP's new policy charges subcommittees with the task of proposing to remove a material from the National List. If a subcommittee decides not to propose a material's removal, the full NOSB does not have the opportunity to vote during the sunset process. Had oxytetracycline been a sunset vote (rather than a petition to extend an expiration date), this means that the full Board would not have voted on its removal, since the Crops Subcommittee voted by a one-vote margin against the immediate phase-out of oxytetracycline. Any time a Subcommittee determines that the material should be relisted, there will be no proposal to remove and therefore no opportunity for the full Board to review and vote.

We believe that the USDA's decision minimizes all incentives for creating organic, natural alternative ingredients and lowers the standard for what consumers can expect behind the organic label. Allowing the USDA to automatically relist materials without the recommendation of the NOSB erodes the Board's legal authority over materials decisions, a key to consumer trust in the organic label. The fact that the agency made this decision without any public input only adds to the violation felt by watchdog groups and consumers alike.

Potentially allowing an indefinite listing of non-natural ingredients and requiring a super-majority vote to retire a substance after five years undermines the spirit of the law for how materials head into "sunset" or retirement. It is unfair to producers trying to produce a truly organic product and it is unfair to consumers trying to make meaningful purchasing decisions. Simply put, this lowers the bar for much of the organic market. We believe the USDA must reverse course and we intend to mount a fierce campaign to hold the agency accountable to the millions of Americans who expect more from the government—and the organic label.