



BEYOND PESTICIDES

701 E Street, SE ■ Washington DC 20003
202-543-5450 phone ■ 202-543-4791 fax
info@beyondpesticides.org ■ www.beyondpesticides.org

October 12, 2016

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave., SW
Room 2648-S, Mail Stop 0268
Washington, DC 20250-0268

Re. HS: Xanthan gum

These comments to the National Organic Standards Board (NOSB) on its Fall 2016 agenda are submitted on behalf of Beyond Pesticides. Founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, Beyond Pesticides advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and the world.

These comments address the decision, captured in the notes of the Handling Subcommittee (HS) and based on a National Organic Program (NOP) recommendation, to provide a “written update” on the issue of the reclassification of xanthan gum, rather than including it on the NOSB Fall 2016 agenda for public discussion and vote.

Although these comments focus on Board process and not the substantive issues, we agree with the subcommittee determination.

The reasons for the HS determination that xanthan gum is synthetic are not given in the HS notes. However, the notes do state that its decision is based on the Technical Review (TR). The TR states that several synthetic nutrients are used in the fermentation process, and the xanthan gum is recovered with precipitation with isopropyl alcohol, which can remain in the final product at a concentration of up to 750 parts per million. We agree that this presence of isopropyl alcohol should result in a classification of synthetic.

We also believe that the NOSB should undertake guidance on products of fermentation that would spell out the allowable and prohibited methods of production of substances used in organic production and handling.

Xanthan gum is produced by fermentation of crop pathogenic bacteria in a complex nutrient broth, extracted by a difficult process involving a number of synthetic solvents. Effluents from

manufacture are unknown, as are ancillary substances. Xanthan gum can cause respiratory symptoms in workers; necrotizing enterocolitis in infants; allergies, depending on source of fermentation medium; and intestinal distress, including bloating and diarrhea, in consumers.¹

Xanthan gum is a good example of the need for guidance regarding the classification and acceptability of products of fermentation. Xanthan is the product of fermentation that uses a plant pathogenic organism. The fermentation medium is a complex chemical mixture, and the recovery of xanthan gum from the fermentation broth is a difficult and expensive process that depends on a number of synthetic solvents:

The main steps of the recovery process are deactivation and removal (or lysis) of the microbial cells, precipitation of the biopolymer, dewatering, drying, and milling. Processing must be done without degrading the biopolymer. The final product is usually a dry powder or a concentrated solution. Numerous methods have been developed to deactivate, lyse, or remove cells from the broth. Treatment with chemicals (e.g. alkali, hypochlorite, enzymes), by mechanical means, and thermal treatment are used. Chemical treatment at elevated pH can cause depyruvylation of the product. When enzymes are used, they must be removed from the medium and this adds to costs. Usually, the fermentation broth is pasteurized or sterilized to kill the cells. These thermal treatments also enhance xanthan removal from the cells. Pasteurization of the fermentation broth at a high temperature often causes thermal degradation of the microbial exopolysaccharides. When the broth is treated under proper conditions (80±130°C, 10±20 min, pH 6.3±6.9) enhanced xanthan dissolution occurs without thermal degradation and disruption of cells is observed. The increased temperature also reduces the viscosity of the broth to ease removal of the insolubles by centrifugation or filtration.

For highly viscous xanthan broths, viscosity reduction must precede filtration. Viscosity is reduced by dilution or heating. The fermentation broth is usually diluted in water, alcohol, or mixtures of alcohol and salts in quantities lower than those needed for xanthan precipitation. The diluted and/or heated broth is filtered to remove the solids. Filtration is improved in presence of alcohol.

Xanthan in solution can be viewed as a hydrophilic colloid forming a true solution in water. Precipitation of polymer is achieved by decreasing the solubility of the dissolved colloid using methods such as addition of salts, water-miscible non-solvents, and concentration by evaporation. Recovery options that have been studied include precipitation with organic solvent such as ethanol and isopropyl alcohol (IPA); the use of mixtures of salts and alcohol; and precipitation with trivalent or tetravalent salts. Also, the use of ultrafiltration has been reported. The most common technique used for the primary isolation and purification of polysaccharides is precipitation using water miscible non-solvents such as alcohols. Both the cost of alcohol for recovery and the inevitable losses contribute significantly to the total cost of production. A knowledge of

¹ http://en.wikipedia.org/wiki/Xanthan_gum#Health.

the mechanisms controlling phase separation is useful for devising alternatives to alcohol precipitation and for determining the conditions under which alcohol usage can be minimized.

The lower alcohols (methanol, ethanol, isopropanol) and acetone, which are non-solvents for the polysaccharide, can be added to the fermentation broth not only to decrease the solubility until phase separation occurs, but also to wash out impurities such as colored components, salts, and cells.²

So, unlike glycerin, which may be made by fermenting an agricultural product, xanthan gum is the result of fermenting a broth that may or may not be synthetic by OFPA standards, but is certainly not an agricultural product. Two of the TAP reviewers considered xanthan gum to be synthetic by virtue of the use of synthetic solvents to purify it, and the other considered it to be nonsynthetic.³ Absent guidance on fermentation processes, however, it is not clear what criteria the NOSB should apply in classifying materials like xanthan gum. In addition, it is not clear how the NOSB should evaluate the manufacture and compatibility of a product made by such a process.

FACA rules require the full NOSB to vote.

The FACA final rule makes it clear that although subcommittees of FACA committees may make final recommendations to the agency, they may only do so if the rules applying to FACA committees are followed by the subcommittee.

The FACA regulations state:

§ 102–3.145 What policies apply to subcommittee meetings?

If a subcommittee makes recommendations directly to a Federal officer or agency, or if its recommendations will be adopted by the parent advisory committee without further deliberations by the parent advisory committee, then the subcommittee's meetings must be conducted in accordance with all openness requirements of this subpart.

This is further clarified in the preamble to the final rule:

The Act defines the term “advisory committee” as “any committee, * * * or any subcommittee or other subgroup thereof which is established or utilized by the President or an agency in the interest of obtaining advice or recommendations for the President or one or more agencies or officers of the Federal Government”. Under this definition, a subcommittee is an “advisory committee” subject to the Act if it provides advice to the President or a Federal officer or agency. Most subcommittees, however, report only to a parent advisory committee and it is the parent committee that is normally responsible for providing advice or recommendations to the Government. In

² Garcia-Ochoa, F., Santos, V. E., Casas, J. A., & Gomez, E. (2000). Xanthan gum: production, recovery, and properties. *Biotechnology advances*, 18(7), 549-579.

³ TAP, pp. 5, 7.

this conventional scenario, the subcommittee is not subject to the Act because it is not providing advice to the Government.

Citing *National Anti-Hunger Coalition v. Executive Committee*, 557 F.Supp. 524 (D.D.C.), *aff'd*, 711 F.2d 1071 (D.C. Cir. 1983), the preamble says:

GSA believes that as a result of this decision, subcommittees that report to a parent advisory committee generally are not subject to the Act. GSA also believes that subcommittees whose advice or recommendations are provided directly to a Federal officer or agency are subject to the Act. However, GSA further believes that this decision does not shield those subcommittees from coverage under the Act whose advice or recommendations are not subject to deliberation by their parent advisory committees.

From this reasoning, it is not permissible for parent advisory committees simply to “rubber-stamp” the advice or recommendations of their subcommittees, thereby depriving the public of its opportunity to know about, and participate contemporaneously in, an advisory committee’s deliberations. Agencies are cautioned to avoid excluding the public from attending any meeting where a subcommittee develops advice or recommendations that are not expected to be reviewed and considered by the parent advisory committee before being submitted to a Federal officer or agency. [emphasis added] These exclusions may run counter to the provisions of the Act that require contemporaneous access to the advisory committee deliberative process.

The reclassification of xanthan gum was placed on the work agenda through accepted means.

HS notes from May 26, 2015 say:

A member discussed some materials that may be candidates for reclassification, such as Xanthan gum and Tocopherols.

The group discussed the possibility of requesting supplemental or limited scope TRs for Xanthan gum and Phosphates.

The notes for June 2, 2015 say:

Xanthan gum. The lead indicated that the NOSB received many comments, the majority of which were in support of reclassification of xanthan gum from 205.605(b) to 205.605(a). Members discussed the draft classification guidance with regard to fermentation, and the NOP suggested moving forward with the review and not waiting for final guidance. The lead reviewer mentioned an article that was referenced during public comment at the last meeting, and suggested the group discuss this on the next call. The vote will be deferred until then.

The notes for June 16, 2015 say:

Xanthan gum. The lead noted that Xanthan gum, which is non-synthetic and listed on 205.605(b), is made in a similar manner as gellan gum, which is listed on 205.605(a). She proposed that the NOSB reclassify the material. It was noted that public comment included a claim that xanthan gum had adverse health effects when used as a thickener in food for infants. Upon further research of the references, it was noted that the cause may have been contamination of the product, and therefore was not a valid concern. The members discussed the need for a limited scope TR, acknowledging that it would not arrive in time for the fall sunset review. The HS will request one, proceed with a vote on sunset and work on a reclassification proposal separately. Xanthan gum satisfies all OFPA criteria.

From August 18 through October 6, 2015

From August 18 through October 6, 2015, the work agenda said xanthan gum reclassification was "Pending NOP Approval."

November 17, 2015

The November 17, 2015 work agenda said that there was a TR on xanthan gum reclassification in development. The notes for that day also say, "The HS also sen[t] a request to NOP to add Xanthan gum reclassification, which was approved in August."

The notes for February 2, 2016 say,

Xanthan gum reclassification (ZS). The HS will defer this project to the fall 2016 meeting since the TR is not available.

The notes for June 7, 2016 say,

Work agenda chart:

TR in development. TR request send to NOP 10 26 15. TR expected May 2016. TR sent to HS 04 22 16. Response due 06 21 16. Review scheduled Jun 7. TR found sufficient 06 07 16. HS will not go forth with reclassification - Waiting for NOP re: how to finalize.

Notes:

Xanthan Gum (ZS). The HS received a TR that focused on manufacturing, which they found sufficient. At this time, and in light of the TR, the HS decided that xanthan gum does not warrant reclassification. The Subcommittee will consult with the NOP about how to close the loop so future Boards know that reclassification was considered but was deemed unnecessary.

June 21, 2016

The notes for June 21, 2016 say, "NOP determined that a verbal update at the fall 2016 meeting would suffice," and also:

Xanthan gum. During a prior discussion, the HS determined that a reclassification of xanthan gum was not necessary and therefore will not proceed with this project. The HS would like to provide a written update at the meeting, so there is a written account of the project for the public and future Boards, in the event that it is revisited.

Statement on proposed reclassification of xanthan gum

The statement in the proposal document says,

The Handling Subcommittee requested an updated technical report on xanthan gum, focusing on the manufacturing process, to determine if it is synthetic or non-synthetic. After reviewing the information provided, it appears that there is more than one way to produce xanthan gum; some of the methods may be non-synthetic while others may lead to what the NOSB would classify as synthetic. Based on this determination, the Handling Subcommittee has concluded to take no further action on re-classification of xanthan gum at this time.

Conclusion

Thus, the issue of xanthan gum reclassification went through all the steps of being put on the NOSB work agenda, evaluation through a Technical Review, and subcommittee determination – though the notes do not indicate whether the subcommittee voted on the issue. If the subcommittee voted, the vote should be reported in the subcommittee notes and the statement published with subcommittee proposals. Since the subcommittee cannot by itself make decisions on behalf of the NOSB and given that the consideration was a workplan item, the HS must put its proposal concerning the reclassification of xanthan gum on the NOSB agenda for public comment, Board discussion, and a vote.

We agree that the synthetic classification should not change.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Terry Shistar".

Terry Shistar, Ph.D.
Board of Directors