FORMAL RECOMMENDATION BY THE NATIONAL ORGANIC STANDARDS BOARD (NOSB) TO THE NATIONAL ORGANIC PROGRAM (NOP)

Date:April 22, 2008
Subject: Gellan Gum for addition to National List under §205.605a
Chair: Rigoberto Delgado
Recommendation
The NOSB hereby recommends to the NOP the following: Rulemaking Action:XXX Guidance Statement: Other:
Statement of the Recommendation (including Recount of Vote): The Board recommends the inclusion of Gellan Gum on §205.605a – Nonagricultural (nonorganic) allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group (s)).
Motion: Julie Weisman Second: Steve DeMuri
November 30, 2007 Board vote: Yes -15 No-0 Abstain- 0 Absent -0 Rationale Supporting Recommendation (including consistency with OFPA and NOP):
The National List of Allowed and Prohibited Substances §205.605a
3_0010000
Response by the NOP:

National Organic Standards Board

Final Recommendation for Gellan Gum

December 21, 2007

I. List:

National Organic Program Subpart G: The National List of Allowed and Prohibited Substances. §205.605a Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food groups(s))."

(b) Synthetics allowed

II. Committee Summary:

The petitioner for Gellan Gum made the case that Gellan Gum presents unique qualities as compared to the other gums currently on the National Organic list and gave a few examples of the attributes that Gellan Gum provides in comparison to other materials on the National List that are also used as thickeners. The petitioner mentioned that Gellan gum provides many characteristics, some of which are better than and some that are similar to the currently listed gums (either non-synthetic or synthetic).

Although the petitioner mentioned the benefits of this gum to be similar to those gums already approved and listed on the National Organic list, there was significant confusion when discussion at the April 2007 NOSB meeting regarding the possibility of one of the currently listed National List items being used as a substitute for Gellan Gum might be considered.

In the TAP report it is noted that "similar substances listed as non-synthetic non-agricultural (non-organic) substances allowed as ingredients in or on processed products (7 CFR § 205.605)a)) include agar-agar and carrageenan. Synthetic substances allowed for the same purposes (7 CFR § 205.605)b)) include alginates, pectin (low-methoxy), and xanthan gum. Like gellan gum, carrageenen, pectin, alginate, and agar are all gelling agents (Wanous, 2004). ... Determining which gum to use in an application greatly depends on the type of functionality needed and the applications processing parameters." Because of these comments in the TAP and the petition the NOSB sought further information and clarification.

During the NOSB meeting Cheryl Van Dyne from CP Kelco Company approached the Chair as representative for the petitioner to try to answer the questions regarding appropriate use and functionality of Gellan Gum in comparison to currently listed thickeners. The ensuing dialog disclosed some of the ambiguity that the Board was having regarding Gellan Gum. (See meeting transcripts.)

Discussion regarding the extraction solvent, isopropyl alcohol, also created confusion among the board. In the appendices the petitioner cited US FDA, 21 CFI 172.665 Gellan Gum dated April 2 2004 which states: "The food additive gellan gum may be safely used in food in accordance with the following prescribed conditions: (a) The additive is a high molecular weight polysaccharide gum produced from Pseudomonas elodea by a pure culture fermentation process and purified by recovery with isopropyl alcohol...."

Because there were conflicting statements regarding Gellan Gums use and functionality and because of the use of isopropyl alcohol in Gellan Gum the Board was indecisive in understanding the complete form and function of Gellan Gum and it failed for inclusion on 205.605b in March of 2007.

At the November 2007 meeting of the NOSB, motion was made and passed to re-consider the earlier decision. Three representatives of the petitioner, CP Kelco, were on hand to answer Board members questions regarding the production and use of this material. Based on this deliberation, the Board reached the conclusion that this material was appropriate for listing on § 205. 605a of the National List. The recommendation to consider Gellan Gum non-synthetic was motioned by Joe Smillie and seconded by Bea James. The Board vote was 13 in favor and 2 opposed.

The Board considered what constitutes "essential" for organic handling of a finished retail product and how that may be different from that of a material used in crop or livestock production. It was agreed that certain materials might be essential for creating a product that meets consumer expectations of taste or texture. A number of commenters cited Gellan Gum would greatly enhance the organic consumer products they make for this reason. One commenter stated that Gellan Gum has unique functionality that is not offered by similarly-produced gums that are currently allowed in organic handling. There were no public comments specifically opposing the listing of Gellan Gum on § 205.605.

III. Board Recommendation

The Board recommends the inclusion of Gellan Gum fails f on §205.605a of the National List of allowed and prohibited substances.

Motion to re-consider: Joe Smillie Second: Bea James

Board vote: Yes: 13 No: 2 Absent: 0 Abstain: 0

Motion to include on § 205.605a:

Moved: Julie Weisman Second: Steve DeMuri

Board vote: Yes- 15 No- 0 Absent- 0 Abstain-0

NOSB RECOMMENDED DECISION FORM Form NOPLIST2. Full Board Transmittal to NOP

For NOSB Meeting:	Substanc	e:	Gellan Gum						
November 2008 Criteria (Applicability noted for each category; Documentation attached) Criteria Satisfied? (see B below)							below)		
1. Impact on Humans and Environment Yes X No □ N/A □									
2. Essential & Availability Criteria Yes X No ☐ N/A ☐									
3. Compatibility & Consistency Yes X No ☐ N/A ☐									
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606) Yes \Box No \Box N/A $f X$									
B. Substance fails criteria?	C. Propo	C. Proposed Annotation:							
Criteria category:								-	
Comments:	Basis for a	Basis for annotation:							
	To meet o	To meet criteria above: Criteria:							
	Other regi	ulatory c	riteria: Cit	ation:					
D. Final Board Action & Vote (State Actual Motion) : The Board recommends the inclusion of Gellan Gum on § 205.605a – Non agricultural (non organic) allowed as ingredients in or on processed products labeled as "organic" or "made with (specified ingredients									
or food group(s)).	as ingredie	1115 111 01	on processed proc	iucis iau	eleu as u	nganic or	maue v	viiii (Spe	cilied irigiedients
Motion: _Julie Weisman Seco	nd Steve D)eMuri	Yes	15 N	lo: 0	Abstain:	0	Absent:	0
	gricultural		Nonagricultural	X	Cro			7.000	
<u> </u>	Synthetic		Not synthetic	X		stock			
<u> </u>	Allowed	X	Prohibited	^	Han		Х		
	restriction	^	Deferred4		Reje	3			
<u> </u>						0.00			
Brief Narrative (if Board action is different than original subcommittee recommendation): At this meeting the Board voted to reconsider it's previous vote (March 2007) not to list Gellan Gum on § 205.605a please refer to the transcripts of that meeting as well as the narrative of the November 30 2007 Final recommendation for a detailed description of that decision and the deliberation which led to this Recommendation.									
1—substance voted to be added as "allowed" on National List on National List to § 205. 605a with Annotation (if any):									
2—substance to be added to "prohibited" paragraph of National List to § 205Describe why a prohibited substance:									
3—substance was rejected by vote for amending National List to § 205 Describe why material was rejected:									
4-substance was recommended who conducts follow-up	to be deferred	d § 205.	Describe v	hy defe	rred; if any	y follow-up	is need	ed. If foll	ow-up needed,
E. Approved by NOSB Chair to	ransmit to NC)P:							
Rigoberto Delgado NOSB Chair		_	April 22, 2008 Date						
F. NOP Action: Include in FR Return to NOSB Reason:		tional Lis							
			Date			_			

NOSB Meeting Transcripts Excerpted from November 30, 2007

- MS. JULIE S. WEISMAN: Okay. We have a second item, petitioned item, up for vote this morning. It was—it's Gellan Gum, which was voted at the spring meeting but we—a motion was made and we voted yesterday to reconsider this item. We've heard quite—well, I shouldn't [unintelligible]. We've heard a lot of public comment in the past few days on Gellan Gum. We had an opportunity here, a lot of expert information was offered during this meeting and so we now—we now have a recommendation and I move—the motion is for Gellan Gum to be added to Section 605a of the national list. That is a nonagricultural, nonsynthetic—did I say something [unintelligible]? Okay. Nonagricultural, nonsynthetic material.
- MS. ANDREA CAROE: Is there a second?
- MR. JOSEPH SMILLIE: Yes, seconded.
- MS. ANDREA CAROE: Motion is made by Julie Weisman, seconded by Joe Smillie. Is there discussion on this item? Katrina.
- MS. KRISTINE ELLOR: Maybe a point of clarification. My understanding is that our recommendation is for listing on 605b.
- MS. JULIE S. WEISMAN: No. That's incorrect. I want to make sure that it is absolutely clear, the petition was made—the petitioner asked for a listing on 605b but it is—after all of our deliberations and all of the explanations we've heard in the last three days, this is absolutely material being recommended for inclusion on 605a.
- MS. KRISTINE ELLOR: I'm looking at the screen, that's why I'm confused.

MS. JULIE S. WEISMAN: Okay.

MALE VOICE: Madame Chair-

- MS. ANDREA CAROE: [Interposing] I'll have to—that's something I'll have to update for the record. Dan?
- MR. DANIEL G. GIACOMINI: This was also a reconsider of the previous vote. So if we had—it needs to be the same as the vote at the March meeting. If we want to change from that, that motion would then need to be amended.

FEMALE VOICE: Fair enough. So we have actually a motion for 605b and we can amend it at that time—at this time if somebody wants to offer an amendment.

MALE VOICE: Madame Chair?

MS. ANDREA CAROE: Dan.

- MR. DANIEL G. GIACOMINI: I move to amend the motion to 605a.
- MS. ANDREA CAROE: Is it accepted by the principal motion? Julie, do you accept that?
- MS. JULIE S. WEISMAN: Absolutely.
- MS. ANDREA CAROE: Joe, do you accept that as a second?
- MR. JOSEPH SMILLIE: Yes.
- MS. ANDREA CAROE: Okay. So now we have a motion on the table for listing of Gellan Gum on 605a. Discussion?
- MALE VOICE: Just a technicality. Actually, since I was not here in March, I did not vote on this, does that come into play here? Is it the same people voting or it's present here and now?
- MS. ANDREA CAROE: No. You're on the Board. Any other discussion on this? This is a reconsideration and we really want to make sure that we're discussing this. **Katrina?**
- MS. KATRINA HEINZE: I am under the belief that it still belongs on 605b. Gellan Gum is processed in a way very similar to Xanthan [phonetic] Gum, which is on the national list under 605b. Both are fermentation products that are separated by isopropyl alcohol. So I just wanted to get that out for folks' discussion as we vote on whether it's listed on 605a or 605b.

- MS. ANDREA CAROE: Dan?
- MR. DANIEL G. GIACOMINI: In the procedure of—the person making the motion and the second both accepting it, at this time your only option then would be to make another amendment or vote it down.
- MS. KATRINA HEINZE: Vote the material
- MS. ANDREA CAROE: [Interposing] Katrina.
- MS. KATRINA HEINZE: —or make a second amendment. Are those my choices? MALE VOICE: Vote no or second amendment.
- MS. KATRINA HEINZE: I move that Gellan Gum-I'm not sure exactly what to move. Let's see. I move that Gellan Gum, the recommendation be changed to list it on 605b.
- MS. ANDREA CAROE: Is there a second for it?

MALE VOICE: Second.

- MS. ANDREA CAROE: Okay. Oh, wait a second. I'm sorry. I shouldn't have done it that way. If it's a friendly amendment it is accepted by you, Julie, as the principal motion. Do you accept the amendment?
- MS. JULIE S. WEISMAN: I don't.
- MS. ANDREA CAROE: Okay. It's an unfriendly amendment, I guess. So is there a second to that? Am I doing this right, Dan?
- MR. DANIEL G. GIACOMINI: Yes.
- MS. ANDREA CAROE: Okay. So is there a second to Katrina's unfriendly amendment?
- MR. GERALD A. DAVIS: Second.
- MS. ANDREA CAROE: Gerald. Okay. So now—where are we? Do we have to vote on the amendment?

MALE VOICE: Yes.

- MS. ANDREA CAROE: Okay. We have to vote now and we'll do this by voice vote to amend—we are voting to amend the motion to change the placement of Gellan Gum to 605b instead of 605a. Is there discussion on this? Tracy, and then Jeff.
- MS. TRACY MIEDEMA: Yes, a point of discussion and clarification from yesterday. My understanding is that the most germane issue is that we're voting whether to add something to the national list and that ultimately the program will decide whether it resides under A or B?
- MS. ANDREA CAROE: That's true. Jeff?
- MR. JEFFREY W. MOYER: My question was just to Julie to see if she could explain why she wanted it on A because I already got Katrina's explanation on why she wanted it on B.
- MS. JULIE S. WEISMAN: Yeah. The fact that there is a synthetic processing aid does not make this a synthetic product. It's a processing aid, it's not an ingredient. Okay. And I also think that the fact the although we do look at the—although it is certainly our charge to respect the decisions of previous Boards, the definitions of material has not been consistent over the years and I don't think the fact that Xanthan gum, having a similar process—and I haven't looked, compared those two—but I don't think the fact that that resides on a different part of the list should set the precedent for where this one—we should go on our own.
- MR. JEFFREY W. MOYER: But the petitioner originally asked to be put on B; is that correct?
- MS. JULIE S. WEISMAN: Yes. And petitioners often don't, I mean they have their own understanding and some of it is some—the level of their understand varies, as does ours, about where things belong at different times.
- MS. ANDREA CAROE: Just a clarification. We're not beholden to what they're asking for placement. Just to get it—just the material. So Joe, you had a point?

MR. JOSEPH SMILLIE: Point of order, Madame Chair, I would request that we vote on this amendment in the same manner as the other votes rather than up or down, or request that we—

MS. ANDREA CAROE: [Interposing] A poll vote?

MR. JOSEPH SMILLIE: A poll vote. Yes, ma'am.

MS. ANDREA CAROE: Okay. Hue. I'm sorry.

MR. HUBERT J. KARREMAN: Okay. I'm a little confused but regarding the A and the B, they have different definitions and I know in Sunset we're not trying to—we're not trying to declare if it's in the right category or not. We're just voting on it. But this is a petition material; correct? I mean this is like first time on the list. So we need to know clearly—at least I do—what I'm going to be voting on here, if it's going to be under A or B. Sorry. I know we're trying to get to that but it makes a difference in the vote. don't—because—not because, but—or will the NOP still place it where it needs to go. But regardless of that, we need to know how to vote, like what it's coming into as far as our purview.

MS. ANDREA CAROE: Bob?

BOB POOLER: Bob Pooler, USDA National Organic Program. Traditionally the Board has initially voted on whether material is synthetic or nonsynthetic and than after that vote decide—you know, that vote decides where, what section material may go in if it's approved.

MS. ANDREA CAROE: Thank you for that, Bob. I'd like—I know we've got more questions, but I'd like Kim Dietz, if you can come up and just help sort this out.

KIM DIETZ: Kim Dietz, and I don't represent the NOP so, you know, I'm just going on history and what we've done in the past. So I'll just have to give you my guidance from that and Bob is correct. Typically when you vote on a material you do vote synthetic, nonsynthetic. We've done that to help clarify so you know what section of the list to go on. At the same time, you're making your best judgment with the information that you have and if you recommend that it goes on A and it really should go on B, then you would hope that gets clarified through public comment when you post the Federal register notice and you have to make the best judgment that you can.

So that being said, also if you have a similar product that's in the wrong place, there are mechanisms to move that, to petition to move it or if there's a clarification of the national list, you can move things because you know there are things in the wrong places. So hopefully that answers your question.

MS. ANDREA CAROE: Bea has a question.

MS. BEA E. JAMES: No, I don't.

[Crosstalk.]

MS. ANDREA CAROE: Bea has a question and then Gerald. Do you have any? [Crosstalk.]

FEMALE VOICE: If you vote to put this on the national list, this is the beginning of rulemaking. Then we will get public comment and, you know, there will ultimately be—you know, there'll be a lot of feedback and it may ultimately turn out that when the program writes the final rule it will say well, hey, even though we just, you know, the Board said it should go, we say it should go on a 605, ultimately it has been determined through the public comment and, you know, whatever, that while the Board said it should go on 605b or a, that the program has determined that it really should go on A or B. But, you know, this can get sorted out. So I just—I guess what I'm trying to say is don't—this isn't like do or die, really, I mean I know—you do it the best that you can given the information that you have. I just don't want to see you have dueling sword battles over this and say oh my god, if it's,

you know, if we can't determine whether it's A or B, well, we're just not going to—we'll reject the whole thing out of—because that's what I—where I sort of sense you're about to go. If we can't make up our minds here, we'll just vote it off. Don't do that. Take your best—do the best you can with the information that you have and we'll get this sorted out through a process. MS. ANDREA CAROE: Okay. Bea?

MALE VOICE: No, go ahead. I was going to say something else. [Crosstalk.]

MS. BEA E. JAMES: Okay. I think because of all of the confusion, for some reason this material has got a jinx on it or something, I don't know, but I would like to ask that the people from CP Kelco come up and just very briefly explain why you petitioned for it to be on B, which is synthetic, instead of A, which is nonsynthetic.

[Crosstalk.]

FEMALE VOICE: Hold on, hold on. Gerald? [Crosstalk.]

MR. GERALD A. DAVIS: I wanted to point out what Kelco said yesterday was that—and the influencing factor that caused me to second Katrina's motion was the 500 parts, 450 to 500 parts per million of isopropyl alcohol that remains in the Gellan Gum. That's within their allowed—amounts are allowed and everything, but that is what remains and that's why in our discussions over the last few years over what is synthetic versus nonsynthetic is how much extraction is left in the finished product and whether—

MS. ANDREA CAROE: [Interposing] Okay.

MR. GERALD A. DAVIS: —that influences whether it's synthetic or not. FEMALE VOICE: Let me just qualify. This motion is not to add isopropyl alcohol to our list. It's to add Gellan Gum.

MR. GERALD A. DAVIS: I understand.

FEMALE VOICE: No-but Gellan Gum [unintelligible] material.

MR. GERALD A. DAVIS: I know.

[Crosstalk.]

MR. GERALD A. DAVIS: Which is nothing wrong with that it's just—MS. ANDREA CAROE: [Interposing] All right. Let's get the gentleman from CP Kelco to address this very quickly.

FEMALE VOICE: Can I make one more comment? Your handling committee has made a recommendation. Your handling committee has determined, to the best of their knowledge, whether it's synthetic or nonsynthetic. Your handling committee are the experts on the Board on a material. So that's one thing. The amount of alcohol, the amount of the—whatever the extraction, is considered a processing, an aid under the CFRs. Doesn't that deem something synthetic, it's an allowed processing and remember the consistency of what your doing and remember your definitions and again, just do the best you can.

MS. ANDREA CAROE: Okay. I'm going to rein this in. I do want to hear from the

MS. ANDREA CAROE: Okay. I'm going to rein this in. I do want to hear from the gentleman from CP Kelco and why-addressing Bea James' question, why you initially asked for 605b listing.

RICK GREEN: Okay. Again, I'm Rick Green from CP Kelco and we basically just put it in the same place, 605b, because Xanthan was there because it was thevery similar material. So we were just going on what the previous, you know, decision was made and, you know, we don't have any—if we had thought 605a was a better choice we could have petitioned for that. That was really the only reason, is that we looked for the most similar material and it seemed to make sense that it would go there. So if that material was initially, you know, mislisted, you know, we have no objection to, you know, having it on either list. That's, you know, the basic reason was because it seemed to make sense to us at the time.

- MS. ANDREA CAROE: Okay. I'll ask for more questions, but I just want to remind this Board that diminimus [phonetic] processing aids, just like Kim Dietz has just indicated, are not what we consider and they are allowed through other federal regulation. It's inconsistent with other Board deliberations for us to take those insignificant amounts and disqualify useful materials for organic production. I think that's kind of over and above. Go ahead, Katrina.
- MS. KATRINA HEINZE: I do want to remind the Board that in addition to the isopropyl alcohol or maybe separately from that is a better phrasing, that there is some discussion that the functionality of this ingredient can be slightly modified to the changes of the acetyl groups and that similar to Xanthan Gum—or is very similar to Xanthan Gum. So my belief that it's on 605b has more—is related to that.
- MS. ANDREA CAROE: Would the gentleman from CP Kelco like to address the acetyl group manipulation?
- RICK GREEN: I think as we pointed out yesterday, you know, in the TAP [phonetic] review they addressed that same—it doesn't really change the food identity. It wouldn't change the cas number. It's basically Gellan Gum. So, you know, it's still the same food material and I'm not sure what more detail you'd like on that.
- MS. KATRINA HEINZE: It's just my point that it goes through some chemical change during that, as indicated in the TAP. Very minor. It's just some change in the acetyls.
- MS. ANDREA CAROE: Tina.
- MS. KRISTINE ELLOR: Yeah, I have to say that when we originally looked at Gellan Gum I considered it to be synthetic based on that it was—there were changes in the acetyl groups. So, you know, were there changes to food identity? Is that still a chemical change? That would be my question, I guess.
- RICK GREEN: I guess that would be better for a chemist to decide because chemical changes can be part of the actual, you know, the bacterial fermentation itself. So if the bacteria makes the change, you know, if there's inherent variability in the Gellan itself, is that a chemical change in processing? It's—as to whether it goes on 605a or 605b, it's really not an issue for us or for the end users.
- MS. ANDREA CAROE: Tina.
- MS. KRISTINE ELLOR: My question would be are the acetyl changes taking place as part of the downstream processing after the fermentation? And that would make that clear.
- RICK GREEN: Well, they could take place either after fermentation or during fermentation because the amount of acetyl that's made by the bacteria is variable. So if you have a batch where it's got low acetyl or high acetyl, then you don't have any further changes. You could, you know, manipulate it further if you needed to do that as well.
- ${\tt MS.}$ KRISTINE ELLOR: Do you manipulate it further? Do you manipulate the acetyl groups as part of your downstream processing?

RICK GREEN: You can reduce the acetyl groups, yes.

MS. KRISTINE ELLOR: Do you?

RICK GREEN: As to whether we do, I would say yes. And it's really a matter of batch variability because if you need low ethol [unintelligible) because someone has an application and your bacteria is producing higher [Unintelligible.] [Phonetic.] then you can chemically change it. But you don't necessarily need to. And because these are biological batch processes, it will vary. But so yes, it can be chemically modified and if necessary we

could do that. So if that would make it a synthetic as opposed to a nonsynthetic...

MS. ANDREA CAROE: Okay. Hue.

MR. HUBERT J. KARREMAN: Well, I think from what you're just saying, that the original change is due to the biological processing fermentation, to me then says that's a natural process because it's biological and that's your—and then occasionally you have to change it because of biological variability, but now I understand what you're saying, Katrina. But if it's due to the fermentation and that's a biological process, that to me is the basis for it to be still natural.

MS. ANDREA CAROE: Any other discussion? At this time, just to clean this up I would make the recommendation that we withdraw the present motion that's on the table and that perhaps somebody move that we deem this synthetic or nonsynthetic, however you want to word it, and vote on that portion first.

MS. KATRINA HEINZE: I withdraw my motion.

MS. ANDREA CAROE: Katrina, it's not your motion, actually. The motion on the floor—[Crosstalk.]

MS. ANDREA CAROE: Okay. You're withdrawing your motion. Okay. Then I need also, Julie, for you to withdraw your motion.

MS. JULIE S. WEISMAN: Okay. I will withdraw my motion.

MS. ANDREA CAROE: Okay. So we have no motions on the floor at this time. All right. Anybody want to make one?

[Laughter.]

MS. ANDREA CAROE: Julie? Oh, Joe?

MR. JOSEPH SMILLIE: I'd like to move that Gellan Gum be considered as a nonsynthetic and placed on 605a.

MS. ANDREA CAROE: No. We don't want to get in the mess. Let's just deem in synthetic or nonsynthetic at this time.

MR. JOSEPH SMILLIE: I'll withdraw that. I would like to move, Madame Chair, that Gellan Gum be regarded as nonsynthetic.

MALE VOICE: Second. Okay.

MS. ANDREA CAROE: I didn't catch that. Who second?

FEMALE VOICE: Bea.

MS. ANDREA CAROE: Bea. Okay. All right. Now, we can have more discussion on this. So-

MALE VOICE: [Interposing] Madame Chairman, question to the program. Mark, would this be a decisive vote?

MARK: This should just go one way or the other.

[Crosstalk.]

FEMALE VOICE: So what do you want him to have, a majority?

MALE VOICE: Just a simple majority.

MS. ANDREA CAROE: A simple majority will do. We're not adding anything to the list at this point. We're just-

FEMALE VOICE: You're just making up your mind.

[Crosstalk.]

MS. ANDREA CAROE: I'll refrain from comment on that. Okay, so the discussion is whether—well, the discussion is on the motion that Gellan Gum is nonsynthetic. Any discussion? Tina.

MS. KRISTINE ELLOR: I'd actually love to hear from [unintelligible] on this, if we could indulge me.

MS. ANDREA CAROE: We invite Brian Baker to the podium to give his words of wisdom.

FEMALE VOICE: State your name and affiliation.

BRIAN BAKER: Thank you. Brian Baker, research director, Organic Materials Review Institute and also former TAP reviewer, and NOSB wannabe. I would

point out to the Board that this is an important decision, whether it's synthetic or nonsynthetic and it has-there's an implicit source restriction in 605. If something is on 605a, that means that it has to be from a nonsynthetic or natural source. There are a number of items that are on 605a that can be from a synthetic or nonsynthetic source. For example, calcium chloride can be extracted from brine. It can also be produced by the [unintelligible] process. If someone were to ask to have a product with, for example, calcium chloride, then-to be used in organic processing, for processing a produce labeled as organic, that would need to be documented to be a nonsynthetic source. Similarly with Xanthan Gum, there was a discussion about the various different sources of Xanthan Gums. Many are nonsynthetic. Some are chemically modified by means similar to what was discussed. So if you decide that only the nonsynthetic sources of Gellan Gum are permitted, and it's on 605a, there is an implicit source restriction there that will need to be verified by the certifiers and by their agents. If on the other hand it is on 605b, it is less restrictive and the source is less important and these chemically modified Gellan Gums would then be permitted. MS. ANDREA CAROE: Thank you, Brian. Any further discussion on the nonsynthetic nature of Gellan Gum? Hearing none, we will vote on this motion. I will restate, the motion is to consider Gellan Gum nonsynthetic. The motion was made by Joe Smillie and seconded by Bea James. And we are starting with Dan. MR. DANIEL G. GIACOMINI: Yes.

- MS. ANDREA CAROE: Rigo?
- MR. RIGOBERTO I. DELGADO: Yes.
- MS. ANDREA CAROE: Jennifer?
- MS. JENNIFER M. HALL: Yes.
- MS. ANDREA CAROE: Jeff?
- MR. JEFFREY W. MOYER: Yes.
- MS. ANDREA CAROE: Kevin?
- MR. KEVIN ENGELBERT: Yes.
- MS. ANDREA CAROE: Hue?
- MR. HUBERT J. KARREMAN: Yes.
- MS. ANDREA CAROE: Tina?
- MS. KRISTINE ELLOR: I'm going to say no.
- MS. ANDREA CAROE: Gerald?
- MR. GERALD A. DAVIS: Yes.
- MS. ANDREA CAROE: Steve?
- MR. STEVE DEMURI: Yes.
- MS. ANDREA CAROE: Tracy?
- MS. TRACY MIEDEMA: Yes.
- MS. ANDREA CAROE: Katrina?
- MS. KATRINA HEINZE: No.
- MS. ANDREA CAROE: Joe?
- MR. JOSEPH SMILLIE: Yes.
- MS. ANDREA CAROE: Bea?
- MS. BEA E. JAMES: Yes.
- MS. ANDREA CAROE: Julie?
- MS. JULIE S. WEISMAN: Yes.
- MS. ANDREA CAROE: And the chair votes yes. So that is two against and thirteen in favor. Gellan Gum is now nonsynthetic.
- Now, next up?
- MS. JULIE S. WEISMAN: I move that Gellan Gum be added to Section 605a of the national list.
- MS. ANDREA CAROE: Is there a second?
- MS. JULIE S. WEISMAN: Be added, excuse me.

- MR. STEVE DEMURI: Second.
- MS. ANDREA CAROE: Steve. Motion is made by Julie Weisman and seconded by Steve Demuri. Further discussion on adding Gellan Gum to 605a? Katrina.
- MS. KATRINA HEINZE: All that being said, the last [unintelligible] that we spent, this material has lots of good uses for organic products and I would ask the Board to consider that many similar gums exist on the list and are widely used.
- MS. ANDREA CAROE: I would say that that is not a criteria for 605a. It is a criteria for 605b.
- MS. KATRINA HEINZE: Thank you.
- MS. ANDREA CAROE: Dan?
- MR. DANIEL G. GIACOMINI: I would just like to make a very quick point, but to get it on the record that the discussion that we've been having over this whole period on this item makes—the problems we had with it at the last meeting was far more than just a little bit of nonlinear issues and being late in the day and some people leaving. It's a complicated issue with a lot of possibilities. It's good we're reconsidering it but I just want to go back that for people that were critical of that decision, they look at the process that even at this point in time this is still taking.
- MS. ANDREA CAROE: Well, we all feel vindicated now. Any further discussion on Gellan Gum for addition to 605a? Going, going. Okay. Time to vote. We will start with Rigo.
- MR. RIGOBERTO I. DELGADO: Yes.
- FEMALE VOICE: I'm sorry. I'm having trouble.
- MS. ANDREA CAROE: Jennifer?
- MS. JENNIFER M. HALL: Yes.
- MS. ANDREA CAROE: Jeff?
- MR. JEFFREY W. MOYER: Yes.
- MS. ANDREA CAROE: Kevin?
- MR. KEVIN ENGELBERT: Yes.
- MS. ANDREA CAROE: Hue?
- MR. HUBERT J. KARREMAN: Yes.
- MS. ANDREA CAROE: Tina?
- MS. KRISTINE ELLOR: Yes.
- MS. ANDREA CAROE: Gerald?
- MR. GERALD A. DAVIS: Yes.
- MS. ANDREA CAROE: Steve?
- MR. STEVE DEMURI: Yes.
- MS. ANDREA CAROE: Tracy?
- MS. TRACY MIEDEMA: Yes.
- MS. ANDREA CAROE: Katrina?
- MS. KATRINA HEINZE: Yes.
- MS. ANDREA CAROE: Joe?
- MR. JOSEPH SMILLIE: Yes.
- MS. ANDREA CAROE: Bea?
- MS. BEA E. JAMES: Yes.
- MS. ANDREA CAROE: Julie?
- MS. JULIE S. WEISMAN: Yes.
- MS. ANDREA CAROE: Dan?
- MR. DANIEL G. GIACOMINI: Yes.
- MS. ANDREA CAROE: And the chair votes yes. Hallelujah, we're done.
- FEMALE VOICE: Let's move from Gellan Gum.
- MS. ANDREA CAROE: The vote was zero against, fifteen in favor. The motion passes

FORMAL RECOMMENDATION BY THE NATIONAL ORGANIC STANDARDS BOARD (NOSB) TO THE NATIONAL ORGANIC PROGRAM (NOP)

Date: <u>4/21/2007</u>
Subject: Gellan Gum for addition to National List under, §205.605B, synthetics.
Chair: Andrea Caroe
<u>Recommendation</u>
The NOSB hereby recommends to the NOP the following: Rulemaking Action: Guidance Statement: Other:
Statement of the Recommendation (including Recount of Vote): The Board recommends NOT adding Gellan Gum, to the National List under §205.605b, synthetics allowed.
NOSB Vote: Motion: Julie Weisman Second: Steve DeMuri
Board vote: Yes -6 No-4 Abstain- 1 Absent -4 Recuse-0
Rationale Supporting Recommendation (including consistency with OFPA and NOP):
The National List of Allowed and Prohibited Substances §205.605b
Response by the NOP:

National Organic Standards Board

Final Recommendation for

Date: April 21, 2007

I. List:

National Organic Program Subpart G: The National List of Allowed and Prohibited Substances. §205.605a Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food groups(s))."

(b) Synthetics allowed

II. Committee Summary:

The petitioner for Gellan Gum made the case that Gellan Gum presents unique qualities as compared to the other gums currently on the National Organic list and gave a few examples of the attributes that Gellan Gum provides in comparison to other materials on the National List that are also used as thickeners. The petitioner mentioned that Gellan gum provides many characteristics, some of which are better than and some that are similar to the currently listed gums (either non-synthetic or synthetic).

Although the petitioner mentioned the benefits of this gum to be similar to those gums already approved and listed on the National Organic list, there was significant confusion when discussion at the April 2007 NOSB meeting regarding the possibility of one of the currently listed National List items being used as a substitute for Gellan Gum might be considered.

In the TAP report it is noted that "similar substances listed as non-synthetic non-agricultural (non-organic) substances allowed as ingredients in or on processed products (7 CFR § 205.605)a)) include agar-agar and carrageenan. Synthetic substances allowed for the same purposes (7 CFR § 205.605)b)) include alginates, pectin (low-methoxy), and xanthan gum. Like gellan gum, carrageenen, pectin, alginate, and agar are all gelling agents (Wanous, 2004). ...Determining which gum to use in an application greatly depends on the type of functionality needed and the applications processing parameters." Because of these comments in the TAP and the petition, the NOSB sought further information and clarification.

During the NOSB meeting, Cheryl Van Dyne from CP Kelco Company, approached the Chair as representative for the petition to try to answer the questions regarding appropriate use and functionality of Gellan Gum in comparison to currently listed thickeners. The following dialog was taken directly from the NOSB April 2007 meeting and discloses some of the ambiguity that the Board was having regarding Gellan Gum.

"Cheryl Vandine, CP Company, petitioner for gellan gum, 205.605B, Could you ask the specific question so that I can answer you?

MS. JAMES: Could you tell me the type of products that you're -- and the consistency that you're looking for specifically with the gellan gum?

MS. VANDINE: Okay. We've been working with various beverage formulators and actually White Wave presented comments about the stability that gellan gum provides in beverages and it's not present with similar but not the same type of additives. It provides the ability to stabilize the nutrients and minerals in certain beverages like soy beverages or milk beverages.

MS. JAMES: Are you currently making products without it that are okay?

MS. VANDINE: No, not organic but, they are in the like the chocolate milks and soy milks that are not organic at this time. Their organic industry asked us to move towards this petition, put this petition forth, for beverages at one point, but, gellan gum has some neat functionalities as xanthin gum wouldn't have. It doesn't require protein to suspend. It has its own matrix so it has a better suspense system ending property set than some of the other gums. We currently make xanthin and I can speak for that.

MS. JAMES: Okay. Thank you.

MR. GIACOMINI: Okay. Wait, wait, wait. I have a question. The TAP review identifies as a fermentation product which would normally be non-synthetic. You specifically requested listed on B which [is] synthetic. Do you have justification for doing that?

MS. VANDINE: Well, at the time xanthin gum is on the 605B and we put it in the same place as xanthin. Xanthin is also fermentation derived.

MS. CAROE: If the information from the TAP reviewer can be pulled up, the TAP reviewer should clarify appropriate listing.

-Rescinded. Board needed time to research TAP. Resumed-

MS. HEINZE: I have the TAP for gellan gum on my computer. I just need a reminder of what I was looking for.

MS. MIEDEMA: Question.

MS. CAROE: Tracy?

MS. MIEDEMA: It seems that the question was around what consistency properties were imparted by this substance, ingredient.

MS. CAROE: I believe we had the petitioner up and answered that question.

MS. MIEDEMA: Yeah, and it didn't seem to satisfy the group at that moment.

MS. CAROE: Jennifer?

MS. HALL: The reason that we tabled it was to clarify why she applied under the category she did and she wasn't quite clear. She basically said she did so because the other product they produced with similar properties fell under that category currently.

MS. CAROE: Right. And as I remember we were going to look at the TAP to see what the TAP contract said. Katrina?

MS. HEINZE: Evaluation question number one on the TAP, the question is, has the petitioner in some sense formulated or manufactured by a chemical process. The second paragraph they say it's produced by naturally occurring biological process and a chemical process is used to extract the gellan gum from the gelatation medium and to formulate the desired thickness of the gum. Then further down in evaluation question number 2 it says the formulation and manufacturing process involves partial removal of aceto groups which in turn affects the thickness and hardness of the gel. I do remember now in subcommittee we had discussion about that which caused us to concur that it should be on 205B -- 205.605B.

MS. CAROE: Julie?

MS. WEISMAN: I also, in looking at the references to the TAP under evaluation criteria, I also see that the extraction solvent is isopropyl alcohol which is a synthetic which is further weight that this should be 205.605B."

Discussion regarding the extraction solvent, isopropyl alcohol, also created confusion among the board. In the appendices the petitioner cited US FDA, 21 CFI 172.665 Gellan Gum dated April 2 2004 which states: "The food additive gellan gum may be safely used in food in accordance with the following prescribed conditions: (a) The additive is a high molecular weight polysaccharide

gum produced from Pseudomonas elodea by a pure culture fermentation process and purified by recovery with isopropyl alcohol...."

Because there was conflicting statements regarding Gellan Gums use and functionality and because of the use of isopropyl alcohol in Gellan Gum the Board was indecisive in understanding the complete form and function of Gellan Gum, and it failed for inclusion on 205.605b.

The Handling Committee also considered what constitutes "essential" for organic handling of a finished retail product and how that may be different from that of a material used in crop or livestock production. It was agreed that certain materials might be essential for creating a product that meets consumer expectations of taste or texture that is authentic to a specific ethnic cuisine. A number of commenters cited Gellan Gum as an essential ingredient in the organic consumer products they make for this reason. There were no public comments specifically opposing the listing of Gellan Gum on § 205.605b.

III. Board Recommendation

Gellan Gum fails for inclusion on §205.605b and will not be added to the National List of allowed and prohibited substances.

Moved: Julie Weisman Second: Steve DeMuri

Board vote: Yes- 6 No- 4 Absent- 4 Abstain-1 Recuse-0