

**National Organic Standards Board (NOSB)
Handling Committee
Tuesday, January 17, 2011, 1:00 pm ET**

Present: Katrina Heinze, Nick Maravell , Steve DeMuri (Chairperson), John Foster (Vice Chairperson), and Tracy Miedema **Absent:** Mac Stone and Joe Dickson **New Members:** Tracy Favre and Zea Sonnabend **Staff:** Emily Brown-Rosen and Lorraine Coke

| Petitioned Substances | | | | | |
|---|------------|----------|----------------|----------------|--|
| Name | NL Section | Reviewer | Meeting | TR Requested ? | Notes |
| Ascorbyl palmitate | 205.605 | MS | Spring 2012 | | Petition sent on 9/6/2011. Petition sufficiency review? |
| Barley Betafiber | 205.606 | KH | TBD | Yes | Revised petition sent 6/20/11.. TR requested, (to cover fibers as a class) Will not be on fall agenda. |
| Bergamot Bitter Orange Powder | 205.606 | KH | TBD | Y | Petition Sufficiency Review; TR Request sent to contractor 12/5/2011 |
| Beta-carotene (synthetic) in infant formula | 205.605 | ? | TBD | | TR requested 1/17/2012. |
| Caramunch malt | 205.606 | KH | TBD | | Petition is insufficient; return to petitioner. |
| Choline | 205.605 | TM | Spring 2012(?) | Yes | TR request sent to contractor on 5/31/2011; revised request on 8/4/2011 for new petition; expect TR in October. |
| Curry leaves | 205.606 | SD | | | Petition sent to HC on 8/26 sufficiency review due 10/26 |
| Dextrin | 205.605 | KH | Spring 2012 | Yes | Petition is sufficient. TR is sufficient. Additional questions for petitioner (previously submitted). |
| Gibberellic acid | 205.605 | JFo | Spring 2012 | Yes | Petition is sufficient. TR requested. |
| Inositol | 205.605 | TM | Spring 2012 | | Petition sent to HC on 7/25. Review for sufficiency. TR already requested, expected in January. |
| Kaffir lime leaves | 205.606 | SD | Spring 2012 | | Petition received. Need sufficiency review by 10/26 |
| Lutein | | | | | Petition sent to HC 11/16/2011 |
| Lycopene | 205.605 | SD | Spring 2012 | | Petition sent to HC 9/22/2011; TR Request Sent to Contractor 10/12/2011; Petition sufficiency review due by 11/22/2011 |
| L-carnitine | 205.605 | | | | Petition Sufficiency Review; TR Request sent to contractor 12/5/2011 |
| L-Methionine | 205.605 | ? | Spring 2012 | | Petition sufficiency review due 1/02/12 |
| Nucleotides | 205.605 | MS | Spring 2012 | | Petition sufficiency review? |
| Sodium gluconate | 205.605 | JD | Spring 2012 | | Petition sent to HC on 3/22/2011; for use in soap; TR Requested 11/15/2011 |

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|---|--------------|-----------------|----------------|------------|---|
| Sugar Beet Fiber | 205.606 | KH | TBD | Yes | Revised petition sufficient. TR requested 5/20/11. |
| Sulfuric acid | 205.605 | JD | Spring 2012 | Yes | Petition sent to Committee 8/17/2010; TR Requested 11/15/2011 |
| Taurine (in formula) | 205.605 | TM | Spring 2012 | Yes | TR sent to committee, sufficiency review due by 12/27/2011 |
| Sunset 2013 - §205.605 (a) Nonsynthetics Allowed | | | | | |
| Name | CAS # | Reviewer | Meeting | TR? | Notes |
| Agar-agar | | SD | Spring 2012 | Yes | TR sent 10 |
| Calcium sulfate | | JFo | Spring 2012 | Yes | Last TR 2/8/2001 |
| Carrageenan | | JFo | Spring 2012 | Yes | Last TR 1995 |
| Glucono delta-lactone | | MS | Spring 2012 | Yes | Last TR 8/26/2002 |
| Sunset 2013 - §205.605 (b) Synthetics Allowed | | | | | |
| Cellulose | | NM | | Yes | Last TR 9/28/2001 |

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| Other Topics | | | | | |
| Name | Reviewer | Meeting | TR? | Notes | |
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Agenda:

- Petition to remove Tartaric acid
- Petition to list Beta carotene
- Technical report for Dextrin
- Review HC work plan and latest (12/06/2011) materials report

Discussion:

Plan to discuss work plan

Katrina reviewed tartaric acid and NOSB voted to let it sunset from 605(b) and let the other sunset

Beta carotene on 605(b) – this is part of NVM topic – the Board voted to list Beta carotene (as color) at Nov 2011 meeting. This petition was reviewed and appears to be sufficient. NOSB does have TR, but would recommend to get TR amendment for this particular use (in infant formula).

Sufficiency review for TR on Dextrin – there were some details that were missing, but those have been addressed. The TR appears to be sufficient now. Still awaiting response from petitioner.

Review of materials that will Sunset in 2013:

Agar agar – SD will look at TR and get back to the committee

Calcium sulfate

Carrageenan – JFo will look at TR and get back to the committee

Glucono delta lactone

Cellulose

Other priority materials
Nutrients – still need several TRs

Is there a review/assessment on how to prioritize these materials?

Adjustments on the TRs to account for how important/relevant these materials are, including economic information

Have we ever received a TR that has attempted to address commercial availability? Is it appropriate to ask this?

→Typically the information that would inform commercial availability is not available to the contractors (it is private business information).

When looking at certain materials it is helpful/relevant to ask for additional information and seek input from the industry.

There was a lot of input at the Nov meeting regarding GMO ingredients and there is a concern about how the review process is completed and outline how excluded methods were not present in any material that is approved by the Board. What is “sufficient” evidence at the review process? Perhaps this issue could go to the Materials Committee? It is important to address this issue to ensure that previous work is not questioned/considered insufficient.

Summary of next steps for HC:

*Review the five 2013 Sunset materials

*wait until Lisa B. puts out next version of materials report

*additional TRs

The NOP requested policy statement on review of “additional materials” or “additives” present in petitioned materials. This topic should be discussed/considered with Materials Committee. There may be specific areas of overlap. Suggestion to look at policies/processes for livestock and crops committees and how they look at “additional materials” present in petitioned materials. How far does the HC need to delve into this review? One committee member felt that this is definitely a HC topic, but might require some consultation with other committees.

Upcoming meetings and potential agenda items:

January 31

Welcome new members, review materials and assign responsibilities(?).

February 7

February 21

| Milestone | Deadline |
|------------------------------|------------------------|
| Spring 2012 Agenda Finalized | Friday, March 23, 2012 |
| Committee Proposals Due | Monday, April 2, 2012 |
| Spring 2012 NOSB Meeting | May 21 – 24, 2012 |

Note: Committee notes may include preliminary discussions regarding substances considered for addition to or removal from the National List. They do not represent official National Organic Program (NOP) policy or regulations. Please see the NOP website for official NOP policy, regulations, and status of substances used in organic production and handling.

**National Organic Standards Board (NOSB)
Handling Committee
Tuesday, January 31, 2011, 1:00 pm ET**

Present: John Foster (Chair)(JFo), Harold Austin (Vice-Chair)(HA), Nick Maravell (NM), and Joe Dickson (JD)

Absent: Zea Sonnabend and Tracy Favre

Staff: Emily Brown-Rosen and Lorraine Coke

| Petitioned Substances - Status of current review process | | | | | |
|--|------------|----------|--------------|-----------------------------|---|
| Name | NL Section | Reviewer | Meeting | Tech Review (TR) Requested? | Notes |
| Ascorbyl palmitate | 205.605 | NM | Spring 2012 | | Petition sent to HC 9/6/11; TR Request sent to Contractor 10/12/2011 |
| Barley Betafiber | 205.606 | ? | TBD | Yes | Revised petition sent to HC on 6/20/11; determined sufficient and TR Requested on 9/22/2011; assigned to contractor on 12/7/11 |
| Bergamot Bitter Orange Powder | 205.606 | ? | TBD | Y | Sent to HC on 3/22/2011; TR Requested 5/23/11; sent to contractor on 10/27/11 |
| Beta-carotene (synthetic) in infant formula | 205.605 | ? | TBD | | Petition sent to HC on 10/13/2011; Supplemental TR requested 1/17/12 |
| Caramunch malt | 205.606 | ? | TBD | | Petition deemed insufficient by HC on 1/4/2011; petitioner notified 1/25/2011 |
| Choline | 205.605 | ZS | Spring 2012? | Yes | Petition sent to HC on 7/1/2011; TR Request sent to contractor on 5/31/11; revised request on 8/4/11 for new petition; TR sent to HC on 1/24/12 |
| Curry leaf | 205.606 | | | | Petition sent to HC on 8/26/11; TR requested, but HC to reevaluate TR request |
| Dextrin | 205.605 | | Spring 2012 | Yes | Revised TR sent to HC 10/17/2011; TR accepted as sufficient 1/17/12; petitioner notified on 1/23/12 that additional information is needed. |
| Gibberellic acid | 205.605 | ZS | Spring 2012 | Yes | TR Request rec'd 5/22/11; TR Request sent to contractor on 5/31/11; petition amendment rec'd from petitioner on 8/12/11; |

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| | | | | | TR sent to HC on 12/16/2011 |
| Inositol | 205.605 | JFo | Spring 2012 | | Petition sent to HC on 7/25. Review for sufficiency. TR already requested, expected in January. |
| Kaffir lime leaves | 205.606 | ? | Spring 2012 | | Petition sent to HC on 8/26/11; TR requested, but HC to reevaluate TR request |
| Lutein | | | | | Petition sent to HC 11/16/2011 |
| Lycopene | 205.605 | NM | Spring 2012 | | Petition sent to HC 9/22/2011; TR Request Sent to Contractor 10/12/2011 |
| L-carnatine | 205.605 | | | | Petition sent to HC 12/5/11 |
| L-Methionine | 205.605 | ? | Spring 2012? | | Petition sent to HC on 11/1/2011; TR anticipated in March. |
| Nucleotides | 205.605 | JFo | Spring 2012 | | Petition sent to HC on 9/21/11; TR Request sent to Contractor 9/28/11 |
| Sodium gluconate | 205.605 | JD | Spring 2012 | | Petition sent to HC on 3/22/2011; for use in soap; TR Requested 11/15/2011 |
| Sugar Beet Fiber | 205.606 | ? | TBD | Yes | Revised petition sent to Committee 2/10/2011; Revised petition deemed sufficient on 5/13/11; TR Requested 5/23/11; assigned to contractor on 12/7/2011 |
| Sulfuric acid | 205.605 | JD | Spring 2012? | Yes | Petition sent to Committee 8/17/2010; TR Requested 11/15/2011 |
| Taurine (for infant formula) | 205.605 | TF | Spring 2012 | Yes | Petition sent to HC 9/20/11; TR sent to HC 10/28/2011 |

Sunset 2013 - §205.605 (a) Nonsynthetics Allowed - Status of current review process

| Name | CAS # | Reviewer | Meeting | TR? | Notes |
|-----------------------|-------|----------|-------------|-----|--|
| Agar-agar | | HA | Spring 2012 | Yes | 205.605(a); TR requested 5/23/11; TR request sent to contractor 5/25/11; ANPR comments due 8/1/11; TR sent to HC 10/11/11; TR determined to be sufficient on 1/19/2012 |
| Calcium sulfate | | JD | Spring 2012 | Yes | 205.605(a); last TR 2/8/2001 |
| Carrageenan | | HA | Spring 2012 | Yes | 205.605(a); TR requested 5/23/11; TR request sent to contractor 5/25/11; ANPR comments due 8/1/11; TR sent to HC 10/11/11; TR determined to be sufficient on 1/20/2012 |
| Glucono delta-lactone | | JD | Spring 2012 | Yes | 205.605(a); Last TR 8/26/2002 |

Sunset 2013 - §205.605 (b) Synthetics Allowed - Status of current review process

| | | | | | |
|-----------|--|----|-------------|-----|-------------------------------|
| Cellulose | | JD | Spring 2012 | Yes | 205.605(b); Last TR 9/28/2001 |
|-----------|--|----|-------------|-----|-------------------------------|

Other Topics

| Name | Reviewer | Meeting | Notes |
|------|----------|---------|-------|
|------|----------|---------|-------|

| | | | |
|-------------------------------|--|--------------|---|
| Auxiliary/"other" ingredients | | Spring 2012? | Possible discussion document and/or a report back to the NOP work and progress on this topic for spring 2012. May be better to have this as a discussion ore presentation, but not a public document that would receive comments. |
|-------------------------------|--|--------------|---|

Agenda:

1. Welcome and introductions of committee members - 15 min
2. Approve minutes of January 17 meeting - 5 min
3. Deadlines and topic assignments - 20 min
 - Relevant dates from Lorraine
 - Sunset 2013 materials
 - Petitioned materials for which we are likely to have TRs by March 1
4. Other topics on work plan - 15 min
 - Auxiliary ('other') ingredients
 - More?
5. Next meeting and meeting schedule - 5 min

Discussion:

1. Introductions:
 - Harold Austin
 - Nick Maravell
 - Joe Dickson
 - John Foster
2. Discussion of approval of minutes
3. Deadlines
 - Committee Proposals – due dates
 - Materials prioritization: Sunset 2013 Materials, then petitioned materials with TRs (or TRs forthcoming in next month), unless TR is received by early March then it will be difficult to complete by April 2 deadline. Expect to move fastest on Sunset materials in next two weeks.
4. Other topics
 - Auxiliary or “other” ingredients: this topic may require more time than there is available between now and the spring meeting. How important is this to the NOP to review and develop something now? It is a big deal, but it should not be rushed. Another option is a discussion document and/or a report back to the NOP/NOSB about work and progress on this topic. It could be helpful to have this discussion, but not as a public document that would receive comments. A general progress report may be a good idea.
 - Sulfur dioxide – in wine not made from grapes (other fruit wines and hard ciders). This topic was briefly discussed in HC last year, but no decision was made. Relating to the regulations, is there any language that would make this review/work not possible? Is hard cider and defined as “wine” by TTB? Yes, TTB considers it a fruit wine. Could use the TR from last year and propose an annotation amendment. Committee determined that this would be possible if it is relatively straightforward.

Upcoming meetings and potential agenda items:

February 7 – Review and discuss Sunset materials/proposals

February 21 – Gibberellic acid, choline, and any other left over Sunset materials.

March 6 – Taurine, nucleotides, inositol, and “other” ingredients.

March 20 –

April 3 –

April 17 –

May 1 –

| Milestone | Deadline |
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**National Organic Standards Board (NOSB)
Handling Committee
Tuesday, February 7, 2011, 1:00 pm ET**

Present: John Foster (Chair)(JFo), Harold Austin (Vice-Chair)(HA), Nick Maravell (NM), and Joe Dickson (JD), Zea Sonnabend (ZS) and Tracy Favre (TF)

Absent: none

Staff: Miles McEvoy, Emily Brown-Rosen and Lorraine Coke

| Petitioned Substances - Status of current review process | | | | | |
|--|------------|----------|--------------|---------------|---|
| Name | NL Section | Reviewer | Meeting | TR Requested? | Notes* |
| Ascorbyl palmitate | 205.605 | NM | Spring 2012 | Yes | Petition sent to HC 9/6/11; TR Request sent to Contractor 10/12/2011 |
| Barley Betafiber | 205.606 | ? | Fall 2012? | Yes | Revised petition sent to HC on 6/20/11; determined sufficient and TR Requested on 9/22/2011; assigned to contractor on 12/7/11 |
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| Curry leaf | 205.606 | JFo | Spring 2012 | No | Petition sent to HC on 8/26/11; HC decided no TR necessary on 2/7/2012. Draft recommendation. |
| Dextrin | 205.605 | ZS | Fall 2012? | Yes | Revised TR sent to HC 10/17/2011; TR accepted as sufficient 1/17/12; petitioner notified on 1/23/12 - waiting for petitioner response |
| Gibberellic acid | 205.605 | ZS | Spring 2012 | Yes | TR Request rec'd 5/22/11; TR Request sent to contractor on 5/31/11; petition amendment rec'd from petitioner on 8/12/11; TR sent to HC on 12/16/2011; TR Sufficiency review |

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| Inositol | 205.605 | JFo | Spring 2012 | Yes | Petition sent to HC on 7/25. Review for sufficiency. TR sent to HC 2/9/12. TR sufficiency review |
| Kaffir lime leaves | 205.606 | JFo | Spring 2012 | No | Petition sent to HC on 8/26/11; HC decided no TR necessary on 2/7/2012; Draft recommendation. |
| Lutein | 205.606 | ? | TBD | Yes | Petition sent to HC 11/16/2011; TR requested; Petition sufficiency review overdue |
| Lycopene | 205.605 | NM | Spring 2012 | Yes | Petition sent to HC 9/22/2011; TR Requested; Petition sufficiency review overdue |
| L-carnitine | 205.605 | ? | Fall 2012? | Yes | Petition sent to HC 12/5/11; TR requested; Petition sufficiency review overdue; |
| L-Methionine | 205.605 | ? | Fall 2012? | Yes | Petition sent to HC on 11/1/2011; TR requested, due late March; Petition sufficiency review overdue |
| Nucleotides | 205.605 | JFo | Spring 2012 | Yes | Petition sent to HC on 9/21/11; TR Requested, due in Feb; Petition sufficiency review overdue |
| Sodium gluconate | 205.605 | JD | ? | Yes | Petition sent to HC on 3/22/2011; for use in soap; TR Requested 11/15/2011 |
| Sugar Beet Fiber | 205.606 | ? | TBD | Yes | Revised petition sent to Committee 2/10/2011; Revised petition deemed sufficient on 5/13/11; TR Requested 5/23/11; assigned to contractor on 12/7/2011 |
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| Taurine (for infant formula) | 205.605 | TF | Spring 2012 | Yes | Petition sent to HC 9/20/11; TR sent to HC 10/28/2011; TR sufficiency review |
| Sunset 2013 - §205.605 (a) Nonsynthetics Allowed - Status of current review process | | | | | |
| Name | CAS # | Reviewer | Meeting | TR? | Notes |
| Agar-agar | | HA | Spring 2012 | Yes | 205.605(a); TR requested 5/23/11; TR request sent to contractor 5/25/11; ANPR comments due 8/1/11; TR sent to HC 10/11/11; TR determined to be sufficient on 1/19/2012; Draft recommendation |
| Calcium sulfate | | JD | Spring 2012 | Yes | 205.605(a); last TR 2/8/2001; Draft recommendation |
| Carrageenan | | HA | Spring 2012 | Yes | 205.605(a); TR requested 5/23/11; TR request sent to contractor 5/25/11; ANPR comments due 8/1/11; TR sent to HC 10/11/11; TR determined to be sufficient on 1/20/2012; Draft recommendation |
| Glucono delta-lactone | | JD | Spring 2012 | Yes | 205.605(a); Last TR 8/26/2002; Draft recommendation |

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| Sunset 2013 - §205.605 (a) Nonsynthetics Allowed - Status of current review process | | | | | |
|---|-------|----------|-------------|-----|--|
| Name | CAS # | Reviewer | Meeting | TR? | Notes |
| Sunset 2013 - §205.605 (b) Synthetics Allowed - - Status of current review process | | | | | |
| Cellulose | | JD | Spring 2012 | Yes | 205.605(b); Last TR 9/28/2001; Draft recommendation |

| Other Topics | | | |
|-------------------------------|----------|------------------------------|---|
| Name | Reviewer | Meeting | Notes |
| Auxiliary/"other" ingredients | ZS | Fall 2012? Update in Spring? | Possible discussion document and/or a report back to the NOP work and progress on this topic for spring 2012. May be better to have this as a discussion ore presentation, but not a public document that would receive comments. |

* Highlight indicates committee action needed.

Agenda:

1. Review/approve minutes from last call
2. Review and discuss Sunset materials/proposals
 - Agar-agar
 - Calcium sulfate
 - Carrageenan
 - Glucono delta-lactone
 - Cellulose

Discussion:

→ Review and approve meeting minutes from 1/31/2012 – approved.

→ Review and discuss sunset materials

-Agar agar: some questions on extraction of agar agar from algae, it is heat treated with a sodium hydroxide (alkaline) solution and whether it may be synthetic. The TR states that this form of extraction would be synthetic. There are other forms of extraction that are non-synthetic. TR did not list most common form of extraction, so where to go from here? [NOP note – see lines 202-209 of the TR, state that natural form is only 1-2% of supply] This TR specifies that there is a molecular change in the product. This is a case where we have a new TR and first time an in-depth TR review. This may be new information that was not available to previous NOSB. Another factor to consider is the forthcoming draft guidance doc regarding classification of materials as synthetic/nonsynthetic from NOP (based on rec from NOSB). Could relist and then finalize when the classification doc is finished. → Could continue to do review, then defer synthetic/non-synthetic discussion to another time, but make note of it. Classification guidance was passed by NOSB in 2009 - for now the committee should refer to this for guidance in situations like this. There is precedent for putting on a material on 605(a) and 605(b).

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Should we go elicit information from petitioners to obtain more information on how agar agar is extracted?

Is there any resulting desirable functional difference in the different extraction processes? → Natural extraction process is not as readily available in US markets (more common in Asian markets). Comments were to relist the material. Option to relist as is, but note that the final guidance will allow for opportunity to review categorization. Determination in May will be how the rule-making will move forward. A determination regarding sunset relisting must be made in May. It can still be used in organic processing whether it is classified as synthetic/non-synthetic. Could make specific annotation to limit synthetic/non-synthetic (similar to calcium sulfate, etc.)

-Carrageenan: two extraction processes – these are the same as in agar agar, more uses now for carrageenan than before. Stabilizer, preserve fruit and vegetables, etc. The alkaline extraction process is still concerning because it is changing the molecular structure. Suggestion to move these materials forward and rewrite the proposals/recommendations to approve them. How do people feel about looking at the 2009 recommendation and voting based on that? → Most committee members expressed that they would be agreeable to that decision. The 2009 recommendation is on the NOP website for reference. Next step: look at the TRs and 2009 recommendation – then discuss and vote at the next (February 21) meeting.

- Calcium sulfate: on 605(a) with restriction – (limited to mined form); interesting that it is listed as non-synthetic and the annotation clarifies that.

-Glucono delta-lactone: on 605(a) with restriction – source that doesn't involve oxidation of glucose with bromine water

-Cellulose

→ decision to vote on these 5 on the next call on February 21. Could have email discussion of synthetic status on agar/carrageenan. Need draft proposal on each sunset substance.

Reviewing other materials and assignments:

Need to review kaffir lime leaves and curry leaf and determine whether a TR is necessary. These two are processed very simply, ie drying. TRs do not generally provide economic data about commercial availability. Current contracts for TRs do not address this issue – therefore, how do Board members review this for listing on 606? For these two items, many committee members agreed that the TR may not be necessary. If the committee decides to list the kaffir lime leaves, it may be better to use Latin name. Can the committee agree that the TRs are not needed? No objections, John F. agreed to review the petitions.

Barley beta fiber – getting a TR, but may not be available in time for the spring meeting.

Bergamont bitter orange – TR is in development

Caramunch malt – TR in development

Upcoming meetings and potential agenda items:

February 21 – Gibberellic acid, choline, and any other left over Sunset (agar agar and carrageenan) materials.

March 6 – Taurine, nucleotides, inositol, and “other” ingredients. Kaffir lime leaves and curry leaf.

March 20 – Sulfites in MWO wine, that does not contain grapes

April 3 –

April 17 –

May 1 –

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| 1,3-dibromo-5,5-dimethylhydantoin (DBDMH) | 205.605 | ? | Fall 2012? | ? | Petition sent to HC on 2/16/2012. Petition sufficiency review. |
| Dextrin | 205.605 | ZS | Fall 2012? | Yes | Revised TR sent to HC 10/17/2011; TR accepted as sufficient 1/17/12; petitioner notified on 1/23/12 - waiting for petitioner response |

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| Gibberellic acid | 205.605 | ZS | Spring 2012 | Yes | TR Request rec'd 5/22/11; TR Request sent to contractor on 5/31/11; petition amendment rec'd from petitioner on 8/12/11; TR sent to HC on 12/16/2011; TR Sufficiency review |
| Inositol | 205.605 | JFo | Spring 2012 | Yes | Petition sent to HC on 7/25. Review for sufficiency. TR sent to HC 2/9/12. TR sufficiency review |
| Kaffir lime leaves | 205.606 | JFo | Spring 2012 | No | Petition sent to HC on 8/26/11; HC decided no TR necessary on 2/7/2012; Draft recommendation. |
| Lutein | 205.606 | ? | TBD | Yes | Petition sent to HC 11/16/2011; TR requested; Petition sufficiency review overdue |
| Lycopene | 205.605 | NM | Fall 2012 | Yes | Petition sent to HC 9/22/2011; TR Requested |
| L-carnitine | 205.605 | ? | Fall 2012? | Yes | Petition sent to HC 12/5/11; TR requested; |
| L-Methionine | 205.605 | ? | Fall 2012? | Yes | Petition sent to HC on 11/1/2011; TR requested, due late March; |
| Nucleotides | 205.605 | JFo | Fall 2012 | Yes | Petition sent to HC on 9/21/11; TR Requested, due in Feb; |
| Sodium gluconate | 205.605 | JD | ? | Yes | Petition sent to HC on 3/22/2011; for use in soap; TR Requested 11/15/2011. |
| Sugar Beet Fiber | 205.606 | ? | TBD | Yes | Revised petition sent to Committee 2/10/2011; Revised petition deemed sufficient on 5/13/11; TR Requested 5/23/11; assigned to contractor on 12/7/2011 |
| Sulfuric acid | 205.605 | JD | Spring 2012? | Yes | Petition sent to Committee 8/17/2010; TR Requested 11/15/2011 |
| Taurine (for infant formula) | 205.605 | TF | Spring 2012 | Yes | Petition sent to HC 9/20/11; TR sent to HC 10/28/2011; TR sufficiency review |
| Sunset 2013 - §205.605 (a) Nonsynthetics Allowed - Status of current review process | | | | | |
| Name | CAS # | Reviewer | Meeting | TR? | Notes |
| Agar-agar | | HA | Spring 2012 | Yes | 205.605(a); TR requested 5/23/11; TR request sent to contractor 5/25/11; ANPR comments due 8/1/11; TR sent to HC 10/11/11; TR determined to be sufficient on 1/19/2012; Draft recommendation |
| Calcium sulfate | | JD | Spring 2012 | Yes | 205.605(a); last TR 2/8/2001; Draft recommendation |
| Carrageenan | | HA | Spring 2012 | Yes | 205.605(a); TR requested 5/23/11; TR request sent to contractor 5/25/11; ANPR comments due 8/1/11; TR sent to HC 10/11/11; TR determined to be sufficient on 1/20/2012; Draft recommendation |
| Glucono delta-lactone | | JD | Spring 2012 | Yes | 205.605(a); Last TR 8/26/2002; Draft recommendation |

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| Sunset 2013 - §205.605 (a) Nonsynthetics Allowed - Status of current review process | | | | | |
|---|-------|----------|-------------|-----|--|
| Name | CAS # | Reviewer | Meeting | TR? | Notes |
| Sunset 2013 - §205.605 (b) Synthetics Allowed - - Status of current review process | | | | | |
| Cellulose | | JD | Spring 2012 | Yes | 205.605(b); Last TR 9/28/2001; Draft recommendation |

| Other Topics | | | |
|-------------------------------|----------|------------------------------|---|
| Name | Reviewer | Meeting | Notes |
| Auxiliary/"other" ingredients | ZS | Fall 2012? Update in Spring? | Possible discussion document and/or a report back to the NOP work and progress on this topic for spring 2012. May be better to have this as a discussion ore presentation, but not a public document that would receive comments. |

* Highlight indicates committee action needed.

Agenda:

1. Review/approve minutes from last call
2. Review and discuss materials/petitions
 - Agar-agar
 - Carrageenan
 - Gibberellic acid

Discussion:

→Review and approve meeting minutes from 2/7/2012 – approved.

→Review and discuss materials:

-Gibberellic acid: thought TR was sufficient, would have liked to see additional use - in wax on citrus (could send it back for that or could ask public to comment on that during public comment). Summarized GA issue: It is a non-synthetic material. It is a natural material used in an “unnatural” way as a growth promoter. There are some “cultural practices” that may require further questions. The overall nutritional quality could suffer (especially in citrus) when used on fruits. If the nutritional quality is compromised should the public be notified (i.e. would the NOSB require labeling – is there precedent in this type of labeling?). The petition did not provide sufficient background information on cultural practices. The classification on the use of the product is not aligned with other post-harvest materials. Everything that is used for crops (post-harvest) would have to be relisted? If committee determines the TR is sufficient today, then would move on and develop proposal. If there are some simple questions (i.e. the labeling) then they could send them back to the contractor.

Clarifying questions on cultural practices (an issue that should be addressed by the NOSB) is an evaluation question, not a question for the contractor.

Questions to send back to reviewer:

Use of GA in waxes?

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Alternatives?

HC decided TR was sufficient. Email will be sent to Lisa B.

-Agar-agar: a review of the information provided implies that the process used in agar agar is synthetic – recommend relisting as listed (non-synthetic) and also as synthetic (due to information in TR) – on 205.605(a) and 205.605(b). Did the initial review include review of biodiversity and information on harvesting of seaweed? Yes, this was included. It didn't seem necessary to flag at this point. It may be helpful to address this issue in the proposal because there may be some questions about it. The documentation did not fully support the concerns regarding the environmental effects related to harvesting.

Did TR reach conclusion on level of concern regarding these issues?

If the HC were to list this as recommended (both synthetic/non-synthetic options), is there any obvious component that is missing (that may cause friction or problems) for certifiers or producers?

Some other materials on list have synthetic/non-synthetic differentiation (i.e humic acids and aquatic plants – as fertilizers) on the national list.

Are the HC members reviewing/scrutinizing other materials in the same way?

Would the HC like to vote on this today or get more info on biodiversity and environmental impact?

Vote:

Motion to relist with annotation change: Nick made motion, it was seconded by Zea. There was a discussion on the annotation – Harold will change to list as allowed on both 205.605(a) and 205.605(b). Additional information on biodiversity and harvesting will be added in final committee proposal.

5 – yes. 1 – absent.

Motion to relist as is on national list; Harold seconded the motion. There was a discussion on the process and why this type of vote is needed.

5 – yes. 1 – absent.

-Carrageenan: there doesn't seem to be a natural or non-synthetic form of material that is extracted – alcohol/alkali extraction process. The FDA approved as long as sourced from 8 different varieties of seaweed. The alkali process determined final form (more brittle gel, more liquid, or viscose).

The recommendation should be stated as allowed to sunset (as it is currently listed) and then relisted as synthetic. Once draft guidance on classification of materials is issued, it will need to be revisited. Should be listed under proper classification as synthetic. Questions on procedural part of this listing – can the NOSB allow a material to sunset off the list then relist on different section? Will need two votes: one to relist and one to add to 605(b)

Need to change the way it is listed – 2 recommendations – allow sunset, recommend new listing on 605(b). Need to include this in proposal.

Motion to accept the recommendation (allow 605(a) to sunset and relist on 605(b) – Tracy, Nick seconded.

5 – yes. 1 – absent.

Motion to relist as is on 205.605(a). Nick made motion, Harold made second.

5 – yes. 1 – absent.

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→Reviewing other materials and assignments:

Beta-carotene: HC had requested supplemental TR for use as nutrient (prior TR is for color). The current question is a little vague – need to clean it up a little bit. The current TR does discuss manufacturing and some nutritional elements, but doesn't address allergy issue and/or synthetic versions. Impacts on human health? TF will draft some questions.

Upcoming meetings and potential agenda items:

March 6 – Discuss kaffir lime leaves and curry leaf. Review and discuss cellulose, calcium sulfate, and glucono delta lactone.

March 20 – Choline, taurine, nucleotides, inositol, and “other” ingredients.

April 3 – Sulfites in MWO wines, that do not contain grapes.

April 17 –

May 1 –

| Milestone | Deadline |
|------------------------------|------------------------|
| Spring 2012 Agenda Finalized | Friday, March 23, 2012 |
| Committee Proposals Due | Monday, April 2, 2012 |
| Spring 2012 NOSB Meeting | May 21 – 24, 2012 |

Note: Committee notes may include preliminary discussions regarding substances considered for addition to or removal from the National List. They do not represent official National Organic Program (NOP) policy or regulations. Please see the NOP website for official NOP policy, regulations, and status of substances used in organic production and handling.

**National Organic Standards Board (NOSB)
Handling Committee
Tuesday, March 6, 2011, 1:00 pm ET**

Present: John Foster (Chair)(JFo), Harold Austin (Vice-Chair)(HA), Nick Maravell (NM), Zea Sonnabend (ZS) and Tracy Favre (TF)

Absent: Joe Dickson (JD)

Staff: Emily Brown-Rosen and Lorraine Coke

| Petitioned Substances - Status of current review process | | | | | | |
|--|------------|----------|--------------|-----------------------------|----------|---|
| Name | NL Section | Reviewer | Meeting | Tech Review (TR) Requested? | TR rec'd | Notes* |
| Ascorbyl palmitate | 205.605 | NM | tbd | Yes | No | Petition sent to HC 9/6/11; TR Request sent to Contractor 10/12/2011 |
| Barley Betafiber | 205.606 | ? | Fall 2012? | Yes | No | Revised petition sent to HC on 6/20/11; determined sufficient and TR Requested on 9/22/2011; assigned to contractor on 12/7/11 |
| Bergamot Bitter Orange Powder | 205.606 | TF | Spring 2012? | Yes | Yes | Sent to HC on 3/22/2011; TR Requested 5/23/11; sent to contractor on 10/27/11. TR sent to HC on 2/16 ; TR sufficiency review |
| Beta-carotene (synthetic) in infant formula | 205.605 | TF | TBD | Yes | No | Petition sent to HC on 10/13/2011; Supplemental TR requested 1/17/12- HC asked by NOP to review the question asked, questions sent 3/6/12 |
| Caramunch malt | 205.606 | ? | TBD | | | Petition deemed insufficient by HC on 1/4/2011; petitioner notified 1/25/2011 – waiting for petitioner response |
| Choline | 205.605 | ZS | Spring 2012? | Yes | Yes | Petition sent to HC on 7/1/2011; TR Request sent to contractor on 5/31/11; revised request on 8/4/11 for new petition; TR sent to HC on 1/24/12; TR sufficiency review |
| Curry leaf | 205.606 | JFo | Spring 2012 | No | n/a | Petition sent to HC on 8/26/11; HC decided no TR necessary on 2/7/2012. Draft recommendation. |
| 1,3-dibromo-5,5-dimethylhydantoin (DBDMH) | 205.605 | JFo | Fall 2012? | ? | | Petition sent to HC on 2/16/2012. Petition sufficiency review. |

Note: Committee notes may include preliminary discussions regarding substances considered for addition to or removal from the National List. They do not represent official National Organic Program (NOP) policy or regulations. Please see the NOP website for official NOP policy, regulations, and status of substances used in organic production and handling.

| | | | | | | |
|------------------------------|---------|-----|-------------|-----|-----|--|
| Dextrin | 205.605 | ZS | Fall 2012? | Yes | Yes | Revised TR sent to HC 10/17/2011; TR accepted as sufficient 1/17/12; petitioner notified on 1/23/12 - waiting for petitioner response (may not get one) |
| Gibberellic acid | 205.605 | ZS | Spring 2012 | Yes | Yes | TR Request rec'd 5/22/11; TR Request sent to contractor on 5/31/11; petition amendment rec'd from petitioner on 8/12/11; TR sent to HC on 12/16/2011; TR Sufficiency review |
| Inositol | 205.605 | JFo | Spring 2012 | Yes | Yes | Petition sent to HC on 7/25. Review for sufficiency. TR sent to HC 2/9/12. TR sufficiency review |
| Kaffir lime leaves | 205.606 | JFo | Spring 2012 | No | N/a | Petition sent to HC on 8/26/11; HC decided no TR necessary on 2/7/2012; Draft recommendation. |
| Lutein | 205.606 | ? | TBD | Yes | No | Petition sent to HC 11/16/2011; TR requested; Petition sufficiency review |
| Lycopene | 205.605 | NM | Fall 2012 | Yes | No | Petition sent to HC 9/22/2011; TR Requested; Petition sufficiency review |
| L-carnitine | 205.605 | ? | Fall 2012? | Yes | No | Petition sent to HC 12/5/11; TR requested; Petition sufficiency review |
| L-Methionine | 205.605 | ? | Fall 2012? | Yes | No | Petition sent to HC on 11/1/2011; TR requested, due late March; Petition sufficiency review |
| Nucleotides | 205.605 | JFo | Fall 2012 | Yes | No | Petition sent to HC on 9/21/11; TR Requested, due in Feb; Petition sufficiency review |
| Sodium gluconate | 205.605 | JD | ? | Yes | | Petition sent to HC on 3/22/2011; for use in soap; TR Requested 11/15/2011. On hold, for cosmetic use. |
| Sugar Beet Fiber | 205.606 | ? | TBD | Yes | Yes | Revised petition sent to Committee 2/10/2011; Revised petition deemed sufficient on 5/13/11; TR Requested 5/23/11; TR sent to HC on 3-8-12 |
| Sulfuric acid | 205.605 | JD | Fall 2012? | Yes | No | Petition sent to Committee 8/17/2010; TR Requested 11/15/2011 |
| Taurine (for infant formula) | 205.605 | TF | Spring 2012 | Yes | Yes | Petition sent to HC 9/20/11; TR sent to HC 10/28/2011; TR sufficiency review |

Sunset 2013 - §205.605 (a) Nonsynthetics Allowed - Status of current review process

| Name | CAS # | Reviewer | Meeting | TR? | Notes* |
|-----------|-------|----------|-------------|-----|--|
| Agar-agar | | HA | Spring 2012 | Yes | 205.605(a); TR requested 5/23/11; TR request sent to contractor 5/25/11; ANPR comments due 8/1/11; TR sent to HC 10/11/11; TR determined to be sufficient on 1/19/2012; Draft |

Note: Committee notes may include preliminary discussions regarding substances considered for addition to or removal from the National List. They do not represent official National Organic Program (NOP) policy or regulations. Please see the NOP website for official NOP policy, regulations, and status of substances used in organic production and handling.

| Sunset 2013 - §205.605 (a) Nonsynthetics Allowed - Status of current review process | | | | | |
|---|-------|----------|-------------|-----|--|
| Name | CAS # | Reviewer | Meeting | TR? | Notes* |
| | | | | | recommendation |
| Calcium sulfate | | JD | Spring 2012 | Yes | 205.605(a); last TR 2/8/2001; Draft recommendation |
| Carrageenan | | HA | Spring 2012 | Yes | 205.605(a); TR requested 5/23/11; TR request sent to contractor 5/25/11; ANPR comments due 8/1/11; TR sent to HC 10/11/11; TR determined to be sufficient on 1/20/2012; Draft recommendation |
| Glucono delta-lactone | | JD | Spring 2012 | Yes | 205.605(a); Last TR 8/26/2002; Draft recommendation |
| Sunset 2013 - §205.605 (b) Synthetics Allowed - Status of current review process | | | | | |
| Cellulose | | JD | Spring 2012 | Yes | 205.605(b); Last TR 9/28/2001; Draft recommendation |

| Other Topics | | | |
|-------------------------------|----------|------------------------------|--|
| Name | Reviewer | Meeting | Notes* |
| Auxiliary/"other" ingredients | ZS | Fall 2012? Update in Spring? | Possible discussion document and/or a report back to the NOP work and progress on this topic for spring 2012. May be better to have this as a discussion or presentation, but not a public document that would receive comments. |

* Highlight indicates committee action needed.

Agenda:

1. Review/approve minutes from last call
2. Review and discuss kaffir lime leaves and curry leaf
3. Discuss proposed rule on NVM and how it applies to choline, taurine, lutein, nucleotides, etc.

Discussion:

→ Review and approve meeting minutes from 2/21/2012 – some minor edits made to table.

→ Agar agar and carrageenan were moved forward, final proposals drafted

→ Kaffir lime and curry leaf

-decided not to request TR for these because they do not provide information on commercial availability

Note: Committee notes may include preliminary discussions regarding substances considered for addition to or removal from the National List. They do not represent official National Organic Program (NOP) policy or regulations. Please see the NOP website for official NOP policy, regulations, and status of substances used in organic production and handling.

- often used in Thai food recipes (unique flavor that is not easily substitutable)
- product is quarantined in Thailand due to insect infestation/problem (may be available from other locations)
- very hard to find economic data and commercial availability information
- working through material checklist
- according to information submitted by petitioner – there is one organic grower in southern CA, but only produces ~30lbs a year, the petitioner will need approximately 30x more

Questions:

- same information about Asian citrus psyllid on both petitions – does this affect curry leaf? Curry leaf is the citrus family?
- what course of action when there is no other market information that is readily available (except what is in petition)?
- make it incumbent on petitioner to find additional data/resources?

Steps forward

- finish checklist
- try to find more info on insect problem
- circulate to committee
- drafts to committee, then vote on next call

→ Proposed rule on nutrient vitamins and minerals (to clarify “nutrient vitamins and minerals”) – some HC unclear about what the proper procedure would be on how to proceed with similarly petitioned items (i.e. choline, taurine, lutein, inositol, nucleotides, etc.)
-from table in proposed rule: if ok for infant formula, then ok for other uses in other foods? Does this mean that it does not have to be petitioned for infant formula specifically? Proposed rule would allow only uses deemed essential by FDA, if limited to infant formula then only that use would be allowed. Right now it is only proposed rule. Would make sense for committee to state their opinion on these nutrients in infant formula, in response to petitions for this use. Should vote on it for infant formula? If it is required for infant formula, but don’t think it is necessary in everything else then vote on other uses?

Yes, committee should vote on these materials for infant formula. If this is process moving forward then there may be two recommendations for each material.

Need to be clear that the HC would have two recs – part of rationale is that some of these materials are complex and synthetic.

In relation to checklist, where does the “discussion” section go? An appendix can be added if needed.

Choline – on chart in proposed rule, choline, inositol and biotin are required only in non-dairy infant formula (soy)

→ Beta-carotene

- couple questions for revising TR?
- review of petition and TR – not sure if there is particular question regarding infant formula, but question on synthetic version and health impact.
- original TR was adequate on use in infant formula? Yes, but some questions

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→Prior to next meeting

summaries on calcium sulfate, glucono delta lactone, and cellulose; these will be circulated to the committee for review

Upcoming meetings and agenda items:

March 20 – Review and vote on cellulose, calcium sulfate, and glucono delta lactone. Discuss choline, taurine, nucleotides (if TR is received), inositol.

April 3 – Sulfites in MWO wines, that do not contain grapes (John and Zea will work together to address). Vote on Kaffir lime leave and curry leaves.

April 17 –

May 1 –

| Milestone | Deadline |
|------------------------------|------------------------|
| Spring 2012 Agenda Finalized | Friday, March 23, 2012 |
| Committee Proposals Due | Monday, April 2, 2012 |
| Spring 2012 NOSB Meeting | May 21 – 24, 2012 |

Note: Committee notes may include preliminary discussions regarding substances considered for addition to or removal from the National List. They do not represent official National Organic Program (NOP) policy or regulations. Please see the NOP website for official NOP policy, regulations, and status of substances used in organic production and handling.

**National Organic Standards Board (NOSB)
Handling Committee
Tuesday, March 20, 2011, 1:00 pm ET**

Present: John Foster (Chair)(JFo), Harold Austin (Vice-Chair)(HA), Nick Maravell (NM), Zea Sonnabend (ZS) and Tracy Favre (TF)

Absent: Joe Dickson (JD)

Staff: Emily Brown-Rosen, Michelle Arsenault and Lorraine Coke

| Petitioned Substances - Status of current review process | | | | | | |
|--|------------|----------|--------------|------------------------------|----------|---|
| Name | NL Section | Reviewer | Meeting | Tech Review (TR) Requested ? | TR rec'd | Notes* |
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| Barley Betafiber | 205.606 | ? | Fall 2012? | Yes | No | Revised petition sent to HC on 6/20/11; determined sufficient and TR Requested on 9/22/2011; assigned to contractor on 12/7/11; TR sent to HC 3/16/12; TR sufficiency review |
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| Caramunch malt | 205.606 | ? | TBD | | | Petition deemed insufficient by HC on 1/4/2011; petitioner notified 1/25/2011 – waiting for petitioner response |
| Choline | 205.605 | ZS | Spring 2012? | Yes | Yes | Petition sent to HC on 7/1/2011; TR Request sent to contractor on 5/31/11; revised request on 8/4/11 for new petition; TR sent to HC on 1/24/12; TR accepted as sufficient 3/27/12 |
| Curry leaf | 205.606 | JFo | Spring 2012 | No | n/a | Petition sent to HC on 8/26/11; HC decided no TR necessary on 2/7/2012. Draft recommendation. |
| 1,3-dibromo-5,5- | 205.605 | JFo | Fall 2012? | ? | | Petition sent to HC on 2/16/2012. Petition sufficiency |

| | | | | | | |
|------------------------------|---------|-----|-------------|-----|-----|---|
| dimethylhydantoin (DBDMH) | | | | | | review. |
| Dextrin | 205.605 | ZS | Fall 2012? | Yes | Yes | Revised TR sent to HC 10/17/2011; TR accepted as sufficient 1/17/12; petitioner notified on 1/23/12 - waiting for petitioner response (may not get one) |
| Gibberellic acid | 205.605 | ZS | Spring 2012 | Yes | Yes | TR Request rec'd 5/22/11; TR Request sent to contractor on 5/31/11; petition amendment rec'd from petitioner on 8/12/11; TR sent to HC on 12/16/2011; TR accepted as sufficient 3/27/12 |
| Inositol | 205.605 | JFo | Spring 2012 | Yes | Yes | Petition sent to HC on 7/25. Review for sufficiency. TR sent to HC 2/9/12. TR accepted as sufficient 3/27/12 |
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| L-carnitine | 205.605 | ? | Fall 2012? | Yes | No | Petition sent to HC 12/5/11; TR requested; Petition sufficiency review |
| L-Methionine | 205.605 | ? | Fall 2012? | Yes | No | Petition sent to HC on 11/1/2011; TR requested, due late March; Petition sufficiency review |
| Nucleotides | 205.605 | JFo | Fall 2012 | Yes | No | Petition sent to HC on 9/21/11; TR Requested, due in Feb; Petition sufficiency review |
| Sodium gluconate | 205.605 | JD | ? | Yes | | Petition sent to HC on 3/22/2011; for use in soap; TR Requested 11/15/2011. On hold, for cosmetic use. |
| Sugar Beet Fiber | 205.606 | ? | TBD | Yes | Yes | Revised petition sent to Committee 2/10/2011; Revised petition deemed sufficient on 5/13/11; TR Requested 5/23/11; TR sent to HC on 3-8-12 |
| Sulfuric acid | 205.605 | JD | Fall 2012? | Yes | No | Petition sent to Committee 8/17/2010; TR Requested 11/15/2011 |
| Taurine (for infant formula) | 205.605 | TF | Fall 2012 | Yes | Yes | Petition sent to HC 9/20/11; TR sent to HC 10/28/2011; TR accepted as sufficient 3/27/12 |

Sunset 2013 - §205.605 (a) Nonsynthetics Allowed - Status of current review process

| Name | CAS # | Reviewer | Meeting | TR? | Notes* |
|-----------------|-------|----------|-------------|-----|--|
| Agar-agar | | HA | Spring 2012 | Yes | 205.605(a); TR requested 5/23/11; TR request sent to contractor 5/25/11; ANPR comments due 8/1/11; TR sent to HC 10/11/11; TR determined to be sufficient on 1/19/2012; Draft recommendation |
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| Carrageenan | | HA | Spring 2012 | Yes | 205.605(a); TR requested 5/23/11; TR request sent to contractor |

| Sunset 2013 - §205.605 (a) Nonsynthetics Allowed - Status of current review process | | | | | |
|---|-------|----------|-------------|-----|---|
| Name | CAS # | Reviewer | Meeting | TR? | Notes* |
| | | | | | 5/25/11; ANPR comments due 8/1/11; TR sent to HC 10/11/11; TR determined to be sufficient on 1/20/2012; Draft recommendation |
| Glucono delta-lactone | | JD | Spring 2012 | Yes | 205.605(a); Last TR 8/26/2002; Draft recommendation |
| Sunset 2013 - §205.605 (b) Synthetics Allowed - Status of current review process | | | | | |
| Cellulose | | JD | Spring 2012 | Yes | 205.605(b); Last TR 9/28/2001; Draft recommendation |

| Other Topics | | | |
|-------------------------------|----------|------------------------------|--|
| Name | Reviewer | Meeting | Notes* |
| Auxiliary/"other" ingredients | ZS | Fall 2012? Update in Spring? | Possible discussion document and/or a report back to the NOP work and progress on this topic for spring 2012. May be better to have this as a discussion or presentation, but not a public document that would receive comments. |

* Highlight indicates committee action needed.

Agenda:

1. Review/approve minutes from last call
2. Review, discuss, and vote on cellulose, calcium sulfate, glucono delta lactone, gibberellic acid, choline, inositol, citrus hystrix and curry leaf
3. Taurine, Bergmont bitter orange and nucleotides?

Discussion:

Notes – reviewed and approved notes from last meeting.

GDL, Cellulose, Calcium sulfate discussion

Reviewed documents for cellulose– no substantive changes, committee agreed that recommendation was sufficient as written. Harold made motion to renew cellulose, Zea seconded the motion, Vote: 5-yes, 1-absent.

Reviewed calcium sulfate (non-synthetic, mined only) – no comments regarding recommendation to relist. TF made motion to renew calcium sulfate, HA made second. Vote: 5-yes, 1-absent.

Reviewed documents for GDL – no concerns or questions from HC. When first put on the list there was an argument to list it because could not make silken tofu without this material.

JFo made motion to renew GDL, Tracy seconded the motion. Vote: 5-yes, 1-absent.

Discussion on Gibberellic acid

The information provided showed that it is important for bananas, but not sufficient information to determine need for pineapple and citrus.

Based on information provided, the reviewer suggested allowing for bananas (not pineapple or citrus). In the proposal there was a suggestion to highlight that the committee is seeking public input regarding cultural practices.

General hesitation from the reviewer on whether to recommend at all. Other committee member recalled some previous NOSB meetings and the public comments received. It was perceived as a material that is very helpful in banana production. There was a thought/suggestion that it could help more growers convert to organic production.

→Would this be a barrier to EU entry for products that use it?

It was not expressed as a variance during talks at BioFach and discussion over EU/US equivalency arrangements. Committee members will look a little more into this.

*Reminder to reviewers to double-check the TR to ensure that any references to TR match the correct section of the TR.

Two votes needed:

Zea made motion to classify gibberellic acid as non-synthetic, Harold seconded the motion. Vote: 5-yes, 1-absent.

Zea made motion to add to 205.605 for post-harvest use on bananas only, Tracy seconded. Vote: 5-yes, 1-absent.

Discussion on Choline

Choline is petitioned as a nutrient for infant formula. Feeling is that this nutrient is not necessary as fortification in “adult” or “other” foods.

Proposal for allowing it in “organic” infant formula and in “made with” products only.

Suggestion to amend proposal to clarify “required by FDA for non-milk based infant formula.”

Comments: several committee members thought that the layout was well organized, but wondered if it needed to be broken out into two separate recommendations.

Two votes needed:

Zea made motion to classify choline (as petitioned) as synthetic, Harold seconded it. Discussion to transfer this language to the inositol/taurine since they are similar. Vote: 5-yes, 1-absent.

Zea moved to add to 205.605(b) for use in organic infant formula either labeled as “organic” or “made with organic”, Harold seconded. Vote: 5-yes, 1-absent.

Zea moved to add to 205.605(b) for use in “made with organic” agricultural products, Tracy seconded. Vote: 5-yes, 1-absent.

Discussion on Inositol

Many of the topics discussed for Choline apply to Inositol. Adults generally can get adequate amount of this nutrient from a balanced diet, therefore idea to restrict to infant formula.

Suggestion to vote on inositol, citrus hystrix, and curry leaf on email. Committee members will circulate these documents.

Taurine? Committee felt it would be best to push this discussion to the fall.

Upcoming meetings and agenda items:

April 3 – Sulfites in MWO wines, that do not contain grapes (John and Zea will work together to address). Vote on Kaffir lime leave and curry leaves.

April 17 –

May 1 –

| Milestone | Deadline |
|-----------|----------|
|-----------|----------|

| | |
|------------------------------|------------------------|
| Spring 2012 Agenda Finalized | Friday, March 23, 2012 |
| Committee Proposals Due | Monday, April 2, 2012 |
| Spring 2012 NOSB Meeting | May 21 – 24, 2012 |

Note: Committee notes may include preliminary discussions regarding substances considered for addition to or removal from the National List. They do not represent official National Organic Program (NOP) policy or regulations. Please see the NOP website for official NOP policy, regulations, and status of substances used in organic production and handling.

**National Organic Standards Board (NOSB)
Handling Committee (HC) Meeting Notes
Tuesday, April 3, 2012, 1:00 pm EDT**

Present: John Foster (Chair) (JFo), Harold Austin (Vice-Chair) (HA), Zea Sonnabend (ZS), Joe Dickson (JD) and Tracy Favre (TF)

Absent: Nick Maravell (NM),

Staff: Emily Brown Rosen (EBR), Michelle Arsenault (MA)

Work Plan

| Petitioned Substances - Status of current review process | | | | | | |
|--|-----------------------|----------|-------------|------------------------------|----------|---|
| Name | National List Section | Reviewer | Meeting | Technical Review (TR) Rqstd? | TR rec'd | Notes* |
| Ascorbyl palmitate | 205.605 | NM | tbd | Yes | No | Petition sent to HC 9/6/11; TR Request sent to Contractor 10/12/2011 |
| Barley Betafiber | 205.606 | JFo | Fall 2012 | Yes | Yes | Revised petition sent to HC on 6/20/11; determined sufficient and TR Requested on 9/22/2011; assigned to contractor on 12/7/11; TR sent to HC 3/16/12; TR sufficiency review |
| Bergamot Bitter Orange Powder | 205.606 | TF | Fall 2012 | Yes | Yes | Sent to HC on 3/22/2011; TR Requested 5/23/11; sent to contractor on 10/27/11. TR sent to HC on 2/16 ; TR sufficiency review TR sent to HC. TR accepted as sufficient 4/02/12 |
| Beta-carotene (synthetic) in infant formula | 205.605 | TF | TBD | Yes | No | Petition sent to HC on 10/13/2011; Supplemental TR requested 1/17/12- HC asked by NOP to review the question asked - questions sent 3/6/12 |
| Caramunch malt | 205.606 | ? | TBD | | | Petition deemed insufficient by HC on 1/4/2011; petitioner notified 1/25/2011 – waiting for petitioner response |
| Choline | 205.605 | ZS | Spring 2012 | Yes | Yes | Petition sent to HC on 7/1/2011; TR Request sent to contractor on 5/31/11; revised request on 8/4/11 for new petition; TR sent to HC on 1/24/12; TR accepted as sufficient 3/27/12 |
| Curry leaf | 205.606 | JFo | Spring 2012 | No | N/A | Petition sent to HC on 8/26/11; HC decided no TR necessary on 2/7/2012. Draft proposal. |

| | | | | | | |
|---|---------|-----|-------------|-----|-----|---|
| 1,3-dibromo-5,5-dimethylhydantoin (DBDMH) | 205.605 | JFo | Fall 2012? | ? | | Petition sent to HC on 2/16/2012. TR requested |
| Dextrin | 205.605 | ZS | Fall 2012? | Yes | Yes | Revised TR sent to HC 10/17/2011; TR accepted as sufficient 1/17/12; petitioner notified on 1/23/12 that additional info needed, - waiting for petitioner response |
| Gibberellic acid | 205.605 | ZS | Spring 2012 | Yes | Yes | TR Request rec'd 5/22/11; TR Request sent to contractor on 5/31/11; petition amendment rec'd from petitioner on 8/12/11; TR sent to HC on 12/16/2011; TR accepted as sufficient 3/27/12 |
| Inositol | 205.605 | JFo | Spring 2012 | Yes | Yes | Petition sent to HC on 7/25. Review for sufficiency. TR sent to HC 2/9/12. TR accepted as sufficient 3/27/12 |
| Citrus hystrix (Kaffir lime leaves) | 205.606 | JFo | Spring 2012 | No | N/A | Petition sent to HC on 8/26/11; HC decided no TR necessary on 2/7/2012; Draft proposal. |
| Lutein | 205.606 | HA | TBD | Yes | No | Petition sent to HC 11/16/2011; TR requested; Petition sufficiency review . TR sent to TR 11/21/11. Expected mid-April 2012 |
| Lycopene | 205.605 | NM | Fall 2012 | Yes | No | Petition sent to HC 9/22/2011; TR Requested; Petition sufficiency review . TR Request Sent to Contractor 10/12/2011. Expected mid-April 2012 |
| L-carnitine | 205.605 | ZS | Fall 2012 | Yes | No | Petition sent to HC 12/5/11; TR requested; Petition sufficiency review . Sent to TR contractor 12/5/11. Expected mid-April 2012 |
| L-Methionine | 205.605 | TF | Fall 2012 | Yes | Yes | Petition sent to HC on 11/1/2011; TR requested, due late March; Petition sufficiency review. TR sent to HC 3/27/12 Requested response by May 29, 2012 |
| Nucleotides | 205.605 | JFo | Fall 2012 | Yes | Yes | Petition sent to HC on 9/21/11; TR Requested, due in Feb; Petition sufficiency review. TR sent to HC on 3/9/2012 |
| Sodium gluconate | 205.605 | JD | ? | Yes | | Petition sent to HC on 3/22/2011; for use in soap; TR Requested 11/15/2011. On hold, for cosmetic use. |
| Sugar Beet Fiber | 205.606 | JFo | TBD | Yes | Yes | Revised petition sent to Committee 2/10/2011; Revised petition deemed sufficient on 5/13/11; TR Requested 5/23/11; TR sent to HC on 3-8-12 |
| Sulfuric acid | 205.605 | JD | Fall 2012? | Yes | No | Petition sent to Committee 8/17/2010; TR Requested 11/15/2011. Expected Apr-2012) |

| | | | | | | |
|------------------------------|---------|----|-----------|-----|-----|--|
| Taurine (for infant formula) | 205.605 | TF | Fall 2012 | Yes | Yes | Petition sent to HC 9/20/11; TR sent to HC 10/28/2011; TR accepted as sufficient 3/27/12 |
|------------------------------|---------|----|-----------|-----|-----|--|

Sunset 2013 - §205.605 (a) Nonsynthetics Allowed - Status of current review process

| Name | CAS # | Reviewer | Meeting | TR? | Notes* |
|-----------------------|-------|----------|-------------|-----|--|
| Agar-agar | | HA | Spring 2012 | Yes | 205.605(a); TR requested 5/23/11; TR request sent to contractor 5/25/11; ANPR comments due 8/1/11; TR sent to HC 10/11/11; TR determined to be sufficient on 1/19/2012; Draft proposal |
| Calcium sulfate | | JD | Spring 2012 | Yes | 205.605(a); last TR 2/8/2001; Draft proposal |
| Carrageenan | | HA | Spring 2012 | Yes | 205.605(a); TR requested 5/23/11; TR request sent to contractor 5/25/11; ANPR comments due 8/1/11; TR sent to HC 10/11/11; TR determined to be sufficient on 1/20/2012; Draft proposal |
| Glucono delta-lactone | | JD | Spring 2012 | Yes | 205.605(a); Last TR 8/26/2002; Draft proposal |

Sunset 2013 - §205.605 (b) Synthetics Allowed - Status of current review process

| | | | | | |
|-----------|--|----|-------------|-----|---|
| Cellulose | | JD | Spring 2012 | Yes | 205.605(b); Last TR 9/28/2001; Draft proposal |
|-----------|--|----|-------------|-----|---|

Other Topics

| Name | Reviewer | Meeting | Notes* |
|-------------------------------|----------|-----------------------------|---|
| Auxiliary/"other" ingredients | ZS | Fall 2012 Update in Spring? | Possible discussion document and/or a report back to the NOP work and progress on this topic for spring 2012. |

* Highlight indicates committee action needed.

Agenda:

- Review/approve notes from last call (March 20)
- Review and confirm assignments for review of materials in front of the HC for the fall meeting
- Review and assign sufficiency determinations we need to catch up on, and assign those to HC members.
- Get a sense from the committee about our respective workloads from May through the fall meeting
- Discuss how to proceed on the 'other/auxiliary ingredients' topic
- Sulfites in wines made with other things besides grapes

Discussion:

- Notes from March 20th approved with no changes
- Reviewed and confirmed assignments for review of materials for the fall meeting. NOP would like petition reviews before next meeting.

- Reviewed and assigned sufficiency determinations to HC members
Will submit all outstanding sufficiency documents except 4 things the committee already submitted proposals for. Will wait until new materials Excel sheet update is sent. Gibberellic acid is only outstanding item. Nucleotides, Taurine, methionine, lycopene, lutein, carnitine, ascorbic palmitate, beta carotene, barley beta fiber, DBDMH, sugar beet fiber (noted on Excel sheet) are not going to be addressed at spring mtg). Committee will concentrate on ones that are overdue.
- Committee member workloads prior to fall meeting: Four or five calls scheduled before fall meeting, and most likely will have 12+ materials to discuss. Acknowledged compressed schedule and limited work time. HC needs to have Technical Reports (TRs) in hand by July 15 in order to make proposals for fall. Fall agenda must be final and posted by Aug. 27. TR reviews now received awaiting review include: Barley beta fiber, L methionine, nucleotides (for April 17th call), sugar beet fiber, Taurine (JFo will make this a priority and then L methionine). Members will collaborate to make nutrient proposals more uniform and to discuss format, etc.
- Other/auxiliary ingredients topic. Committee discussed how to proceed on auxiliary ingredients. Complex topic. A member has contacted the former industry materials working group to reactivate and provide assistance.. They sent preliminary invitations to previous members. Calls will start soon. If any HC committee members would like to join they are welcome. Committee is made up of manufacturers, certifiers, and Material Review Organizations. Need to characterize auxiliary ingredients and what purpose they serve before talking about regulations. If this is going to be a discussion doc for fall the proposal should be submitted to HC by August 1. Committee chair would like to add standing item on future agendas to discuss 'other/auxiliary ingredients' topics. A member would like CC to discuss botanical pesticide, Rotenone. New info has come to light about Rotenone and it is off the market, and member would like committee to re-review it. In US it has no pesticide registration but it is allowed in other countries. Perhaps it should be “prohibited natural”?

Upcoming meetings and agenda items:

April 17 - nucleotides, barley fiber, sugar beet fiber, taurine, L-methionine , bergamot powder

May 1 – Cancelled

May 9 – Additional call 3PM EDT, Discuss comments

May 15 – Hold if necessary

| Milestone | Deadline |
|--------------------------|------------------------------|
| Public Comment Period | April 9 - May 3, 2012 |
| Informal prep meeting | May 21, 4pm (in Albuquerque) |
| Spring 2012 NOSB Meeting | May 22 – 25, 2012 |

Note: Committee notes may include preliminary discussions regarding substances considered for addition to or removal from the National List. They do not represent official National Organic Program (NOP) policy or regulations. Please see the NOP website for official NOP policy, regulations, and status of substances used in organic production and handling.

**National Organic Standards Board (NOSB)
Handling Committee (HC) Meeting Notes
Tuesday, April 17, 2012, 1:00 pm EDT**

Present: John Foster (Chair) (JFo), Harold Austin (Vice-Chair) (HA), and Tracy Favre (TF), Nick Maravell (NM), Zea Sonnabend (ZS), Joe Dickson (JD)

Absent: none

Staff: Emily Brown Rosen (EBR), Michelle Arsenault (MA)

Work Plan

| Petitioned Substances - Status of current review process | | | | | | |
|--|-----------------------|----------|-------------|------------------------------|----------|--|
| Name | National List Section | Reviewer | Meeting | Technical Review (TR) Rqstd? | TR rec'd | Notes* |
| Ascorbyl palmitate | 205.605 | NM | tbd | Yes | No | Petition sent to HC 9/6/11; TR Request sent to Contractor 10/12/2011. TR sent to HC 03/20/12. Response requested by May 21, 2012 |
| Barley Betafiber | 205.606 | JFo | Fall 2012 | Yes | Yes | Revised petition sent to HC on 6/20/11; determined sufficient and TR Requested on 9/22/2011; assigned to contractor on 12/7/11; TR sent to HC 3/16/12; TR sufficiency review |
| Bergamot Bitter Orange Powder | 205.606 | TF | Fall 2012 | Yes | Yes | Sent to HC on 3/22/2011; TR Requested 5/23/11; sent to contractor on 10/27/11. TR sent to HC on 2/16 ; . |
| Beta-carotene (synthetic) in infant formula | 205.605 | TF | TBD | Yes | No | Petition sent to HC on 10/13/2011; Supplemental TR requested 1/17/12- HC asked by NOP to review the question asked - questions sent 3/6/12 |
| Caramunch malt | 205.606 | ? | TBD | | | Petition deemed insufficient by HC on 1/4/2011; petitioner notified 1/25/2011 – waiting for petitioner response |
| Choline | 205.605 | ZS | Spring 2012 | Yes | Yes | Petition sent to HC on 7/1/2011; TR Request sent to contractor on 5/31/11; revised request on 8/4/11 for new petition; TR sent to HC on 1/24/12; TR accepted as sufficient 3/27/12. Proposal posted. |

| | | | | | | |
|---|---------|-----|-------------|-----|-----|---|
| Curry leaf | 205.606 | JFo | Spring 2012 | No | N/A | Petition sent to HC on 8/26/11; HC decided no TR necessary on 2/7/2012. Proposal posted. |
| 1,3-dibromo-5,5-dimethylhydantoin (DBDMH) | 205.605 | JFo | Fall 2012? | ? | | Petition sent to HC on 2/16/2012. TR requested |
| Dextrin | 205.605 | ZS | Fall 2012 | Yes | Yes | Revised TR sent to HC 10/17/2011; TR accepted as sufficient 1/17/12; petitioner notified on 1/23/12 that additional info needed. Petition withdrawn by petitioner 4 20 12 |
| Gibberellic acid | 205.605 | ZS | Spring 2012 | Yes | Yes | TR Request rec'd 5/22/11; TR Request sent to contractor on 5/31/11; petition amendment rec'd from petitioner on 8/12/11; TR sent to HC on 12/16/2011; TR accepted as sufficient 3/27/12. Proposal posted. |
| Inositol | 205.605 | JFo | Spring 2012 | Yes | Yes | Petition sent to HC on 7/25. Review for sufficiency. TR sent to HC 2/9/12. TR accepted as sufficient 3/27/12. Proposal |
| Citrus hystrix (Kaffir lime leaves) | 205.606 | JFo | Spring 2012 | No | N/A | Petition sent to HC on 8/26/11; HC decided no TR necessary on 2/7/2012; Proposal posted. |
| Lutein | 205.606 | HA | TBD | Yes | No | Petition sent to HC 11/16/2011; TR requested; Petition sufficiency review. TR request sent 11/21/11. Expected mid-April 2012 |
| Lycopene | 205.605 | NM | Fall 2012 | Yes | No | Petition sent to HC 9/22/2011; TR Requested; Petition sufficiency review. TR Request Sent to Contractor 10/12/2011. TR sent to HC 04 25 12 |
| L-carnitine | 205.605 | ZS | Fall 2012 | Yes | No | Petition sent to HC 12/5/11; TR requested; Petition sufficiency review. Sent to TR contractor 12/5/11. Expected mid-April 2012 |
| L-Methionine | 205.605 | TF | Fall 2012 | Yes | Yes | Petition sent to HC on 11/1/2011; TR requested, due late March; Petition sufficiency review. TR sent to HC 3/27/12 Requested response by May 29, 2012 |
| Nucleotides | 205.605 | JFo | Fall 2012 | Yes | Yes | Petition sent to HC on 9/21/11; TR Requested, due in Feb; Petition sufficiency review. TR sent to HC on 3/9/2012. Revised TR sent to HC 4/26/12. |

| | | | | | | |
|------------------------------|---------|-----|------------|-----|-----|---|
| Sodium gluconate | 205.605 | JD | ? | Yes | | Petition sent to HC on 3/22/2011; for use in soap; TR Requested 11/15/2011. On hold, for cosmetic use. |
| Sugar Beet Fiber | 205.606 | JFo | TBD | Yes | Yes | Revised petition sent to Committee 2/10/2011; Revised petition deemed sufficient on 5/13/11; TR Requested 5/23/11; TR sent to HC on 3-8-12 |
| Sulfuric acid | 205.605 | JD | Fall 2012? | Yes | No | Petition sent to Committee 8/17/2010; TR Requested 11/15/2011. Expected Apr-2012) |
| Taurine (for infant formula) | 205.605 | TF | Fall 2012 | Yes | Yes | Petition sent to HC 9/20/11; TR sent to HC 10/28/2011; TR accepted as sufficient 3/27/12 |

Sunset 2013 - §205.605 (a) Nonsynthetics Allowed - Status of current review process

| Name | CAS # | Reviewer | Meeting | TR? | Notes* |
|-----------------------|-------|----------|-------------|-----|--|
| Agar-agar | | HA | Spring 2012 | Yes | 205.605(a); TR requested 5/23/11; TR request sent to contractor 5/25/11; ANPR comments due 8/1/11; TR sent to HC 10/11/11; TR determined to be sufficient on 1/19/2012; Proposal posted. |
| Calcium sulfate | | JD | Spring 2012 | Yes | 205.605(a); last TR 2/8/2001; Proposal posted. |
| Carrageenan | | HA | Spring 2012 | Yes | 205.605(a); TR requested 5/23/11; TR request sent to contractor 5/25/11; ANPR comments due 8/1/11; TR sent to HC 10/11/11; TR determined to be sufficient on 1/20/2012; Proposal posted. |
| Glucono delta-lactone | | JD | Spring 2012 | Yes | 205.605(a); Last TR 8/26/2002; Proposal posted. |

Sunset 2013 - §205.605 (b) Synthetics Allowed - Status of current review process

| | | | | | |
|-----------|--|----|-------------|-----|---|
| Cellulose | | JD | Spring 2012 | Yes | 205.605(b); Last TR 9/28/2001; proposal posted. |
|-----------|--|----|-------------|-----|---|

Other Topics

| Name | Reviewer | Meeting | Notes* |
|-------------------------------|----------|-----------------------------|---|
| Auxiliary/"other" ingredients | ZS | Fall 2012 Update in Spring? | Possible discussion document and/or a report back to the NOP work and progress on this topic for spring 2012. |

* Highlight indicates committee action needed.

Agenda:

- Review/approve notes from April 3 call
- Linking with the ad hoc GMO committee
- Carrageenan
- Nucleotides checklist

Discussion:

- Approval of April 3 meeting notes deferred to next meeting
- Committee discussed how to connect the HC with the GMO ad-hoc committee: Topics of interest for HC committee might include: identification of potential GMOs; what are the review criteria, how far back in the production process must one review inputs for food ingredients and additives, (e.g. manufacturing of ingredients such as tocopherols, lecithin, starch: substrate for microorganisms such as dairy cultures and yeast). NOSB and NOP have not addressed this but OMRI has developed a decision tree. It would be helpful to have NOSB look at this issue and determine if “one step back” review of sources is adequate. Another potential topic might be how to verify the accuracy and completeness of non-GMO affidavits that are filled out for food ingredients.
- Carrageenan. There seems to be some controversy about this substance and “degraded carrageenan” or polygeenan. NOP indicated that there is information included in the new Technical Review. An HC member suggested an annotation for carrageenan to distinguish between the two. Perhaps use of the molecular weight instead of the terms “degraded or un-degraded”. The TR seems to indicate that polygeenan may be present as a breakdown product from carrageenan, or is created as a metabolite when consumed. The committee will conduct a review of the food science papers in an effort to facilitate a more detailed discussion and response to comments.
- Committee discussed the nucleotides checklist. With regard to the draft TR, several clarifications were proposed for correction by the contractor.

Upcoming meetings and agenda items:

May 1 – cancelled

May 9 – call at 3pm EDT: public comments, finish carrageenan discussion, discuss bergamot powder if time

May 15 – hold if necessary

| Milestone | Deadline |
|--------------------------|------------------------------|
| Public Comment Period | April 9 - May 3, 2012 |
| Informal prep meeting | May 21, 4pm (in Albuquerque) |
| Spring 2012 NOSB Meeting | May 22 – 25, 2012 |

Note: Committee notes may include preliminary discussions regarding substances considered for addition to or removal from the National List. They do not represent official National Organic Program (NOP) policy or regulations. Please see the NOP website for official NOP policy, regulations, and status of substances used in organic production and handling.

**National Organic Standards Board (NOSB)
 Handling Committee (HC) Meeting Notes
 Tuesday, May 9, 2012, 3:00 pm EDT**

Present: John Foster (Chair) (JFo), Harold Austin (Vice-Chair) (HA), and Tracy Favre (TF), Nick Maravell (NM), Zea Sonnabend (ZS), Joe Dickson (JD), Barry Flamm (BF) sitting in

Absent: none

Staff: Emily Brown Rosen (EBR), Michelle Arsenault (MA)

Work Plan

| Petitioned Substances - Status of current review process | | | | | | |
|--|-----------------------|----------|-------------|------------------------------|----------|--|
| Name | National List Section | Reviewer | Meeting | Technical Review (TR) Rqstd? | TR rec'd | Notes* |
| Ascorbyl palmitate | 205.605 | NM | TBD | Yes | Yes | Petition sent to HC 9/6/11; TR Request sent to Contractor 10/12/2011. TR sent to HC 03/20/12. Response requested by 05/21/12. TR accepted as sufficient 4/30/12. |
| Barley Betafiber | 205.606 | JFo | Fall 2012 | Yes | Yes | Revised petition sent to HC on 6/20/11; determined sufficient and TR Requested on 9/22/2011; assigned to contractor on 12/7/11; TR sent to HC 3/16/12; TR sufficiency review. TR accepted as sufficient 4/30/12. |
| Bergamot Bitter Orange Powder | 205.606 | TF | Fall 2012 | Yes | Yes | Sent to HC on 3/22/2011; TR Requested 5/23/11; sent to contractor on 10/27/11. TR sent to HC on 2/16; Updated TR sent to HC 04 30 12. |
| Beta-carotene (synthetic) in infant formula | 205.605 | TF | TBD | Yes | Yes | Petition sent to HC on 10/13/2011; Supplemental TR requested 1/17/12- HC asked by NOP to review the question asked - questions sent 3/6/12 |
| Caramunch malt | 205.606 | ? | TBD | | | Petition deemed insufficient by HC on 1/4/2011; petitioner notified 1/25/2011 – waiting for petitioner response |
| Choline | 205.605 | ZS | Spring 2012 | Yes | Yes | Petition sent to HC on 7/1/2011; TR Request sent to contractor on 5/31/11; revised request on 8/4/11 for new |

| Petitioned Substances - Status of current review process | | | | | | |
|--|-----------------------|----------|-------------|------------------------------|----------|---|
| Name | National List Section | Reviewer | Meeting | Technical Review (TR) Rqstd? | TR rec'd | Notes* |
| | | | | | | petition; TR sent to HC on 1/24/12; TR accepted as sufficient 3/27/12. Proposal posted. |
| Curry leaf | 205.606 | JFo | Spring 2012 | No | N/A | Petition sent to HC on 8/26/11; HC decided no TR necessary on 2/7/2012. Proposal posted. |
| 1,3-dibromo-5,5-dimethylhydantoin (DBDMH) | 205.605 | JFo | Fall 2012? | ? | | Petition sent to HC on 2/16/2012. TR requested |
| Dextrin | 205.605 | ZS | Withdrawn | Yes | Yes | Revised TR sent to HC 10/17/2011; TR accepted as sufficient 1/17/12; petitioner notified on 1/23/12 that additional info needed. Petition withdrawn by petitioner 4 20 12 |
| Gibberellic acid | 205.605 | ZS | Spring 2012 | Yes | Yes | TR Request rec'd 5/22/11; TR Request sent to contractor on 5/31/11; petition amendment rec'd from petitioner on 8/12/11; TR sent to HC on 12/16/2011; TR accepted as sufficient 3/27/12. Proposal posted. |
| Inositol | 205.605 | JFo | Spring 2012 | Yes | Yes | Petition sent to HC on 7/25. Review for sufficiency. TR sent to HC 2/9/12. TR accepted as sufficient 3/27/12. Proposal posted |
| Citrus hystrix (Kaffir lime leaves) | 205.606 | JFo | Spring 2012 | No | N/A | Petition sent to HC on 8/26/11; HC decided no TR necessary on 2/7/2012; Proposal posted. |
| Lutein | 205.606 | HA | TBD | Yes | Yes | Petition sent to HC 11/16/2011; TR requested; Petition sufficiency review. TR request sent 11/21/11. TR sent 4/27/12 |
| Lycopene | 205.605 | NM | Fall 2012 | Yes | Yes | Petition sent to HC 9/22/2011; TR Requested; Petition sufficiency review. TR Request Sent to Contractor 10/12/2011. TR sent to HC 04 25 12 |
| L-carnitine | 205.605 | ZS | Fall 2012 | Yes | Yes | Petition sent to HC 12/5/11; TR requested; Petition sufficiency review. Sent to TR contractor 12/5/11. Expected mid-April 2012. TR sent to HC 05 02 12 |

| Petitioned Substances - Status of current review process | | | | | | |
|---|-----------------------|----------|-------------|------------------------------|----------|--|
| Name | National List Section | Reviewer | Meeting | Technical Review (TR) Rqstd? | TR rec'd | Notes* |
| L-Methionine | 205.605 | TF | Fall 2012 | Yes | Yes | Petition sent to HC on 11/1/2011; TR requested, due late March; Petition sufficiency review. TR sent to HC 3/27/12 Requested response by 05/29/12. TR accepted as sufficient 4/30/12. |
| Nucleotides | 205.605 | JFo | Fall 2012 | Yes | Yes | Petition sent to HC on 9/21/11; TR Requested, due Feb; Petition sufficiency review. TR sent to HC on 3/9/2012. Revised TR sent to HC 04/26/12. TR accepted as sufficient 4/30/12. |
| Sodium gluconate | 205.605 | JD | ? | Yes | | Petition sent to HC on 3/22/2011; for use in soap; TR Requested 11/15/2011. On hold, for cosmetic use. |
| Sugar Beet Fiber | 205.606 | JFo | TBD | Yes | Yes | Revised petition sent to Committee 2/10/2011; Revised petition deemed sufficient on 5/13/11; TR Requested 5/23/11; Revised TR sent to HC 04/26/12 accepted as sufficient 4/30/12. |
| Sulfuric acid | 205.605 | JD | Fall 2012? | Yes | Yes | Petition sent to Committee 8/17/2010; TR Requested 11/15/2011.. TR sent to HC 05/01/12 |
| Taurine (for infant formula) | 205.605 | TF | Fall 2012 | Yes | Yes | Petition sent to HC 9/20/11; TR sent to HC 10/28/2011; TR accepted as sufficient 3/27/12 |
| Sunset 2013 - §205.605 (a) Nonsynthetics Allowed - Status of current review process | | | | | | |
| Name | CAS # | Reviewer | Meeting | TR? | | Notes* |
| Agar-agar | | HA | Spring 2012 | Yes | | 205.605(a); TR requested 5/23/11; TR request sent to contractor 5/25/11; ANPR comments due 8/1/11; TR sent to HC 10/11/11; TR determined to be sufficient on 1/19/2012; Proposal posted. |
| Calcium sulfate | | JD | Spring 2012 | Yes | | 205.605(a); last TR 2/8/2001; Proposal posted. |
| Carrageenan | | HA | Spring 2012 | Yes | | 205.605(a); TR requested 5/23/11; TR request sent to contractor 5/25/11; ANPR comments due 8/1/11; TR sent to HC 10/11/11; TR |

| Sunset 2013 - §205.605 (a) Nonsynthetics Allowed - Status of current review process | | | | | |
|---|-------|----------|-------------|-----|--|
| Name | CAS # | Reviewer | Meeting | TR? | Notes* |
| | | | | | determined to be sufficient on 1/20/2012; Proposal posted. |
| Glucono delta-lactone | | JD | Spring 2012 | Yes | 205.605(a); Last TR 8/26/2002; Proposal posted. |
| Sunset 2013 - §205.605 (b) Synthetics Allowed - Status of current review process | | | | | |
| Cellulose | | JD | Spring 2012 | Yes | 205.605(b); Last TR 9/28/2001; proposal posted. |

| Other Topics | | | |
|-------------------------------|----------|-----------------------------|---|
| Name | Reviewer | Meeting | Notes* |
| Auxiliary/"other" ingredients | ZS | Fall 2012 Update in Spring? | Possible discussion document and/or a report back to the NOP work and progress on this topic for spring 2012. |

* Highlight indicates committee action needed.

Agenda:

- Public comment
- Questions about MC presentations
- Workplan

Discussion:

- Public comment
 - Public comments on carrageenan and gibberellic acid were significant. Many of the public comments were technical. Three types of un-degraded carrageenan and different amounts of alkali are used to extract it. Discussed specific technical comments and scientific evidence. Discussed whether or not the NOSB should adopt the JEFCA 2007 guidance (Joint Committee on Food and Agriculture/World Health-UN). Carrageenan is not specified, but they disallow it in infant formula in EU. EU Scientific Committee on Food concluded that there was not enough information to make a determination. Is it necessary to distinguish between polygeenan and carrageenan, so perhaps reference to the CAS # could be used to make the distinction. Carrageenan has 4 CAS #'s, so instead of specifying molecular weight just refer to CAS # which is information that is readily available on the spec sheet.

Committee decided to: 1. Hold off on reclassification until NOP guidance is out. 2. Add annotation to restrict use of carrageenan as not allowed in infant formula (e.g. JFCA). Chair will revise document based on this discussion and notify the other NOSB members prior to the meeting.

Motion to list CAS #s to define carrageenan and to adopt recommendation from EU to not allow it in infant formula:

Motion made by: ZS, Seconded by HA. Yes: 6 No: 0 Abstain: 0 Absent: 0 Recuse: 0 This replaces the earlier motion.

Gibberellic acid: Committee received one substantive comment about inerts. Received very little input from people who wanted gibberellic acid. Didn't get much comment from growers. A member indicated that there is concern about effect on nutritional content. Cultural practices resolve the need for having to use gibberellic acid.

Choline and inositol: member referenced comment about limiting this in infant formula.

- Questions about MC presentations at meeting? NOP will be presenting on each material but not in depth. Logistics/meeting format (i.e. comments, then voting) was changed so the discussion could occur closer to the vote.
- Workplan. Didn't have time to discuss workplan

Upcoming meetings and agenda items:

June 5, 2012, 1PM EDT

June 19, 2012 1PM EDT

July 3, 2012, 1PM EDT

July 17, 2012, 1PM EDT

| Milestone | Deadline |
|---------------------------|------------------------------------|
| | |
| Fall proposals due to NOP | August 20, 2012 |
| Fall 2012 NOSB Meeting | October 16-19, 2012 Providence, RI |

Note: Subcommittee notes may include preliminary discussions regarding substances considered for addition to or removal from the National List. They do not represent official National Organic Program (NOP) policy or regulations. Please see the NOP website for official NOP policy, regulations, and status of substances used in organic production and handling.

**National Organic Standards Board (NOSB)
Handling Subcommittee (HS) Meeting Notes
Tuesday, June 5, 2012, 1:00 pm EDT**

Present: Joe Dickson (JD), Harold Austin (Vice-Chair) (HA), Zea Sonnabend (ZS), Nick Maravell (NM)

Absent: Tracy Favre (TF), John Foster (Chair) (JFo)

Staff: Emily Brown Rosen (EBR), Michelle Arsenault (MA)

Work Plan

| Petitioned Substances - Status of current review process | | | | | | |
|--|-----------------------|----------|-------------|------------------------------|----------|---|
| Name | National List Section | Reviewer | Meeting | Technical Review (TR) Rqstd? | TR rec'd | Notes* |
| Ascorbyl palmitate | 205.605 | NM | Fall 2012 | Yes | Yes | TR accepted as sufficient 4/30/12. |
| Barley Betafiber | 205.606 | JFo | Fall 2012 | Yes | Yes | Revised petition sent to HC on 6/20/11; TR accepted as sufficient 4/30/12. |
| Bergamot Bitter Orange Powder | 205.606 | TF | Spring 2013 | Yes | Yes | Sent to HC on 3/22/2011; TR Requested 5/23/11; sent to contractor on 10/27/11. TR sent to HC on 2/16; Updated TR sent to HC 04 30 12. Need TR sufficiency |
| Beta-carotene (synthetic) in infant formula | 205.605 | TF | Fall 2012 | Yes | Yes | Petition sent to HC on 10/13/2011; Supplemental TR requested 1/17/12- HC asked by NOP to review the question asked - questions sent 3/6/12. Updated TR sent to NOSB. Due 6/29/2012 |
| 1,3-dibromo-5,5-dimethylhydantoin (DBDMH) | 205.605 | JFo | Fall 2012 | Yes | No | Petition sent to HC on 2/16/2012. TR requested |
| Lutein | 205.606 | HA | Fall 2012 | Yes | Yes | Petition sent to HC 11/16/2011; TR sent to HC on 4/27/2012. TR Sufficiency Review due 06/27/12 |
| Lycopene | 205.605 | NM | Fall 2012 | Yes | Yes | Petition sent to HC 9/22/2011; TR sent to HC 04 25 12. TR Sufficiency Review due 6/25/201 |

| Petitioned Substances - Status of current review process | | | | | | |
|--|-----------------------|----------|-------------|------------------------------|----------|--|
| Name | National List Section | Reviewer | Meeting | Technical Review (TR) Rqstd? | TR rec'd | Notes* |
| L-carnitine | 205.605 | ZS | Fall 2012 | Yes | Yes | Petition sent to HC 12/5/11; TR requested; Petition sufficiency review. Sent to TR contractor 12/5/11. Expected mid-April 2012. TR sent to HC 05 02 12 |
| L-methionine | 205.605 | TF | Fall 2012 | Yes | Yes | Petition sent to HC on 11/1/2011 TR accepted as sufficient 4/30/12. |
| Nucleotides | 205.605 | JFo | Fall 2012 | Yes | Yes | Petition sent to HC on 9/21/11; Revised TR sent to HC 04/26/12. TR accepted as sufficient 4/30/12. |
| Sugar Beet Fiber | 205.606 | JFo | Fall 2012 | Yes | Yes | Revised petition sent to Committee 2/10/2011; Revised TR sent to HC 04/26/12. TR accepted as sufficient 4/30/12. |
| Taurine (for infant formula) | 205.605 | TF | Fall 2012 | Yes | Yes | Petition sent to HC 9/20/11; TR sent to HC 10/28/2011; TR accepted as sufficient 3/27/12 |
| Sodium gluconate | 205.605 | JD | ? | Yes | | Petition sent to HC on 3/22/2011; for use in soap; TR Requested 11/15/2011. On hold, for cosmetic use. |
| Sulfuric acid | 205.605 | JD | Spring 2013 | Yes | Yes | Petition sent to Committee 8/17/2010; TR Requested 11/15/2011. Draft TR sent to HC 05/01/12. Review by 7/2/2012 |

Sunset 2015 - §205.605 (a) Nonsynthetics Allowed - Status of current review process

| Name | CAS # | Reviewer | Meeting | TR? | Notes* |
|------|-------|----------|---------|-----|--------|
|------|-------|----------|---------|-----|--------|

Sunset 2015 - §205.605 (b) Synthetics Allowed - Status of current review process

| Other Topics | | | | |
|-------------------------------|----------|-----------|--------------------------------|--|
| Name | Reviewer | Meeting | Notes* | |
| Auxiliary/"other" ingredients | ZS | Fall 2012 | Discussion document fall 2012. | |

* Highlight indicates committee action needed.

Agenda:

- Approve previous 3 HC meeting minutes.
- Nucleotides -discussion and voting if possible, leaving open the option to email votes for those in absentia
- Bergamot bitter orange powder - discussion and voting as above.
- Agree to future conf call schedule, with 1 extra call in June, July and August to make sure we can cover all the materials on the work plan.
- Confirm and codify materials and reviewer in the meeting minutes.
- Please consider which materials still need petition sufficiency (see last meeting minutes) review and make sure those reviews are done by the following call. We need to pay special attention to the materials petitioned for infant formulas, so that in case we have additional questions for the TR contractor or petitioner, we still have time to get responses and get our proposals done by, say, August 20th.

Discussion:

- April 3rd meeting minutes: accepted with no changes. April 17 meeting minutes: accepted with no changes, May 9 meeting minutes: accepted with no changes.
- Nucleotides. Subcommittee members had several questions about the draft motion and checklist: Motion is not entirely clear. Didn't understand comment written on checklist about "redundant with narrative form". Several other questions about checklist arose as well: more details needed on classification determination, need to describe alternatives(proteins are normally digested into nucleotides), compatible/consistency criteria can be answered. Will table discussion until JFo is present.
- Bergamot bitter orange powder document needs some clarification from TF. Need to determine whether or not this is regulated by EPA. A member asked about the history of this material from 2005, about solvents used in processing. In 2005, the manufacturer asked if they needed to petition this particular material as part of a wash product, and they were told yes, unless they were planning to use organic bitter orange powder. Since this is the intention, then the question of whether or not it is "certified organic" is not germane. Was the checklist completed with the notion that the product is an ingredient or a processing aid? Committee had more questions for TF before moving forward. EBR will ask NOP staff for input since it could be considered a post-harvest material and get back to back to Subcommittee. [Note – this material is scheduled for spring 2013, HC may want to delay further review, especially if there are a number of questions to be resolved]
- Scheduled future conference call schedule, with 1 extra call in June, July, and August.
- At next meeting Subcommittee will address 6 items: ZS will discuss L-carnitine; NM will discuss ascorbyl palmitate; Subcommittee will take votes on BBO and nucleotides; JD will discuss sulfuric acid [note –this is scheduled for spring 2013 review, NOP suggests delaying

this review until fall materials are all complete]; HA will discuss lutein. ZS indicated that she is opposed to any unnecessary fortification of adult food. NM echoed that sentiment.

- Reviewed materials to determine which ones still need petition sufficiency (see last meeting minutes). Chair directed subcommittee to pay special attention to the materials petitioned for infant formulas, so that in case there are additional questions for the TR contractor or petitioner, there is still time to get responses and get proposals done by August 20th.
- Jean Richardson expressed an interest in joining the Handling Subcommittee and there was a question about how to proceed. Members asked that this be addressed on the next Executive Subcommittee call.

Upcoming meetings and agenda items:

June 19, 2012 1:00 EDT:

1. nucleotides : discuss and vote
2. bergamot bitter orange: discuss and vote (if enough info to go forward)
3. ZS will discuss L-carnitine;
4. NM will discuss ascorbyl palmitate;
5. HA will discuss lutein
6. JD – can you discuss Beta carotene?

June 26, 2012 4:00 EDT (ZS away)

1. Vote on L-carnitine;
2. Vote on ascorbyl palmitate;;
3. Vote on lutein
4. Vote on beta carotene
5. Discuss L methionine – TF (may be on vacation this week)
6. Discuss Taurine – TF
7. Discuss Lycopene -NM

July 3, 2012 1:00 EDT (ZS away)

1. Vote on L methionine
2. Vote on Taurine
3. Vote on Lycopene
4. Discuss barley beta fiber – JFO

- 5. Discuss sugar beet fiber – JFO

July 17, 2012 1:00 EDT

- 1. Vote on barley beta fiber
- 2. Vote on sugar beet fiber
- 3. Discuss sulfuric acid – JD if time

July 24, 2012 4:00 EDT

- 1. Vote on sulfuric if done
- 2. Discuss DBDMH if TR is done

August 7, 2012 1:00 EDT

August 14, 2012 4:00 EDT

- 1. Vote on DBDMH
- 2. Any leftover materials
- 3. Discuss Other ingredients

| Milestone | Deadline |
|--|---------------------|
| NOP - "Finalize" agenda | August 13, 2012 |
| Fall 2012 proposals due to NOP | August 20, 2012 |
| NOP - Post proposals, Publish FRN, Open public comment | August 27, 2012 |
| Public comment closes | September 24, 2012 |
| NOP - Send compiled public comments to NOSB | October 1, 2012 |
| Fall 2012 NOSB Meeting – Providence, RI | October 15-18, 2012 |

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**National Organic Standards Board (NOSB)
Handling Subcommittee (HS) Meeting Notes
Tuesday, June 19, 2012, 1:00 pm EDT**

Present: John Foster (Chair) (JFo), Harold Austin (Vice-Chair) (HA), Zea Sonnabend (ZS), Nick Maravell (NM), Tracy Favre (TF)

Absent: Joe Dickson (JD)

Staff: Emily Brown Rosen (EBR), Michelle Arsenault (MA)

Work Plan

| Petitioned Substances - Status of current review process | | | | | | |
|--|-----------------------|----------|-------------|------------------------------|----------|---|
| Name | National List Section | Reviewer | Meeting | Technical Review (TR) Rqstd? | TR rec'd | Notes* |
| Ascorbyl palmitate | 205.605 | NM | Fall 2012 | Yes | Yes | TR accepted as sufficient 4/30/12. |
| Barley Betafiber | 205.606 | JFo | Fall 2012 | Yes | Yes | Revised petition sent to HC on 6/20/11; TR accepted as sufficient 4/30/12. |
| Bergamot Bitter Orange Powder | 205.606 | TF | Spring 2013 | Yes | Yes | Sent to HC on 3/22/2011; TR Requested 5/23/11; sent to contractor on 10/27/11. TR sent to HC on 2/16; Updated TR sent to HC 04 30 12. Need TR sufficiency |
| Beta-carotene (synthetic) in infant formula | 205.605 | TF | Fall 2012 | Yes | Yes | Petition sent to HC on 10/13/2011; Supplemental TR requested 1/17/12- HC asked by NOP to review the question asked - questions sent 3/6/12. Updated TR sent to NOSB. Due 6/29/2012 |
| 1,3-dibromo-5,5-dimethylhydantoin (DBDMH) | 205.605 | JFo | Fall 2012 | Yes | No | Petition sent to HC on 2/16/2012. TR requested |
| Lutein | 205.606 | HA | Fall 2012 | Yes | Yes | Petition sent to HC 11/16/2011; TR sent to HC on 4/27/2012. TR Sufficiency Review due 06/27/12 |
| Lycopene | 205.605 | NM | Fall 2012 | Yes | Yes | Petition sent to HC 9/22/2011; TR sent to HC 04 25 12. TR Sufficiency Review due 6/25/201 |

| Petitioned Substances - Status of current review process | | | | | | |
|--|-----------------------|----------|-------------|------------------------------|----------|--|
| Name | National List Section | Reviewer | Meeting | Technical Review (TR) Rqstd? | TR rec'd | Notes* |
| L-carnitine | 205.605 | ZS | Fall 2012 | Yes | Yes | Petition sent to HC 12/5/11; TR requested; Petition sufficiency review. Sent to TR contractor 12/5/11. Expected mid-April 2012. TR sent to HC 05 02 12. TR accepted as sufficient 06 19 12 |
| L-methionine | 205.605 | TF | Fall 2012 | Yes | Yes | Petition sent to HC on 11/1/2011 TR accepted as sufficient 4/30/12. |
| Nucleotides | 205.605 | JFo | Fall 2012 | Yes | Yes | Petition sent to HC on 9/21/11; Revised TR sent to HC 04/26/12. TR accepted as sufficient 4/30/12. |
| Sugar Beet Fiber | 205.606 | JFo | Fall 2012 | Yes | Yes | Revised petition sent to Committee 2/10/2011; Revised TR sent to HC 04/26/12. TR accepted as sufficient 4/30/12. |
| Taurine (for infant formula) | 205.605 | TF | Fall 2012 | Yes | Yes | Petition sent to HC 9/20/11; TR sent to HC 10/28/2011; TR accepted as sufficient 3/27/12 |
| Sodium gluconate | 205.605 | JD | ? | Yes | | Petition sent to HC on 3/22/2011; for use in soap; TR Requested 11/15/2011. On hold, for cosmetic use. |
| Sulfuric acid | 205.605 | JD | Spring 2013 | Yes | Yes | Petition sent to Committee 8/17/2010; TR Requested 11/15/2011. Draft TR sent to HC 05/01/12. Review by 7/2/2012 |

Sunset 2015 - §205.605 (a) Nonsynthetics Allowed - Status of current review process

| Name | CAS # | Reviewer | Meeting | TR? | Notes* |
|------|-------|----------|---------|-----|--------|
|------|-------|----------|---------|-----|--------|

Sunset 2015 - §205.605 (b) Synthetics Allowed - Status of current review process

| Other Topics | | | |
|-------------------------------|----------|-----------|--------------------------------|
| Name | Reviewer | Meeting | Notes* |
| Auxiliary/"other" ingredients | ZS | Fall 2012 | Discussion document fall 2012. |

* Highlight indicates committee action needed.

Agenda:

- Approve June 5 minutes
- Bergamot Bitter Orange (BBO), vote --although if there are many unresolved concerns, we may elect to hold over for spring 2013.
- L-carnitine, discussion, ZS
- Ascorbyl palmitate, discussion, NM
- Nucleotides, vote
- Lutein, HA.
- Sulfuric acid--scheduled for spring 2013 review, NOP suggests delaying this review until fall materials are all complete.

Discussion:

- June 5 meeting minutes accepted with no changes.
- Bergamot Bitter Orange: EBR responded to request for clarification about the petition for bergamot bitter orange powder. She checked with EPA and this substance does not have a residue tolerance, or exemption from tolerance and must be registered as a pesticide to use as an antimicrobial sanitizer. The petitioner is applying to EPA for registration, but has not yet received it. The petitioner is amending the request for use, to change to a crops use only. EBR circulated a few proposed minor changes to the TR to describe the EPA status and petitioned use, so petition is on hold for time being. HS still needs to determine TR sufficiency. Subcommittee agreed to allow for email votes for members that are away. Will institute a 7 day post-discussion window for voting.
- L-carnitine:
 - Petition for synthetic form. Used in infant formula but not considered essential in FDA regulations. Can extract and make carnitine from non-synthetic sources fairly easily. ZS will make motion to list, using "as petitioned" and then take vote. Committee discussed whether or not to add the language about "Medical enteral". It appears it is not necessary in this case. Minor revisions were made to doc and it will be circulated post-meeting. JFo indicated that the checklist needs to be revised; an item that has been discussed over the last 2 years. The form is redundant, and it was suggested that Crops and Livestock be segregated. MA is working with L Brines to update. TR is accepted as sufficient by HS, with minor correction to the comment about pet food.

VOTE:

Motion to classify as synthetic made by: CoB,
Seconded by: NM.

Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0 (JD will vote via email)

DFO note: JD did not vote, so final vote is yes: 5, absent: 2

Motion to add L-carnitine, (CAS #541-15-1) to list 205.605b for infant formula: made by CoB, seconded by HA.

Yes: 2 No: 3 Abstain: 0 Absent: 1 Recuse: 0 (JD will vote via email)

DFO note: JD did not vote, so final vote is yes: 5, absent: 2

- Ascorbyl palmitate (NM)
 - Synthetic being petitioned for use in infant formula. Ascorbyl palmitate is an antioxidant and source of vitamin C. It is used as a preservative, and is on the GRAS list (Generally Regarded as Safe). Two issues/questions were discussed: Does it have unique properties for use in infant formula and are there other preservatives that can be substituted? NM recommends that Ascorbyl palmitate be classified as synthetic and is not essential. Subcommittee feels that this may lead to problems with “other ingredients”. A member asked if ascorbic acid (synthetic and is on list) is an alternative and if there was a difference between it and Ascorbyl palmitate. According to the information in the TR, ascorbic acid is one half of Ascorbyl palmitate, and ascorbic acid is water soluble while Ascorbyl palmitate is both fat and water soluble. Additionally Ascorbyl palmitate may be more synergistic with other antioxidants, such as tocopherols, rendering both of them more effective. The Chair noted that when the proposal is put forth, the HS will ask for more information about alternatives and whether the other materials are usable. Staff noted the 205.600(b)(4) criteria about use as preservative. Is this the primary use? TR has not been posted yet so NM will look at sufficiency criteria.
- Nucleotides. Occur in food but TR didn't explain it very well, so this was not addressed in the previously completed checklist. (Category 2 question 6, 7, 9, and 10). JFo will review checklist and get back to group. Subcommittee feels that the TR is not sufficient, but it was already submitted as sufficient and posted to NOP website. Subcommittee considered a discussion document in an effort to collect public comment.
- Lutein-discussion deferred until next call.

Upcoming meetings and agenda items:

June 26, 2012 4:00 EDT (ZS away)

- Vote on L-carnitine: **done**
- Discussion on Ascorbyl palmitate: **done**
- Discuss (vote?) on lutein
- Vote on beta carotene
- Discuss L methionine – TF
- Discuss Taurine – TF

- Discuss Lycopene -NM

July 3, 2012 1:00 EDT (ZS away)

- Vote on L methionine
- Vote on Taurine
- Vote on Lycopene
- Discuss barley beta fiber – JFO
- Discuss sugar beet fiber – JFO

July 17, 2012 1:00 EDT

- Vote on barley beta fiber
- Vote on sugar beet fiber (ZS back)
- Discuss sulfuric acid – JD if time

July 24, 2012 4:00 EDT

- Vote on sulfuric if done
- Discuss DBDMH if TR is done

August 7, 2012 1:00 EDT

- Other ingredients

August 14, 2012 4:00 EDT

- Vote on DBDMH
- Any leftover materials
- Discuss Other ingredients
- Other ingredients continued if necessary.

| Milestone | Deadline |
|--|-----------------|
| NOP - "Finalize" agenda | August 13, 2012 |
| Fall 2012 proposals due to NOP | August 20, 2012 |
| NOP - Post proposals, Publish FRN, Open public comment | August 27, 2012 |

| | |
|---|---------------------|
| Public comment closes | September 24, 2012 |
| NOP - Send compiled public comments to NOSB | October 1, 2012 |
| Fall 2012 NOSB Meeting – Providence, RI | October 15-18, 2012 |

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**National Organic Standards Board (NOSB)
Handling Subcommittee (HS) Meeting Notes
Tuesday, June 26, 2012, 4:00 pm EDT**

Present: John Foster (Chair) (JFo), Harold Austin (Vice-Chair) (HA), Nick Maravell (NM), Tracy Favre (TF), Jean Richardson (JR)

Absent: Joe Dickson (JD), Zea Sonnabend (ZS)

Staff: Emily Brown Rosen (EBR), Michelle Arsenault (MA)

Work Plan

| Petitioned Substances - Status of current review process | | | | | | |
|--|-----------------------|----------|-----------|------------------------------|----------|--|
| Name | National List Section | Reviewer | Meeting | Technical Review (TR) Rqstd? | TR rec'd | Notes* |
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| Barley Betafiber | 205.606 | JFo | fall 2012 | Yes | Yes | Revised petition sent to HC on 6/20/11; TR accepted as sufficient 4/30/12. |
| Beta-carotene (synthetic) in infant formula | 205.605 | TF | fall 2012 | Yes | Yes | Petition sent to HC on 10/13/2011; Supplemental TR requested 1/17/12- HC asked by NOP to review the question asked - questions sent 3/6/12. Updated TR sent to NOSB. Petition and amended TR accepted as sufficient. |
| 1,3-dibromo-5,5-dimethylhydantoin (DBDMH) | 205.605 | JFo | fall 2012 | Yes | No | Petition sent to HC on 2/16/2012. TR requested. Expected mid-July. |
| Lutein | 205.606 | HA | fall 2012 | Yes | Yes | Petition sent to HC 11/16/2011; TR sent to HC on 4/27/2012. TR accepted as sufficient 06/26/12 |
| Lycopene | 205.605 | NM | fall 2012 | Yes | Yes | Petition sent to HC 9/22/2011; TR sent to HC 04 25 12. TR Sufficiency Review due 6/25/201 |
| L-carnitine | 205.605 | ZS | fall 2012 | Yes | Yes | Petition sent to HC 12/5/11; TR requested; Petition sufficiency review. Sent to TR contractor 12/5/11. Expected mid-April 2012. TR sent to HC 05 02 12. TR accepted as sufficient 06 19 12. TR posted 06/25/12 |

| Petitioned Substances - Status of current review process | | | | | | |
|---|-----------------------|----------|--------------|------------------------------|----------|--|
| Name | National List Section | Reviewer | Meeting | Technical Review (TR) Rqstd? | TR rec'd | Notes* |
| L-methionine | 205.605 | TF | fall 2012 | Yes | Yes | Petition sent to HC on 11/1/2011 TR accepted as sufficient 4/30/12. |
| Nucleotides | 205.605 | JFo | fall 2012 | Yes | Yes | Petition sent to HC on 9/21/11; Revised TR sent to HC 04/26/12. TR accepted as sufficient 4/30/12. |
| Sugar Beet Fiber | 205.606 | JFo | fall 2012 | Yes | Yes | Revised petition sent to Committee 2/10/2011; Revised TR sent to HC 04/26/12. TR accepted as sufficient 4/30/12. TR posted 06/25/12 |
| Taurine (for infant formula) | 205.605 | JR | fall 2012 | Yes | Yes | Petition sent to HC 9/20/11; TR sent to HC 10/28/2011; TR accepted as sufficient 3/27/12. TR posted |
| Bergamot Bitter Orange Powder | 205.606 | TF | spring 2013? | Yes | Yes | Sent to HC on 3/22/2011; TR Requested 5/23/11; sent to contractor on 10/27/11. TR sent to HC on 2/16; Updated TR sent to HC 04 30 12. TR posted 06/25/12. On hold. |
| Sulfuric acid | 205.605 | JD | spring 2013 | Yes | Yes | Petition sent to Committee 8/17/2010; TR Requested 11/15/2011. Draft TR sent to HC 05/01/12. Review by 7/2/2012 |
| Sodium gluconate | 205.605 | JD | ? | Yes | | Petition sent to HC on 3/22/2011; for use in soap; TR Requested 11/15/2011. On hold, for cosmetic use. |
| Sunset 2015 - §205.605 (a) Nonsynthetics Allowed - Status of current review process | | | | | | |
| Name | CAS # | Reviewer | Meeting | TR? | Notes* | |
| Sunset 2015 - §205.605 (b) Synthetics Allowed - Status of current review process | | | | | | |

| Other Topics | | | |
|-------------------------------|----------|-----------|--------------------------------|
| Name | Reviewer | Meeting | Notes* |
| Auxiliary/"other" ingredients | ZS | fall 2012 | Discussion document fall 2012. |

* Highlight indicates committee action needed.

Agenda:

- Approve minutes from 06 19 12
- Lutein discussion
- Discuss beta carotene
- Discuss lycopene

Discussion:

- Minutes from June 19th call approved with no changes
- Lutein is being petitioned to be added as an organic non-agricultural product in baby formula. Lutein has potential implications for human health as it plays a role in eye health. Derived from marigolds and is available in leafy greens and breast milk. Extraction process is similar to beta carotene in that Hexane is used, as well as isopropyl alcohol and a number of other possible solvents. A member asked what percent of conventional baby foods contain lutein. Petition and TR were accepted as sufficient by HS. NOP suggested looking at Lutein, beta-carotene, lycopene, Taurine, and L carnitine with a side by side comparison. HA will do more research and continue discussion next week.
- Beta carotene: petitioned material is for the synthetic form in infant formula, as antioxidant (to stabilize fats). . Subcommittee approved petition and amended TR.
- Lycopene: Synthetic. Currently used in Similac. Petitioner wants to use it in organic products, but subcommittee does not see it as an essential ingredient. There doesn't appear to be any definitive scientific information that lycopene is essential to infants. It's unclear as to why it should be added to infant formula.
- It was noted that TR templates are being updated for new contract bids, should have better information about alternatives.

Upcoming meetings and agenda items:

June 26, 2012 4:00 EDT (ZS away)-Additional meeting

- Vote on L-carnitine: done
- Discussion on Ascorbyl palmitate: done
- Discuss beta carotene – TF
- Discuss L methionine – TF – deferred to July 3
- Discuss Taurine – JR – deferred to July 3
- Discuss Lycopene –NM
- Discuss Lutein - HA

July 3, 2012 1:00 EDT (ZS away)

- Discuss/vote on L methionine
- Discuss/vote on Taurine (JR)
- Vote on Lycopene
- Vote on Lutein
- Discuss barley beta fiber – JFO
- Discuss sugar beet fiber – JFO
- Discuss/vote on beta carotene – TR
- Vote on Ascorbyl palmitate

July 17, 2012 1:00 EDT

- Vote on barley beta fiber (JFo)
- Vote on sugar beet fiber (ZS)
- Discuss sulfuric acid – JD if time

July 24, 2012 4:00 EDT

- Vote on sulfuric if done
- Discuss DBDMH if TR is done

August 7, 2012 1:00 EDT

- Other ingredients

August 14, 2012 4:00 EDT

- Vote on DBDMH
- Any leftover materials
- Discuss other ingredients
- Other ingredients continued if necessary

August 21, 2012 1:00 EDT

| Milestone | Deadline |
|--------------------------------|-----------------|
| NOP - "Finalize" agenda | August 13, 2012 |
| Fall 2012 proposals due to NOP | August 20, 2012 |

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**National Organic Standards Board (NOSB)
Handling Subcommittee (HS) Meeting Notes
Tuesday, July 3, 2012, 1:00 pm EDT**

Present: John Foster (Chair) (JFo), Harold Austin (Vice-Chair) (HA), Tracy Favre (TF), Joe Dickson (JD), Jean Richardson (JR)

Absent: Zea Sonnabend (ZS), Nick Maravell (NM)

Staff: Emily Brown Rosen (EBR), Michelle Arsenault (MA)

Work Plan

| Petitioned Substances - Status of current review process | | | | | | |
|--|-----------------------|----------|-----------|------------------------------|----------|--|
| Name | National List Section | Reviewer | Meeting | Technical Review (TR) Rqstd? | TR rec'd | Notes* |
| Ascorbyl palmitate | 205.605 | NM | fall 2012 | Yes | Yes | TR accepted as sufficient 4/30/12. |
| Barley Betafiber | 205.606 | JFo | fall 2012 | Yes | Yes | Revised petition sent to HS on 6/20/11; TR accepted as sufficient 4/30/12. |
| Beta-carotene (synthetic) in infant formula | 205.605 | TF | fall 2012 | Yes | Yes | Petition sent to HS on 10/13/2011; Supplemental TR requested 1/17/12- HS asked by NOP to review the question asked - questions sent 3/6/12. Updated TR sent to NOSB. Petition and amended TR accepted as sufficient. |
| 1,3-dibromo-5,5-dimethylhydantoin (DBDMH) | 205.605 | JFo | fall 2012 | Yes | No | Petition sent to HS on 2/16/2012. TR requested. Rcvd and sent to contractor for revision. Should be back soon |
| Lutein | 205.606 | HA | fall 2012 | Yes | Yes | Petition sent to HS 11/16/2011; TR sent to HS on 4/27/2012. TR accepted as sufficient 06/26/12 |
| Lycopene | 205.605 | NM | fall 2012 | Yes | Yes | Petition sent to HS 9/22/2011; TR sent to HS 04 25 12. TR Sufficiency Review due 6/25/201 |
| L-carnitine | 205.605 | ZS | fall 2012 | Yes | Yes | Petition sent to HS 12/5/11; TR requested; Petition sufficiency review. Sent to TR contractor 12/5/11. Expected mid-April 2012. TR sent to HS 05 02 12. TR accepted as sufficient 06 19 12. TR posted 06/25/12 |

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|---|-----------------------|----------|--------------|------------------------------|----------|--|
| Name | National List Section | Reviewer | Meeting | Technical Review (TR) Rqstd? | TR rec'd | Notes* |
| L-methionine | 205.605 | TF | fall 2012 | Yes | Yes | Petition sent to HS on 11/1/2011 TR accepted as sufficient 4/30/12. |
| Nucleotides | 205.605 | JFo | fall 2012 | Yes | Yes | Petition sent to HS on 9/21/11; Revised TR sent to HS 04/26/12. TR accepted as sufficient 4/30/12. |
| Sugar Beet Fiber | 205.606 | JFo? ZS? | fall 2012 | Yes | Yes | Revised petition sent to Committee 2/10/2011; Revised TR sent to HS 04/26/12. TR accepted as sufficient 4/30/12. TR posted 06/25/12 |
| Taurine (for infant formula) | 205.605b | JR | fall 2012 | Yes | Yes | Petition sent to HS 9/20/11; TR sent to HS 10/28/2011; TR accepted as sufficient 3/27/12. TR posted |
| Bergamot Bitter Orange Powder | 205.606 | TF | spring 2013? | Yes | Yes | Sent to HS on 3/22/2011; TR Requested 5/23/11; sent to contractor on 10/27/11. TR sent to HS on 2/16; Updated TR sent to HS 04 30 12. TR posted 06/25/12. On hold. |
| Sulfuric acid | 205.605 | JD | spring 2013 | Yes | Yes | Petition sent to Committee 8/17/2010; TR Requested 11/15/2011. Draft TR sent to HS 05/01/12. Review by 7/2/2012 |
| Sodium gluconate | 205.605 | JD | ? | Yes | | Petition sent to HS on 3/22/2011; for use in soap; TR Requested 11/15/2011. On hold, for cosmetic use. |
| Sunset 2015 - §205.605 (a) Nonsynthetics Allowed - Status of current review process | | | | | | |
| Name | CAS # | Reviewer | Meeting | TR? | Notes* | |
| Sunset 2015 - §205.605 (b) Synthetics Allowed - Status of current review process | | | | | | |

| Other Topics | | | |
|-------------------------------|----------|-----------|--------------------------------|
| Name | Reviewer | Meeting | Notes* |
| Auxiliary/"other" ingredients | ZS | fall 2012 | Discussion document fall 2012. |

* Highlight indicates committee action needed.

Agenda:

- Approve minutes from 06 26 12

Discussion:

- Minutes from June 26th call approved
- L methionine. Several versions exist but L methionine is the only one approved for human consumption. Used in soy-based infant formulas. Cannot be synthesized by the body, so must be consumed, and there is no alternative. It was indicated in the petition that it is essential for proper growth of infants, but EBR noted that the FDA does not require this in any infant formula. The HS discussed policy and market implications surrounding this and other similar materials. A question was posed about the market consequences of not adding L methionine to allowed list: will consumers choose conventional products that contain L methionine over organic products that do not? The group discussed the fact that the interaction and synergistic relationship between substances is ultimately what they should be evaluating, instead of looking at them as isolated materials. It was noted that accessory nutrients and amino acids in general, have been used in organic infant formula since 2006. The group supports the use of them but a member added that the NOSB should take into consideration the essentiality criteria and the fact that the FDA does not require L methionine. The petition claims that supplementation is needed in infant formula in order to meet FDA requirements for protein quality. NOP suggested adding questions to the proposal to elicit public input. EBR indicated that she would work with TF to gather more info, and the HS chose to defer the vote on L methionine until then. Will allow for email votes.
- Taurine. Not a true amino acid; found in seafood, beef and chicken; can be produced non-synthetically, but is not available in large quantities. May aid in digestion of fat in humans. Not essential or required in infant formula, but is important for cats. Found in products such as Red Bull. It was noted that Taurine is not permitted in EU organics and not allowed in Canada. The group recommendation is to not add Taurine to 205.605 for infant formula. Livestock Subcommittee is looking at Taurine use in pet food, so the HS is only evaluating it for use in infant form.

Motion to classify Taurine as synthetic:

Motion made by: JR

Seconded by: JD

No additional discussion

Yes: 4 No: 0 Abstain: 0 Absent: 3 Recuse: 0

Motion to list Taurine to 206.605b on the National List for use in infant formula only:

Motion made by: JR

Seconded by JD

No additional discussion

Yes: 0 No: 4 Abstain: 0 Absent: 3 Recuse: 0

- Lutein. See comprehensive discussion in previous minutes. Petitioned as food additive and in infant formula. Not required by FDA in formula or considered essential as nutrient. Lutein is a pigment that is helpful in filtering blue light in the eye. Found in many foods (eggs, kale, spinach, etc.). Extraction process uses hexane isopropyl alcohol, or other possible solvents. After extraction, the substance is saponified using propylene glycol or methanol-potassium hydroxide, which is a synthetic process. The reviewer recommendation is to include lutein in infant formula but not as a food additive.
- Motion to classify Lutein as synthetic:
- Motion made by: HA
- Seconded by: JR
- No additional discussion
- Yes: 4 No: 0 Abstain: 0 Absent: 3 Recuse: 0

- Motion to list Lutein to 206.205b (CAS 127-40-2) for use in infant formula only:
- Motion made by: HA
- Seconded by: TF
- Group took a tentative vote until they could gather additional info from NOP, and discussed the possibility of adding an annotation “the annotation that was in question for Lutein is: 'when mixed with organic delivery ingredients including organic corn or safflower oil, and organic sugar and starch”.
- Yes: 4 No: 0 Abstain: 0 Absent: 3 Recuse: 0

Upcoming meetings and agenda items:

July 3, 2012 1:00 EDT (ZS away)

- Discuss/vote on L methionine- deferred vote while awaiting more info.
- Discuss/vote on Taurine (JR)-done
- Vote on Lycopene - postponed
- Vote on Lutein - done
- Discuss barley beta fiber – JFO -postponed
- Discuss sugar beet fiber – JFO -postponed
- Discuss/vote on beta carotene – TF postponed
- Vote on Ascorbyl palmitate -postponed

July 17, 2012 1:00 EDT

- Discuss/Vote on L methionine
- Vote on Lycopene (NM)
- Vote on Ascorbyl palmitate (NM)
- Discuss Nucleotides (JFo)
- Discuss Beta Carotene (TF)

July 24, 2012 4:00 EDT

- Vote on Nucleotides (JFo)
- Vote on Beta Carotene (TF)
- Discuss DBDMH if TR is received (JFo)
- Discuss Other ingredients

August 7, 2012 1:00 EDT

- Vote on DBDMH (JFo)
- Vote on Other ingredients
- Discuss barley beta fiber (JFo)
- Discuss sugar beet fiber (JFo? ZS?)

August 14, 2012 4:00 EDT

- Vote on barley beta fiber (JFo)
- Vote sugar beet fiber (JFo? ZS?)
- Discuss sulfuric acid (JD)
- Vote on sulfuric acid (if done)
- Any leftover materials

August 21, 2012 1:00 EDT

| Milestone | Deadline |
|-----------|----------|
|-----------|----------|

| | |
|--|---------------------|
| NOP - "Finalize" tentative agenda | August 13, 2012 |
| Fall 2012 proposals due to NOP | August 20, 2012 |
| NOP - Post proposals, Publish FRN, Open public comment | August 27, 2012 |
| Public comment closes | September 24, 2012 |
| NOP - Send compiled public comments to NOSB | October 1, 2012 |
| Fall 2012 NOSB Meeting – Providence, RI | October 15-18, 2012 |

Note: Subcommittee notes may include preliminary discussions regarding substances considered for addition to or removal from the National List. They do not represent official National Organic Program (NOP) policy or regulations. Please see the NOP website for official NOP policy, regulations, and status of substances used in organic production and handling.

**National Organic Standards Board (NOSB)
Handling Subcommittee (HS) Meeting Notes
Tuesday, July 17, 2012, 1:00 pm EDT**

Present: John Foster (Chair) (JFo), Harold Austin (Vice-Chair) (HA), Tracy Favre (TF), Joe Dickson (JD), Jean Richardson (JR), Zea Sonnabend (ZS)

Absent: Nick Maravell (NM)

Staff: Emily Brown Rosen (EBR), Michelle Arsenault (MA)

Work Plan

| Petitioned Substances - Status of current review process | | | | | | |
|--|-----------------------|----------|-----------|------------------------------|----------|--|
| Name | National List Section | Reviewer | Meeting | Technical Review (TR) Rqstd? | TR rec'd | Notes* |
| Ascorbyl palmitate | 205.605 | NM | fall 2012 | Yes | Yes | TR accepted as sufficient 4/30/12. |
| Barley Betafiber | 205.606 | JFo | fall 2012 | Yes | Yes | Revised petition sent to HS on 6/20/11; TR accepted as sufficient 4/30/12. |
| Beta-carotene (synthetic) in infant formula | 205.605 | TF | fall 2012 | Yes | Yes | Petition sent to HS on 10/13/2011; Supplemental TR requested 1/17/12- HS asked by NOP to review the question asked - questions sent 3/6/12. Updated TR sent to NOSB. Petition and amended TR accepted as sufficient. |
| 1,3-dibromo-5,5-dimethylhydantoin (DBDMH) | 205.605(b) | JFo | fall 2012 | Yes | No | Petition sent to HS on 2/16/2012. TR requested. Rcvd and sent to contractor for revision. TR sent to HS 07 19 12 |
| Lutein | 205.605(b) | HA | fall 2012 | Yes | Yes | Petition sent to HS 11/16/2011; TR sent to HS on 4/27/2012. TR accepted as sufficient 06/26/12 |
| Lycopene | 205.605 | NM | fall 2012 | Yes | Yes | Petition sent to HS 9/22/2011; TR sent to HS 04 25 12. TR Sufficiency Review due 6/25/201 |
| L-carnitine | 205.605 | ZS | fall 2012 | Yes | Yes | Petition sent to HS 12/5/11; TR requested; Petition sufficiency review. Sent to TR contractor 12/5/11. Expected mid-April 2012. TR sent to HS 05 02 12. TR accepted as sufficient 06 19 12. TR posted 06/25/12 |

| Petitioned Substances - Status of current review process | | | | | | |
|---|-----------------------|----------|--------------|------------------------------|----------|--|
| Name | National List Section | Reviewer | Meeting | Technical Review (TR) Rqstd? | TR rec'd | Notes* |
| L-methionine | 205.605(b) | TF | fall 2012 | Yes | Yes | Petition sent to HS on 11/1/2011 TR accepted as sufficient 4/30/12. |
| Nucleotides | 205.605 | JFo | fall 2012 | Yes | Yes | Petition sent to HS on 9/21/11; Revised TR sent to HS 04/26/12. TR accepted as sufficient 4/30/12. |
| Sugar Beet Fiber | 205.606 | JFo? ZS? | fall 2012 | Yes | Yes | Revised petition sent to Committee 2/10/2011; Revised TR sent to HS 04/26/12. TR accepted as sufficient 4/30/12. TR posted 06/25/12 |
| Taurine (for infant formula) | 205.605(b) | JR | fall 2012 | Yes | Yes | Petition sent to HS 9/20/11; TR sent to HS 10/28/2011; TR accepted as sufficient 3/27/12. TR posted |
| Bergamot Bitter Orange Powder | 205.606 | TF | spring 2013? | Yes | Yes | Sent to HS on 3/22/2011; TR Requested 5/23/11; sent to contractor on 10/27/11. TR sent to HS on 2/16; Updated TR sent to HS 04 30 12. TR posted 06/25/12. On hold. |
| Sulfuric acid | 205.605 | JD | spring 2013 | Yes | Yes | Petition sent to Committee 8/17/2010; TR Requested 11/15/2011. Draft TR sent to HS 05/01/12. Review by 7/2/2012 |
| Sodium gluconate | 205.605 | JD | ? | Yes | | Petition sent to HS on 3/22/2011; for use in soap; TR Requested 11/15/2011. On hold, for cosmetic use. |
| Sunset 2015 - §205.605 (a) Nonsynthetics Allowed - Status of current review process | | | | | | |
| Name | CAS # | Reviewer | Meeting | TR? | Notes* | |
| Sunset 2015 - §205.605 (b) Synthetics Allowed - Status of current review process | | | | | | |

| Other Topics | | | |
|-------------------------------|----------|-----------|--------------------------------|
| Name | Reviewer | Meeting | Notes* |
| Auxiliary/"other" ingredients | ZS | fall 2012 | Discussion document fall 2012. |

* Highlight indicates committee action needed.

Agenda:

- Approve minutes from 07 03 12

Discussion:

- Minutes from July 3rd call approved with no changes.
- L Methionine. Group discussed information collected by EBR. The Team Leader for Infant Formula Regulation at FDA provided information about the need for L-Methionine in soy based formulas in order to meet requirements for protein quality at 21 CFR 107.100 (f) . TF had reservations about approving synthetic L Methionine, because toxic solvents are used in extraction process. She reluctantly made a recommendation to approve, acknowledging the fact that if L-Methionine is not added to soy formula there would be no organic soy based formula. The group discussed the fact that protein is the essential building block and there does not seem to be an alternate source of non-milk protein available in commerce for use for infant formula. The group voted on L Methionine:

Motion to classify L-Methionine (205.605) as synthetic:

Motion made by: TF

Seconded by: HA

No additional discussion

Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Motion to list L Methionine for inclusion on 205.605(b) synthetic, non-agricultural. For use in or on processed infant formula labeled as “organic” or “made with organic ingredients”. Annotated: For use only in infant formula made with isolated soy-based protein. EBR suggestion: in proposal better to word the motion as:

Motion to list L Methionine for inclusion on 205.605(b). For use only in infant formula made with isolated soy-based protein.]

Motion made by: TF

Seconded by: HA

Additional comments: The Handling Subcommittee would welcome public comment about alternatives. The chair added that if concerns surface, the group could annotate the language to include “medical enteral” as they did with Inositol and Choline.

Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

- Group discussed Lutein and the potential addition of the annotation 'when mixed with organic delivery ingredients including organic corn or safflower oil, and organic sugar and starch'. NOP staff suggested not prescribing specific language about which organic ingredients can and can't be used, and instead, just decide if the HS should include a restriction requiring only organic agricultural “other” ingredients. ZS addressed some important points she felt were left off of the checklist. The checklist does not acknowledge the paragraph in the TR about making lutein from microalgae which would make it non-synthetic. Checklist should also mention the CBI of

the manufacturing process because it is not known if any other synthetics are used in manufacturing. She added that lutein is not required, was not used until 2010, and is not used in all formulas (just “higher tier” ones) and would not approve a synthetic version.

The subcommittee discussed whether a restriction was needed on “other” ingredients, noting that annotations like this are sometimes difficult to verify. Another option is to make it clear in the proposal that the recommendation is only for lutein, and that all other ingredients must be in compliance.

The group had a discussion about spec sheets used in review of ingredients. JR added that organic sub-ingredients are listed on the spec sheets more commonly now.

A tentative vote was taken during the July 3rd call and the group chose to take a re-vote on Lutein: ZS indicated that she may have a COI with this. NOP indicated that she does not have a COI, and should not recuse herself from voting. The Subcommittee recommended making these COI pronouncements at the beginning of the meeting and not before each item to be voted on.

Motion to classify Lutein as synthetic as petitioned:

Motion made by: HA

Seconded by: JR

No additional discussion

Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Motion to list Lutein to 206.605b (CAS 127-40-2) for use in infant formula only:

Motion made by: HA

Seconded by: JFo

Additional discussion: ZS asked about writing a minority opinion, but chair suggested incorporating both views into summary of proposed action, as opposed to writing a minority opinion. Will forward to HA for inclusion in the checklist. Chair will seek vote from NM and allow him a week to reply.

Yes: 3 No: 4 Abstain: 0 Absent: 0 Recuse: 0

- Vote on Lycopene postponed until NM could be present
- Vote on Ascorbyl palmitate postponed until NM could be present
- Nucleotides – no revised checklist. ZS indicated that the TR did not seem very robust, especially with regard to discussing alternatives, such as breast feeding. JFo (or ZS) will complete the checklist and will include questions that were not addressed in TR. And the checklist does ask about alternative ingredients and alternative methods.

Upcoming meetings and agenda items:

July 3, 2012 1:00 EDT (ZS away)

- Discuss/vote on L methionine- deferred vote while awaiting more info.
- Discuss/vote on Taurine (JR)-done
- Vote on Lycopene - postponed
- Vote on Lutein - done
- Discuss barley beta fiber – JFO -postponed
- Discuss sugar beet fiber – JFO -postponed
- Discuss/vote on beta carotene – TF postponed
- Vote on Ascorbyl palmitate -postponed

July 17, 2012 1:00 EDT

- Discuss/Vote on L methionine
- Vote on Lycopene (NM)-postponed
- Vote on Ascorbyl palmitate (NM)-postponed
- Discuss Nucleotides (JFo)-to be continued July 24
- Discuss Beta Carotene (TF)-postponed

July 24, 2012 4:00 EDT

- Vote on Lycopene (NM)-postponed from July 17
- Vote on Ascorbyl palmitate (NM)-postponed from July 17
- Discuss /Vote on Nucleotides (JFo)
- Discuss/Vote Beta Carotene (TF)
- Discuss DBDMH if TR is received (JFo)
- Discuss Other ingredients

August 7, 2012 1:00 EDT

- Dr. Sue Anderson
- Vote on DBDMH (JFo)
- Vote on Other ingredients
- Discuss barley beta fiber (JFo)
- Discuss sugar beet fiber (JFo? ZS?)

August 14, 2012 4:00 EDT

- Vote on barley beta fiber (JFo)
- Vote sugar beet fiber (JFo? ZS?)
- Discuss sulfuric acid (JD)
- Vote on sulfuric acid (if done)
- Any leftover materials

August 21, 2012 1:00 EDT

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**National Organic Standards Board (NOSB)
 Handling Subcommittee (HS) Meeting Notes
 Tuesday, July 24, 2012, 4:00 pm EDT**

Present: John Foster (Chair) (JFo), Harold Austin (Vice-Chair) (HA), Tracy Favre (TF), Jean Richardson (JR), Zea Sonnabend (ZS)

Absent: Joe Dickson (JD), Nick Maravell (NM)

Staff: Emily Brown Rosen (EBR), Michelle Arsenault (MA)

Work Plan

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| Lutein | 205.605(b) | HA | Fall 2012 | Yes | Yes | Petition sent to HS 11/16/2011; TR sent to HS on 4/27/2012. TR accepted as sufficient 06/26/12. TR posted. |
| Lycopene | 205.605 | NM | Fall 2012 | Yes | Yes | Petition sent to HS 9/22/2011; TR sent to HS 04 25 12. TR accepted as sufficient. TR Posted 07 25 12. Voted 07 24 |
| L-carnitine | 205.605 | ZS | Fall 2012 | Yes | Yes | Petition sent to HS 12/5/11; TR requested; Petition sufficiency review. Sent to TR contractor 12/5/11. Expected mid-April 2012. TR sent to HS 05 02 12. TR accepted as sufficient 06 19 12. TR posted 06/25/12 |

| Petitioned Substances - Status of current review process | | | | | | |
|---|-----------------------|-----------|--------------------------------|-----------------------------|----------|--|
| Name | National List Section | Reviewer | Meeting | Technical Review (TR) rqst? | TR rec'd | Notes* |
| L-methionine | 205.605(b) | TF | Fall 2012 | Yes | Yes | Petition sent to HS on 11/1/2011. TR accepted as sufficient 4/30/12, but not posted. Edits needed before posting TR. |
| Nucleotides | 205.605 | JFo | Fall 2012 | Yes | Yes | Petition sent to HS on 9/21/11; Revised TR sent to HS 04/26/12. TR accepted as sufficient 4/30/12. TR posted |
| Sugar Beet Fiber | 205.606 | JFo? ZS? | Fall 2012 | Yes | Yes | Revised petition sent to Committee 2/10/2011; Revised TR sent to HS 04/26/12. TR accepted as sufficient 4/30/12. TR posted 06/25/12 |
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| Sunset 2015 - §205.605 (a) Nonsynthetics Allowed - Status of current review process | | | | | | |
| Name | CAS # | Reviewer | Meeting | TR? | Notes* | |
| Sunset 2015 - §205.605 (b) Synthetics Allowed - Status of current review process | | | | | | |
| Other Topics | | | | | | |
| Name | Reviewer | Meeting | Notes* | | | |
| Auxiliary/"other" ingredients | ZS | Fall 2012 | Discussion document fall 2012. | | | |

* Highlight indicates committee action needed.

Agenda:

- Approve minutes from July 17, 2012

Discussion:

- Minutes from July 17, 2012 meeting approved with no changes
- 2 Fibers (Sugar Beet Fiber and Barley Beta Fiber) and DBDMH might be postponed until Spring 2013 meeting
- Group is in the process of identifying research priorities from the last two NOSB Meetings. They will then send these to Materials subcommittee. JFo will consult with JD and NM to come up with some topics from Savannah and Albuquerque.
- Materials WG has been meeting weekly and is composed of a wide spectrum of people from the community. WG has composed a 35-page document that ZS will forward to Subcommittee prior to the August 7th call. The intent of discussion document is to provide guidance about “other ingredients”. Doc will also include a list of those who participated on calls: (Product manufacturers, certifiers, NGOs, casual bystanders, consultants). ZS feels that product is robust and thorough.

- Vote on Lycopene (NM)

Motion to classify Lycopene as synthetic as petitioned:

Motion made by: ZS

Seconded by: TF

No additional discussion:

Yes: 5 No: 0 Abstain: 0 Absent: 2 Recuse: 0

Motion to list Lycopene to 206.605(b) (CAS 502-65-8) for use in infant formula only:

Motion made by: JR

Seconded by: HA

Additional discussion: ZS added that this ingredient was found only in one brand of the infant formulas that she surveyed.

Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

- Ascorbyl palmitate discussion continued. The Handling Subcommittee discussed various aspects of ascorbyl palmitate and its relationship to vitamin C. Lingering questions include whether or not ascorbyl palmitate is recognized as a vitamin, and if it is the same as ascorbic acid? A member noted that ascorbyl palmitate is listed in the vitamin section on many labels, and that there are products that list both. It's being petitioned as a preservative, which has the same function as beta carotene, and the group would like to know more about the relationship between the two ingredients, and the merits of one over the other. According to the petition, beta carotene is only fat soluble while ascorbyl palmitate is soluble in both water and fat. A member asked if it would change the conversation of

ascorbyl palmitate were identified as primarily an antioxidant as opposed to a vitamin. One member thought it might be preferable to allow synthetic ascorbyl palmitate for use as an antioxidant rather than the synthetic form of beta-carotene, which is also available in non-synthetic form. Questions were raised about the absorption and bioavailability of natural forms. The group requested more information regarding this issue.

- JR will miss August 7 call but will vote via email.
- TF and JR both volunteered to take on NM work if he is unavailable.

Upcoming meetings and agenda items:

July 3, 2012 1:00 EDT (ZS away)

- Discuss/vote on L methionine- deferred vote while awaiting more info.
- Discuss/vote on Taurine (JR)-done
- Vote on Lycopene - postponed
- Vote on Lutein - done
- Discuss barley beta fiber – JFO -postponed
- Discuss sugar beet fiber – JFO -postponed
- Discuss/vote on beta carotene – TF postponed
- Vote on Ascorbyl palmitate -postponed

July 17, 2012 1:00 EDT

- Discuss/Vote on L methionine
- Vote on Lycopene (NM)-postponed
- Vote on Ascorbyl palmitate (NM)-postponed
- Discuss Nucleotides (JFo)-to be continued July 24
- Discuss Beta Carotene (TF)-postponed

July 24, 2012 4:00 EDT

- Vote on Lycopene (NM)-postponed from July 17-done
- Vote on Ascorbyl palmitate (NM)-postponed from July 17. Vote postponed
- Discuss/Vote on Nucleotides (JFo) -postponed
- Discuss Beta Carotene (TF) - postponed

- Report on Materials WG

July 31

- Discuss Nucleotides (JFo)-done'ish
- Discuss beta carotene (TF)
- Discuss barley beta fiber (JFo)
- Discuss sugar beet fiber (JFo? ZS?)

August 7, 2012 1:00 EDT

- Qs for Dr. Sue Anderson
 - Ascorbyl palmitate –why do some products have both beta carotene and ascorbyl palmitate, and both are listed under vitamins.
 - On what resources does the FDA rely for information?
 - Is ascorbyl palmitate a source of vitamin C?
- Vote on Ascorbyl palmitate (NM)-postponed from July 24
- Vote on Nucleotides (JFo)
- Discuss “Other” ingredients
- Discuss DBDMH if TR is received (JFo)

August 14, 2012 4:00 EDT

- Vote on DBDMH (JFo)
- Vote beta carotene (TF)
- Vote on barley beta fiber (JFo)
- Vote sugar beet fiber (JFo? ZS?)
- Vote on “Other” ingredients
- Discuss sulfuric acid/Vote (if done) (JD)
- Any leftover materials

August 21, 2012 1:00 EDT

September 4, 2012 1:00 EDT

September 18, 2012 1:00 EDT

October 2, 2012 1:00 EDT

| Milestone | Deadline |
|--|---------------------|
| NOP - "Finalize" tentative agenda | August 10, 2012 |
| Fall 2012 proposals due to NOP | August 20, 2012 |
| NOP - Post proposals, Publish FRN, Open public comment | August 27, 2012 |
| Public comment closes | September 24, 2012 |
| NOP - Send compiled public comments to NOSB | October 1, 2012 |
| Fall 2012 NOSB Meeting – Providence, RI | October 15-18, 2012 |

Note: Subcommittee notes may include preliminary discussions regarding substances considered for addition to or removal from the National List. They do not represent official National Organic Program (NOP) policy or regulations. Please see the NOP website for official NOP policy, regulations, and status of substances used in organic production and handling.

**National Organic Standards Board (NOSB)
Handling Subcommittee (HS) Meeting Notes
Tuesday, July 31, 2012, 1:00 pm EDT**

Present: John Foster (Chair) (JFo), Harold Austin (Vice-Chair) (HA), Zea Sonnabend (ZS)

Absent: Joe Dickson (JD), Nick Maravell (NM), Jean Richardson (JR), Tracy Favre (TF)

Staff: Emily Brown Rosen (EBR), Michelle Arsenault (MA)

Work Plan

| Petitioned Substances - Status of current review process | | | | | | | |
|--|-----------------------|------|--------------|-----------------------------|-----------|---------|--|
| Name | National List Section | Rvwr | Mtng | Technical Review (TR) rqst? | TR rcv'd? | Vote? | Notes* |
| Ascorbyl palmitate | 205.605 | NM | Fall 2012 | Yes | Yes | | TR accepted as sufficient 4/30/12. TR Posted 07 25 12 |
| Barley Betafiber | 205.606 | JFo | Fall 2012? | Yes | Yes | | Revised petition sent to HS on 6/20/11; TR accepted as sufficient 4/30/12. TR Posted 07 25 12 |
| Beta-carotene (synthetic) in infant formula | 205.605 | TF | Fall 2012 | Yes | Yes | | Petition sent to HS on 10/13/2011; Supplemental TR requested 1/17/12- HS asked by NOP to review the question asked - questions sent 3/6/12. Updated TR sent to NOSB. Petition and amended TR accepted as sufficient. |
| 1,3-dibromo-5,5-dimethylhydantoin (DBDMH) | 205.605(b) | JFo | Spring 2013? | Yes | No | | Petition sent to HS on 2/16/2012. TR requested. Rcvd and sent to contractor for revision. TR sent to HS 07 19 12 |
| Lutein | 205.605(b) | HA | Fall 2012 | Yes | Yes | 7 17 12 | Petition sent to HS 11/16/2011; TR sent to HS on 4/27/2012. TR accepted as sufficient 06/26/12. TR posted. |
| Lycopene | 205.605 | NM | Fall 2012 | Yes | Yes | 7 24 12 | Petition sent to HS 9/22/2011; TR sent to HS 04 25 12. TR accepted as sufficient. TR Posted 07 25 12. Voted 07 24 |
| L-carnitine | 205.605 | ZS | Fall 2012 | Yes | Yes | 6 19 12 | Petition sent to HS 12/5/11; TR requested; Petition sufficiency review. Sent to TR contractor 12/5/11. Expected mid-April 2012. TR sent to HS 05 02 12. TR accepted as sufficient 06 19 12. TR posted 06/25/12 |

| Petitioned Substances - Status of current review process | | | | | | | |
|---|-----------------------|-------------|--------------|-----------------------------|-----------|---------|--|
| Name | National List Section | Rvwr | Mtng | Technical Review (TR) rqst? | TR rcv'd? | Vote? | Notes* |
| L-methionine | 205.605(b) | TF | Fall 2012 | Yes | Yes | 7 17 12 | Petition sent to HS on 11/1/2011. TR accepted as sufficient 4/30/12, but not posted. Edits needed before posting TR. |
| Nucleotides | 205.605 | JFo | Fall 2012 | Yes | Yes | | Petition sent to HS on 9/21/11; Revised TR sent to HS 04/26/12. TR accepted as sufficient 4/30/12. TR posted |
| Sugar Beet Fiber | 205.606 | JFo? ZS? | Fall 2012? | Yes | Yes | | Revised petition sent to Committee 2/10/2011; Revised TR sent to HS 04/26/12. TR accepted as sufficient 4/30/12. TR posted 06/25/12 |
| Taurine (for infant formula) | 205.605(b) | JR | Fall 2012 | Yes | Yes | | Petition sent to HS 9/20/11; TR sent to HS 10/28/2011; TR accepted as sufficient 3/27/12. TR posted |
| Bergamot Bitter Orange Powder | 205.606 | TF | Spring 2013? | Yes | Yes | | Sent to HS on 3/22/2011; TR Requested 5/23/11; sent to contractor on 10/27/11. TR sent to HS on 2/16; Updated TR sent to HS 04 30 12. TR posted 06/25/12. On hold. |
| Sulfuric acid | 205.605 | JD | Fall 2012? | Yes | Yes | | Petition sent to Committee 8/17/2010; TR Requested 11/15/2011. Draft TR sent to HS 05/01/12. Review by 7/2/2012 -OVERDUE |
| Sodium gluconate | 205.605 | JD | ? | Yes | | | Petition sent to HS on 3/22/2011; for use in soap; TR Requested 11/15/2011. On hold, for cosmetic use. |
| Sunset 2015 - §205.605 (a) Nonsynthetics Allowed - Status of current review process | | | | | | | |
| Name | CAS # | Rvwr | Meeting | | TR reqtd? | | Notes* |
| Sunset 2015 - §205.605 (b) Synthetics Allowed - Status of current review process | | | | | | | |
| Other Topics | | | | | | | |
| Name | Reviewer | | Meeting | | | | Notes* |
| Auxiliary/"other" ingredients | ZS | | Fall 2012 | | | | Discussion document fall 2012. |

* Highlight indicates committee action needed.

Agenda:

- Approve minutes from July 24, 2012
- Continue discussions of materials on workplan scheduled for fall meeting

Discussion:

- Minutes from July 24, 2012 meeting not approved due to lack of quorum.
- Group composed list of questions for Dr. Sue Anderson at FDA, for next call
- Nucleotides – A member asked why yeast can't be used as an ingredient without extracting the nucleotides since yeast is on National List already. The team discussed and edited various questions on the proposal checklist, including:
 - Purity and concentration (EBR will craft a question about this for Sue Anderson)
 - Category 2 question # 7 (Is there a wholly natural substitute product?) and # 9 (Are there alternative substances?). A question was raised about yeast being the precursor for nucleotides, and what wholly natural means. This question comes from language in OFPA "use of the substance is necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products:"
 - Category 3: difference between compatible and essential. One member is inclined to answer yes since products similar to this are already allowed in organic products. The group discussed terminology and definitions used in checklist, which needs some revision.
 - With regard to question about "criteria satisfied? –Y or N", the group agreed that it's not always all or nothing, and discussed whether a substance that fails one of the criteria would fail this compatibility question. In past decisions, NOSB has taken the overall picture into consideration, a substance may fail one criterion, but the substance could still be deemed necessary if the positives outweigh the negatives.
 - An alternative that is not well explored in the TR may be either protein from organic sources, or nucleotides derived from organic yeast. Should this be classed as an agricultural substance?
 - Compatibility is a subjective criterion whereas essentiality is more objective. The group discussed this differentiation using pectin as an example. There are substitutes for pectin, therefore it is not essential; however, it was acknowledged that in a commercial context, the definition of essentiality changes. The group noted that having this conversation about the definition was very helpful. Chair will make some edits to the nucleotides checklist and will recirculate to the group.
 - A member asked if the Lutein vote tie (from July 17th meeting) had been broken by NM. Chair indicated that it had not, but that he would follow up.

Upcoming meetings and agenda items:

July 3, 2012 1:00 EDT (ZS away)

- Discuss/vote on L methionine- deferred vote while awaiting more info.
- Discuss/vote on Taurine (JR)-done
- Vote on Lycopene - postponed
- Vote on Lutein - done
- Discuss barley beta fiber – JFO -postponed
- Discuss sugar beet fiber – JFO -postponed
- Discuss/vote on beta carotene – TF postponed
- Vote on Ascorbyl palmitate -postponed

July 17, 2012 1:00 EDT

- Discuss/Vote on L methionine-done
- Vote on Lycopene (NM)-postponed
- Vote on Ascorbyl palmitate (NM)-postponed
- Discuss Nucleotides (JFo)-to be continued July 24
- Discuss Beta Carotene (TF)-postponed

July 24, 2012 4:00 EDT

- Vote on Lycopene (NM)-postponed from July 17-done
- Vote on Ascorbyl palmitate (NM)-postponed from July 17. Vote postponed
- Discuss/Vote on Nucleotides (JFo) -postponed
- Discuss Beta Carotene (TF) - postponed
- Report on Materials WG

July 31

- Discuss Nucleotides (JFo)-done'ish
- Discuss beta carotene (TF) - postponed

- Discuss barley beta fiber (JFo) - postponed
- Discuss sugar beet fiber (JFo? ZS?) - postponed

August 7, 2012 1:00 EDT

Qs for Dr. Sue Anderson

- Please explain how FDA develops baseline standards for essential nutrients in infant formula: are these based on other sources, such as the National Academy of Science, Institute of Medicine, other? (i.e. on what resources does the FDA rely for information?)
- Ascorbyl palmitate has been petitioned to NOP primarily as an antioxidant for use to stabilize lipids in infant formula. Can it be used to supply Vitamin C in food or in infant formula? It seems to be listed on ingredients panels as a vitamin, or grouped with vitamins, is this correct?
- The infant formula regulations at 107.100 (a) specifies Vitamin C (ascorbic acid). Does this mean ascorbyl palmitate is not acceptable as a Vitamin C source in infant formula?
- Beta carotene has been petitioned as an alternate substances for use as an antioxidant, why are both beta carotene and ascorbyl palmitate used in some products? Beta carotene may be listed as a source of Vitamin A, but is it true that only synthetic forms are permitted in infant formula?
- Do you know of any evidence that natural forms of vitamins are better absorbed or more bioavailable than synthetic forms (or vice versa)?
- Are you aware of a need for nucleotides rather than complete proteins in infant formula? The petitioner indicates that nucleotides are extracted from yeast using enzymes. Can yeast be used in infant formula as an ingredient, would it be a source of nucleotides for the infant?
- Lycopene – has been petitioned to NOP for use as a supplemental nutrient in infant formula. There have been many notifications of GRAS status filed with FDA, for both synthetic forms and some derived from fungi, though these do not mention use in infant formula. Is it permitted to add these to infant formula, or do the GRAS notifications have to specify the use in formula?

FDA (U.S. Food and Drug Administration). 2005a. Agency Response Letter GRAS Notice No. GRN 000119: Synthetic Lycopene. Retrieved November 7, 2011 from <http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/ucm153934.htm>

FDA (U.S. Food and Drug Administration). 2005b. Agency Response Letter GRAS Notice No. GRN 000173: Lycopene from *B. trispora*. Retrieved November 7, 2011 from <http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/ucm154597.htm>

- Discuss beta carotene (TF)
- Discuss barley beta fiber (JFo)
- Discuss sugar beet fiber (JFo? ZS?)
- Vote on Ascorbyl palmitate (NM)-postponed from July 24
- More discussion?/Vote on Nucleotides (JFo)
- Discuss “Other” ingredients (ZS)

August 14, 2012 4:00 EDT

- Discuss/vote on DBDMH (JFo)-may postpone until Spring 2013
- Vote beta carotene (TF)
- Vote on barley beta fiber (JFo)
- Vote sugar beet fiber (JFo? ZS?)
- Vote on “Other” ingredients
- Discuss sulfuric acid/Vote (if done) (JD)
- Any leftover materials

August 21, 2012 1:00 EDT

September 4, 2012 1:00 EDT

September 18, 2012 1:00 EDT

October 2, 2012 1:00 EDT

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Note: Subcommittee notes may include preliminary discussions regarding substances considered for addition to or removal from the National List. They do not represent official National Organic Program (NOP) policy or regulations. Please see the NOP website for official NOP policy, regulations, and status of substances used in organic production and handling.

**National Organic Standards Board (NOSB)
Handling Subcommittee (HS) Meeting Notes
Tuesday, August 7, 2012, 1:00 pm EDT**

Present: Harold Austin (Vice-Chair) (HA), Zea Sonnabend (ZS), Joe Dickson (JD), Nick Maravell (NM), Tracy Favre (TF)

Absent: John Foster (Chair) (JFo), Jean Richardson (JR)

Staff: Emily Brown Rosen (EBR), Michelle Arsenault (MA)

Work Plan

| Petitioned Substances - Status of current review process | | | | | | | |
|--|-----------------------|------|--------------|-----------------------------|-----------|----------|--|
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| Barley Betafiber | 205.606 | JFo | Fall 2012? | Yes | Yes | | Revised petition sent to HS on 6/20/11; TR accepted as sufficient 4/30/12. TR Posted 07 25 12 |
| Beta-carotene (synthetic) in infant formula | 205.605 | TF | Fall 2012 | Yes | Yes | 08 07 12 | Petition sent to HS on 10/13/2011; Supplemental TR requested 1/17/12- HS asked by NOP to review the question asked - questions sent 3/6/12. Updated TR sent to NOSB. Petition and amended TR accepted as sufficient. |
| 1,3-dibromo-5,5-dimethylhydantoin (DBDMH) | 205.605(b) | JFo | Spring 2013? | Yes | No | | Petition sent to HS on 2/16/2012. TR requested. Rcvd and sent to contractor for revision. TR sent to HS 07 19 12 |
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| Lycopene | 205.605 | NM | Fall 2012 | Yes | Yes | 7 24 12 | Petition sent to HS 9/22/2011; TR sent to HS 04 25 12. TR accepted as sufficient. TR Posted 07 25 12. Voted 07 24 |
| L-carnitine | 205.605 | ZS | Fall 2012 | Yes | Yes | 6 19 12 | Petition sent to HS 12/5/11; TR requested; Petition sufficiency review. Sent to TR contractor 12/5/11. Expected mid-April 2012. TR sent to HS 05 02 12. TR accepted as sufficient 06 19 12. TR posted 06/25/12 |

| Petitioned Substances - Status of current review process | | | | | | | |
|---|-----------------------|-------------|--------------|-----------------------------|-----------|----------|--|
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| Nucleotides | 205.605 | JFo | Fall 2012 | Yes | Yes | | Petition sent to HS on 9/21/11; Revised TR sent to HS 04/26/12. TR accepted as sufficient 4/30/12. TR posted |
| Sugar Beet Fiber | 205.606 | JFo? ZS? | Fall 2012? | Yes | Yes | | Revised petition sent to Committee 2/10/2011; Revised TR sent to HS 04/26/12. TR accepted as sufficient 4/30/12. TR posted 06/25/12 |
| Taurine (for infant formula) | 205.605(b) | JR | Fall 2012 | Yes | Yes | 07 03 12 | Petition sent to HS 9/20/11; TR sent to HS 10/28/2011; TR accepted as sufficient 3/27/12. TR posted |
| Bergamot Bitter Orange Powder | 205.606 | TF | Spring 2013? | Yes | Yes | | Sent to HS on 3/22/2011; TR Requested 5/23/11; sent to contractor on 10/27/11. TR sent to HS on 2/16; Updated TR sent to HS 04 30 12. TR posted 06/25/12. On hold. |
| Sulfuric acid | 205.605 | JD | Fall 2012? | Yes | Yes | | Petition sent to Committee 8/17/2010; TR Requested 11/15/2011. Draft TR sent to HS 05/01/12. Review by 7/2/2012 -OVERDUE |
| Sodium gluconate | 205.605 | JD | ? | Yes | | | Petition sent to HS on 3/22/2011; for use in soap; TR Requested 11/15/2011. On hold, for cosmetic use. |
| Sunset 2015 - §205.605 (a) Nonsynthetics Allowed - Status of current review process | | | | | | | |
| Name | CAS # | Rvwr | Meeting | | TR reqtd? | | Notes* |
| Sunset 2015 - §205.605 (b) Synthetics Allowed - Status of current review process | | | | | | | |
| Other Topics | | | | | | | |
| Name | Reviewer | | Meeting | | | | Notes* |
| Auxiliary/"other" ingredients | ZS | | Fall 2012 | | | | Discussion document fall 2012. |

* Highlight indicates committee action needed.

Agenda:

- Approve minutes from July 24 (no quorum) and July 31, 2012 (not sent to HS yet)
- Discuss beta carotene (TF)
- Discuss minor edits to Lycopene checklist
- Research Priorities Framework
- Discuss “Other” Ingredients (see email from ZS)
- Vote on Ascorbyl palmitate (NM)-postponed from July 24- will discuss and then send to group for further review
- More discussion?/Vote on Nucleotides (JFo)
- Discuss barley beta fiber (JFo)
- Discuss sugar beet fiber (JFo? ZS?)

Discussion:

- Minutes from July 24 and July 31, 2012 approved with no changes
- Beta carotene - Petitioner indicated that only synthetic can be used in infant formula. EBR synthesized response from FDA and suggested the group ask additional questions of the FDA representative next week. TF sent checklist to group and left some of the questions blank until the group could discuss more. Group discussed similarities/differences between Beta Carotene and Ascorbyl Palmitate. The main difference between the two is that Ascorbyl Palmitate is always synthetic; both are being petitioned as antioxidants. Beta carotene is a source of Vitamin A. There are commercially available natural sources of beta carotene but these do not appear to have the status as Generally Regarded as Safe (GRAS) and are not used in infant formula.

Vote on Beta Carotene

- Motion to classify beta carotene (205.605) as synthetic:
 - Motion made by: TF
 - Seconded by: HA
 - No additional discussion
 - Yes: 5 No: 0 Abstain: 0 Absent: 2 Recuse: 0

- Motion to list beta carotene for inclusion on 205.605(b) as petitioned for use in infant formula
 - Motion made by: TF
 - Seconded by: JD
 - No additional discussion
 - Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

- Lycopene – NM will recirculate checklist with some minor edits for group to approve.
- Research priorities. ZS made a plea to the group to send questions/topics that the other Subcommittees would like to include in the Research Priorities document. EBR suggested that the document include background information about why the NOSB is working on this document. Sulfur dioxide: group felt no amount of additional research would alter the opinion about this so it is not a priority. With regard to DHA/ARA, the group felt that various health claims might need further research, and the need in infant formula could be the subject of continuing research. NOP staff noted that... some of these priorities should be tabled until the rulemaking process is complete. It was noted that this approach would then limit the research priorities to items that are on the National List.
- “Other” ingredients – EBR indicated that the group needs to focus the document based on the memo that NOP sent to the group. ZS indicated that the group was moving forward based on comments from NOP that were made at the spring 2012 (Albuquerque) meeting. EBR asked that this document focus more on substances used in 205.605 ingredients, instead of other topics like livestock feed and sanitizers, which are not primary for this review. NOP also asked specific questions about use of non-organic agricultural substances, (e.g. nonorganic sugar or dextrin as standardizing agent) and preservatives. Three Options were put forth: a) Allow most other ingredients meeting baseline criteria, except for those specifically restricted by annotation b) have NOP maintain a database of other ingredients that are reviewed and allowed along with every substance, c) Individually review every ingredient and add to new section of National List developed for other ingredients. .

Upcoming meetings and agenda items:

July 3, 2012 1:00 EDT (ZS away)

- Discuss/vote on L methionine- deferred vote while awaiting more info.
- Discuss/vote on Taurine (JR)-done
- Vote on Lycopene - postponed
- Vote on Lutein - done
- Discuss barley beta fiber – JFO -postponed
- Discuss sugar beet fiber – JFO -postponed
- Discuss/vote on beta carotene – TF postponed
- Vote on Ascorbyl palmitate -postponed

July 17, 2012 1:00 EDT

- Discuss/Vote on L methionine-done

- Vote on Lycopene (NM)-postponed
- Vote on Ascorbyl palmitate (NM)-postponed
- Discuss Nucleotides (JFo)-to be continued July 24
- Discuss Beta Carotene (TF)-postponed

July 24, 2012 4:00 EDT

- Vote on Lycopene (NM)-postponed from July 17-done
- Vote on Ascorbyl palmitate (NM)-postponed from July 17. Vote postponed
- Discuss/Vote on Nucleotides (JFo) -postponed
- Discuss Beta Carotene (TF) - postponed
- Report on Materials WG

July 31

- Discuss Nucleotides (JFo)-done'ish
- Discuss beta carotene (TF) - postponed
- Discuss barley beta fiber (JFo) - postponed
- Discuss sugar beet fiber (JFo? ZS?) - postponed

August 7, 2012 1:00 EDT

- Discuss edits to Lycopene checklist-done, NM will edit and recirculate
- Discuss beta carotene (TF)-done, voted 08 07
- Vote on Ascorbyl palmitate (NM)-postponed
- More discussion?/Vote on Nucleotides (JFo)
- Discuss "Other" ingredients (ZS)
- Discuss barley beta fiber (JFo)-postponed
- Discuss sugar beet fiber (JFo? ZS?)-postponed

August 14, 2012 4:00 EDT

- Vote on Ascorbyl palmitate (NM)-postponed from August 7
- More discussion?/vote on Nucleotides (JFo)
- Vote on "Other" ingredients

- Discuss sulfuric acid/vote (if done) (JD)
- Any leftover materials
- Discuss barley beta fiber (JFo) - may postpone until Spring 2013
- Discuss sugar beet fiber (JFo? ZS?) - may postpone until Spring 2013
- Discuss/vote on DBDMH (JFo)-may postpone until Spring 2013

Qs and responses by email from Dr. Sue Anderson, FDA

1. Please explain how FDA develops baseline standards for essential nutrients in infant formula: are these based on other sources, such as the National Academy of Science, Institute of Medicine, other?

The nutrient levels in the Infant Formula Act and in FDA's regulations in 21 CFR 107.100 were based on recommendations to Congress and the agency from the American Academy of Pediatrics. Any revisions to the regulatory specifications for nutrients in infant formulas would be based on the available scientific information. In order to change any of these levels or add nutrients to those currently required, FDA would have to amend the regulations through the formal rule-making process.

2. Ascorbyl palmitate has been petitioned to NOP primarily as an antioxidant for use to stabilize lipids in infant formula. Can it be used to supply Vitamin C in food or in infant formula? It seems to be listed on ingredients panels as a vitamin, or grouped with vitamins, is this correct?

Although most often used as an antioxidant, ascorbyl palmitate could be considered for use as a source of ascorbic acid (vitamin C) in food and infant formula. Also see response to question 2.

Labeling regulations (21 CFR 101.4(a)(2)) allow all ingredients present in amounts of 2% or less by weight to be listed at the end of the ingredient statement following a qualifying statement such as "Less than __ percent of ____." As vitamins, minerals, and ingredients added for technological purposes (e.g., antioxidants) are added in very small amounts, they are often listed in this category on infant formula labels. The regulation does not require a particular order for listing of ingredients present in amounts of 2% or less.

3. The infant formula regulations at 107.100 (a) specifies Vitamin C (ascorbic acid). Does this mean ascorbyl palmitate is not acceptable as a Vitamin C source in infant formula?

The regulations in 21 CFR 107.100 specify the nutrients that must be present in infant formula; however, they do not specify which forms manufacturers must use in formulating their products. Forms of vitamin C that are commercially available include ascorbic acid, sodium ascorbate, potassium ascorbate, calcium ascorbate, and ascorbyl palmitate. Manufacturers may select a particular form of the vitamin (e.g., sodium ascorbate, which would provide both sodium and vitamin C) to achieve the desired composition of the formula. Other functional characteristics of a particular vitamin form (e.g., solubility in an infant formula matrix or heat stability

during processing) must also be considered.

4. Beta carotene has been petitioned as an alternate substances for use as an antioxidant, why are both beta carotene and ascorbyl palmitate both used in some products? Beta carotene may be listed as a source of Vitamin A, but is it true that only synthetic forms are permitted in infant formula?

The activity of antioxidants in finished food products depends on the nature of the antioxidant(s), the food matrix in which they are used, and the processing that the product undergoes. All of these factors need to be considered in determining whether a single antioxidant or antioxidant mixture will provide the antioxidant function needed for the product.

Beta-carotene is affirmed as GRAS for use as a nutrient supplement in infant formula (21 CFR 184.1245(c)(2)). 21 CFR 184.1245(b) lists the Food Chemicals Codex specifications for B-carotene used in food. Any B-carotene, regardless of source, would have to meet those specifications if it is used in food. Depending on the extraction process used and the source material, B-carotene extracted from plants or other sources may contain contaminants that would not be contained in the synthesized product.

FDA does not approve the use of GRAS substances in food, including infant formula. Manufacturers are responsible for the safe use of ingredients that they use in all foods including infant formula. The submission of a GRAS notice for use of an ingredient is voluntary; however, FDA strongly encourages manufacturers to resolve any ingredient safety questions before submitting an infant formula notification, which is mandatory when changes in formulation, processing, or packaging are made for infant formulas.

5. Do you know of any evidence that natural forms of vitamins are absorbed better or more bioavailable than synthetic forms (or vice versa)?

I don't have information at hand on bioavailability of synthetic or natural forms of vitamins. However, nutrient bioavailability is a complex issue and multiple factors must be taken into consideration. The food matrix (the total composition of the finished food) is a critical factor for absorption of nutrients from foods. For example, phytates in soy products inhibit the absorption of calcium and other minerals. Processing of products and final home preparation can also increase or decrease the bioavailability of nutrients in the food. For example, extreme heat treatment can reduce the bioavailability of protein.

6. Are you aware of a need for nucleotides rather than complete proteins in infant formula? The petitioner indicated that nucleotides are extracted from yeast using enzymes; can yeast be used in infant formula as an ingredient, would it be a source of nucleotides for the infant?

Nucleotides cannot substitute for protein in any food, including infant formula.

Use of yeast as a source of nucleotides would require addition of at least 12 times the amount of extracted nucleotides, assuming that nucleotides are present at a concentration of about 8% in yeast and are extracted very efficiently. It should also be noted that

yeast may contain contaminants that would not be present in the extracted nucleotides, depending on the extraction process. Safety of use of yeast as an ingredient in infant formula has not been evaluated by the agency.

7. Lycopene – has been petitioned to NOP for use as a supplemental nutrient in infant formula. There have been many notifications of GRAS status filed with FDA, for both synthetic forms and some derived from fungi, though these do not mention use in infant formula. Is it permitted to add these to infant formula, or do the GRAS notifications have to specify the use in formula?

FDA (U.S. Food and Drug Administration). 2005a. Agency Response Letter GRAS Notice No. GRN 000119: Synthetic Lycopene. Retrieved November 7, 2011 from <http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/ucm153934.htm>

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FDA encourages manufacturers to submit separate GRAS notices for use of ingredients in infant formulas; however, a manufacturer may elect to include use in infant formula in a notice for multiple uses. Also, please keep in mind that GRAS notices are voluntary and manufacturers are not required to submit a GRAS notice before adding a new ingredient to infant formula. Formulas containing mixed carotenoids (B-carotene, lutein, and lycopene) are currently marketed in the U.S.

August 21, 2012 1:00 EDT
September 4, 2012 1:00 EDT
September 18, 2012 1:00 EDT
October 2, 2012 1:00 EDT

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|--|---------------------|
| NOP - Post proposals, Publish FRN, Open public comment | August 27, 2012 |
| Public comment closes | September 24, 2012 |
| NOP - Send compiled public comments to NOSB | October 1, 2012 |
| Fall 2012 NOSB Meeting – Providence, RI | October 15-18, 2012 |

Note: Subcommittee notes may include preliminary discussions regarding substances considered for addition to or removal from the National List. They do not represent official National Organic Program (NOP) policy or regulations. Please see the NOP website for official NOP policy, regulations, and status of substances used in organic production and handling.

**National Organic Standards Board (NOSB)
Handling Subcommittee (HS) Meeting Notes
Tuesday, August 14, 2012, 4:00 pm EDT**

Present: Harold Austin (Vice-Chair) (HA), Zea Sonnabend (ZS), Joe Dickson (JD), Nick Maravell (NM), Tracy Favre (TF), Jean Richardson (JR)

Absent: John Foster (Chair) (JFo)

Staff: Emily Brown Rosen (EBR), Michelle Arsenault (MA)

Guests: Leila Beker, Dr. Sue Anderson, Dr. Benson Silverman

Work Plan

| Petitioned Substances - Status of current review process | | | | | | | |
|--|-----------------------|------|-----------|-----------------------------|-----------|----------|--|
| Name | National List Section | Rvwr | Mtng | Technical Review (TR) rqst? | TR rcv'd? | Vote? | Notes* |
| Ascorbyl palmitate | 205.605(b) | NM | Fall 2012 | Yes | Yes | 08 14 12 | TR accepted as sufficient 4/30/12. TR Posted 07 25 12 |
| Beta-carotene (synthetic) in infant formula | 205.605 | TF | Fall 2012 | Yes | Yes | 08 07 12 | Petition sent to HS on 10/13/2011; Supplemental TR requested 1/17/12- HS asked by NOP to review the question asked - questions sent 3/6/12. Updated TR sent to NOSB. Petition and amended TR accepted as sufficient. |
| Lutein | 205.605(b) | HA | Fall 2012 | Yes | Yes | 7 17 12 | Petition sent to HS 11/16/2011; TR sent to HS on 4/27/2012. TR accepted as sufficient 06/26/12. TR posted. |
| Lycopene | 205.605 | NM | Fall 2012 | Yes | Yes | 7 24 12 | Petition sent to HS 9/22/2011; TR sent to HS 04 25 12. TR accepted as sufficient. TR Posted 07 25 12. Voted 07 24 |
| L-carnitine | 205.605 | ZS | Fall 2012 | Yes | Yes | 6 19 12 | Petition sent to HS 12/5/11; TR requested; Petition sufficiency review. Sent to TR contractor 12/5/11. Expected mid-April 2012. TR sent to HS 05 02 12. TR accepted as sufficient 06 19 12. TR posted 06/25/12 |
| L-methionine | 205.605(b) | TF | Fall 2012 | Yes | Yes | 7 17 12 | Petition sent to HS on 11/1/2011. TR accepted as sufficient 4/30/12, but not posted. Edits needed before posting TR. |

| Petitioned Substances - Status of current review process | | | | | | | |
|--|-----------------------|-------------|--------------|-----------------------------|-----------|----------|--|
| Name | National List Section | Rvwr | Mtng | Technical Review (TR) rqst? | TR rcv'd? | Vote? | Notes* |
| Taurine (for infant formula) | 205.605(b) | JR | Fall 2012 | Yes | Yes | 07 03 12 | Petition sent to HS 9/20/11; TR sent to HS 10/28/2011; TR accepted as sufficient 3/27/12. TR posted |
| 1,3-dibromo-5,5-dimethylhydantoin (DBDMH) | 205.605(b) | JFo | Spring 2013? | Yes | No | | Petition sent to HS on 2/16/2012. TR requested. Rcvd and sent to contractor for revision. TR sent to HS 07 19 12 |
| Nucleotides | 205.605 | JFo | Fall 2012 | Yes | Yes | | Petition sent to HS on 9/21/11; Revised TR sent to HS 04/26/12. TR accepted as sufficient 4/30/12. TR posted |
| Barley Betafiber | 205.606 | JFo | Spring 2013 | Yes | Yes | | Revised petition sent to HS on 6/20/11; TR accepted as sufficient 4/30/12. TR Posted 07 25 12 |
| Sugar Beet Fiber | 205.606 | JFo? ZS? | Spring 2013 | Yes | Yes | | Revised petition sent to Committee 2/10/2011; Revised TR sent to HS 04/26/12. TR accepted as sufficient 4/30/12. TR posted 06/25/12 |
| Bergamot Bitter Orange Powder | 205.606 | TF | Spring 2013? | Yes | Yes | | Sent to HS on 3/22/2011; TR Requested 5/23/11; sent to contractor on 10/27/11. TR sent to HS on 2/16; Updated TR sent to HS 04 30 12. TR posted 06/25/12. On hold. |
| Sulfuric acid | 205.605 | JD | Spring 2013 | Yes | Yes | | Petition sent to Committee 8/17/2010; TR Requested 11/15/2011. Draft TR sent to HS 05/01/12. Review by 7/2/2012 -OVERDUE |
| Sodium gluconate | 205.605 | JD | ? | Yes | | | Petition sent to HS on 3/22/2011; for use in soap; TR Requested 11/15/2011. On hold, for cosmetic use. |
| | | | | | | | |

| Sunset 2015 - §205.605 (a) Nonsynthetics Allowed - Status of current review process | | | | | | |
|---|----------|------|-----------|--|-----------|--------------------------------|
| Name | CAS # | Rvwr | Meeting | | TR reqtd? | Notes* |
| Sunset 2015 - §205.605 (b) Synthetics Allowed - Status of current review process | | | | | | |
| Other Topics | | | | | | |
| Name | Reviewer | | Meeting | | | Notes* |
| Auxiliary/"other" ingredients | ZS | | Fall 2012 | | | Discussion document fall 2012. |

* Highlight indicates committee action needed.

Agenda:

- Approve minutes from August 7, 2012
- Dr. Sue Andersons' visit
- Vote on Ascorbyl palmitate (NM) - postponed from August 7
- More discussion?/vote on Nucleotides (JFo)
- Vote on "Other" ingredients
- Discuss sulfuric acid/Vote (if done) (JD)
- Any leftover materials
- Discuss barley beta fiber (JFo) - may postpone until Spring 2013
- Discuss sugar beet fiber (JFo? ZS?) - may postpone until Spring 2013
- Discuss/vote on DBDMH (JFo)-may postpone until Spring 2013

Discussion:

- Minutes from August 7 not yet sent to HS
- Dr. Sue Anderson; Team Leader, Infant Formula and Medical Foods Regulation and Review Team ,
Dr. Benson Silverman ; Director of the Infant Formula and Medical Foods Staff, and Dr. Leila Beker, Clinical Nutrition Reviewer from FDA
CFSAN were present on the call to answer questions about infant formula.
 - Question: Is ascorbyl palmitate allowed in infant formula as a source of vitamin C?
 - Answer: Yes, the FDA requires vitamin C in formula and there are different forms that vary in bioavailability depending on the matrix of the product. The regulations in 21 CFR 107.100 specify the nutrients that must be present in infant formula; however, they do not specify which forms manufacturers must use in formulating their products. Forms of vitamin C that are commercially available include ascorbic acid, sodium ascorbate, potassium ascorbate, calcium ascorbate, and ascorbyl palmitate.
 - Question: we have seen "Vitamin C palmitate" on labels. Is this permitted?
 - Answer: there is no regulation that prohibits this.
 - Question: Is a shorter "use by date" an alternative to using ascorbyl palmitate as an antioxidant?
 - Answer: Infant formula is required to have a "use by" date, and if a manufacturer chooses not to use a preservative, they can shorten the "use by" time. A follow up question was asked about the shelf life of infant formula. The long chain polyunsaturated fatty acids used in formula are very susceptible to oxidation, and rancidity could develop quickly, especially in powdered forms which have a large surface area. The date is set by the manufacturer, subject periodic testing. Powdered formula has a shelf life of up to 3 years, while liquid has a shelf life of about 1 year. Without ascorbyl palmitate, the shelf life is shorter but Dr. Anderson

was unsure how long it would be.

- Question: What is the relationship between beta carotene (also petitioned) and ascorbyl palmitate, and why are they both present in some products?
- Answer: Dr. Anderson indicated that it depends on the matrix of the product. Sometimes a combination works better.

- Question: Is Lutein also used for a similar reason?
- Answer: Lutein is not added as an antioxidant to protect the product; it may be added to provide an antioxidant for the baby. . Lutein is not classified by the National Academies Institute of Medicine (IOM) as an essential nutrient for infants. It's considered optional. IOM considers beta carotene a source of Vitamin A but not lutein or lycopene.

- Question: Why is lutein important to eye health?
- Answer: There is evidence to show it is concentrated in the macula of the eye, and may have importance in eye development, but there isn't firm evidence of this. FDA bases its regulation on safety, not on efficacy. Formula must provide for adequate protein for growth of the baby. Other ingredients are optional.

- Question: How does FDA develop baseline for ingredients.
- Answer: Infant Formula Act of 1980 is based on levels were prescribed by the American Academy of Pediatrics. The regulations set minimum levels for 29 nutrients and maximum levels for 9. The regulations have been updated since then.

- Question: Is it true that only synthetic forms of beta carotene are allowed in formula?
- Answer: With regard to beta carotene, a synthetic form is affirmed as GRAS for use as a nutrient supplement in infant formula, and it must meet Food Chemicals Codex specifications. Any B-carotene, regardless of source, would have to meet those specifications if it is used in food. . Beta carotene is also approved as a color additive, and may be prepared synthetically or obtained from natural sources. A person could submit a food additive petition or Generally Regarded as Safe (GRAS) notice for other forms of beta carotene which would have to include safety information. The submission of a GRAS notice for use of an ingredient is voluntary; however, FDA strongly encourages manufacturers to resolve any ingredient safety questions before submitting an infant formula notification.

- Question: Are there any differences between synthetic and natural forms of beta carotene with regard to absorption?
- Answer: Nutrient bioavailability is a complex issue and multiple factors must be taken into consideration. The food matrix (the total composition of the finished food) is a critical factor for absorption of nutrients from foods.

- Question: Are you aware of a need for nucleotides instead of complete proteins in infant formula?

- Answer: Nucleotides and complete proteins are not interchangeable. There is a protein requirement for infant formula and nucleotides do not contribute to that requirement. .
- Question: Can yeast be used in infant formula as an ingredient? Would it be a source of nucleotides for the infant?
- Answer: The safety of the yeast would have to be verified. And most likely the amount of yeast needed would be prohibitive. A follow up question was asked about the value of nucleotides, to which the FDA responded they are optional. Some studies have indicated that nucleotides improve response to vaccinations.
- Question: Lycopene has some GRAS notification notices posted, but none mention infant formula. Is this required?
- Answer: GRAS notification is voluntary, and it should include the use for which it is requested. An FDA response to a GRAS notification is not considered approval by the FDA. A third process for use of an additive (in addition to food additive petition or GRAS notification) is called “embedded GRAS”. This means that the manufacturer included confidential information in their infant formula registration to claim the substance is GRAS.
- The Subcommittee further discussed ascorbyl palmitate, which has been petitioned for use as preservative in infant formula. There are alternatives for ascorbyl palmitate but they may not be as effective. The criterion at §205.605(b) 4 states that primary use should not be as a preservative. Group noted that this fails to meet essentiality criteria. ZS suggested that use of a shorter “use by” date on a product should be added to the checklist as a possible alternative. NM will make changes, and will combine narrative into the checklist for posting. Having reviewed all the pertinent information and data, and questioning experts on infant formula from the FDA, the group moved to vote on ascorbyl palmitate.

Vote on Ascorbyl Palmitate

- Motion to classify Ascorbyl Palmitate (CAS 137666) as synthetic:
- Motion made by: NM
- Seconded by: JR
- Additional discussion: wanted to make sure CAS number was included
- Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0
- Motion to list Ascorbyl Palmitate (CAS 137666) for inclusion on 205.605(b) as a preservative for use in infant formula.
- Motion made by: NM
- Seconded by: JR
- No additional discussion
- Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

A member asked if this prohibition for infant formula will have an effect on other substances, e.g. DHA and ARA, where NOSB previously approved the use as an “other ingredient”. Several others indicated that it will have no effect, as that allowance was specific to those substances only.

Upcoming meetings and agenda items:

July 3, 2012 1:00 EDT (ZS away)

- Discuss/vote on L methionine- deferred vote while awaiting more info.
- Discuss/vote on Taurine (JR)-done
- Vote on Lycopene - postponed
- Vote on Lutein - done
- Discuss barley beta fiber – JFO -postponed
- Discuss sugar beet fiber – JFO -postponed
- Discuss/vote on beta carotene – TF postponed
- Vote on Ascorbyl palmitate -postponed

July 17, 2012 1:00 EDT

- Discuss/Vote on L methionine-done
- Vote on Lycopene (NM)-postponed
- Vote on Ascorbyl palmitate (NM)-postponed
- Discuss Nucleotides (JFo)-to be continued July 24
- Discuss Beta Carotene (TF)-postponed

July 24, 2012 4:00 EDT

- Vote on Lycopene (NM)-postponed from July 17-done
- Vote on Ascorbyl palmitate (NM)-postponed from July 17. Vote postponed
- Discuss/Vote on Nucleotides (JFo) -postponed
- Discuss Beta Carotene (TF) - postponed
- Report on Materials WG

July 31

- Discuss Nucleotides (JFo)-done'ish
- Discuss beta carotene (TF) - postponed

- Discuss barley beta fiber (JFo) - postponed
- Discuss sugar beet fiber (JFo? ZS?) - postponed

August 7, 2012 1:00 EDT

- Discuss edits to Lycopene checklist-done, NM will edit and recirculate
- Discuss beta carotene (TF)-done, voted 08 07
- Vote on Ascorbyl palmitate (NM)-postponed
- More discussion?/Vote on Nucleotides (JFo)
- Discuss "Other" ingredients (ZS)
- Discuss barley beta fiber (JFo)-postponed
- Discuss sugar beet fiber (JFo? ZS?)-postponed

August 14, 2012 4:00 EDT

- Guests: FDA Infant formula experts
- Vote on Ascorbyl palmitate (NM)-postponed from August 7-done
- More discussion?/Vote on Nucleotides (JFo) - postponed
- Vote on "Other" ingredients - postponed
- Discuss sulfuric acid/Vote (if done) (JD) - postponed
- Any leftover materials
- Discuss barley beta fiber (JFo) - may postpone until Spring 2013
- Discuss sugar beet fiber (JFo? ZS?) - may postpone until Spring 2013
- Discuss/vote on DBDMH (JFo)-may postpone until Spring 2013

August 21, 2012 1:00 EDT

- More discussion?/vote on Nucleotides (JFo) – postponed previously
- Vote on "Other" ingredients – postponed previously
- Discuss sulfuric acid/Vote (if done) (JD) – postponed previously
- Any leftover materials
- Discuss barley beta fiber (JFo) - may postpone until Spring 2013
- Discuss sugar beet fiber (JFo? ZS?) - may postpone until Spring 2013
- Discuss/vote on DBDMH (JFo)-may postpone until Spring 2013

September 4, 2012 1:00 EDT
September 18, 2012 1:00 EDT
October 2, 2012 1:00 EDT

| Milestone | Deadline |
|--|---------------------|
| NOP - "Finalize" tentative agenda | August 10, 2012 |
| Fall 2012 proposals due to NOP | August 20, 2012 |
| NOP - Post proposals, Publish FRN, Open public comment | August 27, 2012 |
| Public comment closes | September 24, 2012 |
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**National Organic Standards Board (NOSB)
Handling Subcommittee (HS) Meeting Notes
Tuesday, August 21, 2012, 1:00 pm EDT**

Present: John Foster (Chair) (JFo), Harold Austin (Vice-Chair) (HA), Zea Sonnabend (ZS), Joe Dickson (JD), Tracy Favre (TF), Jean Richardson (JR), Nick Maravell (NM)

Absent: Emily Brown Rosen (EBR)

Staff: Michelle Arsenault (MA), Melissa Bailey (MB)

Work Plan

| Petitioned Substances - Status of current review process | | | | | | | |
|--|-----------------------|------|-----------------------------|-----------|-----------|----------|--|
| Name | National List Section | Rvwr | Technical Review (TR) rqst? | TR rcv'd? | Mtng | Vote? | Notes* |
| Ascorbyl palmitate | 205.605(b) | NM | Yes | Yes | Fall 2012 | 08 14 12 | TR accepted as sufficient 4/30/12. TR Posted 07 25 12 |
| Beta-carotene (synthetic) in infant formula | 205.605 | TF | Yes | Yes | Fall 2012 | 08 07 12 | Petition sent to HS on 10/13/2011; Supplemental TR requested 1/17/12- HS asked by NOP to review the question asked - questions sent 3/6/12. Updated TR sent to NOSB. Petition and amended TR accepted as sufficient. |
| Lutein | 205.605(b) | HA | Yes | Yes | Fall 2012 | 7 17 12 | Petition sent to HS 11/16/2011; TR sent to HS on 4/27/2012. TR accepted as sufficient 06/26/12. TR posted. |
| Lycopene | 205.605 | NM | Yes | Yes | Fall 2012 | 7 24 12 | Petition sent to HS 9/22/2011; TR sent to HS 04 25 12. TR accepted as sufficient. TR Posted 07 25 12. Voted 07 24 |
| L-carnitine | 205.605 | ZS | Yes | Yes | Fall 2012 | 6 19 12 | Petition sent to HS 12/5/11; TR requested; Petition sufficiency review. Sent to TR contractor 12/5/11. Expected mid-April 2012. TR sent to HS 05 02 12. TR accepted as sufficient 06 19 12. TR posted 06/25/12 |
| L-methionine | 205.605(b) | TF | Yes | Yes | Fall 2012 | 7 17 12 | Petition sent to HS on 11/1/2011. TR accepted as sufficient 4/30/12, but not posted. Edits needed before posting TR. |

| Petitioned Substances - Status of current review process | | | | | | | |
|---|-----------------------|-------------|-----------------------------|-----------|-----------|--------------------------------|--|
| Name | National List Section | Rvwr | Technical Review (TR) rqst? | TR rcv'd? | Mtng | Vote? | Notes* |
| Taurine (for infant formula) | 205.605(b) | JR | Yes | Yes | Fall 2012 | 07 03 12 | Petition sent to HS 9/20/11; TR sent to HS 10/28/2011; TR accepted as sufficient 3/27/12. TR posted |
| Nucleotides | 205.605 | JFo | Yes | Yes | Fall 2012 | 08 22 12 | Petition sent to HS on 9/21/11; Revised TR sent to HS 04/26/12. TR accepted as sufficient 4/30/12. TR posted |
| 1,3-dibromo-5,5-dimethylhydantoin (DBDMH) | 205.605(b) | JFo | Yes | No | Spr 2013 | | Petition sent to HS on 2/16/2012. TR requested. Rcvd and sent to contractor for revision. TR sent to HS 07 19 12. ASAP !! Drop dead for Sept 30 |
| Barley Betafiber | 205.606 | JFo | Yes | Yes | Spr 2013 | | Revised petition sent to HS on 6/20/11; TR accepted as sufficient 4/30/12. TR Posted 07 25 12 |
| Sugar Beet fiber | 205.606 | JFo? ZS? | Yes | Yes | Spr 2013 | | Revised petition sent to Committee 2/10/2011; Revised TR sent to HS 04/26/12. TR accepted as sufficient 4/30/12. TR posted 06/25/12 |
| Bergamot Bitter Orange Powder | 205.606 | TF | Yes | Yes | Spr 2013 | | Sent to HS on 3/22/2011; TR Requested 5/23/11; sent to contractor on 10/27/11. TR sent to HS on 2/16; Updated TR sent to HS 04 30 12. TR posted 06/25/12. On hold. |
| Sulfuric acid | 205.605 | JD | Yes | Yes | Spr 2013 | | Petition sent to Committee 8/17/2010; TR Requested 11/15/2011. Draft TR sent to HS 05/01/12. Review by 7/2/2012 -OVERDUE |
| Sodium gluconate | 205.605 | JD | Yes | | | On hold | Petition sent to HS on 3/22/2011; for use in soap; TR Requested 11/15/2011. On hold, for cosmetic use. |
| Gibberellic acid | | ZS, TF | | | | | Petition sent to HS 07/27/12. Petition Sufficiency Response Due Date: 09/27/12 |
| Sunset 2015 - §205.605 (a) Nonsynthetics Allowed - Status of current review process | | | | | | | |
| Name | CAS # | Rvwr | TR rqst? | TR rcv'd? | Meeting | Vote | Notes* |
| | | | | | | | Begin review fall 2013 |
| Other Topics | | | | | | | |
| Name | | Reviewer | | Meeting | Vote | Notes* | |
| Auxiliary/"other" ingredients | | ZS | | Fall 2012 | 08 22 12 | Discussion document fall 2012. | |

* Highlight indicates committee action needed.

Agenda:

- Approve minutes from August 7 & 14, 2012 (not sent to HS yet)
- More discussion?/vote on Nucleotides (JFo)
- Vote on “Other” ingredients
- Discuss sulfuric acid/Vote (if done) (JD)
- Any leftover materials

Discussion:

- Minutes from August 7 & 14, 2012 not sent to HS yet

Vote on Nucleotides

- Motion to classify Nucleotides (205.605) as synthetic as petitioned
- Motion made by: TF
- Seconded by: HA
- No additional discussion:
- Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

- Motion to list Nucleotides for inclusion on 205.605(b) allowed for infant formulas only in the “organic” and “made with organic categories”. Nucleotides are allowed for the “made with organic claim” on all other food products.
- Motion made by: JFo
- Seconded by: JR
- Additional discussion: Group discussed annotation, and would prefer to keep it broader as opposed to narrowing the scope.
- Yes: 4 No: 3 Abstain: 0 temporary Absent: Recuse: 0

Group discussed Auxiliary/“other” ingredients discussion document. ZS asked about including the spreadsheet and how best to incorporate it into the final discussion document. Will add footnote about working group.

Vote on Auxiliary/“other” ingredients

- Motion to accept Auxiliary/“other” discussion document and
- Motion made by: ZS
- Seconded by: TF
- No additional discussion
- Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

The Handling Subcommittee discussed various items on the work plan, including the TR sufficiency of sulfuric acid, which JD will work on; the Research Priorities for the Materials Subcommittee, and the Sunset 2015 materials. MA will compile list of sunset 2015 materials and forward them to JFo. A member mentioned an update that needs to be made to the materials spreadsheet: Bergamot bitter orange date was not updated.

A question was raised about a new petition for gibberellic acid and whether the Subcommittee or NOP was responsible for determining if there was new information. NOP indicated that they did a preliminary review and determined that it included new information; therefore it was forwarded to the HS to make the final determination.

Upcoming meetings and agenda items:

July 3, 2012 1:00 EDT (ZS away)

- Discuss/vote on L methionine- deferred vote while awaiting more info.
- Discuss/vote on Taurine (JR)-done
- Vote on Lycopene - postponed
- Vote on Lutein - done
- Discuss barley beta fiber – JFO -postponed
- Discuss sugar beet fiber – JFO -postponed
- Discuss/vote on beta carotene – TF postponed
- Vote on Ascorbyl palmitate -postponed

July 17, 2012 1:00 EDT

- Discuss/Vote on L methionine-done
- Vote on Lycopene (NM)-postponed
- Vote on Ascorbyl palmitate (NM)-postponed
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July 31

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- Discuss beta carotene (TF) - postponed
- Discuss barley beta fiber (JFo) - postponed
- Discuss sugar beet fiber (JFo? ZS?) - postponed

August 7, 2012 1:00 EDT

- Discuss edits to Lycopene checklist-done, NM will edit and recirculate
- Discuss beta carotene (TF)-done, voted 08 07
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- More discussion?/Vote on Nucleotides (JFo)
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- Guests: FDA Infant formula experts
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- Discuss/vote on DBDMH (JFo)-may postpone until Spring 2013

August 21, 2012 1:00 EDT

- More discussion?/vote on Nucleotides (JFo) - done
- Vote on "Other" ingredients – postponed previously

September 4, 2012 1:00 EDT-canceled

September 18 2012 1:00 EDT

- Discuss Gibberellic acid
- Discuss sulfuric acid TR sufficiency
- Discuss barley beta fiber (JFo) - may postpone until Spring 2013
- Discuss sugar beet fiber (JFo? ZS?) - may postpone until Spring 2013
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October 2, 2012 1:00 EDT

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Absent: Emily Brown Rosen (EBR), Zea Sonnabend (ZS), Nick Maravell (NM)

Staff: Michelle Arsenault (MA), Melissa Bailey (MB)

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| Taurine (for infant formula) | 205.605(b) | JR | Yes | Yes | Fall 2012 | 07 03 12 | Petition sent to HS 9/20/11; TR sent to HS 10/28/2011; TR accepted as sufficient 3/27/12. TR posted |
| Nucleotides | 205.605 | JFo | Yes | Yes | Fall 2012 | 08 22 12 | Petition sent to HS on 9/21/11; Revised TR sent to HS 04/26/12. TR accepted as sufficient 4/30/12. TR posted |
| 1,3-dibromo-5,5-dimethylhydantoin (DBDMH) | 205.605(b) | JFo | Yes | No | Spr 2013 | | Petition sent to HS on 2/16/2012. TR requested. Rcvd and sent to contractor for revision. TR sent to HS 07 19 12. ASAP !! Due no later than Sept 30 |
| Barley Betafiber | 205.606 | JFo | Yes | Yes | Spr 2013 | | Revised petition sent to HS on 6/20/11; TR accepted as sufficient 4/30/12. TR Posted 07 25 12 |
| Sugar Beet fiber | 205.606 | JFo? ZS? | Yes | Yes | Spr 2013 | | Revised petition sent to Committee 2/10/2011; Revised TR sent to HS 04/26/12. TR accepted as sufficient 4/30/12. TR posted 06/25/12 |
| Bergamot Bitter Orange Powder | 205.606 | TF | Yes | Yes | Spr 2013? | On hold | Sent to HS on 3/22/2011; TR Requested 5/23/11; sent to contractor on 10/27/11. TR sent to HS on 2/16; Updated TR sent to HS 04 30 12. TR posted 06/25/12. On hold. |
| Sulfuric acid | 205.605 | JD | Yes | Yes | Spr 2013 | | Petition sent to Committee 8/17/2010; TR Requested 11/15/2011. Draft TR sent to HS 05/01/12. Review by 7/2/2012 -OVERDUE |
| Sodium gluconate | 205.605 | JD | Yes | | | On hold | Petition sent to HS on 3/22/2011; for use in soap; TR Requested 11/15/2011. On hold, for cosmetic use. |
| Gibberellic acid | | ZS, TF | | | Spr 2013? | | Petition sent to HS 07/27/12. Petition Sufficiency Response Due Date: 09/27/12 |
| Sunset 2015 - §205.605 (a) Nonsynthetics Allowed - Status of current review process | | | | | | | |
| Name | CAS # | Rvwr | TR rqst? | TR rcv'd? | Meeting | Vote | Notes* |
| | | | | | | | Begin review fall 2013 |
| Other Topics | | | | | | | |
| Name | | Reviewer | | Meeting | Vote | Notes* | |
| Auxiliary/"other" ingredients | | ZS | | Fall 2012 | 08 22 12 | Discussion document fall 2012. | |

* Highlight indicates committee action needed.

Agenda:

- Approve minutes from August 7, 14, and 21, 2012
- Discuss sulfuric acid TR sufficiency (JD)
- Discuss barley beta fiber (JFo) - may postpone until Spring 2013
- Discuss sugar beet fiber (JFo? ZS?) - may postpone until Spring 2013
- Discuss/vote on DBDMH (JFo)-may postpone until Spring 2013-last

Discussion:

- Minutes from August 7, 14, and 21, 2012 not approved yet. Members will review and approve via email.
- Sulfuric acid TR sufficiency (JD) – will discuss on next call.
- DBDMH – will discuss on next call and vote soon.
- Workplan: Five materials, plus five or six (?) sunset materials for 2015. A question was asked about sanitizers and MB noted that EBR is going to provide an overview of sanitizers and processing aids to the Compliance, Accreditation and Certification (CAC) Subcommittee, and if needed, Handling, The Handling Subcommittee will wait until NOP provides this overview before taking this on as a workplan item.
- Some of the 2015 sunset materials could be moved to spring 2013, but MB is still working the process and will let the subcommittee know.
- The group discussed other workplan items, and Non-materials related issues, of which there were none.

Upcoming meetings and agenda items:

August 21, 2012 1:00 EDT

- More discussion?/vote on Nucleotides (JFo) - done
- Vote on “Other” ingredients – postponed previously

September 4, 2012 1:00 EDT-cancelled

September 18 2012 1:00 EDT

- Discuss Gibberellic acid - postponed
- Discuss sulfuric acid TR sufficiency - postponed
- Discuss barley beta fiber (JFo) - may postpone until Spring 2013
- Discuss sugar beet fiber (JFo? ZS?) - may postpone until Spring 2013

- Discuss/vote on DBDMH (JFo)-may postpone until Spring 2013-last
October 2, 2012 1:00 EDT

- Discuss/vote on DBDMH (JFo)
- Discuss Gibberellic acid (ZS, TF)
- Discuss sulfuric acid TR sufficiency (JD)
- Discuss barley beta fiber (JFo)
- Discuss sugar beet fiber (JFo? ZS)

November 6, 2012 1:00 EDT

November 20, 2012 1:00 EDT

| Milestone | Deadline |
|--|---------------------|
| NOP - "Finalize" tentative agenda | August 10, 2012 |
| Fall 2012 proposals due to NOP | August 20, 2012 |
| NOP - Post proposals, Publish FRN, Open public comment | August 27, 2012 |
| Public comment closes | September 24, 2012 |
| NOP - Send compiled public comments to NOSB | October 1, 2012 |
| Fall 2012 NOSB Meeting – Providence, RI | October 15-18, 2012 |

Note: Subcommittee notes may include preliminary discussions regarding substances considered for addition to or removal from the National List. They do not represent official National Organic Program (NOP) policy or regulations. Please see the NOP website for official NOP policy, regulations, and status of substances used in organic production and handling.

**National Organic Standards Board (NOSB)
Handling Subcommittee (HS) Meeting Notes
Tuesday, October 2, 2012, 1:00 pm EDT**

Present: Harold Austin (Vice-Chair) (HA), Jean Richardson (JR), Zea Sonnabend (ZS), Nick Maravell (NM), Tracy Favre (TF)

Absent: John Foster (Chair) (JFo), Joe Dickson (JD)

Staff: Michelle Arsenault (MA), Emily Brown Rosen (EBR)

Work Plan

| Petitioned Substances - Status of current review process | | | | | | | |
|--|-----------------------|------|-----------------------------|-----------|-----------|----------|--|
| Name | National List Section | Rvwr | Technical Review (TR) rqst? | TR rcv'd? | Mtng | Vote? | Notes* |
| Ascorbyl palmitate | 205.605(b) | NM | Yes | Yes | Fall 2012 | 08 14 12 | TR accepted as sufficient 4/30/12. TR Posted 07 25 12 |
| Beta-carotene (synthetic) in infant formula | 205.605 | TF | Yes | Yes | Fall 2012 | 08 07 12 | Petition sent to HS on 10/13/2011; Supplemental TR requested 1/17/12- HS asked by NOP to review the question asked - questions sent 3/6/12. Updated TR sent to NOSB. Petition and amended TR accepted as sufficient. |
| Lutein | 205.605(b) | HA | Yes | Yes | Fall 2012 | 7 17 12 | Petition sent to HS 11/16/2011; TR sent to HS on 4/27/2012. TR accepted as sufficient 06/26/12. TR posted. |
| Lycopene | 205.605 | NM | Yes | Yes | Fall 2012 | 7 24 12 | Petition sent to HS 9/22/2011; TR sent to HS 04 25 12. TR accepted as sufficient. TR Posted 07 25 12. Voted 07 24 |
| L-carnitine | 205.605 | ZS | Yes | Yes | Fall 2012 | 6 19 12 | Petition sent to HS 12/5/11; TR requested; Petition sufficiency review. Sent to TR contractor 12/5/11. Expected mid-April 2012. TR sent to HS 05 02 12. TR accepted as sufficient 06 19 12. TR posted 06/25/12 |
| L-methionine | 205.605(b) | TF | Yes | Yes | Fall 2012 | 7 17 12 | Petition sent to HS on 11/1/2011. TR accepted as sufficient 4/30/12, but not posted. Edits needed before posting TR. |
| Taurine (for infant formula) | 205.605(b) | JR | Yes | Yes | Fall 2012 | 07 03 12 | Petition sent to HS 9/20/11; TR sent to HS 10/28/2011; TR accepted as sufficient 3/27/12. TR posted |

| Petitioned Substances - Status of current review process | | | | | | | |
|---|-----------------------|-------------|-----------------------------|-----------|-----------|--------------------------------|--|
| Name | National List Section | Rvwr | Technical Review (TR) rqst? | TR rcv'd? | Mtng | Vote? | Notes* |
| Nucleotides | 205.605 | JFo | Yes | Yes | Fall 2012 | 08 22 12 | Petition sent to HS on 9/21/11; Revised TR sent to HS 04/26/12. TR accepted as sufficient 4/30/12. TR posted |
| 1,3-dibromo-5,5-dimethylhydantoin (DBDMH) | 205.605(b) | JFo | Yes | No | Spr 2013 | | Petition sent to HS on 2/16/2012. TR requested. Rcvd and sent to contractor for revision. TR sent to HS 07 19 12. Due no later than Sept 30. TR was accepted by NOP as sufficient as is (Contract expired at end of FY 2012) |
| Barley Betafiber | 205.606 | JFo | Yes | Yes | Spr 2013 | | Revised petition sent to HS on 6/20/11; TR accepted as sufficient 4/30/12. TR Posted 07 25 12 |
| Sugar Beet fiber | 205.606 | JFo? ZS? | Yes | Yes | Spr 2013 | | Revised petition sent to Committee 2/10/2011; Revised TR sent to HS 04/26/12. TR accepted as sufficient 4/30/12. TR posted 06/25/12 |
| Bergamot Bitter Orange Powder | 205.606 | TF | Yes | Yes | Spr 2013? | On hold | Sent to HS on 3/22/2011; TR Requested 5/23/11; sent to contractor on 10/27/11. TR sent to HS on 2/16; Updated TR sent to HS 04 30 12. TR posted 06/25/12. On hold. |
| Sulfuric acid | 205.605 | JD | Yes | Yes | Spr 2013 | | Petition sent to Committee 8/17/2010; TR Requested 11/15/2011. Draft TR sent to HS 05/01/12. Review by 7/2/2012 |
| Sodium gluconate | 205.605 | JD | Yes | | | On hold | Petition sent to HS on 3/22/2011; for use in soap; TR Requested 11/15/2011. On hold, for cosmetic use. |
| Gibberellic acid | | ZS, TF | | | Spr 2013 | | Petition sent to HS 07/27/12. Petition Sufficiency Response Due Date: 09/27/12 |
| Sunset 2015 - §205.605 (a) Nonsynthetics Allowed - Status of current review process | | | | | | | |
| Name | CAS # | Rvwr | TR rqst? | TR rcv'd? | Meeting | Vote | Notes* |
| | | | | | | | Begin review fall 2013 |
| Other Topics | | | | | | | |
| Name | | Reviewer | | Meeting | Vote | Notes* | |
| Auxiliary/"other" ingredients | | ZS | | Fall 2012 | 08 22 12 | Discussion document fall 2012. | |

* Highlight indicates committee action needed.

Agenda:

- Approve minutes from September 18, 2012
- Discuss/vote on DBDMH (JFo)
- Discuss Gibberellic acid (ZS, TF)
- Discuss sulfuric acid TR sufficiency (JD)
- Discuss barley beta fiber (JFo)
- Discuss sugar beet fiber (JFo? ZS)

Discussion:

- Minutes from September 18, 2012 approved as is.
- The discussion on DBDMH was postponed until after the fall meeting
- The discussion on Gibberellic acid was postponed until after the fall meeting, when members had more time to review the new petition
- MA will ask JD to provide any information to the group about sulfuric acid so they can determine if the TR is sufficient
- The discussion on barley beta fiber was postponed until after the fall meeting
- The discussion on sugar beet fiber was postponed until after the fall meeting
- Public Comments:
 - The group discussed several comments that nucleotides are non-synthetic, and noted that the TR was not very clear about this. In general the Subcommittee agrees that nucleotides are non-synthetic and that they are derived from yeast extracts which are allowed on the list. The Subcommittee will prepare a revised draft of the proposal in preparation for the fall meeting.
 - The phrase “isolated soy based protein” was included in the L- methionine proposal, and the group agreed that it should not have included the word “isolated”. This will be revised for the NOSB meeting discussion.
 - A question was raised in the public comments about beta carotene and the options if it is excluded from the list. The members agreed that this may be a question for the FDA/AAP reps. If beta carotene is allowed as a vitamin and not an antioxidant it creates complications and would make certification difficult. The group felt that the same complication applies to ascorbyl palmitate. ZS is preparing a list of questions for Drs. Anderson and Bhatia who will be at the NOSB meeting to answer questions. One of the lingering questions involves the issue of rancidity and preservation. On an earlier call, Dr. Anderson indicated that infant formula had approximately a 3-year shelf life. The members felt that if the removal of ascorbyl palmitate would drastically reduce the shelf-life then that could inform their decision.
 - With regard to Taurine, it was stated in the TR that most is synthetic though there may be some -natural forms available. The group questioned whether or not Taurine is required for infants or if infants synthesize it from other amino acids, and agreed this this would be a good question for Dr. Bhatia.

- EBR asked about the presentation format for each of the nutrients and how the comments will be presented. Some possibilities that were discussed include having each lead person present the items they were responsible for, or grouping similar items and presenting them together. HA will look at public comments about the nutrients and touch base with JFo to discuss the presentation format. The Subcommittee requested that MA rearrange the discussion order to place the similar nutrients together: i.e. Beta Carotene and ascorbyl palmitate together, lycopene and lutein, and L-Carnitine and L-methionine together.

Upcoming meetings and agenda items:

August 21, 2012 1:00 EDT

- More discussion?/vote on Nucleotides (JFo) - done
- Vote on “Other” ingredients – postponed previously

September 4, 2012 1:00 EDT-cancelled

September 18 2012 1:00 EDT

- Discuss Gibberellic acid - postponed
- Discuss sulfuric acid TR sufficiency - postponed
- Discuss barley beta fiber (JFo) - may postpone until Spring 2013
- Discuss sugar beet fiber (JFo? ZS?) - may postpone until Spring 2013
- Discuss/vote on DBDMH (JFo)-may postpone until Spring 2013-last

October 2, 2012 1:00 EDT

- Discuss/vote on DBDMH (JFo)
- Discuss Gibberellic acid (ZS, TF)
- Discuss sulfuric acid TR sufficiency (JD)
- Discuss barley beta fiber (JFo)
- Discuss sugar beet fiber (JFo? ZS)

November 6, 2012 1:00 EDT

November 20, 2012 1:00 EDT

| Milestone | Deadline |
|--|---------------------|
| NOP - "Finalize" tentative agenda | August 10, 2012 |
| Fall 2012 proposals due to NOP | August 20, 2012 |
| NOP - Post proposals, Publish FRN, Open public comment | August 27, 2012 |
| Public comment closes | September 24, 2012 |
| NOP - Send compiled public comments to NOSB | October 1, 2012 |
| Fall 2012 NOSB Meeting – Providence, RI | October 15-18, 2012 |

Note: Subcommittee notes may include preliminary discussions regarding substances considered for addition to or removal from the National List. They do not represent official National Organic Program (NOP) policy or regulations. Please see the NOP website for official NOP policy, regulations, and status of substances used in organic production and handling.

**National Organic Standards Board (NOSB)
Handling Subcommittee (HS) Meeting Notes
Tuesday, November 6, 2012, 1:00 pm EST**

Present: John Foster (Chair) (JFo), Harold Austin (Vice-Chair) (HA), Jean Richardson (JR), Zea Sonnabend (ZS),

Absent: Nick Maravell (NM), Tracy Favre (TF), Joe Dickson (JD), Carmela Beck (CBe)

Staff: Michelle Arsenault (MA), Emily Brown Rosen (EBR)

Work Plan

| Petitioned Substances - Status of current review process | | | | | | | |
|--|-----------------------|------------|-----------------------------|-----------|----------|-------|--|
| Name | National List Section | Rvwr | Technical Review (TR) rqst? | TR rcv'd? | Mtng | Vote? | Notes* |
| 1,3-dibromo-5,5-dimethylhydantoin (DBDMH) | 205.605(b) | JFo | Yes | No | Spr 2013 | | Petition sent to HS on 2/16/2012. TR requested. Rcvd and sent to contractor for revision. TR sent to HS 07 19 12. Due no later than Sept 30. TR was accepted by NOP as sufficient as is (Contract expired at end of FY 2012) |
| Barley Betafiber | 205.606 | JFo | Yes | Yes | Spr 2013 | | Revised petition sent to HS on 6/20/11; TR accepted as sufficient 4/30/12. TR Posted 07 25 12 |
| Sugar Beet fiber | 205.606 | JFo/ ZS | Yes | Yes | Spr 2013 | | Revised petition sent to Committee 2/10/2011; Revised TR sent to HS 04/26/12. TR accepted as sufficient 4/30/12. TR posted 06/25/12 |
| Sulfuric acid (H ₂ SO ₄) | 205.605 | JD | Yes | Yes | Spr 2013 | | Petition sent to Committee 8/17/2010; TR Requested 11/15/2011. Draft TR sent to HS 05/01/12. Review by 7/2/2012 -OVERDUE |
| Sodium gluconate | 205.605 | JD | Yes | | On hold | | Petition sent to HS on 3/22/2011; for use in soap; TR Requested 11/15/2011. On hold, for cosmetic use. |
| Bergamot Bitter Orange Powder | 205.606 | TF | Yes | Yes | On hold | | Sent to HS on 3/22/2011; TR Requested 5/23/11; sent to contractor on 10/27/11. TR sent to HS on 2/16; Updated TR sent to HS 04 30 12. TR posted 06/25/12. On hold. |

| Petitioned Substances - Status of current review process | | | | | | | |
|--|-----------------------|----------|-----------------------------|--------------------------------|-----------|-------|--|
| Name | National List Section | Rvwr | Technical Review (TR) rqst? | TR rcv'd? | Mtng | Vote? | Notes* |
| Gibberellic acid | 205.605 | ZS, TF | | | Fall 2013 | | Petition sent to HS 07/27/12. Petition Sufficiency Response Due Date: 09/27/12 |
| Ammonium hydroxide (boiler water additive) | 205.605 | JR | | | Fall 2013 | | Petition sent to HS 11/06/12. Petition Sufficiency Response Due Date: 01/27/13 |
| Sunset 2015 - Status of current review process | | | | | | | |
| Name | CAS # | Rvwr | TR rqst? | TR rcv'd? | Meeting | Vote | Notes* |
| Gellan gum 205.605(a) | | | | | Fall 2013 | | |
| Marsala at 205.606 | | | | | Fall 2013 | | |
| Sherry at 205.606 | | | | | Fall 2013 | | |
| Tragacanth at 205.606 | | | | | Fall 2013 | | |
| Other Topics | | | | | | | |
| Name | Reviewer | Meeting | Vote | Notes* | | | |
| Auxiliary/"Other" ingredients | ZS | Spr 2013 | | Discussion document fall 2012. | | | |

* Highlight indicates committee action needed.

Agenda

- Approve minutes from October 2, 2012
- Approve two draft technical reports for posting: Sulfuric Acid and DBDMH. Note: the TR contract for these ended Sept 30, so NOP is unable to make additional changes to these reports.

- Discuss Sunset 2015 Materials
- Discuss Gibberellic acid
- Discuss other workplan items

Discussion

- Minutes from October 2 approved without changes
- DBDMH and Sulfuric Acid TRs deemed sufficient and ready for posting
- The group discussed the Sunset 2015 materials.
 - Gellan gum (205.605(a)) has a recent TR, but other sunset materials do not. The other materials are on 205.606 and traditionally the issue that arises with 606 items is commercial availability, and since the TRs don't usually address that, there doesn't seem to be a need to request TRs. The group asked about the possibility of requesting specific information about commercial availability and economic indicators. Will look at the 606 Sunset materials before requesting additional information.
 - Tragacanth might be the only substance that warrants a request for a TR as there may be a classification issue. EBR noted that other gums are on listed on 606. A member asked about gathering information about commercial availability, and asked if the new TR contracts included the potential for responding to questions about economic indicators. EBR will send the HS the previous information for the 4 sunset materials so the Subcommittee can discuss them on the December 4 call. NOP indicated that since the Sunset materials aren't on the agenda until fall 2013, the Subcommittee has time to request TRs
- Gibberellic Acid: A new petition was submitted but does not seem to contain much new information, and it also contains Confidential Business Information (CBI), which is not available to the Subcommittee. The group discussed a number of options, which includes sending the petition back to the petitioner with a request for more information, requesting a TR, or voting on the petition as is. The group decided to deem the petition insufficient and will send it back to petitioner with a request for additional information. ZS will compile a list of questions and send them to MA and EBR.
- Other Workplan items:
 - Ammonium hydroxide - JR will take lead and look at petition for sufficiency
 - Sugar Beet fiber (ZS). Will discuss during November 20 call
 - Bergamot Bitter Orange Powder (TF). Item is on hold because it was petitioned as an antimicrobial, yet is not registered with EPA for that use. Currently NOP is waiting for petitioner. EBR will look into status.
 - Auxiliary/Other ingredients: Will need 30 minutes on November 20 call to discuss.
- The Chair asked about the potential of receiving any TRs for sunset 2013 items before the spring meeting. EBR will check on the possibility.

Future Call Schedule:

November 20, 2012 1:00 EST

Barley Betafiber (JFo)

Sugar Beet fiber (JFo/ZS)

½ meeting: Auxiliary/”other” ingredients (ZS)

December 4, 2012 1:00 EST

Sunset items

Ammonium hydroxide (determination of petition sufficiency and request for TR?) (JR)

December 18, 2012 1:00 EST

DBDMH (JFo)

Sulfuric Acid (JD)

Gibberellic acid (ZS)

January 9, 2013 1:00 EST

January 15, 2013 1:00 EST

February 5, 2013 1:00 EST

February 19, 2013 1:00 EST

March 5, 2013 1:00 EST

March 19, 2013 1:00 EST

| Milestone | Target date |
|--|-------------------|
| NOP – Complete tentative agenda | February 8, 2013 |
| Spring 2013 proposals due to NOP | February 12, 2013 |
| NOP - Post proposals, Publish FRN, Open public comment | February 19, 2013 |
| Public comment closes | March 19, 2013 |
| NOP - Send compiled public comments to NOSB | March 25, 2013 |
| Spring 2013 NOSB Meeting – Portland, OR | April 8-11, 2013 |

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**National Organic Standards Board (NOSB)
Handling Subcommittee (HS) Meeting Notes
Tuesday, November 20, 2012, 1:00 pm EST**

Present: John Foster (Chair) (JFo), Harold Austin (Vice-Chair) (HA), Jean Richardson (JR), Zea Sonnabend (ZS), Tracy Favre (TF), Carmela Beck (CBe), Mac Stone (MS), Joe Dickson (JD)

Absent: Nick Maravell (NM),

Staff: Michelle Arsenault (MA), Emily Brown Rosen (EBR)

Work Plan

| Petitioned Substances - Status of current review process | | | | | | | |
|---|-----------------------|------------|-----------------------------|---------------------|----------|-------|--|
| Name | National List Section | Rvwr | Technical Review (TR) rqst? | TR rcv'd? | Mtng | Vote? | Notes* |
| 1,3-dibromo-5,5-dimethylhydantoin (DBDMH) | 205.605(b) | JFo | Yes | Yes | Spr 2013 | | Petition sent to HS on 2/16/2012. TR requested. Rcvd and sent to contractor for revision. TR sent to HS 07 19 12. Due no later than Sept 30. TR was accepted by NOP as sufficient as is and posted ~11 06 12 |
| Barley Betafiber | 205.606 | JFo | Yes | Yes | Spr 2013 | | Revised petition sent to HS on 6/20/11; TR accepted as sufficient 4/30/12. TR Posted 07 25 12 |
| Sugar Beet fiber | 205.606 | JFo/ ZS | Yes | Yes | Spr 2013 | | Revised petition sent to Committee 2/10/2011; Revised TR sent to HS 04/26/12. TR accepted as sufficient 4/30/12. TR posted 06/25/12 |
| Sulfuric acid (H₂SO₄) | 205.605 | JD | Yes | Yes | Spr 2013 | | Petition sent to Committee 8/17/2010; TR Requested 11/15/2011. Draft TR sent to HS 05/01/12. Deemed sufficient 11 06 12. TR posted ~11 06 12 |
| Sodium gluconate | 205.605 | JD | Yes | No | On hold | | Petition sent to HS on 3/22/2011; for use in soap; TR Requested 11/15/2011. On hold, for cosmetic use. |
| Bergamot Bitter Orange Powder | 205.606 | TF | Yes | Yes | On hold | | Sent to HS on 3/22/2011; TR Requested 5/23/11; sent to contractor on 10/27/11. TR sent to HS on 2/16; Updated TR sent to HS 04 30 12. TR posted 06/25/12. On hold. |

| Petitioned Substances - Status of current review process | | | | | | | |
|---|-----------------------|----------|-----------------------------|-----------------------|-----------|-------|---|
| Name | National List Section | Rvwr | Technical Review (TR) rqst? | TR rcv'd? | Mtng | Vote? | Notes* |
| Gibberellic acid | 205.605 | ZS, TF | Yes | Yes | Fall 2013 | | Petition sent to HS 07/27/12. Petition Sufficiency Response Due Date: 09/27/12 |
| Ammonium hydroxide (boiler water additive) | 205.605 | JR | | | Fall 2013 | | 2000 petition , 2001 Recommendation , 2001 TAP , 2012 Petition sent to HS 11/06/12. Petition Sufficiency Response Due Date: 01/27/13 |
| Sunset 2015 - Status of current review process | | | | | | | |
| Name | CAS # | Rvwr | TR rqst? | TR rcv'd? | Meeting | Vote | Notes* |
| Gellan gum 205.605(a) | | | | | Fall 2013 | | 2006 TR , 2008 Recommendation |
| Marsala at 205.606 | | | | | Fall 2013 | | No TR rqst, 2008 Recommendation |
| Sherry at 205.606 | | | | | Fall 2013 | | No TR rqst, 2008 Recommendation |
| Tragacanth at 205.606 | | | | | Fall 2013 | | No TR rqst, 2008 Recommendation |
| Other Topics | | | | | | | |
| Name | Rvwr | Meeting | Vote | Notes* | | | |
| Auxiliary/"other" ingredients (2012 disc doc) | ZS | Spr 2013 | | Proposal spring 2013. | | | |

* Highlight indicates committee action needed.

Agenda

- Approve notes from November 6, 2012
- Barley Betafiber (JFo)
- Sugar Beet fiber (JFo/ZS)
- ½ meeting: Auxiliary/"other" ingredients (ZS)
- Appoint Handling representative to GMO ad hoc Subcommittee

Discussion

- Notes from November 6, 2012 approved with no changes
- ZS volunteered to be the Handling representative to the GMO ad hoc Subcommittee as she already serves as the Vice Chair.
- Barley Betafiber (JFo) – Petitioned by Cargill as a food additive to increase soluble fiber content. The petition specifies certain varieties of barley. The original petition was submitted in Sept 2009 and updated in June 2011. The TR speaks to the manufacturing process, although Confidential Business Information (CBI) was redacted from the petition. EBR noted that enzymes are used in the manufacturing process and asked that the group include discussion of the manufacturing process and the potential for GMO issues. A member asked several questions: Are there alternative organic fibers? Why is Barley fiber beneficial over other fibers? The petitioner indicated that the concentration of barley betafiber is higher (10-35x) than that of Rye, Oat bran, other Barleys, and psyllium husk, and also has a milder flavor. The Chair feels that this substance is agriculturally innocuous and has demonstrable health benefits, but will look at the enzymes in the manufacturing process section in the petition a little more closely. JFo will amend the checklist by adding language about the possibility of GMOs, and the group may vote on this during the next meeting. TF asked how the group could get clarification about the enzymatic process, if it is considered CBI. EBR noted that the manufacturing process was mentioned in the TR. JFo will look more closely at the patent/process, and asked that the group reread the petition and TR.
- Sugar beet fiber (ZS). Petitioned by sugar makers. Currently ~85% of sugar beets are genetically engineered, so it may not be feasible that this would be allowed in Organic. Sugar beet fiber does not appear to be made with enzymes, but instead is a byproduct of the physical separation of the pulp from the liquid and may contain bacteria that must be treated with antimicrobials. JD asked about the timing of the petition submission, because there has been a proliferation of GMOs in sugar beets in the last 2 years. The group discussed that fact that the petitioner is from Sweden, and the product is manufactured there, so perhaps GMOs are not an issue. The TR indicates that nonorganic production in Sweden uses pesticides (including aldicarb). A member noted that it was still unclear as to the usefulness or need for this item. The group intendeds on voting on this item at the next meeting.
- Other ingredients - The members discussed the summary of the public comment from the last NOSB meeting regarding how to classify and review auxiliary/"other" ingredients. There were three options presented in the discussion document; A, B, and C, and overall Option B received the most support. Some commenters proposed an additional Option, D. ZS will work on the initial proposal for Option

B, which says the NOSB would adopt the request by the NOP to consider “other ingredients” during their review as substances come up for sunset review or as new petitions are considered. Members asked for feedback from EBR about compiling a database, and she noted this has been discussed in the context of a future Permitted Substance List for processing (a Guidance document) and this may be a good home for this information.

Future Call Schedule:

November 20, 2012 1:00 EST

Barley Betafiber (JFo)

Sugar Beet fiber (JFo/ZS)

½ meeting: Auxiliary/”other” ingredients (ZS)

December 4, 2012 1:00 EST

Vote on Barley Betafiber (JFo)

Vote on Sugar Beet fiber? (JFo/ZS)

Sunset items

Ammonium hydroxide (determination of petition sufficiency and request for TR?) (JR)

December 18, 2012 1:00 EST

Discuss sulfuric acid (JD)

Discuss gibberellic acid (ZS)

Continue discussion on auxiliary/ ”other” ingredients (ZS)

January 9, 2013 1:00 EST

DBDMH (JFo)

January 15, 2013 1:00 EST

February 5, 2013 1:00 EST

February 19, 2013 1:00 EST

March 5, 2013 1:00 EST

March 19, 2013 1:00 EST

| Milestone | Target date |
|--|-------------------|
| NOP – Complete tentative agenda | February 8, 2013 |
| Spring 2013 proposals due to NOP | February 12, 2013 |
| NOP - Post proposals, Publish FRN, Open public comment | February 19, 2013 |
| Public comment closes | March 19, 2013 |
| NOP - Send compiled public comments to NOSB | March 25, 2013 |
| Spring 2013 NOSB Meeting – Portland, OR | April 8-11, 2013 |

Note: Subcommittee notes may include preliminary discussions regarding substances considered for addition to or removal from the National List. They do not represent official National Organic Program (NOP) policy or regulations. Please see the NOP website for official NOP policy, regulations, and status of substances used in organic production and handling.

**National Organic Standards Board (NOSB)
Handling Subcommittee (HS) Meeting Notes
Tuesday, December 4, 2012, 1:00 pm EST**

Present: John Foster (Chair) (JFo), Harold Austin (Vice-Chair) (HA), Jean Richardson (JR), Zea Sonnabend (ZS), Carmela Beck (CBe), Mac Stone (MS), Nick Maravell (NM)

Absent: Tracy Favre (TF), Joe Dickson (JD)

Staff: Michelle Arsenault (MA), Emily Brown Rosen (EBR)

Work Plan

| Petitioned Substances - Status of current review process | | | | | | | |
|---|-----------------------|------------|-----------------------------|---------------------|----------|-------|--|
| Name | National List Section | Rvwr | Technical Review (TR) rqst? | TR rcv'd? | Mtng | Vote? | Notes* |
| 1,3-dibromo-5,5-dimethylhydantoin (DBDMH) | 205.605(b) | JFo | Yes | Yes | Spr 2013 | | Petition sent to HS on 2/16/2012. TR requested. Rcvd and sent to contractor for revision. TR sent to HS 07 19 12. Due no later than Sept 30. TR was accepted by NOP as sufficient as is and posted ~11 06 12 |
| Barley Betafiber | 205.606 | JFo | Yes | Yes | Spr 2013 | | Revised petition sent to HS on 6/20/11; TR accepted as sufficient 4/30/12. TR Posted 07 25 12 |
| Sugar Beet fiber | 205.606 | JFo/ ZS | Yes | Yes | Spr 2013 | | Revised petition sent to Committee 2/10/2011; Revised TR sent to HS 04/26/12. TR accepted as sufficient 4/30/12. TR posted 06/25/12 |
| Sulfuric acid (H₂SO₄) | 205.605 | JD | Yes | Yes | Spr 2013 | | Petition sent to Committee 8/17/2010; TR Requested 11/15/2011. Draft TR sent to HS 05/01/12. Deemed sufficient 11 06 12. TR posted ~11 06 12 |
| Sodium gluconate | 205.605 | JD | Yes | No | On hold | | Petition sent to HS on 3/22/2011; for use in soap; TR Requested 11/15/2011. On hold, for cosmetic use. |
| Bergamot Bitter Orange Powder | 205.606 | TF | Yes | Yes | On hold | | Sent to HS on 3/22/2011; TR Requested 5/23/11; sent to contractor on 10/27/11. TR sent to HS on 2/16; Updated TR sent to HS 04 30 12. TR posted 06/25/12. On hold. |

| Petitioned Substances - Status of current review process | | | | | | | |
|---|-----------------------|----------|-----------------------------|-----------------------|-----------|-------|--|
| Name | National List Section | Rvwr | Technical Review (TR) rqst? | TR rcv'd? | Mtng | Vote? | Notes* |
| Gibberellic acid | 205.605 | ZS, TF | Yes | Yes | Fall 2013 | | Petition sent to HS 07/27/12. Petition Sufficiency Response Due Date: 09/27/12 |
| 2012 Ammonium hydroxide (boiler water additive) | 205.605 | JR | No | NA | Fall 2013 | | 2000 petition , 2001 Recommendation , 2001 TAP , 2001 Background Paper . 2012 Petition sent to HS 11/06/12. Petition Sufficiency Response Due Date: 01/27/13. Petition found sufficient. No TR requested |
| Sunset 2015 - Status of current review process | | | | | | | |
| Name | CAS # | Rvwr | TR rqst? | TR rcv'd? | Meeting | Vote | Notes* |
| Gellan gum 205.605(a) | | JD? | | | Fall 2013 | | 2006 TR , 2008 Recommendation |
| Marsala at 205.606 | | CBe | | | Fall 2013 | | No TR rqst, 2008 Recommendation |
| Sherry at 205.606 | | TF/JD? | | | Fall 2013 | | No TR rqst, 2008 Recommendation |
| Tragacanth at 205.606 | | TF/JD? | | | Fall 2013 | | No TR rqst, 2008 Recommendation |
| Other Topics | | | | | | | |
| Name | Rvwr | Meeting | Vote | Notes* | | | |
| Auxiliary/"other" ingredients (2012 disc doc) | ZS | Spr 2013 | | Proposal spring 2013. | | | |

* Highlight indicates committee action needed.

Agenda

- Approve notes from November 20, 2012
- Ammonium hydroxide (determination of petition sufficiency and request for TR?) (JR)
- Vote on Sugar Beet fiber? (JFo/ZS)
- Vote on Barley Betafiber (JFo)
- Discuss/Assign Sunset items

Discussion

- Notes from November 20, 2012 approved with no changes.
- Ammonium hydroxide (determination of petition sufficiency and request for TR?) (JR) - Oct 2012 Petition appears sufficient and the group does not see a need for a new TR, as the 2001 TAP and background paper on boiler additives (see links in table above) seem adequate. If there are additional questions, it is possible to ask for supplemental information or public comment. The group discussed various usage aspects of ammonium hydroxide in handling and processing. EBR noted that the NOP currently has an employee on detail from Dairy Programs who has knowledge of processing methods used for milk processing, and she will ask him about use of steam. JR will complete the checklist, including any remaining questions, to determine if the Subcommittee should ask for supplemental information.
- Sugar Beet fiber (JFo/ZS) - The checklist was originally circulated May 7, and the group decided to add a discussion of GMO concerns. The group feels that the petitioner didn't make the case for why this particular fiber is preferred over any others, which could be a question directed toward public commenters. A member noted that the petition identified the ratio of soluble vs. insoluble fiber as a unique feature of Sugar Beet Fiber. JFo will add some questions for commenters and language to the checklist (GMOs, unique properties of this type of fiber, phytic acid component and why it makes this item preferential, and why the 1/3 - 2/3 ratio important), bundle all of the supporting documents pertaining to this item, and resend them to the group for further discussion. The group will vote during a future meeting.
- Barley Betafiber (JFo). A member asked if there were any organic fibers on the market. Barley betafiber is being petitioned because the percentage of soluble fiber is high (75%) as opposed to some of the organic products. Organic alternatives include psyllium husk (also 75% soluble) but it is texturally inadequate for certain products because it is gelatinous. The group discussed various aspects of the petition and TR, and determined that more information was needed. Questions to add to the original checklist include: Are their certified alternatives, such as oat? A member noted that Oat beta-glucan soluble fiber was not mentioned in the petition, but a certified

organic source was mentioned in the TR. The members suggested asking for public comments about this. The group also noted that there was no input from manufacturers or consumers, so questioned whether or not there is demand for this product. The Chair will circulate the petitions, TRs and checklist to the members can review and vote during the next call.

- Discuss/Assign Sunset items – Sunset 2015 items were assigned (see above table)

Future Call Schedule:

November 20, 2012 1:00 EST

Barley Betafiber (JFo) - continued on next call

Sugar Beet fiber (JFo/ZS) - continued on next call

½ meeting: Auxiliary/"other" ingredients (ZS)

December 4, 2012 1:00 EST

Vote on Sugar Beet fiber (JFo/ZS) - postponed until Dec 18

Vote on Barley Betafiber (JFo) - postponed until Dec 18

Assign Sunset items - done

Ammonium hydroxides - determine petition sufficiency and request for TR? (JR) – to be continued Dec 18

December 18, 2012 1:00 EST

Vote on Sugar Beet fiber (JFo/ZS)

Vote on Barley Betafiber (JFo)

Ammonium hydroxides – continue discussion of checklist (JR)

Discuss sulfuric acid (JD)

Discuss gibberellic acid (ZS) –sending back to petitioner for further info, so will be delayed to a later meeting

Continue discussion on auxiliary/"other" ingredients (ZS)

January 9, 2013 1:00 EST

DBDMH (JFo)

January 15, 2013 1:00 EST

February 5, 2013 1:00 EST

February 19, 2013 1:00 EST

March 5, 2013 1:00 EST

March 19, 2013 1:00 EST

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**National Organic Standards Board (NOSB)
Handling Subcommittee (HS) Meeting Notes
Tuesday, December 18, 2012, 1:00 pm EST**

Present: John Foster (Chair) (JFo), Harold Austin (Vice-Chair) (HA), Zea Sonnabend (ZS), Carmela Beck (CBe), Mac Stone (MS) - sitting in, Tracy Favre (TF), Joe Dickson (JD), Nick Maravell (NM)

Absent: Jean Richardson (JR)

Staff: Michelle Arsenault (MA) (Advisory Board Specialist (ABS)), Emily Brown Rosen (EBR)

Work Plan

| Petitioned Substances - Status of current review process | | | | | | | |
|---|-----------------------|------------|-----------------------------|---------------------|----------|----------|---|
| Name | National List Section | Rvwr | Technical Review (TR) rqst? | TR rcv'd? | Mtng | Vote? | Notes* |
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| Barley Betafiber | 205.606 | JFo | Yes | Yes | Spr 2013 | 12 18 12 | Revised petition sent to HS on 6/20/11; TR accepted as sufficient 4/30/12. TR Posted 07 25 12 |
| Sugar Beet fiber | 205.606 | JFo/ ZS | Yes | Yes | Spr 2013 | 12 18 12 | Revised petition sent to Committee 2/10/2011; Revised TR sent to HS 04/26/12. TR accepted as sufficient 4/30/12. TR posted 06/25/12 |
| Sulfuric acid (H₂SO₄) | 205.605 | JD | Yes | Yes | Spr 2013 | | Petition sent to Subcommittee 8/17/2010; TR Requested 11/15/2011. Draft TR sent to HS 05/01/12. Deemed sufficient 11 06 12. TR posted ~11 06 12 2012 Formal NOSB recc 2006 Formal NOSB recc |
| Sodium gluconate | 205.605 | JD | Yes | No | On hold | | Petition sent to HS on 3/22/2011; for use in soap; TR Requested 11/15/2011. On hold, for cosmetic use. |

| Petitioned Substances - Status of current review process | | | | | | | |
|---|-----------------------|----------|-----------------------------|-----------------------|-----------|-------|---|
| Name | National List Section | Rvwr | Technical Review (TR) rqst? | TR rcv'd? | Mtng | Vote? | Notes* |
| Bergamot Bitter Orange Powder | 205.606 | TF | Yes | Yes | On hold | | Sent to HS on 3/22/2011; TR Requested 5/23/11; sent to contractor on 10/27/11. TR sent to HS on 2/16; Updated TR sent to HS 04 30 12. TR posted 06/25/12. On hold. |
| Gibberellic acid | 205.605 | ZS, TF | Yes | Yes | Fall 2013 | | Petition sent to HS 07/27/12. Petition Sufficiency Response Due Date: 09/27/12. Additional questions will be sent to petitioner |
| 2012 Ammonium hydroxide (boiler water additive) | 205.605 | JR | No | NA | Fall 2013 | | 2000 petition , 2001 Recommendation , 2001 TAP , 2001 Background Paper . 2012 Petition sent to HS 11/06/12. Petition Sufficiency Response Due Date: 01/27/13. Petition found sufficient 12 18 12. No TR requested |
| Sunset 2015 - Status of current review process | | | | | | | |
| Name | CAS # | Rvwr | TR rqst? | TR rcv'd? | Meeting | Vote | Notes* |
| Gellan gum 205.605(a) | 71010-52-1 | JD? | | | Fall 2013 | | 2006 TR , 2008 Recommendation |
| Marsala at 205.606 | | CBe | | | Fall 2013 | | No TR rqst, 2008 Recommendation |
| Sherry at 205.606 | | TF/JD? | | | Fall 2013 | | No TR rqst, 2008 Recommendation |
| Tragacanth at 205.606 | 9000-65-1 | TF/JD? | | | Fall 2013 | | No TR rqst, 2008 Recommendation |
| Other Topics | | | | | | | |
| Name | Rvwr | Meeting | Vote | Notes* | | | |
| Auxiliary/"other" ingredients (2012 disc doc) | ZS | Spr 2013 | | Proposal spring 2013. | | | |

* Highlight indicates committee action needed.

Agenda

- Approve notes from December 4, 2012
- Added some dates to the table below
- Vote on Sugar Beet fiber (JFo/ZS)
- Vote on Barley Betafiber (JFo)
- Ammonium hydroxides – continue discussion of checklist (JR)
- Discuss sulfuric acid (JD)
- Discuss gibberellic acid (ZS) –sending back to petitioner for further info, so will be delayed to a later meeting
- Continue discussion on auxiliary/”other” ingredients (ZS)

Discussion

- Notes from December 4, 2012 approved without change
- Vote on Sugar Beet fiber - Two members not present for vote, will be allowed to vote via email by December 28th. JFo will send email to NM and JR. (ABS note: JR voted Dec 21 via email. Votes are changed below to reflect this)

Motion to classify sugar beet fiber as petitioned as agricultural

Motion: JFo

Seconded: JD

No further discussion

Yes: 8 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Motion to list sugar beet fiber as petitioned on 205.606

Motion: JFo

Seconded: JD

No further discussion

Yes: 7 No: 0 Abstain: 1 Absent: 0 Recuse: 0

EBR asked about annotations for this proposal and a member noted they would consider annotating if public comment provides more direction.

- Vote on barley beta fiber - Two members not present for vote will be allowed to vote via email by December 28th. JFo will send email to NM and JR. (ABS note: JR voted Dec 21 via email, vote tally below changed to reflect the additional vote)

Motion to classify barley beta fiber as petitioned as agricultural

Motion: JFo

Seconded: JD

No further discussion

Yes: 8 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Motion to list barley beta fiber as petitioned at § 205.606

Motion: JFo

Seconded: JD

Additional discussion:

TF asked about the notes from last meeting indicating that the group had some additional questions and were going to add them to the proposal to solicit public comment. JFo will draft language and add to the discussion section, and JFo will convert the old checklist to the new format and submit it to the Program.

Yes: 7 No: 0 Abstain: 1 Absent: 0 Recuse: 0

- Ammonium hydroxide: The HS previously found the petition sufficient, and determined that a TR was not needed, and JFo notified Lisa Brines via email as such.
- Sulfuric acid (H₂SO₄): The group discussed the fact that there was no compelling argument for essentiality that this processing aid is needed or allowed, and that all of the objections raised by the last Crops Subcommittee proposal (2012) were still relevant and applied to this petition as well. EBR noted that historically H₂SO₄ has never been approved for use in organic. Since CBI was excluded it makes it that much more difficult to determine, which was also acknowledged in the TR as well. JD will complete the proposal for a vote on the next call.
- Gibberellic acid: ZS will compile questions for the petitioner and send them to the Lisa Brines. Further review will be put on hold until the Subcommittee receives a reply.
- Auxiliary/"other" ingredients: The NOSB has twice recommended new definitions for the term "substance", and the Program suggested that redefining this is not a good idea. The NOSB provided a definition in 2005, which was further amended in November of 2009, and since the NOP is using that definition as a basis for materials classification it will be difficult to change. ZS will edit the document, removing the language about the definition of substance. EBR will write a paragraph about GRAS (generally regarded as safe) and send it to the ZS and the group for inclusion. ZS asked that any additional input or comments be emailed to her.

Future Call Schedule:

December 4, 2012 1:00 EST

Vote on Sugar Beet fiber (JFo/ZS) - postponed until Dec 18

Vote on Barley Betafiber (JFo) - postponed until Dec 18

Assign Sunset items - done

Ammonium hydroxides - determine petition sufficiency and request for TR? (JR) – to be continued Dec 18

December 18, 2012 1:00 EST

Vote on Sugar Beet fiber (JFo/ZS) - done

Vote on Barley Betafiber (JFo) - done

Ammonium hydroxides - discussion delayed to January 9th call

Discuss framework for sulfuric acid (JD) -

Discuss gibberellic acid (ZS) - sending back to petitioner for further info, so will be delayed to a later meeting

Continue discussion on auxiliary/"other" ingredients (ZS)

January 9, 2013 1:00 EST

Discuss/vote? DBDMH (JFo)

Vote on Sulfuric Acid proposal (JD)

Continue discussion of ammonium hydroxides checklist (JR)

Continue discussion on auxiliary/"other" ingredients (ZS)

Discuss sunset 2015 materials and next steps

January 15, 2013 1:00 EST

February 5, 2013 1:00 EST

February 19, 2013 1:00 EST

March 5, 2013 1:00 EST

March 19, 2013 1:00 EST

| Spring 2013 Milestones | Target date |
|--|-------------------|
| NOP – Complete tentative agenda | February 8, 2013 |
| Spring 2013 proposals due to NOP | February 12, 2013 |
| NOP - Post proposals, Publish FRN, Open public comment | February 19, 2013 |

| | |
|--|------------------|
| Subcommittees submit tentative workplans to NOP | March 1, 2013 |
| Discuss workplans on ES call | March 8, 2013 |
| NOP provides written comments on workplans to NOSB | March 11, 2013 |
| Public comment closes | March 19, 2013 |
| NOP - Send compiled public comments to NOSB | March 25, 2013 |
| Workplans finalized on ES call | March 29, 2013 |
| Spring 2013 NOSB Meeting – Portland, OR | April 8-11, 2013 |