



May 3, 2012

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2648-So, Ag Stop 0268
Washington, DC 20250-0268

Docket: AMS-NOP-12-0017

RE: Materials Committee – Discussion Documents on Extractants and Solvents and Significant Residues Definition in Classification of Materials Policy

Dear Ms. Arsenault:

Thank you very much for this opportunity to provide comment on the Materials Committee Discussion Documents on Extractants and Solvents and Significant Residues Definition in Classification of Materials Policy.

OTA is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing organic businesses across 49 states. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's Board of Directors is democratically elected by its members. OTA's mission is to promote and protect the growth of organic trade to benefit the environment, farmers, the public and the economy.

OTA is extremely concerned about the timing and content of the proposed discussion documents and their potential conflict with the draft guidance on Classification of Materials that NOP is currently working on. **We respectfully ask the Materials Committee to table these discussion documents and wait for NOP to publish draft guidance on Classification of Materials.** The proposed discussion documents address very complicated topics that are single components to the greater materials classification process. All of the questions in both documents also revisit years of NOSB work and industry collaboration that led to the NOSB Classification of Materials Recommendation that was passed in 2010. We're concerned about the discourse and confusion that may be created, especially for the new NOSB members, if these topics are revisited without the full context of the 2010 Recommendation and subsequent NOP draft guidance.

Instead, we request that the Board urge NOP to complete its work on Classification of Materials as quickly as possible and issue draft guidance. At that time, we can identify any holes or weakness in the guidance and address it accordingly, either through public comment and/or by identifying the issues that need further deliberation by NOSB. We believe this will be the most organized, efficient and effective approach.

OTA fully recognizes the complexity of the Classification of Materials topic and the years it has taken

to develop criteria and definitions that most people can agree on. Unfortunately, this long process has resulted in the turnover of several Boards, slowing the process down even further because of the time to re-educate new NOSB members and work through the varying opinions that arrive with each new member. It is a decade after the implementation of the NOP regulations, yet we still do not have formally approved criteria for classifying materials. We also do not have formal criteria or guidelines for material review in general. This is unacceptable.

There will never be complete agreement on such a complex topic that relies heavily on science and process yet is also embedded in philosophy. We have made good progress over the years, and NOP is now actively working on guidance based on seven years of recommendations that were developed by NOSB and informed by NOP, the Materials Working Group (MWG) and public stakeholders. At this time, we need formally issued guidance so NOSB, certifiers and Material Review Organizations (MROs) can make consistent and transparent decisions.

OTA appreciates the questions being asked by the committee because these provide an opportunity to review the history of Classification of Materials, which should be helpful for new NOSB members. With this in mind, we have answered the questions asked by the committee. We also hope our answers will help explain our request to table the discussion documents until NOP releases its draft guidance.

Extractants and Solvents

How should “volatile synthetic solvent” be defined, especially in relationship to the rule 205.270(c)(2)? Should we make a distinction between different types of solvents? If possible, reference to a standard scientific or regulatory definition is preferred. Should the toxicity of a volatile synthetic solvent affect how it is treated in classification and materials evaluation? Does supercritical carbon dioxide meet the definition?

First, it’s important to realize that § 205.270(c)(2) refers to both volatile synthetic solvents AND synthetic processing aids. Based on this section of the regulation, if the interpretation is that the use of a volatile synthetic solvent would render ANY material synthetic (across all categories – crop, livestock and handling) thus requiring full review by NOSB, this would also need to apply to ANY synthetic processing aid. This would have a devastating impact on the vast majority of non-synthetic crop inputs currently approved by OMRI and certifiers. It would have a crippling effect on organic production. OTA believes this interpretation is in conflict with clarification that has already been provided by NOP. It’s also in conflict with a requirement that is applicable to handling materials only.

The need to focus attention on volatile synthetic solvents depends on the interpretation of § 205.270(c)(2). MWG specifically asked the program to clarify this section of the regulation in its discussion paper submitted to NOSB on synthetic vs. non-synthetic (4-20-09). Additionally, NOP at one time provided clarification in a Q & A on its website, although it has since been taken down. NOP has not incorporated its position into the NOP Handbook, although it did provide verbal clarification at the Fall 2011 Meeting.

With respect to the NOP Q & A, shortly after the implementation of the Rule, NOP posted the following clarification on its website:

Question: Do non-agricultural substances included on the National List of Allowed and Prohibited Substances have to be produced without the use of volatile synthetic solvents? My certifying agent says yes because of the prohibition on the use of volatile synthetic solvents found in section 205.270(c)(2).

Answer: No. Section 205.270(c)(2) prohibits the use of a volatile synthetic solvent unless included on the National List as an allowed substance. However, synthetic solvents do not have to be on the National List to be allowed in the production of an allowed non-agricultural substance found on the National List. The use of volatile synthetic solvents in the production of allowed non-agricultural substances included on the National List is considered approved through the materials review process, unless otherwise stated through an annotation to the approved substance. (Example: § 205.605(a)(9), Flavors—non-synthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.)

Prior NOP clarification supports the regulatory reference to “**the handler of an organic handling operation**” in § 205.270(c), specifying that volatile synthetic solvents and synthetic processing aids may be used by a noncertified handler during the manufacturing of a non-organic nonagricultural substance found on the National List unless otherwise stated through an annotation to the approved substance.

At the Fall 2012 NOSB meeting Emily Brown Rosen addressed the question when Jay Feldman asked Lindsay Fernandez-Salvador from OMRI to comment on § 205.270(c)(2). Lindsay turned it over to the program. Emily’s response was consistent with the Q & A. The transcripts from this discussion are included in Appendix A.

OTA urges NOP to formally clarify in a policy memo its interpretation of § 205.270(c)(2).

Is there a distinction between volatile solvents used for extraction vs. volatile solvents used for other purposes? Solvents are also used for purposes other than extraction, such as purification of a substance via crystallization. Solvents are also common inert ingredients in formulated pesticide products.

Historically, in the context of making synthetic and non-synthetic determinations, the focus is on extraction and manufacturing, and whether or not a synthetic substance (solvent, extractant or other processing aid) chemically changes the non-synthetic substance. Volatile synthetic solvents used as inert ingredients in pesticide products are outside the scope of this discussion.

3. Should the process of extraction change the classification of an agricultural product to a non-agricultural material?

If the extraction process results in a chemical change then the agricultural product could be viewed as a synthetic product. This is supported by the 2010 NOSB Classification of Materials Recommendation and the response from NOP¹. It’s important to recognize, however, that agricultural and non-agricultural determinations are only applicable to Handling and Livestock materials. They do not apply to crop materials and rarely are needed for livestock materials. Livestock feed must be agricultural, so agricultural vs. non-agricultural determinations are applicable. From the 2010 NOSB Classification of Materials Recommendation:

If a material is processed such that it is classified as synthetic, then the material is classified as synthetic *regardless of source. A material of this type would most correctly be referred to as*

¹ September 30, 2010 Memo for the Chairman of the NOSB in Response to the April 2010 and November 2009 Recommendations

an “agriculturally sourced material which has been processed in such a way as to classify the material synthetic.” Materials that are manufactured in full compliance with the final rule are outside the scope of this principle; their status with regards to use in organic is not affected by this recommendation.

From the NOP response to NOSB (September 2010): NOP agrees that an agricultural material can be processed in a manner that renders it synthetic.

Does it matter whether the extractant is synthetic or non-synthetic?

The focus has been on whether the substance being evaluated undergoes a chemical change as a result of the extraction process. The question is whether the use of a synthetic would render the substance synthetic regardless of whether there was a chemical change. If a synthetic extractant is used and it creates a chemical change, the agricultural input under review may be considered synthetic. In the context of agricultural vs. non-agricultural, there was also discussion specific to “processing” and whether or not to exempt mechanical, biological or physical extraction as well as the use of water or other solvents or processing aids on the National List. The idea was to allow the processes and materials that are allowed under the handling regulations in order to avoid classifying an agricultural material as non-agricultural, when it could potentially be certified organic due to certified organic starting material. An example is bleached lecithin, bleached with hydrogen peroxide. However, it was generally agreed upon that agricultural material could be processed to the extent that it would be synthetic. NOP agreed on this point as well. See NOP Response to NOSB below (September 2010).

When this happens to an agricultural material that is currently organically grown, does this changed material then need to be petitioned?

This concept discussed above was taken up by NOSB, and NOP responded to NOSB’s recommendation in September 2010. We expect it will be addressed in NOP draft guidance. NOP’s response:

NOSB Proposed Definitions

Chemical Change An occurrence whereby the identity of a substance is modified, such that the resulting substance possesses a different distinct identity (*see related definition of “substance”*)
Processing, as defined in §205.2, of agricultural products using materials allowed on the applicable section of the National List (i.e., §205.601 for crops, §205.603 for livestock and §205.605 / §205.606 for handling), does not result in chemical change as it applies to classification of materials.

NOP **does not** support the above definition. The additional underlined sentence, as adopted in the May NOSB recommendation, adds a meaning to the term “chemical change” that is contrary to common understanding of a widely used term. It is a tenet of good regulatory drafting that definitions adopted should not contradict commonly understood definitions or include a substantive rule within a definition. The proposal to exempt certain processing methods and synthetic materials from causing the effect of chemical change is a substantial regulatory provision, which conflicts with the common understanding of chemical change, and could cause unintended consequences. *Substances derived from agriculture used in food processing can be classed as agricultural despite common chemical changes achieved through baking, cooking, roasting, etc. This criterion can be added to the evaluation worksheet for determination of agricultural status, and should not be in the larger definition of chemical change.*

NOSB's 2010 Recommendation also stated:

Materials that are manufactured in full compliance with the final rule are outside the scope of this principle; their status with regards to use in organic is not affected by this recommendation.

4. Since §205.270 Organic Handling Requirements explicitly prohibit volatile organic solvents, [“(c) The handler of an organic handling operation must not use in or on agricultural products intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” or in or on any ingredients labeled as organic: (2) A volatile synthetic solvent or other synthetic processing aid not allowed under §205.605: *Except, That, nonorganic ingredients in products labeled “made with organic (specified ingredients or food group(s))” are not subject to this requirement”], should consumers expect that non-agricultural ingredients identified as “organic” be produced or extracted with the same restriction? Please explain the rationale for a different standard for agricultural and non-agricultural if that is the position.*

This question doesn't make sense. What non-agricultural ingredients are identified as “organic?” According to NOP clarification and as discussed above, this section of the rule prohibits the **certified handler** from using a synthetic solvent or processing aid in or on a certified agricultural product sold, labeled or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” or in or on an organic ingredient.

The relationship to an agricultural ingredient is unknown because NOP has only addressed non-agricultural ingredients, and § 205.270(c)(2) does not make a distinction. The reference to "agricultural product," however, is in reference to a certified agricultural product (or organic ingredients).

It's important to note that the heading of § 205.605 refers to “ingredients” only. Under this section, a certified handler is allowed to use the listed substances referred to as “ingredients” in the 5% or 30% of a certified product. The reference to § 205.270(c)(2) is significant to the **handler** of a certified operation because it clarifies that **synthetic solvents and synthetic processing aids** used in or on products labeled “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” must also be on § 205.605 of the National List.

The use and allowance of an ingredient vs. a processing aid has raised many questions over the years. In addition to the clarification provided in § 205.270(c)(2), NOP has also clarified that any processing aid, synthetic or nonsynthetic, used in or on an organic product must be on the National List. Again, this clarification is specific to a certified handler making a certified product. Agricultural processing aids used in or on an organic product must also be on § 205.606 of the National List AND commercially unavailable in organic form. Nonagricultural processing aids used in or on a “made with” product must be on § 205.605, whereas agricultural processing aids used in or on a “made with” product are allowed provided they comprise 30% or less of the product.

5. Similarly, should synthetic substances allowed for use in organic crop production under §205.601 be allowed or prohibited from using volatile synthetic solvents in their production or extraction?

The regulatory reference of § 205.270(c)(2) does not apply to § 205.601 and extending its meaning to crop production could have far reaching implications. However, synthetic and non-synthetic determinations in general do apply. Therefore, the use of a volatile synthetic solvent or synthetic

processing aid is applicable during the classification process, the focus being on whether the synthetic processing aid creates a chemical change and whether a significant amount remains in the final material. For a petitioned material, NOSB would also review the overall manufacturing process to ensure that it meets the Evaluation Review Criteria of OFPA and § 205.600.

Should non-synthetic substances used in organic crop production be allowed or prohibited from using volatile synthetic solvents in their production or extraction, regardless of chemical change or significant residues?

Based on the Classification of Materials Recommendation and clarification from NOP, the focus should be on chemical change and significant residues. If NOSB determines that a synthetic solvent or synthetic processing aid does not meet the National List evaluation criteria and agrees it should be prohibited from use, then we recommend NOSB prohibit its use through the use of an annotation.

6. Is guidance needed concerning whether or under what circumstances the use of an extractant/solvent causes chemical change in the extraction process?

We believe this question is at the heart of the Classification of Materials Recommendation, and it was a primary focus of NOSB and MWG for many years. The question is whether the extractant or solvent results in a chemical change. If so, the input would be synthetic. Chemical change was defined in the MWG Discussion Document of 4-20-09 & NOSB Classification of Materials Recommendation. The documents also defined ‘Substance,’ ‘Extract,’ ‘Formulate’ and ‘Manufacture.’ The following documents addressing this question were produced over the years:

National Organic Standards Board Recommendations & other documents:

- Materials and Handling Committee, “Clarification of the definition of Synthetic as it is applied to Substances Petitioned for Addition or Prohibition to the National List(s),” June 23, 2005
- Handling Committee, “Recommendations Relative to “Agricultural” and “Nonagricultural” Substances,” July 14, 2005
- Handling Committee and Materials Committee, “Recommendations Relative to ‘Agricultural’ and ‘Nonagricultural’ Substances for National List Consideration,” September 15, 2006
- Materials and Handling Committees, “Discussion Document on the Definition of Materials,” October 19, 2007
- Materials and Handling Committees, "Final Recommendation on Classification of Materials, " May 24, 2010
- Materials and Handling Committees, “Update and Proposed Guidance Document - Classification of Materials,” March 4, 2011 (this one includes the recommendation on Significant Residues that received a 8 yes, 6 no vote)

Material Working Group

- May 2008 presentation at National Organic Standards Board meeting titled “Clarification of Definitions -- Agricultural vs. Non-agricultural”
- November 2008 presentation at National Organic Standards Board meeting titled “Clarification of Definitions -- Agricultural vs. Non-agricultural”
- May 2009 presentation at National Organic Standards Board meeting titled “Clarification of Definition of Synthetic Substance”

National Organic Program

- “Evaluation of the NOSB Recommendation on the Definition of Synthetic,” March 9, 2006
- September 30, 2010, Memo for the Chairman of the NOSB in Response to the April 2010 and November 2009 Recommendations
- August 11, 2011 Memo for the Chairman of the NOSB in Response to the April 2011 and November 2009 Recommendations

7. What is a significant residue of a synthetic solvent?

See Questions from Significant Residues Discussion (below)

Should the prohibition on the use of volatile synthetic solvents include the use in any ingredient in the history of the product?

No. The language in § 205.270(c)(2) is specific to the certified handler. The review of a volatile synthetic solvent would be conducted by NOSB on a case-by-case basis or by a certifier or MRO making a synthetic/non-synthetic determination. If NOP’s recent clarification stands, a volatile synthetic solvent or synthetic processing aid is not outright prohibited in the production of any non-organic ingredient.

8. For substances already on the National List, should it be assumed that any extractant is allowed, or should the NOSB attempt to specify allowed extractants moving forward or for previously listed substances?

This is an important question and one that was at the center of attention during the last NOSB meeting. It’s also at the heart of the § 205.270(c)(2) discussion, and is related to the use of an annotation (to prohibit or allow) and the role of the Board to decide what materials are compatible with organic principles.

Based on clarification from the program, any extractant used during the manufacturing of an allowed non-organic ingredient should be allowed unless it is specifically prohibited by an annotation or specifically prohibited elsewhere in the regulation.

Significant Residues Definition in Classification of Materials Policy

Under what circumstances, should the presence of a synthetic impurity trigger an examination of the impacts of the synthetic in relation to OFPA criteria?

This question depends on whether the review is being conducted by NOSB or by a certifier or MRO. For the certifier or MRO, review of a synthetic residue would be the final step of determining whether a material is non-synthetic. If the synthetic residue is significant, it would not trigger NOSB review but rather the input would be denied, or allowed if that synthetic were on the National List. At the NOSB level, an otherwise prohibited material under review for addition to the National List would be evaluated to OFPA criteria.

OTA supported the first approach proposed by the Materials Committee in the April 2011 recommendation. This position states that a “significant level” of a synthetic substance in the final material means a level exceeding any applicable regulatory limits, where in effect for the material being classified, and a level without any technical or functional effects in the final material. In the case

where no regulatory limit is available, technical and functional effects of any remaining synthetic would need to be evaluated. In the case where multiple regulatory limits exist, the reviewer would evaluate which best applies for the classification.

We supported this approach because it is consistent with past NOSB practice and precedent. The NOSB Recommendation to the NOP in 2005 states:

“As long as a chemical reaction does not occur, the substances that are removed from a natural occurring plant, animal or mineral source are non-synthetic, provided any synthetic substance used in the extraction process do not remain in the final product above insignificant levels and do not have any technical or functional effect.”

This idea has guided the decision-making of previous Boards and it has guided the decision-making of ACAs and Organic Material Review Institute (OMRI). It was also incorporated into the NOP Recommended Framework Document of 2006 further supporting the practice. We recognize that further definition is needed in terms of the reference to applicable regulatory limits. However, we believe NOP is in the position to utilize its resources and decide if there are regulatory references that would be appropriate. Again, we expect this to be addressed in draft guidance.

2. Do any of the three approaches described make sense? If so, why?

The first approach makes the most sense, although there are aspects of the third approach that should be incorporated, namely providing certifiers and MROs with guidance on how to determine if a synthetic residue is significant.

We're extremely concerned about the disruption that would be caused to the organic sector if the second approach were adopted, and we are equally concerned about the reality and long-term consistency of detecting “any known level” as this would depend on the detection method, which would be a moving target over time. The level of sensitivity of the detection method determines the likelihood of finding “any known level.” If the detection method is very sensitive, it will pick up minute residues; if it is not very sensitive, it may well miss significant residues. Practically speaking and for the sake of consistency, we believe that detection limits and tolerance levels would need to be set for “any known level,” and this would essentially take us to the same place as trying to define “significant” and “insignificant.”

Furthermore, if a non-synthetic material is manufactured using a synthetic processing aid, it can be assumed that some known level would be present in the final material or the environment. The minority opinion then suggests that any non-synthetic material manufactured using a synthetic processing aid (regardless of whether a chemical change occurs or not) would need to be subjected to the National List Process in order to determine the associated health and environmental impact of that synthetic. This approach would be extremely disruptive to the industry, and would significantly increase the workload of NOSB.

3. Is it reasonable to tie the definition of “significance” in materials classification to the need for review under OFPA? If not, is there another way to ensure that the presence of a synthetic impurity in levels of consequence under OFPA trigger a review? And how would “significance” be defined in the context of materials classification if not in relation to the need for review under OFPA?

See answer #1

4. The need for defining a significant residue arises from the Classification of Materials Policy adopted earlier that says that the use of a synthetic extractant or reactant does not affect the classification of a material, thereby allowing the use of synthetic extractants, reactants, or processing aids that may end up as impurities in the material. Should that policy be changed instead?

First, this question does not accurately convey the Classification of Materials Policy. The policy adopted states that the use of a synthetic processing aid does not affect the classification of a material **IF** it does not result in a chemical change or if it does not remain in the final product in a significant amount.

Second, the recommendation was passed by NOSB, and NOP is now working on subsequent guidance. Comments should be directed to NOP when the draft guidance is released.

5. When residues of a certain synthetic impurity are identified as significant, how should the review proceed (a) if the material containing the impurity is under review by a MRO prior to use, (b) if the significant residues are discovered by a MRO/ACA when the material is in use, (c) if the material is under review by the NOSB?

If the residue is synthetic, it needs to be on the National List. If it's not on the National List, the material cannot be allowed. This is consistent with the Decision Trees that were produced by NOP and the MWG, as well as the Recommendation by NOSB. This is also the process that OMRI uses.

Conclusion

Once again, OTA requests that NOSB table the discussion documents on 'Extractants and Solvents' and 'Significant Residues' and postpone any future discussion document or recommendation until after NOP has released draft guidance.

With respect to the controversy surrounding volatile synthetic solvents and § 205.270(c)(2), we ask NOSB to urge NOP to formally clarify in a policy memo its interpretation of § 205.270(c)(2) and how it relates to NOSB's review of petitioned materials.

In support of the Compliance, Accreditation and Certification Committee recommendation on Criteria for MROs, we also urge NOP to expedite its work as stated in the MRO recommendation:

Establish that material review organizations may not make synthetic vs. non-synthetic or agricultural vs. non-agricultural determinations except when made in strict compliance with NOP guidance. **We urge NOP to expedite the publication of clear guidance for making such determinations, based on earlier recommendations of NOSB.** The classification of materials is of foundational importance to the integrity of organic products, and such **guidance is extremely critical, given the thousands of synthetic vs. non-synthetic and agricultural vs. non-agricultural determinations made by certifiers each year.**

As we move forward in our process of formalizing material review criteria, we ask NOSB to carefully consider and respect previous NOSB decisions and to understand the criteria that's currently guiding the decisions made by well-established and respected MROs such as OMRI and WSDA. The draft guidance NOP is currently working on is based on such efforts. We believe there is currently confusion between the extent of the generic material review process that should be performed by NOSB and the role of the certifier or MRO during its review of brand name products. While there are material review

criteria that will be shared by NOSB and MROs, there is a place where NOSB's role ends and the role of the certifier or MRO begins. NOSB will never be able to capture and review every known process and material that could ever be possibly used to make an allowed input. Material approval and denial happens every day, and it's done on a case-by-case basis. **It's for this reason that uniform procedures for material review be implemented as an integral part of NOP as quickly as possible and be done under adequate oversight and enforcement of NOP.**

Again, on behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment.

Respectfully submitted,



Gwendolyn Wyard
Associate Director of Organic Standards and Industry Outreach
Organic Trade Association (OTA)

CC: Laura Batcha
Executive Vice President
Organic Trade Association (OTA)

Attachment A: NOSB Meeting Transcripts - Fall, 2011 – pgs. 138 - 139

for years. How much criteria do we need to give certifiers to do small approvals within their own program not trying to go on a marketable scale?

Lindsay Fernandez-Salvador: Absolutely that's a really tough question because the same expertise that is needed for that high nitrogen liquid fertilizer off the top of your head is different for something that you need to approve leaves that are used as mulch. Right? Or limestone. But just because a certifier is also approving – or the majority of what they're approving is relatively non-complex materials, doesn't mean that they don't have the opportunity to approve complex materials.

So in all honesty, we believe that you need the criteria in order to make sure that both those ranges are being covered and evaluated appropriately on the same page.

Tracy Miedema: Any other questions? Was that a hand? Jay Feldman.

Jay Feldman: Thank you. I'm trying to figure out on this solvent issue – maybe you can help with this – there is a prohibition, is there not, under 205 105 of volatile synthetic. Can you explain how that would affect us in this decision on DHA or others?

Lindsay Fernandez-Salvador: I really actually would defer to the program. That's a legal interpretation. And I don't have a – the rule in front of me. So I wouldn't answer that right now.

Jay Feldman: Can I read it?

Lindsay Fernandez-Salvador: Yeah. But I won't comment on it. So. Yeah.

Tracy Miedema: Please restate your question for the NOP to answer.

Jay Feldman: Okay. This is 105, right? "A volatile synthetic solvent or other synthetic processing aid not allowed under 605 except that non-organic ingredients in products labeled made with specified ingredients or food groups are not subject to this requirement." So these are practices that are prohibited under paragraph E and F of 105. Does that come into play at all here? With DHA and this solvent?

Female: This has been a kind of a gray area but if you look at it closely, the 270 C, that section of regulation says that you cannot use synthetic solvents in or on organic products or in organic ingredients and that NOSB has

historically reviewed the solvent use as part of the manufacturing process for quite a few of the substances on 605.

Female: Examples would be lecithin, leaf pectin. I'm sure there's more. We, you know, so, no. It doesn't, you know, you – you know, if it's part of the review of the non-organic substance that's your, you know, you have that ability to do that.

Tracy Miedema: I'm not the expert here. I want to make sure I restate this so that I understand. You just said that synthetic solvents are allowed on materials on 605 A including materials like pectin and lecithin that are on the list right now today.

Female: If that was part of your, you know, when you reviewed the material to put it on the list you considered that – or the former NOSB considered that and decided that it was not an issue. So, yes. I mean, they may be produced. I believe lecithin is commonly extracted with hexane. So, you know, that has been considered in the past and that's been the practice. And that's, you know, a literal reading of what the rule says there so that's what we agreed.

Tracy Miedema: Thank you, Emily. This is important for us. Just reminders. What the rules are, the rules of the game here, it's one thing to call a ball or a strike but it's another thing altogether to suddenly say the game has four strikes. And sections – and our rule in 7C of part 205, 605 materials may use synthetic solvents. So we – it would be nice if we didn't flog this one all afternoon. Jay Feldman.

Jay Feldman: Thank you. So, Emily, on the flip side of this, can you give us the examples of 605 materials that have prohibited as through annotation the use of hexane or other materials that have been approved for use that are not – that would otherwise allow the use of hexane?

Female: Yeah. Natural flavors. They're on the list with no solvent extraction. And the board is also recommended, actually, on 606 to adapt the similar no synthetic colors for solvents for colors. Correct?

Tracy Miedema: Thank you very much. Katrina.

Katrina Heinze: It feels like we've wandered a bit away from public comment and into board deliberation.

Tracy Miedema: I think your feeling is spot on. Michael Cox is up next. Thank you very much, Lindsay. Will Fantle is on deck.