#### Formal Recommendation by the National Organic Standards Board (NOSB) to the National Organic Program (NOP)

Date: April 29, 2011

Subject: Classification determination- Corn steep liquor

Chair: Tracy Miedema

The NOSB hereby fails to make a classification determination.

Rulemaking Action Guidance Statement Other X

# Statement of the Recommendation (Including Recount of Vote):

Corn Steep Liquor (CSL) is a byproduct of the corn wet milling process, as well as several other commercial corn processing industries. CSL material from the wet milling process has been considered non-synthetic in the past by stakeholders including accredited certifying agents (ACAs) and the Organic Materials Review Institute (OMRI). It has been used for many years as a nonsynthetic input mostly in liquid fertilizer formulations for organic crop production. A new clarification was passed by the NOSB in November of 2009 that the Crops Committee (CC) used in their deliberations and determination. The Crops Committee deliberated on the matter for many months and voted once to recommend determining CSL to be synthetic but withdrew that recommendation prior to NOSB voting in 2010. The final Crops Committee recommendation that CSL be determined non-synthetic is attached; the committee vote was 4 yes, 3 no. The NOP clarified prior to the NOSB meeting that CSL would continue to be allowed in organic production if the vote was not decisive and did not reach a 2/3 majority.

At the April 2011 NOSB meeting, a motion was made and seconded that Corn Steep Liquor produced via the traditional countercurrent corn wet milling process be considered as non-synthetic and allowed for use in organic crop production.

The vote was not decisive, not reaching a 2/3 majority.

# Rationale Supporting Recommendation (including consistency with OFPA and NOP):

Please see attached recommendation.

IOSB Vote:	Classification a	s a non-synthetic ຣເ	ubstance		
Moved: Joh	n Foster	Second: Steve I	DeMuri		
Yes: 5	No: 6	Abstain: 1	Absent: 0	Recusal:	2

#### National Organic Standards Board Crops Committee Corn Steep Liquor Proposed Synthetic/Nonsynthetic Determination

# April 29, 2011

## Introduction

Corn Steep Liquor (CSL) is a byproduct of the corn wet milling process, as well as several other commercial corn processing industries. CSL material from the wet milling process has been considered non-synthetic in the past by stakeholders including accredited certifying agents (ACAs) and the Organic Materials Review Institute (OMRI). It has been used for many years as a nonsynthetic input mostly in liquid fertilizer formulations for organic crop production. CSL was recently reevaluated by OMRI using the NOSB's 2005 clarifications regarding the classification of synthetic and nonsynthetic substances and concluded that CSL should be classified as synthetic based on the use of sulfur dioxide during processing. A new clarification was passed by the NOSB in November of 2009 that is the clarification that the Crops Committee (CC) used in their determination.

# Background

In an action memorandum dated April 23, 2010, the National Organic Program (NOP) requested that the National Organic Standards Board (NOSB) review corn steep liquor (CLS) concerning its classification as synthetic or nonsynthetic as an input for crop production for the Fall 2010 NOSB meeting. In considering this request, the CC asked the following questions of S&T:

- Does the change to the molecule occur to any significant degree under the conditions typically found (temp, pH, form of sulfur present, etc.) in the manufacture of this product? What is the classification of this chemical change if there is a change? For example is it breaking the bond so the protein goes from insoluble to soluble? Is the physical orientation changed versus the chemical structure in terms of molecules – the name of the chemical formula is identical but the rotation is changed?
- 2. If so (and only if so), does the physical re-orientation of the atoms in the bond constitute a *chemical* change, or merely a structural change with no change in chemistry?
- 3. What other materials made from this process that are currently on the National List would be effected if we determine that this process causes a chemical change sufficient to be designated synthetic? And in addition to that, what products that are currently on the list that use these materials would be affected? (i.e. liquid fertilizers that use Corn Steep Liquor and other materials like starch that may be used in fertilizer or pesticide formulations)
- 4. Can CSL be made without the use of prohibited substances? Are there other materials that are more benign that can be used to make CSL?

5. Are there other permitted materials that could be used instead of CSL in its current use?

The Technical Review received in February of 2010, while not answering these questions directly, was deemed adequate by the Crops Committee to go forward with discussions of synthetic/non-synthetic determination for CSL. This determination was discussed over the course of a number of CC weekly meetings.

# Relevant areas in the Rule

In crop production, nonsynthetic substances are allowed unless listed on the NL §205.602, while synthetic substances are prohibited unless listed on the NL §205.601. OFPA defines **Synthetic** as "a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from a naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes" (§2103 (21)) and **Nonsynthetic (natural)** is defined as "a substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in section 6502 (21) of the Act (7 U.S.C. 6502(21)). For the purposes of this part, nonsynthetic is used as a synonym for natural as the term used in the Act" (§205.2 Terms defined).

Chemical change is defined by the November 2009 recommendation as "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). As discussed by the Materials Working Group (MWG) in their recommendation, chemical change is "an event in which one substance becomes one or more difference substances." Chemical change would not necessarily include processes like ion-exchange or pH adjustment if the final material was not a different substance from the initial substance. For clarity, a definition of substance is included in the recommendation as well: <u>Substance</u> An element, molecular species, or chemical compound that possesses a distinct identity (e.g., having a separate Chemical Abstract Service (CAS) number, Codex International Numbering System (INS) number, or FDA or other agency standard of identity).

#### Discussion

The Crops Committee determined that the status of Corn Steep Liquor (CSL) should remain non-synthetic. Last fall, the Crops Committee voted to classify CSL as synthetic based primarily on findings in the Technical Review (TR) (29-30), which states that, "The major objectives for corn steeping are to induce chemical and physical changes in the kernel by leaching the soluble components from the corn. " It goes on to say that "sulfur dioxide is added at rates of 0.1 to 0.2 percent and is used to cleave disulfide linkages, resulting in the degradation of the corn protein that encapsulates the starch granules. " (TR 99-102) The cleavage process breaks chemical bonds, thus releasing amino acids from the protein matrix into the CSL liquid The committee was also concerned that the term "corn steep liquor" may be applied to products of different processes, and that some of these products may have unknown characteristics. This recommendation was forwarded to the USDA NOP and posted for public comment at the Fall 2010 NOSB meeting; however, the CC at that time also withdrew that recommendation from consideration by the full Board immediately prior to the Fall 2010 meeting. Regardless, the Board received 8 public comments in writing and 10 comments in person for and at the Fall 2010 meeting. While all the public comments were given full attention and consideration one commenter, Dragan Macura from Agro-Thrive, gave an excellent presentation to the board on the process of making corn steep liquor via the traditional countercurrent wet milling process. Throughout the detailed discussion it became clear that the sulfur dioxide was added at the end of the process to stop the fermentation process (a biological process) and prevent putrefaction.

Since the Fall 2010 NOSB meeting and a full board discussion of the information and the input from the general public, the CC has voted on January 24, 2011 to classify CSL as non-synthetic when created as a food processing waste from the traditional countercurrent corn wet milling process, based on a through review of all the information, documents, and public comments presented to the committee. The majority of the CC determined that the sulfur dioxide's utility in this process is in holding back a biological process (fermentation) and to prevent putrefaction and does not change the identity of CSL. The consensus of the majority is that this material when created in the manner described should continue to be considered nonsynthetic and appropriate for use in organic crop production. The majority considered that agricultural by products, food waste and products from food waste processing should not be considered as a synthetic ingredient for the purposes of organic crop production or the making of compost.

Corn starch has previously been determined to be nonsynthetic and agricultural by NOSB, and is made using the exact same steeping process as CSL. It is common usage in the organic food system as are other derivatives of this process. In the 1995 TAP Review for native cornstarch, reviewer Richard Theuer stated that "sulfur dioxide is used as a 'temporary' preservative to avoid purification of soaked corn. Later, fermentation inhibits putrefactive organisms." Dr. Theuer's recommendation was that cornstarch be classified as nonsynthetic. That same year, the NOSB determined that the SO2 used in corn starch production was a processing aid.

CSL has a long history of safe use as an added source of nutrition in animal feed, in fermentation processes, and in antibiotic production. It is not a significant source of water or air pollution. Due to the fact that CSL is composed of proteins, amino acids, carbohydrates, organic acids (such as lactic acid), vitamins, minerals and water, no environmental contamination would be expected. These components are all readily utilized by animals and microorganisms. In fact, CSL is a nutrient rich product that has been safely used as a component in livestock feed, fertilizers, and soil conditioners for many years. CSL and other nonsynthetic agricultural by products have historically provided and continue to provide a valuable source of nutrients for both soil microbial communities and organic crops. Historically, synthetic processing aids used in food have not been determined to render agricultural products synthetic; precedents are numerous and well established, with the end result providing organic producers with much needed agricultural by-products for use in composting and as soil amendments, and fertilizers.

Furthermore, the proposal that CSL should be considered to be non-synthetic is attributed to the fact that the SO2 action occurs in the endosperm protein matrix of the corn kernel, not in the steep water. There is compelling evidence that the proteins that the SO2 may alter are insoluble, thus are not a part of the CSL. General analysis of corn steep liquor reports the SO2 in CSL from 0.0009 – 0.015 (Liggett and Koffler, 1948). For use in organic crop production, the CSL is typically blended with other approved materials or used as a compost feedstock, which would further reduce the already insignificant levels of SO2 to be non-detectable.

The action of the SO2 in the countercurrent (traditional) corn wet milling process does not render CSL synthetic; the SO2 provides a buffering action to allow lactic acid fermentation to dominate over putrefaction. There is no evidence indicating that that the identity—that which makes the subject in question unique in its behavior, character, or function—of corn steep liquor as used is any different with or without SO2 as a processing aid. The behavior, character and function of the two are indistinguishable and on that basis alone, CSL remains non-synthetic.

#### Recommendation

The Crops Committee recommends that Corn Steep Liquor produced via the traditional countercurrent corn wet milling process be considered as non-synthetic and allowed for use in organic crop production.

# **Committee Vote**

Motion: Consider CSL to be non-synthetic when produced via the traditional countercurrent corn wet milling process only.

Motion: Jef	f Moyer	Second: Tina Ellor	
Yes: 4	No: 3	Abstain: 0	Absent: 0

# **Minority Opinion**

The issue we are considering, in determining whether CSL is synthetic or non-synthetic, is a foundational issue in the determination of allowable inputs in organic production. The determination itself of whether an input is synthetic does not always determine whether that input is allowable in organic. It simply ensures that the NOSB carries out its responsibility to review and evaluate whether the use of that synthetic material meets the law's standards of sustainability. Organic integrity is built on the principle of objective review and transparency to ensure that the organic consumers' expectations are being met and that there is a level playing field for all those engaged in organic production.

The minority's position that CSL must be defined as a synthetic product is actually very straightforward and follows the policies and history of longstanding positions of the NOSB. Simply put, the process of making CSL --the wet milling countercurrent process-- is different than the natural practices that are defined in our standards, expressly because the process requires adding a synthetic chemical to an otherwise natural steeping/lactic acid fermentation process to effect a chemical change, necessary for the end product to be created. So, even though this process involves corn and a steeping process, the end result would not get that product to where its manufacturer wants without the introduction of a synthetic chemical that breaks chemical bonds and manipulates corn to turn it into something else with distinct functionality. And USDA researchers at the Agricultural Research Service (who do not have a financial interest in this discussion) have confirmed to the Crops Committee that CSL could not be created naturally with biological activity alone or as is allowed in what we have until now understood to be the nonchemical processes, as stated in the organic Rule: "cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, distilling, eviscerating, preserving, freezing, chilling, or otherwise manufacturing and includes the packaging, canning, jarring, or otherwise enclosing food in a container."

# The question is not whether CSL is a good product.

The question before us is whether CSL is synthetic since it is created through chemical change which requires the introduction of a synthetic chemical ingredient. We have been told that CSL is composed of proteins, amino acids, carbohydrates, organic acids (such as lactic acid), vitamins, minerals and water. All this is true. We are told that these components are all readily utilized by animals and microorganisms. And, we're told that CSL is a nutrient rich product that has been safely used as a component in livestock feed, fertilizers, and soil conditioners for many years.

The minority does not dispute this. However, all these valuable assets do not make CSL nonsynthetic. The minority believes that this is really all you need to know: a synthetic chemical introduced into a mixture with an agricultural material forces a change in the chemistry of that agricultural material in a way that would not occur through natural means. You don't really need to go further than that. However, we can shift to the underlying policy of the NOSB that establishes CSL as a synthetic product and all future products that we should review to ensure that the standards of the statute and National List are met. What follows are the policies as they apply to CSL.

## We come to the minority opinion by following the NOSB's process

The minority opinion is based on the policies of the NOSB and the standards that have been developed over time. Here is our thinking, as it relates to the policies and definitions of the type of chemical change (brought on by the introduction of a chemical substance, or not occurring as a result of some natural process).

The classification of materials recommendation adopted by the board in November 2009 established three guiding principles for determining whether a substance is synthetic or non-synthetic:

- The classification of a material is determined by both the source of the inputs and the process used to make the material.
- The same material can be agricultural, non-synthetic or synthetic depending on source and process.
- 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 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.

These guiding principles are central to the classification of corn steep liquor. We have a material whose source is nonsynthetic, however, the source is only the first issue of concern under current standards. The process adopted by the board requires us to look at the processing applied to the source material as well. In this case, corn is an agricultural material (nonsynthetic), and the standard requires an assessment of the wet milling process to which the corn is subjected to determine whether it should be classified as synthetic.

The NOSB's classification of materials recommendation also stated:

It is our intent through this recommendation that a material would be classified as synthetic when:

- The source of the material is not "from mineral, plant, or animal matter" (from the definition of nonsynthetic) and is not a "substance created by naturally occurring biological processes" (from the definition of synthetic) or;
- The process used to manufacture the material is synthetic (per the definition of synthetic and clarifying definitions in our recommendation) or;
- The material contains, at a significant level, a synthetic substance not on the National List of allowed synthetics. (p.5 of 13, Nov. 2009)

In April 2010, the board adopted an addendum to the classification of materials recommendation that sought to clarify the application of the guiding principles. It said, in part:

It is our belief that chemical changes that occur when an agricultural material is processed by itself, or in combination with other agricultural materials, the resulting material should continue to be classified as agricultural. Clearly chemical change happens in these cases, if looked at from a purely chemistry perspective, but from a consumer perspective these materials are agricultural. The committee differentiates between these cases and those when an agricultural material is processed with a non-agricultural material, whether synthetic or non-synthetic. In these latter cases, if chemical change occurs, the resulting material would be classified as synthetic. (p.1 of 19, April 2010)

OFPA defines synthetic:

**Synthetic** is defined as "a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from a naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes" (§2103 (21)).

# And chemical change is defined,

<u>Chemical Change</u> 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") <u>Processing, as defined in §205.2, of agricultural products using</u> <u>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. (April 2010, underlined rejected by NOP)</u>

#### And substance,

<u>Substance</u> An element, molecular species, or chemical compound that possesses a distinct identity (For example, a distinct identity may be demonstrated through the material having a separate Chemical Abstract Service (CAS) number (in some cases the same material may have multiple CAS numbers), Codex International Numbering System (INS) number, or FDA or other agency standard of identity). (p.10 of 19, April 2010)

All of this is background to the following questions:

- 1. Is corn steep liquor a different substance from corn, or anything contained in corn? (If yes, chemical change has occurred.)
- 2. Is breaking disulfide bonds of the corn protein matrix a necessary part of the countercurrent wet milling process that results in corn steep liquor as a by-product?
- 3. Does the sulfur dioxide (a synthetic substance) that is added to the wet milling process break the disulfide bonds in creating the by-product (CSL)?

If the answer to all these questions is "yes," the classification of materials policy defines CSL as synthetic.

And, to follow our policy through to its conclusion, regardless of any of the above questions, the policy requires the following assessment:

4. As a result of added sulfur dioxide to the manufacturing process, are there significant residues of sulfur dioxide in corn steep liquor?

If the answer is "yes," then CSL is synthetic. If it were the case that no chemical change to the source material had occurred as a result of the use of sulfur dioxide, yet if the process of producing CSL results in significant (Nov. 2009) residues of sulfur dioxide, then the policy requires a determination that the CSL is synthetic.