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MEMORANDUM

May 25, 2010

TO: Katrina Heinze
Steve DeMuri
Co-Chairs, Joint Materials and Handling Committee
National Organic Standards Board (NOSB)
Joe Smillie, Member, Joint Materials and Handling Committee

FROM: Richard D. Siegel RDS
Counsel, Marroquin Organic International, Inc.

RE: National List Petition of Marroquin Organic International, Inc.
To Transfer Yeast from Listing under § 205.605(a) to § 205.606 --
Information Requested by the Joint Committee on
Sources of Yeast Strains and Processes Used in Commercial Yeast Production

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Introduction

On November 5, 2009, the NOSB approved the recommendation on Classification of Materials that the Joint Materials and Handling Committee had developed. With specific reference to the Marroquin yeast petition, the recommendation, at page 12, stated as follows:

> Specifically, yeast has been the subject of much discussion and public comment for several years. Currently a petition to change the listing of yeast from §205.605 to §205.606 has been submitted but deferred for consideration by the petitioner. We ask the petitioner to revise the petition, as appropriate, to ensure that a detailed discussion of the source of inputs and the processes used to produce yeast is included. We will consider the petition when it is resubmitted, request a technical review if required and will recommend classification of yeast and the appropriate listing of this material.

On January 15, 2010, Marroquin resubmitted its petition dated August 8, 2006, to the NOP, together with supplementary information on the "sources of inputs and the processes used" in the production of organic yeast by Agrano GmbH & Co. KG, in Riegel am Kaiserstuhl, Germany. Marroquin imports and markets organic yeast products from Agrano, which has had NOP certification since 2003.

The information Marroquin submitted to the NOP on January 15, 2010, included:

- The original petition of August 8, 2006 (Attachment A)
- Agrano's Organic System Plan (Attachment B)
- Specifications for processing eleven separate yeast products (Attachment C)
- The flow diagram showing various steps in production (Attachment D)
- Agrano's brochure (Attachment E) showing a table comparing organic yeast production with conventional yeast production. This table is also shown on page 4 of the cover letter dated January 15, 2010.

In conversations during the recent NOSB meeting in Woodland, California, Katrina Heinze and Joe Smillie requested further information from Marroquin explaining the sources of yeast strains and the processes that are used generally in the commercial manufacturing of yeast. We are happy to provide this memorandum to give the Joint Committee a broader look at the commercial production of yeast. Because Agrano's organic yeast operation is essentially similar to conventional yeast manufacturing except for the inputs, in this memorandum we will build on, and refer to, the specific information that Marroquin has previously provided on Agrano's operation.

We believe that this information will give the Joint Committee a clear picture of the sources of yeast and the processes used to produce yeast commercially. As this memorandum will show:

- All yeast comes from natural sources, and development of pure yeast strains in the laboratory does not change the natural attributes of yeast.
- The manufacturing process for yeast does not change yeast either, but merely nourishes yeast so that it can multiply to commercial quantities and thus perform its role as an ingredient in food and feed.
- Therefore, all yeast should be eligible for status as an "agricultural product" and yeast should be moved from § 205.605(a) to § 206.606.

1. All Yeast Strains in Manufacturing Come from Natural Sources
<u>And Are Not Changed When Pure Yeast Strains are Developed in the Laboratory</u>

We will begin with an explanation of the origin of yeast strains used in yeast manufacturing. In the recommendation on the Classification of Materials, the Joint Committee observed, at page 8, that yeast "can be sourced from certified organic grapes or from a yeast strain whose original source is unknown because it only exists in purified form in a bottle." The

Joint Committee suggested that the nature of the source thus "may affect the classification of yeast" as "agricultural" or "nonsynthetic," i.e. "nonagricultural."

Yeasts are eukaryotic[1] microorganisms that are ubiquitous in nature. They are mostly found on plants, but also can be found on animals, sediments and soils. Although some yeasts have specific habitats, others are found on a variety of natural substrates. Yeast grows and reproduces with the aid of oxygen.[2] However, when yeast is exposed to sugar under anaerobic conditions, its fermentation produces alcohol, and this is the process that produces beer, wine and other alcoholic beverages.[3]

Yeasts found in nature are the source for all yeast strains used in commercial production. For purposes of classifying yeast as "agricultural" or "nonagricultural," we can see no rational distinction between yeast strains in their wild state and yeast strains bred and controlled for purity in a food science laboratory, because even yeast strains encountered in the laboratory have originated from yeast found in nature.

According to Dr. Bernd Bohrer, Agrano's CEO until his retirement in January 2010, the usual practice in the yeast industry is to keep purified yeast strains active "for decades." This makes it difficult, if not impossible, to trace a yeast strain back to its earliest source. Dr. Bohrer further comments, "If you have a yeast cell in the lab you can't see where it originally came from, because the same strain or mutants of a strain could be found on different material" in nature.[4]

Technicians in the laboratory take wild yeast strains and use traditional mutation and selection methods to breed them for use in food production.[5] These techniques do not cause any chemical change; the pure yeast strains are still recognizable as yeast. The work in the laboratory is merely to breed these strains to insure that they will perform effectively as yeast in food or feed production. While genetic manipulation has been introduced recently to develop some yeast strains, these would be prohibited in organic production.

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[1] Fungi such as yeast are eukaryotes, the domain of biological classification that includes plants, animals and fungi. Eukaryotes are distinguished from prokaryotes, such as bacteria, by their more complex cell structure. See "Classification, biological," McGraw-Hill Encyclopedia of Science and Technology, 10th ed. (2007).

[2] Fell, Phaff & Walker, "Yeast - Ecology," in AccessScience@McGraw-Hill, http://www.accessscience.com, DOI 10.1036/1097-8542.753100. (This is the website providing articles from the McGraw-Hill Encyclopedia of Science and Technology (10th ed., 2007)).

[3] Fell, Phaff & Walker, "Yeast – Fermented Beverages," in AccessScience, above. .

[4] In addition to his experience as Agrano's CEO, Dr. Bohrer holds bachelor's and master's degree in food science and technology from the Technical University of Berlin and a Ph.D. from the University of Stuttgart-Hohenheim in general and applied science.

[5] R. Korus, "Industrial microbiology," in AccessScience, above.

To summarize, yeast strains are found in nature and are then bred into pure yeast strains that are best suited to perform in the production of food and feed. The yeast strains that are bred successfully for this purpose are kept active for long periods. The breeding process for yeast is directly analogous to the breeding of livestock. Breeding strains of yeast does not change the essential character of yeast as a natural microorganism. Therefore, we do not see any basis for determining that yeast found in nature would be "agricultural" while these same yeast strains developed in the laboratory in a pure form for functionality would be "non-agricultural."

2. Processes Used in Commercial Yeast Production are All Accepted "Processing" Methods And Do Not Make any Change in the Character of Yeast

Until about 100 years ago, there was no industry to propagate yeast for bakers. Bakers would obtain the yeast they needed from excess yeast (barm) from breweries. However, yeast from these sources was not suited for modern bakeries and as a result baker's yeast and other yeasts are now produced on a commercial scale.[6]

Commercial yeast production involves propagation of specially selected strains of yeast by progressive stages of fermentation in larger and larger vessels. The aim is to grow a far larger quantity of yeast by the end of the production cycle. In order to grow, the yeast is fed with nutrients. Just as breeding yeast strains is analogous to livestock breeding, the feeding of yeast is analogous to livestock feeding. The production process has four main steps and takes approximately five days. We will now give a step-by-step narrative description of the process. A flow chart illustrating this process, prepared by Dakota Baker's Yeast, is attached.[7]

In reviewing the yeast manufacturing process, we can observe that all the phases would be accepted as processing methods for the processing of an "agricultural product." These processes, such as "mixing," "fermenting," "separating," "heating," "dehydrating" and "chilling" -- are all listed in the definition of "processing" in the NOP Final Rule at 7 CFR § 205.2. None of the processes used change the essential character of yeast. Thus yeast would not become "nonagricultural" as a result of the manufacturing process.

First, the feed solution is prepared. The fermentation depends on a feed solution of nutrients mainly composed of sugars that are readily fermentable. In conventional (nonorganic) yeast production, the sugars are supplied by beet or cane molasses, because the sugars in

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[6] Fell, Phaff & Walker, "Yeast – Baker's Yeast," in AccessScience, above.

[7] The narrative description of the yeast production process is based on the detailed information provided by the Minn-Dak Yeast Company, Wahpeton, ND, maker of Dakota Baker's Yeast, on its website: http://www.dakotayeast.com/home.html. This is the source of the flow chart as well. In addition, the yeast production process is described similarly, but more briefly, in Fell, Phaff and Walker, "Yeast – Baker's Yeast," cited in note 6 above.

molasses lend themselves to fermentation. Nitrogen and phosphorus are other nutrients required. In conventional (nonorganic) yeast production, the nitrogen source is ammonia, and phosphoric acid is included as a source of phosphate. When the feed solution is mixed, it is flash sterilized.

The next step is to prepare the yeast strain for fermentation. The yeast strain, as a pure culture, is introduced (inoculated) into a pre-pure culture tank, where it is grown in a growth medium under strict sterile conditions. In the pre-pure culture tank, a batch of the sterilized feed solution is already present when the yeast inoculum is added. After this growth stage, the contents are transferred to a larger pure culture fermenter which will also contain a batch of feed solution. From the pure culture fermenter, the grown yeast cells are transferred to the seed fermenter and two semi-seed fermenters, tanks that are progressively larger. In the seed and semi-seed fermenters, the feed solutions, consisting of molasses, ammonia, phosphoric acid and minerals, are fed to the yeast gradually at a controlled rate (fed-batch cultivation or fermentation). The rate is controlled to maximize the multiplication of yeast while preventing production of alcohol in the fermentation process.

The yeast is now further prepared for the final fermentation. The yeast is separated from the spent molasses, washed and stored as a cream at 34 degrees Fahrenheit. The yeast cream is then ready to be inoculated into the commercial fermentation tanks for the final stage of fermentation.

The third step is the final commercial fermentation process and the subsequent harvesting of the yeast. The commercial fermentation tanks are the largest tanks and the fermentation process takes 15-20 hours. The fermentation involves constant aeration and addition of nutrients. As a result the yeast cells increase five-to-eight fold. At the end of the fermentation, the yeast biomass is harvested. The yeast is separated out from the fermenter broth by centrifuges, then washed and recentrifuged, becoming a concentrated cream that is cooled to about 45 degrees Fahrenheit. In the fourth and final step, the yeast cream is either shipped in that form or filtered and dewatered into a cake-like consistency and then shipped.

The end product is essentially the same as the pure yeast strain that was present at the start, except that there are now commercial quantities of yeast available for the food and feed industries.

Turning to Agrano's organic yeast products, the flow diagram of Agrano's production of organic yeast follows the same basic process as we have just outlined for the production of conventional yeast. The basic feed solution and the pure yeast strain are both prepared in advance of pre-fermentation, and the pre-fermentation is followed by the main fermentation. (See Flow Sheets 1-5 in Agrano's Flow Diagram, Attachment D submitted January 15, 2010.)

Then there is downstream processing of the yeast cream, with separation, concentration, cooling and filtering stages (See Flow Sheets 6 – 13).

3. Conclusion: Yeast Should, Therefore, Be Removed from § 205.605(a) And Placed in § 205.606 as an "Agricultural Product"

As we have demonstrated, yeast in general is all derived from natural sources, and does not undergo essential change when pure yeast strains are developed in the laboratory or when these yeast strains are multiplied in commercial processing. This shows that yeast can be readily considered as an "agricultural product," because of its natural origin and because no essential change takes place in the processing. .

The only distinction that applies between conventional yeast and organic yeast is just that: conventional yeast is an agricultural product processed conventionally and organic yeast is an agricultural product processed in compliance with the NOP regulations. Agrano has demonstrated that yeast can be made commercially in an organic form, but unless conventional yeast is listed in § 205.606, there will be no incentive for conventional yeast companies to depart from the way they make yeast now to take up organic yeast production for the organic market.

The reason why organic yeast has been developed is to substitute organic and organically-compliant inputs for the regular inputs in conventional yeast. In conventional yeast, conventional beet and cane molasses is the main component of the feed solution because molasses is a rich source of sugar. However, as German organic researcher Alexander Beck explained in an article in 2002, because molasses is deficient in phosphorus and nitrogen for the growth of yeast, conventional yeast manufacturing with molasses relies heavily on the addition of synthetic chemicals -- ammonia as a source of nitrogen and phosphoric acid as a source of phosphorus. This in turn requires other synthetic chemicals to control the pH value, such as sulfuric acid and sodium hydroxide. Micronutrients such as synthetic vitamins must also be used to boost yeast growth. Conventional yeast may use synthetic defoaming agents. As a result of the chemicals and nutrients used, yeast must be washed not once but twice. As a result the waste water has chemicals and nutrients and is not easily degraded.[8]

This led Mr. Beck to observe, "These substances (in conventional yeast) are not compatible with the view of food production held by the organic farming community."[9]

This spirit in the European organic community was the stimulus for Agrano to do its pioneering work, starting in 1980, to develop an organic way to manufacture yeast. In 1995 Agrano began selling its Bioreal® organic yeast commercially.

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[8] Alexander Beck, Research Institute of Organic Agriculture (FiBL), Berlin, "Starter Cultures – to be allowed as a matter of course!?" September 18, 2002, pages 2- 3.
[9] Beck, above, page 3.

Instead of having conventional beet and cane molasses be the primary source of sugar in the feed solution, or substrate, for the yeast, Agrano uses only organically grown grains or organic molasses. For the nitrogen source, Agrano uses organically farmed grain and brewer's yeast. Agrano does not need to use sulfuric acid or sodium hydroxide to control the pH, because without ammonia and phosphoric acid, no pH level regulation is necessary. Agrano relies on the nutrients in the natural growth media and does not add synthetic vitamins. As a defoaming agent, it uses organic sunflower oil. There is no need in this process to wash the yeast. For this reason the waste water is able to be reused in further organic production, for example, sourdough.

The petition before the Joint Committee seeks to have all yeast removed from § 205.605(a) and placed in § 205.606. The aim of the petition is to put yeast in its proper place on the National List as an "agricultural product," so that organic yeast will be required if it is "commercially available." During the time that this petition has been pending, since August 8, 2006, there has been an enduring flaw in the NOP regulations. Even though organic yeast is "commercially available" for a great number of processors' uses, processors have been free to use conventional yeast without having to search for "commercially available" organic yeast. This is because the listing of yeast on § 205.605(a) does not require processors to try to source "commercially available" organic yeast.

In the meantime, there have been two significant developments that have advanced the acceptance of organic yeast.

First, the European Union has recognized yeast as eligible to be organic both for food and feed. (See EU Council Regulation (EC) No 834/2007 of 25 June 2007, Article 1, Section 2, and Article 20). It has adopted detailed rules for organic yeast production and has provided that yeast and yeast products be counted as "ingredients of agricultural origin" as of December 31, 2013. (See Commission Regulation (EC) No 1254/2008 of 15 December 2008.)

Second, the NOP confirmed on March 2 of this year that Agrano's yeast products may be certified as organic.[10]

Marroquin appreciates the attention that the Joint Materials and Handling Committee is now devoting to this petition in order to arrive at a recommendation for the fall NOSB meeting. We hope that the information we have supplied will enable the Joint Committee to reach a determination that yeast can be considered an "agricultural product," so that it should be removed from § 205.605(a) and placed in § 205.606.

Please contact us if you have any further questions.

Attachment

[10] NOP Policy Statement, "Certification of Organic Yeast," March 2, 2010.

ATTACHMENT

FLOW CHART

SHOWING

PRODUCTION PROCESS FOR YEAST

PROVIDED BY DAKOTA BAKER'S YEAST

MINN-DAK YEAST COMPANY

WAHPETON, NORTH DAKOTA

DAKOTA
BAKERS-YEAST

PRODUCTION PROCESS