



BEYOND PESTICIDES

701 E Street, SE ■ Washington DC 20003
202-543-5450 phone ■ 202-543-4791 fax
info@beyondpesticides.org ■ www.beyondpesticides.org

October 3, 2014

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave. SW
Room 2648-S, Mail Stop 0268
Washington, DC 20250-0268

Re. HS: Whole algal flour; MS/GMO: Workplan

These comments to the National Organic Standards Board (NOSB) on its Fall 2014 agenda are submitted on behalf of Beyond Pesticides. Founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, Beyond Pesticides advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and groups around the world.

We agree with the Handling Subcommittee's proposals regarding whole algal flour. We agree that there is too much confidential business information to determine whether it meets criteria under the Organic Foods Production Act (OFPA). We also agree that it is not essential. It would replace natural foods including cream, milk, eggs and egg yolks, and butter or shortening. All of these natural foods contribute nutrients to the diet, and it is not clear what whole algal flour contributes to the diet.

Excluded Methods

We have a concern that excluded methods may be used in the manufacture of whole algal flour –if not now, then possibly at some time in the future. Although the narrative portion of the petition claims that the source organism is not genetically modified, Table 2 states that it is. In addition, the manufacturer of whole algal flour, Solazyme, states in its 2014 Annual Report,

We rely on multiple microalgae strains including natural, classically improved, and/or targeted recombinant strains. The key components of our industrial biotechnology platform are strain screening, classical strain improvement, strain optimization through targeted gene recombination, fermentation process development, and downstream process development. Our selection process is iterative; as strains progress through classical strain improvement and targeted recombinant strain optimization they feed back into the strain screening program, re-emerging for additional rounds of strain improvement, strain optimization, and process development. (p. 7)

Our technology platform creates a new paradigm that enables us to produce novel tailored oils that cannot be achieved through blending of existing conventional oils alone. We have made significant investments to protect the intellectual property and know-how related to our technology platform, including screening, classical strain development, targeted recombinant strain optimization, product and applications development and manufacturing capabilities. (p. 14) The use of recombinant microbes like many of our microbial strains is subject to laws and regulations in many countries. In the US, the EPA regulates the commercial use of recombinant microbes as well as potential products from recombinant microbes. When used in an industrial process, our microalgae strains designed using recombinant technology may be considered new chemicals under TSCA, administered by the EPA. We will be required to comply with the EPA's Microbial Commercial Activity Notice (MCAN) process and have filed MCANs for strains of recombinant microalgae that we use for our chemicals and fuels businesses, which have been dropped from review, allowing commercial use. In Brazil, engineered microbes are regulated by CTNBio. We have filed an application, and in the future may file additional applications, for approval from CTNBio to import and use engineered microbes in our Brazilian facilities for research and development purposes. (p. 17)

We have committed, and intend to continue to commit, substantial resources, alone or with collaboration partners, to the development and analysis of new tailored oils and other microalgae-based products by applying recombinant technology to our microalgae strains. There is no guarantee that we will be successful in creating new tailored oil profiles, or other microalgae-based products, that we, our partners or their customers desire. There are significant technological hurdles in successfully applying recombinant technology to microalgae, and if we are unsuccessful at engineering microalgae strains that produce desirable tailored oils and other microalgae-based products, the number and size of the markets we will be able to address will be limited, our expected profit margins could be reduced and the potential profitability of our business could be compromised. (p. 22)

The subject of organisms designed using targeted recombinant technology has received negative publicity, which has aroused public debate. Public attitudes about the safety and environmental hazards of, and ethical concerns over, genetic research and microorganisms designed using targeted recombinant technology could influence public acceptance of our technology and products. In addition, shifting public attitudes regarding, and potential changes to laws governing, ownership of genetic material could harm our intellectual property rights with respect to our genetic material and discourage collaborators from supporting, developing, or commercializing our products, processes and technologies. (p. 35)

Solazyme cites as a concern that may prohibit successful commercialization of its products, "public concerns about the ethical, legal, environmental and social ramifications of the use of targeted recombinant technology, land use and the potential diversion of resources from food production." (p.20)

The manufacturer's commitment to recombinant technology adds to concerns raised by the large amount of redacted CBI in the petition.

Fermentation

This petition raises an issue that should be addressed by the NOSB –what criteria should be applied to determine whether fermentation products are acceptable as inputs in organic production and processing? The draft materials classification guidance treats fermentation as a processing method that does not change the classification of the substrate from agricultural to non-agricultural or from nonsynthetic to synthetic. Yet fermentation processes vary widely from pickling, wine-making, and cheese-making to manufacture of substances that have no apparent relationship to the substrate. Whole algal flour is an example of the last. Glycerin made by fermentation of cornstarch and gellan gum are other examples. The processes vary in nutrients added, physical methods of isolating the product, solvents used, and ancillary substances added. The fact that all of these processes involve the growth of microorganisms does not seem to be sufficient to treat them the same. Therefore, we request that the Materials/GMO Subcommittee add to its workplan the development of criteria for evaluating products of fermentation processes.

Annotation

If the Board were to allow the addition of this material as an exempt prohibited material on the National List, it is essential that the listing include an annotation with a 5-year expiration date. The Board has the statutory prerogative to adopt annotations when it recommends a national listing with language that takes into account concerns it has about health and the environment, essentiality, and other issues of compatibility with organic production and processing. The statute does not prohibit the Board from adopting a specific time frame in which it determines it would like to reassess a material's use, update its evaluation, and vote with the same standards of review that are applied to the petition review to allow initial use.

The specific time frame for an expiration date allows the Board to monitor the use of the material, incentivize alternatives, update its scientific and essentiality review, and vote on the continuation of use pending the receipt of a petition requesting that use be continued. This process, as we saw with tetracycline, allows sufficient time for the Board to vote before the expiration would go into effect, so, if it is approved, there would be no break in market availability. Expiration simply puts on notice those who use or produce the substance that the material will be reviewed with the same rigor in looking for new information that it used when it was initially listed. Under the new sunset policy, an expiration date on a petition is necessary to ensure the kind of periodic rigorous review and vote that many in the organic community have come to expect and depend on to maintain organic integrity and trust in the organic label.

Ancillary Substances

According to the recommendation passed by the NOSB in the spring of 2013, the board defined “ancillary substances” as “additives added during the manufacturing of a non-organic substance and **not** removed.”

The NOSB went on to recommend the following policy:

The NOSB intends to review ancillary substances found in substances on and petitioned for the National List in accordance with OFPA criteria. Comprehensive review does not require these substances to be individually listed on the National List, however. The Board intends to follow the request by NOP to consider ancillary ingredients contained in substances as they come up for review or as new petitions are considered.

In each NOSB review checklist and recommendation cover sheet there will be a clear space to indicate what other ingredients are being reviewed and what restriction if any are placed on them as a result of the review. Restrictions on other ingredients will be included in an annotation and may be for specific individual components, for functional classes of ingredients, or by regulatory reference to another governmental agency such as FDA. The other ingredients restrictions may be incorporated into a permitted substances database for Handling, such as the one that is coming out for crops.

The NOSB recommendation will include a note that the other ingredients were reviewed and accepted. The review of other ingredients will distinguish between synthetic and nonsynthetic ones, as well as agricultural ingredients that might be able to be organically produced. Any additional restrictions will be specified in an annotation.

Ancillary substances in general product categories that are currently on §205.605 and §205.606 and currently used in certified organic processed product will continue to be allowed until they go through their next sunset review and subsequent Rule amendment.

The ancillary substances associated with this material have not been reviewed or even listed. This is an important piece that needs to be incorporated into the review of every material. Thank you for your consideration of these comments.

Sincerely,



Terry Shistar, Ph.D.
Board of Directors