

DISCUSSION DOCUMENT: CONFIDENTIAL BUSINESS INFORMATION IN PETITIONS

SUMMARY

We support proposed recommendation #1.

The Organic Foods Production Act of 1990 (OFPA) specifies that materials may only be added to organic foods or to the National List if certain criteria are met. The NOSB is not able to make an informed decision whether a material meets these criteria if critical information is withheld.

Information necessary to make an informed decision based on OFPA's criteria includes the full list of ingredients, sub-ingredients, processing aids, manufacturing processes, and complete disclosure of all known human health/environmental impacts.

CORNUCOPIA'S COMMENTS

We agree with the Materials Subcommittee that the misunderstanding that certain information can be withheld in petitions "has not served either the petitioner or the NOSB particularly well."

OFPA specifically states (7 USC 6518(l)(2)) that the NOSB must work with manufacturers to obtain a full list of ingredients of petitioned materials.

OFPA also states that materials cannot be added to the National List if they are harmful to human health or the environment. The only way to determine whether a material is harmful to health or the environment is by considering all available data, including knowing which processing aids are used and having access to results from all safety studies. Therefore, petitioners should not be able to withhold any information regarding processing aids or studies on human health effects or environmental impacts.

The discussion document mentions the Trade Secrets Act, but it is important to note that OFPA is not subordinate to the Trade Secrets Act nor does it state that any information necessary to carry out the requirements in OFPA is exempt under the Trade Secrets Act. Clearly, the Trade Secrets Act does not supersede OFPA or the responsibilities of the NOSB to carry out their responsibilities.

Participation in the organic industry is voluntary; if a manufacturer is unwilling to share information about ingredients, processing aids or human health/environmental impacts to protect trade secrets, the USDA is under no obligation to make an exception for such manufacturers.

Manufacturers who wish to keep the public in the dark about the ingredients and processing aids they use can sell their products in conventional foods. The organic label is an alternative to conventional foods—an alternative food system marked by transparency and careful scrutiny of potential health/environmental impacts.

Manufacturers cannot have it both ways; transparency is a prerequisite to participation in the organic food system. Any petition with ingredients, processing aids, and human health/environmental impacts withheld as CBI should automatically be sent back to the petitioner by the NOP. Such petitions should not be forwarded to the NOSB, so as not to waste the NOSB's time with petitions that should never legally be approved.

If a manufacturer has a unique, proprietary manufacturing system, or product formulation, we suggest that they seek protection through the US patent office prior to seeking NOSB approval.

The following should never be considered trade secrets and should not be withheld as CBI:

1. A full list of “other ingredients”

We do not expect a petitioner to disclose the exact recipe with detailed percentages or proportions of the ingredients, but it is clear that a full list of all ingredients should be disclosed.

OFPA states that the NOSB must work with manufacturers to obtain a full list of ingredients (7 USC 6518(l)(2))¹ to allow the NOSB to determine whether all ingredients meet OFPA's requirements.

2. Effects on human health and/or the environment

OFPA requires that materials on the National List must not be harmful to human health or the environment. Such information cannot be withheld as Confidential Business Information.

¹ 7 USC 6518(l)(2): Requirements – In establishing the proposed National List or proposed amendments to the National List, the Board shall work with manufacturers of substances considered for inclusion in the proposed National List to obtain a complete list of ingredients and determine whether such substances contain inert materials that are synthetically produced

In Albemarle Corporation's current petition for the antimicrobial chemical DBDMH, an entire section titled "Effects on Human Health" was redacted as CBI. This suggests that Albemarle Corporation has performed studies and has information on this chemical's effects on human health, but is unwilling to share these results with the public. Under no circumstances should a petition with such redactions be considered eligible for review by the NOSB. Such petitions should be sent back to the petitioner by the NOP.

3. Manufacturing process

While the Material Subcommittee notes that the manufacturing process is considered eligible as a trade secret by the Trade Secrets Act, the Trade Secrets Act does not supersede OFPA. OFPA requires that a material not be harmful to human health and the environment, and that it be compatible with organic handling. The NOSB can only make this determination if the full list of processing aids and manufacturing steps is known.

This information is also needed to determine whether excluded methods were involved in the manufacturing of the product.

CORNUCOPIA'S POSITION

We support Possible Recommendation 1:

"CBI is not allowed in petitions. Petitioners must provide complete information about manufacturing processes and ingredients so that the NOSB and the public can fully evaluate each petitioned material."

Organic foods provide consumers with an alternative to the highly secretive conventional food supply. Approving materials without full disclosure is unacceptable. Petitions with CBI withheld cannot legally be approved, so they are an unproductive use of time for everyone involved, including NOP staff, Technical Review contractors, the NOSB and the public stakeholders who perform requisite research and comment on NOSB recommendations.

These petitions should be sent back to the petitioner by the NOP, so as not to waste the NOSB's time.

DISCUSSION QUESTIONS

- 1. Should Confidential Business Information be allowed in petitions?
Please explain your answer.**

It would be reasonable for a petitioner to withhold certain details about proprietary formulations and/or manufacturing processes.

However, OFPA specifically requires that every ingredient and processing aid in a certified organic product must either be organically produced or appear on the National List. If information about ingredients and processing aids is withheld as Confidential Business Information, the NOSB and USDA cannot legally approve the material.

We therefore believe that a full list of ingredients and processing aids must be disclosed, and this information cannot be considered Confidential Business Information.

The NOP must be clear with petitioners that no petition will be accepted, and will not be forwarded to the NOSB, if the petitioner withholds the full list of ingredients and processing aids as CBI.

However, details about formulations, such as specific quantities and ratios of ingredients, could be withheld as CBI.

2. If CBI is allowed, should it be limited so that it does not involve ingredients or manufacturing processes?

The full list of ingredients, processing aids and manufacturing steps should not be withheld as CBI, but it would be reasonable to allow a petitioner to withhold the specific quantities/ratios of ingredients and processing aids.

Furthermore, information and studies on environmental and human health impacts should never be allowed to be withheld as CBI, as Albemarle Corporation has done in its petition for DMDBH.

3. Do the provisions in Possible Recommendation 2 make sense and are there others that the Board should consider?

We do not support Possible Recommendation 2.

4. Provision I in Possible Recommendation 2 is about using an affidavit to supplement a CBI petition. Comment on whether this is valuable.

Under no circumstances should a petitioner be allowed to sign an affidavit stating that its ingredients and processing aids comply with OFPA, which is essentially a proposal to allow manufacturers to regulate themselves. Such a provision would prevent NOSB members from fulfilling their legal responsibilities under OFPA.

Manufacturers are allowed to “police themselves” by the FDA, which allows manufacturers to make their own determination regarding the safety of new food

additives (the GRAS system). This system has come under heavy criticism—rightfully so—from the Governmental Accountability Office,² the Pew Trust³ and the media.⁴

The organic system was designed to offer an alternative—where independent panels (the NOSB), independent scientists (Technical Reviewers), and the public collaborate on determining whether ingredients, additives and inputs are appropriate in food production and processing.

Allowing manufacturers to sign affidavits would be asking them to essentially perform their own Technical Review, which is entirely unacceptable both in terms of OFPA and consumer confidence in the organic label.

5. Should procedures, such as a Confidentiality Agreement, be developed that would allow the NOSB, but not the public, to see any CBI?

No, for several reasons.

First, the NOSB benefits from public input. If certain information is withheld from the public, it weakens the NOSB's ability to solicit and consider input from the public. Collaboration with members of the public is vital to the NOSB process, and we oppose the proposal to introduce Confidentiality Agreements designed to keep the public in the dark.

The NOSB is not a scientific panel. Members depend on research and a diversity of opinion from professionals in the organic community to help them in their decision-making process.

Second, the NOSB members need to be able to speak freely, and discussions during public meetings must be uninhibited. It would be impossible for NOSB members to discuss a petition if they have information that is confidential and protected from public disclosure.

Furthermore, it would expose Board members and the USDA to possible legal repercussions if it were claimed that a breach of confidentiality took place.

CONCLUSION

We support Possible Recommendation 1.

² <http://www.gao.gov/products/GAO-10-246>

³ http://www.pewtrusts.org/our_work_detail.aspx?id=1203

⁴ http://articles.chicagotribune.com/2012-08-25/health/ct-met-food-ingredients-20120825_1_food-ingredients-pew-health-group-fda

The only way for the NOSB to make the legally required determination on petitions and sunset reviews, based on criteria in OFPA and the federal organic standards, is to have full access to all information necessary to make these determinations. This includes all ingredients, processing aids, manufacturing steps and information on human health/environmental impacts.

Possible Recommendation 2 appears to be an attempt to keep the NOSB and/or the public in the dark. We need to move toward more transparency, not more secrecy.