United States Department of Agriculture
Agricultural Marketing Service | National Organic Program
Document Cover Sheet
https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned

Document Type:

☒ **National List Petition or Petition Update**

A petition is a request to amend the USDA National Organic Program's National List of Allowed and Prohibited Substances (National List).

Any person may submit a petition to have a substance evaluated by the National Organic Standards Board (7 CFR 205.607(a)).

Guidelines for submitting a petition are available in the NOP Handbook as NOP 3011, National List Petition Guidelines.

Petitions are posted for the public on the NOP website for Petitioned Substances.

☐ **Technical Report**

A technical report is developed in response to a petition to amend the National List. Reports are also developed to assist in the review of substances that are already on the National List.

Technical reports are completed by third-party contractors and are available to the public on the NOP website for Petitioned Substances.

Contractor names and dates completed are available in the report.

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April 24, 2020

Christopher Taste
National Organic Program
USDA/AMS/NOP, Standards Division
Attention: National List Manager
Room 2646-S, STOP 0268
1400 Independence Ave. SW
Washington, DC 20250-0268

Re: Responses to Petition to add Cetylpyridinium Chloride ("CPC") to section 205.605 (b) of the National List

Dear Christopher,

This letter is in response to your March 27th, 2020 request for additional information from the NOSB Handling Subcommittee for evaluation of the petition for the addition of cetylpyridinium chloride to the National List.

For ease of reference, we repeat below comments and questions from your March 27 letter, followed by our responses.

1. ***Please provide the exact listing language requested for the purpose described in the petition.***

Cetylpyridinium chloride – Antimicrobial food treatment for use according to FDA limitations.

2. ***a. What requirements and disclosures are necessary for Manufacturers to verify that CPC is produced using sustainable methods and biofuel sourced propylene glycol?***

ASTM methods are currently used to determine the bio-based carbon content in hydrocarbon fuels using gas chromatography, infrared spectroscopy, and accelerator mass spectroscopy.[1,2] The same methods can be applied to determine the quantity of bio-based carbon in CPC and biofuel-sourced propylene glycol used in manufacturing Cecure product.

b. How would a listing be annotated to allow only CPC manufactured by sustainable methods and biofuel sourced propylene glycol?

CPC, the active ingredient of the Cecure® antimicrobial product, is manufactured using a bio-based ethanol source for its feedstock. A letter of guarantee stating the feedstock is from bio-based sources would be obtained from the manufacturers of the CPC ingredient. We would not

require special annotation from the manufacturers of propylene glycol, which is the ancillary substance that acts as a carrying agent for CPC in the Cecure® solution.

3. ***Please verify (and correct, as appropriate) the unit of measurement on Page 7, Section 10b for human acceptable daily intake?***

The units of measure presented on Page 7 are correct. The statement "…the FDA concluded that the no-observable effect level (NOEL) for the dog (the more sensitive species of the two) was 8 mg/kg body weight per day. By applying a 1000-fold safety factor to this value, the FDA determined the acceptable daily intake (ADI) for a 60-kg human as 0.48 mg/p/d." is an excerpt from FDA Code of Federal Register (CFR 173.375).

The calculation used to arrive at the 0.48 mg/p/d value is as follows:

Using the 8 mg/kg body weight from the dog study, the corresponding NOEL for a 60-kg human can be determined as 8 x 60 kg = 480 mg/person. However, in addition, the FDA included a 1000-fold safety factor to this value, hence further reducing the safe intake levels (ADI) value to 0.48 mg/p/d (480 mg/person ÷ 1000 = 0.48 mg/p/d).

4. ***Please correct the reference to the "National Institute of Environmental Health Studies". No such institute exists.***

The correction to "National Institute of Environmental Health Sciences" has been made within the attached revised petition document. The original "studies" reference was copied from the NOP 3011 National List Petition Guidelines document issued in 2016.

* * *

We trust that the information provided will address the subcommittee's needs, and that our petition will be considered complete to support the requested addition of cetylpyridinium chloride to the National List. Should you have any questions, please contact me by email (Beatrice.Maingi@safefoods.net) or by phone (501-534-6833).

Sincerely,

Beatrice Maingi
Senior Manager, Regulatory Affairs & QA/QC Laboratory

Enclosure

References

[1] Haverly, M.R., S.R. Fenwick, F.P.K. Patterson, and D.A.Slade, 2019. Biobased carbon content quantification through AMS radiocarbon analysis of liquid fuels. Fuel 237:1108-1111.
[2] ASTM D6866-20, 2020. Standard Test Methods for Determining the Biobased Content of Solid, Liquid, and Gaseous Samples Using Radiocarbon Analysis, ASTM International, West Conshohocken, PA, www.astm.org

11. Safety information - information about the substance including a Safety Data Sheet (SDS) and a substance report from the National Institute of Environmental Health Sciences. If this information does not exist, the petitioner should state so in the petition.

The current Safety Data Sheet (SDS) is provided as **Attachment 3**. No substance reports for cetylpyridinium chloride were available from the National Institute of Environmental Health Sciences' National Toxicology Program (NTP). As part of FDA's required activities when it reviewed, and subsequently approved, our secondary direct food additive petitions to use CPC as a processing aid onto raw poultry, the FDA published an environmental finding of no significant environmental impact (FONSI) as described in section 10.c.

12. Research information - information about the substance which includes comprehensive substance research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on or removal from the National List. For petitions to include substances onto the National List for organic handling, this information item should include research concerning why the substance should be permitted in the production or handling of an organic product, including the availability of organic alternatives. If research information does not exist for the petitioned substance or for the contrasting position, the petitioner should state so in the petition.

A summary of research is provided in **Attachment 4**.

13. Petition Justification Statement – a statement that provides justification for any of the following actions requested in the petition: *Inclusion of a Synthetic on the National List, § 205.605(b)*

(a) Inclusion of a Synthetic on the National List (7 CFR §§ 205.601, 205.603, 205.605(b))

Recently, USDA's Food Safety and Inspection Service has re-emphasized in its strategic plan its focus on human illness related to *Salmonella* and *Campylobacter*. Modern poultry processing establishments employ a multi-hurdle approach to achieve consistent *Salmonella* and *Campylobacter* control. CPC has been favorably reviewed for safety by the FDA[5] and approved for use in raw poultry as an antimicrobial processing aid. Its conditions of use in poultry processing were subsequently approved by the USDA in FSIS Directive 7120.1, Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products (available at fsis.usda.gov).

The currently approved antimicrobial agents on the National List, although safe and fully consistent with the National Organic Program, nevertheless limit the options that are available to poultry processors. The addition of CPC to the National List would meaningfully expand the options that are available to poultry processors that produce organic poultry. First, CPC is safe and effective as demonstrated by its wide over the counter use, regulatory approval by FDA, and

[5] See: April 2, 2004 Federal Register (69 FR 17297), and November 29, 2007 Federal Register (72 FR 67572)