

**FORMAL RECOMMENDATION BY THE
NATIONAL ORGANIC STANDARDS BOARD (NOSB)
TO THE NATIONAL ORGANIC PROGRAM (NOP)**

Date: 11/05/09

Subject: Cyclohexylamine (CAS # 108-91-8) Sunset Review

Chair: Jeff Moyer

Recommendation

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: X

Guidance Statement:

Other:

Summary Statement of the Recommendation (including Recount of Vote):

Cyclohexylamine, with its annotation, was reviewed for sunset by the NOSB at the November 2009 meeting. The Handling Committee originally recommended that Cyclohexylamine be allowed to sunset off the National List, but based on written comments received after the original recommendation's posting disagreeing with the committee's decision, and verbal public comments received during the meeting also in opposition, the Handling Committee reconsidered its decision and voted to recommend relisting Cyclohexylamine to §205.605(b). Both the original and revised Handling Committee recommendations are attached. The board that originally listed the substance indicated in its discussion that they desired the substance to sunset if no longer required in organic manufacturing facilities. The Handling Committee believed that use of this volatile amine boiler additive was no longer necessary in the organic food processing industry, but public comment indicated otherwise.

The NOSB voted to recommend relisting of Cyclohexylamine (CAS # 108-91-8) for use only as a boiler water additive for packaging sterilization on §205.605(b) with 10 voting yes, 2 no votes, 1 abstention, and 2 absent.

NOSB Vote: **Motion:** Steve DeMuri

Second: Julie Weisman

Board vote: Yes - 10 No- 2 Abstain- 1 Absent - 2

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

Response by the NOP:

National Organic Standards Board
Handling Committee Recommendation for §205.605(b)
Sunset of Cyclohexylamine CAS # 108-91-8

September 1, 2009

I. List:

National Organic Program Subpart G: The National List of Allowed and Prohibited Substances. §205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

(b) Synthetics allowed

II. Committee Summary:

Cyclohexylamine was approved by the NOSB with annotation at the October 2001 NOSB meeting, and added to the National List §205.605(b) effective on September 12, 2006 by Final Rule TM-04-01FR.

Cyclohexylamine is used primarily as a boiler water additive to inhibit boiler and pipe corrosion caused by steam produced from water with problematic mineral content and quality. It is often used in conjunction with other volatile amine containing boiler water additives such as octadecylamine and diethylaminoethanol, sometimes in proprietary blends. It was originally petitioned as one of a group of four boiler, volatile amine containing, chemical additives, diethylaminoethanol, morpholine, octadecylamine, and cyclohexylamine.

A TAP review dated February 15, 2001 (revised) reviewed cyclohexylamine, and found the substance to be toxic to humans through a number of modes, and both the material and its manufacturing process harmful to the environment. It was considered not compatible with organic production or handling practices. Three out of three reviewers recommended it be prohibited from use in organic handling operations, and that it not be listed. There was much discussion by the board regarding the negative results of the TAP versus the potential damage to the organic processing industry if the boiler additive was not allowed. There were board members adamantly opposed to its listing due to its toxic effects on the environment and humans, but some, primarily those with processing backgrounds, who claimed the material was necessary to maintain the condition of boiler and steam delivery systems in organic processing facilities. A compromise position was established through the use of the annotation “for use only as a boiler water additive for packaging sterilization”, since this use was considered to be more incidental in nature and would result in inconsequential amounts of the substance ending up in processed organic products. It was the intent of the board to not allow its use in steam for direct product contact, such as for heating via direct steam injection or sparging, since this would result in more of the compound in the finished organic processed product. A review of the transcripts from the October 2001 NOSB meeting indicated that there was hopeful sentiment among some board members that the industry would implement more organic compatible methods for minimizing boiler steam corrosion, or mitigate the use of the compound during organic production runs, and that future boards would consider sunseting cyclohexylamine off the list when possible. The compound narrowly passed the full board vote with 8 yes votes, 3 no votes, and 3 abstentions (recusals) for conflict of interest reasons. It has come to the attention of the Handling Committee that since the original listing of cyclohexylamine, many organic processors have either replaced cyclohexylamine containing boiler additives with less toxic, non-volatile substances, turn off

the boiler chemical feed prior to and during organic production runs, or they have implemented product contact mitigation procedures, such as a hot water rinse of packaging materials after steam treatment. The committee questions the need for the continued listing of cyclohexylamine in organic handling under 205.605(b).

The NOSB has received 3 public comments in support of the relisting of cyclohexylamine in response to the Federal register notice of the sunset of cyclohexylamine (AMS-TM-07-0136), but none of those comments provided specific reasons for the relisting of the substance, or explained why alternate substances or mitigation procedures could not be implemented. One general public comment was received objecting to the relisting of all substances subject to sunset.

III. Committee Recommendations

The Handling Committee recommends the continued listing of Cyclohexylamine on §205.605(b) for use only as a boiler water additive for packaging sterilization.

Moved: Steve DeMuri

Second: Joe Smillie

Committee Vote: Yes- 0 No- 5 Absent- 1 Abstain- 0 Recuse- 0

National Organic Standards Board
Handling Committee Recommendation for §205.605(b)
Sunset of Cyclohexylamine CAS # 108-91-8

November 4, 2009

I. List:

National Organic Program Subpart G: The National List of Allowed and Prohibited Substances. §205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

(b) Synthetics allowed

II. Committee Summary:

Cyclohexylamine was approved by the NOSB with annotation at the October 2001 NOSB meeting, and added to the National List §205.605(b) effective on September 12, 2006 by Final Rule TM-04-01FR.

Cyclohexylamine is used primarily as a boiler water additive to inhibit boiler and pipe corrosion caused by steam produced from water with problematic mineral content and quality. It is often used in conjunction with other volatile amine containing boiler water additives such as octadecylamine and diethylaminoethanol, sometimes in proprietary blends. It was originally petitioned as one of a group of four boiler, volatile amine containing, chemical additives, diethylaminoethanol, morpholine, octadecylamine, and cyclohexylamine.

A TAP review dated February 15, 2001 (revised) reviewed cyclohexylamine, and found the substance to be toxic to humans through a number of modes, and both the material and its manufacturing process harmful to the environment. It was considered not compatible with organic production or handling practices. Three out of three reviewers recommended it be prohibited from use in organic handling operations, and that it not be listed. There was much discussion by the board regarding the negative results of the TAP versus the potential damage to the organic processing industry if the boiler additive was not allowed. There were board members adamantly opposed to its listing due to its toxic effects on the environment and humans, but some, primarily those with processing backgrounds, who claimed the material was necessary to maintain the condition of boiler and steam delivery systems in organic processing facilities. A compromise position was established through the use of the annotation “for use only as a boiler water additive for packaging sterilization”, since this use was considered to be more incidental in nature and would result in inconsequential amounts of the substance ending up in processed organic products. It was the intent of the board to not allow its use in steam for direct product contact, such as for heating via direct steam injection or sparging, since this would result in more of the compound in the finished organic processed product. A review of the transcripts from the October 2001 NOSB meeting indicated that there was hopeful sentiment among some board members that the industry would implement more organic compatible methods for minimizing boiler steam corrosion, or mitigate the use of the compound during organic production runs, and that future boards would consider sunseting cyclohexylamine off the list when possible. The compound narrowly passed the full board vote with 8 yes votes, 3 no votes, and 3 abstentions (recusals) for conflict of interest reasons. It had come to the attention of the Handling Committee that since the original listing of cyclohexylamine, some organic processors had either replaced cyclohexylamine containing boiler additives with less toxic, non-volatile substances, were turning off the boiler chemical feed prior to and during organic production runs, or they had

implemented product contact mitigation procedures, such as a hot water rinse of packaging materials after steam treatment.

Based on the knowledge that at least some organic processors had found alternatives to using cyclohexylamine containing additives, the committee questioned the need for the continued listing of cyclohexylamine in organic handling under 205.605(b), and rejected relisting by a vote of 5 against, 0 in favor, 1 absent, 0 abstaining, and 0 recusals.

Since the original recommendation dated September 1, 2009 was posted, the NOSB has received 9 comments related to the Handling Committees original recommendation. Comments were received from organic manufacturers, certifiers, trade associations, and consultants to the organic industry. All comments disagree with the September 1, 2009 recommendation, stating that this substance is still a necessary additive to boiler feed water of some organic operations to minimize corrosion of boilers and steam lines, especially for manufacturers who run predominantly organic products, and whose facilities are located in areas where water quality is exceptionally poor. There were no comments posted that agreed with the Handling Committees original decision. Although the Handling Committee had evidence that some organic processors had taken steps to eliminate cyclohexylamine from their operations boiler systems, it was impossible for members to survey every manufacturer in every situation to determine if this substance was still necessary for some. The public comment process worked as it was designed, providing the committee with timely information regarding the necessity for continued use of this material.

III. Committee Recommendations

The Handling Committee recommends the continued listing of Cyclohexylamine on §205.605(b) for use only as a boiler water additive for packaging sterilization.

Moved: Steve DeMuri

Second: Julie Weisman

Committee Vote: Yes- 5 No- 0 Absent- 1 Abstain- 0 Recuse- 0