

Formal Recommendation
From: National Organic Standards Board (NOSB)
To: the National Organic Program (NOP)

Date: October 16, 2012

Subject: Petition to add Rotenone to the National List §205.602 as a Prohibited natural

Chair: Barry Flamm

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: ☒ Petition Passed

Guidance Statement: ☐

Other: ☐

Statement of Recommendation: (Motion # 1)

Passed

Motion to classify Rotenone as a Natural Substance

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

Rotenone is derived from the root of a plant and has long been determined to be non-synthetic. For the purposes of 205.602 it is being classified as "Natural".

Committee Vote:

Moved: Jay Feldman

Seconded: Zea Sonnabend

Yes: 15

No: 0

Abstain: 0

Absent: 0

Recuse: 0

Statement of Recommendation: (Motion # 2)

Passed

Motion to add Rotenone to the National List §205.602 as a Prohibited Natural Substance, effective January 1, 2016.

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

Adverse health effects from Rotenone have been well documented in the time since the NOSB reviewed botanicals in 1994. Although no longer offered for sale in the USA as a pesticide, rotenone is still in use in other countries. While there are compelling reasons to prohibit rotenone, the NOSB is recommending a several year period until this takes effect so alternatives can be researched and registered.

Committee Vote:

Moved: Jay Feldman

Seconded: Zea Sonnabend

Yes: 15

No: 0

Abstain: 0

Absent: 0

Recuse: 0

**National Organic Standards Board
Crops Subcommittee
Proposal to Add Rotenone to National List 205.602
as a Prohibited Natural Substance**

August 7, 2012

Introduction

The NOSB Crops Subcommittee acknowledges the intent and validity of the portion of the Organic Foods Production Act (OFPA) that calls for a Special Review of Botanical Pesticides prior to the establishment of the National List [2119(k)(4)]. We wish at this time to re-review the botanical pesticide Rotenone and add it to the National List section 205.602 as a Prohibited Natural substance.

Background

The NOSB conducted its Special Review of Botanical Pesticides during their meeting that ran from October 10 to 14, 1994. As stipulated in OFPA (below) it was before the National List was established. The Rotenone portion of the minutes is quoted below (from lines 851 to 874 of the official minutes). The references used in the special review in 1994 are cited at the end of this recommendation.

Brown reported on the low LD50 of rotenone when tested on rats, its toxicity to fish and birds and on no records of fatalities or poisonings in humans. Kinsman reported that it is used widely for lice, mange and mites in conventional production. John clarified that the Board is reviewing the natural ground root and not synthetic preparations or the synthetic extracted form of rotenone. Theuer offered that the half-life of rotenone is long and the required 24 hour withdrawal time may not be long enough and that there are many alternatives. Brian Baker stated that rotenone is restricted in its applications by private certifiers and that the California Senate repealed its registration because of incomplete information and not because of health reasons. Merrill Clark requested that the Board take actions to move production away from the use of all botanicals by considering a phase out of all botanicals. David Haehn spoke to its usefulness in livestock and aquaculture. Brian Baker informed the members that rotenone has been debated within the organic community for years and despite its shortcomings a data gaps, there are no alternatives because of the natural/synthetic rule.

Quinn moved and Kinsman seconded to place rotenone on the prohibited natural list.
VOTE Yes - 1. Opposed - 8. Abstain - 4. Failed. Rotenone is kept off the list of prohibited natural substances."

The NOSB and the Secretary have the clear authority to prohibit specific natural substances (see below rule sections). Since 1994 a large amount of information has emerged from research that showed harmful effects of rotenone on the human system, leading to Parkinsons' disease and other health problems.

Rotenone Regulatory History

In March and April 2006, registrants of rotenone in the U.S. requested voluntarily cancellation from the U.S. Environmental Protection Agency (EPA) of all livestock,

residential and home owner uses, domestic pet uses, and all other uses except for piscicide uses. A data call-in was issued in 2004 requiring a sub-chronic (28-day) inhalation neurotoxicity study to further investigate the results of independent studies in animals that led to Parkinson's Disease-like symptoms. At the time the study was required, rotenone had registered uses for dust products in agricultural and residential settings which were of particular concern for inhalation exposure. However, when all agricultural and residential uses, and all food uses were voluntarily cancelled in 2006, this requirement was waived. In July 2006, EPA issued its "Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED)" in which the agency indicated its intent to revoke the three tolerance exemptions for rotenone.

The Registration Eligibility Decision (RED) was completed in 2007. The RED approved piscicidal uses granting that additional personal protective equipment (PPE) including respiratory protection will be required for all remaining uses. However, EPA states that it "cannot quantitatively assess a potentially critical effect (neurotoxicity) at doses to which rotenone users could be exposed; therefore, an additional 10x database uncertainty factor has been applied."

Remaining rotenone products are classified as Restricted Use Pesticides (RUP) due to acute inhalation, acute oral, and aquatic toxicity. According to EPA, "rotenone is applied directly to water to manage fish populations in lakes, ponds, reservoirs, rivers, streams, and in aquaculture. The chemical can be applied to an entire water body to achieve a "complete kill" or to a portion of a water body to achieve a "partial kill." Complete kills are used to eliminate all fish in the treatment area; partial kills are used to reduce or sample fish populations in the treatment area." (Source: USEPA. 2007. Reregistration Eligibility Decision (RED) Document. Office of Pesticide Programs. Washington DC. http://www.epa.gov/oppsrrd1/reregistration/REDs/rotenone_red.pdf)

Updating the National List

While rotenone has been voluntarily cancelled by the manufacturer and its agricultural use is phasing out in the United States, a search of the internet in 2012 shows that rotenone products are still available in other countries. Because of this, and because certifiers, farmers other people involved with organic production are still getting questions from the public about rotenone, board action is needed to clarify the situation by listing rotenone as a prohibited nonsynthetic.

Therefore, the NOSB has re-reviewed this particular botanical pesticide and recommends to the Secretary that it be placed on §205.602 as a prohibited natural substance for organic agriculture. The subsequent checklist and list of references documents the basis for the recommendation.

Relevant areas in the Rule

OFPA

Sec 2118 National List (c) Guidelines for Prohibitions or Exemptions –

(2) Prohibition on the use of Specific Natural Substances

(A) the Secretary determines, in consultation with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency, that the use of such substances

(i) would be harmful to human health or the environment;

Sec 2118 National List (e) Sunset Provision –

No exemptions or prohibition contained in the National List shall be valid unless the National Organic Standards Board has reviewed such exemption or prohibition as provided in this section within 5 years of such exemption or prohibition being adopted or reviewed and the Secretary has renewed such exemption or prohibition.

Sec 2119 National Organic Standards Board (k) Responsibilities of the Board –

(4) Special Review of Botanical Pesticides. The Board shall, prior to the establishment of the National List, review all botanical pesticides used in agricultural production and consider whether any such botanical pesticides should be included in the list of prohibited natural substances."

(l) Requirements –the Board shall –

(1) review available information from the Environmental Protection Agency....., concerning the potential for adverse human and environmental effects of substances considered for inclusion in the proposed National List.

Discussion

The Crops Subcommittee believes that the data indicating harm to human health precipitated the removal of rotenone from the market. Therefore only the checklist for Category 1 is presented here based on the NOSB's own literature review conducted in 2012. The negative results in category 1 are sufficient for prohibition so that the other categories are not evaluated at this time.

Evaluation Criteria:

(Applicability noted for each category; Documentation attached)
(see "B" below)

Criteria Satisfied?

- | | | | |
|---|------------------------------|--|---|
| 1. Impact on Humans and Environment | ☐ Yes | ☒ No | ☐ N/A |
| 2. Essential & Availability Criteria | ☐ Yes | ☒ No | ☐ N/A |
| 3. Compatibility & Consistency | ☐ Yes | ☒ No | ☐ N/A |
| 4. Commercial Supply is Fragile or Potentially Unavailable
as Organic (only for § 205.606) | ☐ Yes | ☐ No | ☒ N/A |

Substance Fails Criteria Category: [1,2,3]

Subcommittee Comments:

Adverse environmental and health impacts, lack of essentiality, and incompatibility with organic principles, as supported by the TR and checklist.

Proposed Annotation (if any):

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Recommended Subcommittee Action & Vote, including classification recommendation
(state actual motion):

Classification Motion:

Crops:Rotenone

Rotenone is a natural substance.

Motion by: Harold Austin Second: Barry Flamm
Yes 6 No 0 Abstain 0 Recuse 0 Absent 2

Listing Motion:

To add Rotenone to the National List 205.602 as a Prohibited Natural Substance.

Motion By: Harold Austin Second: Barry Flamm
Yes 6 No 0 Abstain 0 Recuse 0 Absent 2

Crops	☒	Agricultural	☐	Allowed¹	☐
Livestock	☐	Non-synthetic	☒	Prohibited²	☒
Handling	☐	Synthetic	☐	Rejected³	☐
No restriction	☐	Commercial unavailable as organic	☐	Deferred⁴	☐

¹Substance voted to be added as “allowed” on National List to § 205. 601(h) with Annotation (if any):

²Substance to be added as “prohibited” on National List to § 205 with Annotation (if any):

Describe why a prohibited substance:

³Substance was rejected by vote for amending National List to § 205. Describe why material was rejected:

⁴Substance was recommended to be deferred because

If follow-up needed, who will follow up:

Approved by Subcommittee Chair to Transmit to NOSB

Jay Feldman, Subcommittee Chair

August 7, 2012

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment?

Substance: Rotenone

Question	Yes	No	N/A¹	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]	X			improper use in agriculture can cause the death of fish in nearby water.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		

Crops:Rotenone

3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]			X	
4. Does the substance contain List 1, 2 or 3 inert? [§6517 c (1)(B)(ii); 205.601(m)2]			X	no registered products in the U.S.
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]			X	
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]	X			see fish references and comment.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			X	unknown for livestock or crops, but effects on humans may be transferrable to livestock.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]	X			see #10 below
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]	X			Rotenone inhibits mitochondrial function and has been highly correlated with Parkinsons disease (Tanner, 2011). Tanner's study is highly important because it was based on a human population from the Farming and Movement Evaluation study (FAME), nested in the Agricultural Health Study, of 84,740 private pesticide applicators (mostly farmers) (Alavanja, 1996; Blair, 2002) Rotenone has also been linked to other central nervous system pathology (Greene, 2009).
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]			X	
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]			X	
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]			X	

2012 References Cited:

Crops:Rotenone

Alavanja MC, Sandler DP, McMaster SB, Zahm SH, McDonnell CJ, Lynch CF, et al. 1996. The Agricultural Health Study. *Environ Health Perspect* 104:362–369

Arizona Game and Fish Department 2010. Rotenone - Frequently Asked Questions. http://www.azgfd.gov/h_f/documents/ROTENONE%20FAQ%20committee%20final%20report%20section%201-6-12.pdf

Beyond Pesticides 1987. Safety Source for Pest Management - Beyond Pesticides Least Toxic Service Directory – Rotenone. <http://www.beyondpesticides.org/infoservices/pesticidefactsheets/toxic/ROTENONE.HTM>

Blair A, Tarone R, Sandler D, Lynch CF, Rowland A, Wintersteen W, et al. 2002. Reliability of reporting on life- style and agricultural factors by a sample of participants in the Agricultural Health Study from Iowa. *Epidemiology* 13(1):94–99.

Center for Disease Control and Prevention 2010 - NIOSH Pocket Guide to Chemical Hazards Rotenone. <http://www.cdc.gov/niosh/npg/npgd0548.html>

Chameides, Bill 2011. The Pesticide Rotenone: On the Shelf Instead of Shelved. <http://www.nicholas.duke.edu/thegreengrok/rotenone>

Greene JG, Noorian AR, Srinivasan S. 2009. Delayed gastric emptying and enteric nervous system dysfunction in the rotenone model of Parkinson's disease. *Exp Neurol* 218(1):154–161.

NOSB (National Organic Standards Board) 1994. Minutes from the NOSB meeting in October 1994 in Rohnert Park, CA. Available at: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5057495>

Rotenone Fact Sheet (MSDS) 2008. <http://datasheets.scbt.com/sc-203242.pdf>

Tamm, Dr. Lucius, et. al. 2000. *Use of Rotenone in Organic Agriculture: FiBL Statement - November 2000* Research Institut of Organic Agriculture, Ackerstrasse, CH-5070 Frick. <http://www.pmac.net/rotenone.pdf>

Tanner CM, Kamel F, Ross GW, Hoppin JA, Goldman SM, et al. 2011. Rotenone, Paraquat, and Parkinson's Disease. *Environ Health Perspect* 119(6): doi:10.1289/ehp.1002839

US Environmental Protection Agency (EPA) 2010. EPA-HQ-OPP-2005-0494-0066 Rotenone; Notice of Receipt of Requests to Voluntarily Cancel Pesticide Registrations. *Federal Register* Vol. 75, No. 144, July 28, 2010.

US Environmental Protection Agency (EPA) 2007. EPA 738-R-07-005 Reregistration Eligibility Decision for Rotenone. http://www.epa.gov/oppsrrd1/REDs/rotenone_red.pdf

1994 References Used in NOSB Review (Selected)

EXTONET Oregon State University. 1989. Rotenone

Newsome, Wm.H, and J.B. Shields 1980. Residues of Rotenone and Rotenolone on Lettuce and Tomato Fruit after Treatment in the Field with Rotenone Formulations. American Chemical Society 0021-8561/80/1428-0722

Worthing, Charles, and R. Hance 1968. The Pesticide Manual, 9th ed. British Crop Protection Council.

NOSB (National Organic Standards Board) 1994. Papers used in the Special Review of Botanicals at the NOSB meeting in October 1994 in Rohnert Park, CA. Beyond citations here there was a TAP review from James Johnson, letter from Bart Hall-Beyer of ATTRA, an Agricola Search of citations, MSDS, and several Rotenone Fact Sheets (not well attributed).