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POLICY & ACTION FROM CONSUMER REPORTS

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Comments of Consumers Union to the U.S. Department of Agriculture on the National Organic Program: National List of Allowed and Prohibited Substances Docket No. AMS-NOP-14-0079-0001

Consumers Union, the advocacy division of Consumer Reports,[1] welcomes the opportunity to comment on the proposed rule by the U.S. Department of Agriculture (USDA) to amend the National List of Allowed and Prohibited Substances by implementing 29 National Organic Standards Board (NOSB) recommendations.

Summary

We support the proposal to prohibit rotenone in organic crop production by adding it to §205.602 of the National List (nonsynthetic substances prohibited for use in organic crop production). Rotenone is a botanical pesticide that has been linked to Parkinson's disease in farmers and farmworkers.[2]

The revised annotation for flavors on §205.605(a) of the National List, while not going as far as we think it should go, is an improvement. As long as non-organic flavors are on the National List as allowed substances, we support the requirement to use organic versions when they are commercially available. We therefore support the proposal to amend the annotation for flavors.

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[1] Consumer Reports is an independent, nonprofit member organization that works side by side with consumers for truth, transparency, and fairness in the marketplace. We use our rigorous research, consumer insights, journalism, and policy expertise to inform purchase decisions, improve the products and services that businesses deliver, and drive regulatory and fair competitive practices.

[2] Tanner CM, Kamel F et al. (2011) Rotenone, Paraquat and Parkinson's Disease. *Environmental Health Perspectives* 119(6): 866-872.

We urge the USDA to implement the 2016 NOSB recommendation to remove carrageenan from §205.605(a) of the National List, thereby prohibiting it as an ingredient in organic foods.

Finally, we think too much time has passed since the NOSB's recommendations to allow calcium borogluconate (2000), activated charcoal (2002), calcium propionate (2002), kaolin pectin (2002), mineral oil (2002), and propylene glycol (2002). Since these materials have not been allowed in organic production due to lack of action, they may not be as essential today as they were when the NOSB made their recommendations in 2000 and 2002. We therefore urge the USDA to request that the NOSB reevaluate these materials.

Rotenone

We strongly support the proposal to add rotenone to §205.602 of the National List, thereby prohibit its use in organic crop production. Its use in organic crop production should be prohibited because it poses risks to human health, primarily to farmers and farmworkers.

Rotenone is a natural (nonsynthetic) substance, extracted from a plant and considered a botanical pesticide. While it is unlikely to pose a risk to consumers from residues on produce, it poses a risk to farmers and farmworkers. In experimental animal models, rotenone has been shown to inhibit mitochondrial complex I, induce loss of nigral dopaminergic neurons, and lead to behavioral changes associated with human Parkinson's disease.[3] A 2011 case-control study found that the use of rotenone by pesticide applicators and farmers is associated with the development of Parkinson's disease.[4]

While rotenone is no longer offered for sale in the United States, it is still in use in other countries. Since rotenone is a natural substance, it is not automatically prohibited for use on organic farms. Until the USDA adds it to the National List as a prohibited substance, crops sprayed with it can be sold as "organic." This is not what consumers expect when they buy foods labeled "organic." According to a Consumer Reports survey conducted in 2015, the vast majority of consumers (89%) think that the organic label should mean that no pesticides were used.[5]

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[3] Henchcliffe C and Beal M. (2008). Mitochondrial biology and oxidative stress in Parkinson disease pathogenesis. *Nature Clinical Practice. Neurology, 4*(11), 600-609.

[4] Tanner CM, Kamel F et al. (2011) Rotenone, Paraquat and Parkinson's Disease. *Environmental Health Perspectives* 119(6): 866-872.

[5] Consumer Reports National Research Center, *Natural Food Labels Survey: 2015 Nationally-Representative Phone Survey,* Survey Research Report (Jan. 29, 2016) (online at http://greenerchoices.org/wp-content/uploads/2016/08/CR_2015_Natural_Food_Labels_Survey.pdf)

Public comments submitted to the NOSB in 2012 reveal that rotenone is still in use to grow crops like bananas on certified organic farms abroad.[6] It appears to be used as well in the production of imported olives[7] and tea.[8]

Both the NOSB's crops subcommittee and the full board determined that rotenone meets all criteria under the Organic Foods Production Act of 1990 (OFPA) for prohibiting the use of a natural substance in organic farming.[9] The NOSB noted that rotenone has adverse environmental and health impacts, lacks essentiality, and is incompatible with organic principles. For these reasons, the NOSB voted unanimously in 2012 to recommend to the Secretary of Agriculture that rotenone be added to the National List §205.602 as a prohibited natural substance in organic crop production.

We strongly support the proposed rule to follow through on this recommendation and prohibit rotenone in organic production.

Natural Flavors

We support the proposal to revise the annotation for flavors in §205.605(a) of the National List. The annotation would require the use of organic flavors when they are commercially available. Organic ingredients should be used in certified organic foods.

Ideally, processed foods with the organic label would contain only certified organic ingredients, and the food's flavor would be entirely the result of flavors occurring naturally in these ingredients rather than from adding non-organic flavor substances. In fact, §205.600(b)(4) of the federal organic regulations states that substances should not be added to the National List if their primary use is to recreate or improve flavors. Recreating or improving flavors seems to be the only purpose of the flavors that are on the National List.

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[6] According to our analysis of the USDA Pesticide Data Program 2010-2015 data, there are no residues of rotenone detected on fruits and vegetables. Bananas were tested in 2012, 2013 and 2014.

[7] Simeone V, Baser N et al. (2009) Residues of rotenone, azadirachtin, pyrethrins, and copper used to control Bactrocera oleae (Gmel.) in organic olives and oil. *Food Additives and Contaminants* 26 (04): 475-481.

[8] Han B, Dong W et al. (2004) Present situation of pesticide residues and biological suppression of pests and diseases in Chinese tea gardens. *International Journal of Tea Science* 3. Available online: https://repository.up.ac.za/bitstream/handle/2263/8412/Han_2004.pdf?sequence=1

[9] OFPA states, "the National List may prohibit the use of specific natural substances in an organic farming or handling operation that are otherwise allowed under this title only if—

> (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—
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> (i) would be harmful to human health or the environment; and
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> (ii) is inconsistent with organic farming or handling, and the purposes of this title; and
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> (B) the specific prohibition is developed using the procedures specified in subsection (d).

Subsection (d) lays out the procedure for establishing the National List:

> The National List established by the Secretary shall be based upon a proposed national list or proposed amendments to the National List developed by the National Organic Standards Board."

While we continue to advocate for the removal of flavors from §205.605(a) of the National List, we support this revised annotation as recommended by the NOSB at its October 2015 meeting. The revised annotation is an improvement, since it would require the use of organic flavors when they are commercially available. The annotation maintains the prohibition on the use of synthetic sources, synthetic solvents and carrier systems, and artificial preservatives in flavors added to foods labeled "organic."

This is an important annotation, since the vast majority of consumers expect organic foods to be free from these materials. According to a Consumer Reports survey conducted in 2015, 86% of consumers think that the organic label on packaged foods should mean that no artificial ingredients or colors were used and 86% of consumers think that no artificial materials or chemicals were used during processing.[10]

Carrageenan

This proposed rule implements 29 NOSB recommendations on National List materials, but leaves out a critical recommendation: to remove carrageenan from §205.605(a) of the National List. The NOSB recommended removal of carrageenan from the National List at its November 2016 meeting.

Carrageenan is a non-organically produced, nonsynthetic ingredient derived from seaweed. It has no nutritional value; rather, food processors add carrageenan as a stabilizer and to change the texture, structure and physical appearance of foods, like dairy foods, plant-based beverages, and lunch meats.

The Organic Foods Production Act of 1990 (OFPA) requires that prohibited materials may be added to the National List for a five-year period only if the use of such substances would not be harmful to human health or the environment, and only if it is considered essential because no alternatives exist.

We are concerned with the impact of carrageenan on human health. Research points to undegraded carrageenan (the type used in foods) causing inflammation.[11] Laboratory

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[10] Consumer Reports National Research Center, *Natural Food Labels Survey: 2015 Nationally-Representative Phone Survey,* Survey Research Report (Jan. 29, 2016) (online at http://greenerchoices.org/wp-content/uploads/2016/08/CR_2015_Natural_Food_Labels_Survey.pdf)

[11] Borthakur A, Bhattacharyya S, et al. (2007) Carrageenan induces interleukin-8 production through distinct Bcl10 pathway in normal human colonic epithelial cells. *American Journal of Physiology, Gastrointestinal and Liver Physiology* 292(3): G829-38.

Bhattacharyya, S., Dudeja, P.K. et al. (2008) Carrageenan-induced NFkappaB activation depends on distinct pathways mediated by reactive oxygen species and Hsp27 or by Bcl10. *Biochimica and Biophysica Acta* 1780(7-8): 973-82.

Bhattacharyya S, Borthakur A et al. (2010) B-call CLL/lymphoma 10 (BCL10) is required for NF-kappaB production by both canonical and noncanonical pathways and for NF-kappaB-inducing kinase (NIK) phosphorylation. *Journal of Biological Chemistry* 285: 522-30.

research in animals has shown ulcerative colitis-like disease and intestinal lesions and ulcerations in some animals.[12] Additional studies in animals have shown carrageenan may act as a promoter of colon tumors.[13]

Research, including studies sponsored by the trade group for carrageenan manufacturers, suggests that food-grade carrageenan contains degraded carrageenan.[14] Degraded carrageenan is listed as possibly carcinogenic to humans (group 2B) by the World Health Organization's International Agency for Research on Cancer (IARC).[15] More research is necessary to determine the extent of degraded carrageenan in the food supply and its effect on human health.

Recent research suggests that carrageenan may also contribute to insulin resistance and to the development of Type 2 diabetes.[16] Additional research on this topic is currently

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Borthakur A, Bhattacharyya S et al. (2012) Prolongation of carrageenan-induced inflammation in human colonic epithelial cells by activation of an NK-kappaB-BCL10 loop. *Biochimica and Biophysica Acta* 1822(8): 1300-7.

[12] Watt J and Marcus R. (1969) Ulcerative colitis in the guinea-pig caused by seaweed extract. *Journal of Pharmacy and Pharmacology* 21: 187S-188S.

Grasso P, Sharratt M et al. (1973) Studies on carrageenan and large-bowel ulceration in mammals. *Food and Cosmetics Toxicology* 11:555-564.

Engster M and Abraham R. (1976) Cecal response to different molecular weights and types of carrageenan in the guinea pig. *Toxicology and Applied Pharmacology* 38: 265-282.

Corpet DE, Tache S et al (1997) Carrageenan given as a jelly does not initiate, but promotes the growth of aberrant crypt foci in the rat colon. *Cancer Letters* 114:53-55.

[13] Watanabe K, Reddy BS et al. (1978) Effect of dietary undegraded carrageenan on colon carcinogenesis in F344 rats treated with azoxymethane or methylnitrosourea. *Cancer Research* 38:4427-4430.

Arakawe S, Okumua M et al (1986) Enhancing effect of carrageenan on the induction of rat colonic tumors by 1,2-dimethylhydrazine and its relation to B-glucuronidase activities in feces and other tissues. *Journal of Nutritional Science and Vitaminology* 32:481-485.

[14] Marinalg International, "Status Report on the work of Marinalg International to measure the molecular weight distribution of carrageenan and PES in order to meet the EU specification: less than 5% below 50,000 daltons."

Capron I, Yvon M and Muller G (1996) In-vitro gastric stability of carrageenan. Food Hydrocolloids 10(2): 239-244

Ekström LG (1985) Molecular-weight-distribution and the behaviour of kappa-carrageenan on hydrolysis. Part II. Carbohydrate Research 135: 283-289

Ekström L.G. and Kuivinen J (1983) Molecular weight distribution and hydrolysis behaviour of carrageenans. Carbohydrate Research 116: 89-94

[15] International Agency for Research on Cancer (IARC), Agents Classified by the IARC Monographs, Volumes 1-110. Available online at http://monographs.iarc.fr/ENG/Classification/ClassificationsGroupOrder.pdf

[16] Bhattarachyya S, O'Sullivan I et al. (2012) Exposure to the common food additive carrageenan leads to glucose intolerance, insulin resistance and inhibition of insulin signalling in HepG2 cells and C57BL/6J mice. *Diabetologia* 55(1): 194-203.

Bhattacharyya S, Feferman L et al. (2015) Exposure to Common Food Additive Carrageenan Alone Leads to Fasting Hyperglycemia and in Combination with High Fat Diet Exacerbates Glucose Intolerance and Hyperlipidemia without Effect on Weight. *Journal of Diabetes Research*. http://dx.doi.org/10.1155/2015/513429

underway by two groups of researchers, one at the University of Illinois at Chicago and the other at the University of Tuebingen in Germany.[17]

Carrageenan also fails the essentiality criterion. Given consumer demand for organic foods without potentially harmful ingredients, many companies have responded by eliminating carrageenan from their product formulations, demonstrating that alternatives exist and carrageenan is not essential. Ultimately, the main reason for the NOSB's decision to recommend removing carrageenan from the National List was that it is no longer considered essential.

We strongly urge the USDA to implement this NOSB recommendation from November 2016 to remove carrageenan from the National List.

Substances recommended in 2000 and 2002

Too much time has passed since the NOSB recommended adding the following substances to the National List: calcium borogluconate (2000), activated charcoal (2002), calcium propionate (2002), kaolin pectin (2002), mineral oil (2002), and propylene glycol (2002). These recommendations were based on information available at the time, including information about available alternatives. Much has changed since 2002, which was the year the organic regulations went into effect. To determine whether these substances would still be considered essential today, we urge the USDA to send these recommendations back to the NOSB and request a new evaluation and recommendation.

Thank you for considering our comments.

Respectfully submitted,

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Consumers Union

[17] Available online at http://www.diabetes.org/in-my-community/local-offices/chicago-illinois/research.html and https://clinicaltrials.gov/ct2/show/NCT02629705