



# CENTER FOR FOOD SAFETY

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**RE: Docket No.: AMS-NOP-11-0003; NOP-10-13PR**

The Center for Food Safety (CFS) is a public interest, non-profit, membership organization that works to protect human health and the environment by curbing the proliferation of harmful food production technologies and by promoting organic and sustainable agriculture. Our list of *True Food* members has rapidly grown to include over three hundred thousand people across the country that support organic food and farming, grow organic food, and regularly purchase organic products.

As a public interest organization intent on upholding the integrity of the Organic Foods Production Act (OFPA), CFS hereby submits the following comments outlining our objections to the draft National Organic Program (NOP) Sunset Review Rules and to the improper procedures used by USDA in drafting the Rule. USDA's decision to ignore three National Organic Standards Board (NOSB) recommendations on carrageenan, cellulose, and List 3 inerts not only undermines the NOSB's authority over the National List, but it also contravenes the spirit and intent of OFPA. CFS urges the USDA to withdraw its May 3, 2013 Proposed Rule and to reissue a corrected rule in strict accordance with NOSB recommendations and OFPA requirements, and with an opportunity for public comments.

## PROPOSED RULE VIOLATES OFPA

*NOSB Has Recommendation Authority over the National List*

*"Most consumers believe that absolutely no synthetic substances are used in organic production. For the most part, they are correct and this is the basic tenet of [OFPA]."<sup>1</sup> There are a few limited exceptions to the no-synthetic rule "and the National List is designed to handle these exceptions."<sup>2</sup>*

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<sup>1</sup> S. Rep. Np. 101-357, at 300.

<sup>2</sup> S. Rep. Np. 101-357, at 300.

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OFPA's legislative history illustrates a clear intent to maintain the "integrity" of the organic standards and to ensure that the standards "do not get watered down to satisfy the least common denominator."<sup>3</sup> Keeping this in mind, Congress created a system whereby any and all exceptions to the organic standards must be vetted by the NOSB. That way, as OFPA requires, USDA cannot shoehorn synthetics into organic production systems and in the absence of a robust public participation process. OFPA's Congressional hearings demonstrated notable public opposition to providing the USDA Secretary the authority to add synthetics to the National List of Allowed and Prohibited Substances (National List or NL). During one Subcommittee meeting in particular, *every* agricultural, industry, environmental, and consumer advocate present unanimously opposed allowing the USDA Secretary the ability to add synthetics to the National List without consulting the NOSB.<sup>4</sup> This surprising unanimity among panelists, who were often otherwise advocating very different policies, indicated universal support to grant the NOSB exclusive authority.

Clearly that Subcommittee Panel showed remarkable foresight. Nearly 24 years later, the Agricultural Marketing Service (AMS) is attempting to usurp the NOSB's authority to create restrictive annotations for materials being considered under Sunset—a procedure geared towards limiting and phasing-out materials on the National List. Rejecting a Board-proposed restriction, such as the one recommended for infant formula and carrageenan, constitutes an additional use and a clear violation of OFPA. The USDA's decision to override the NOSB was exactly what the organic sector feared and expressed during those early OFPA hearings.

Because the NOSB has always maintained legal control over the National List,<sup>5</sup> decisions pertaining to the addition or removal of materials from the National List have remained under its purview, in strict accordance with OFPA. As such, the NOSB serves as the final arbiter of all matters related to the National List and it maintains the legal authority to do so.

On May 3, 2013, the AMS published a proposed rule in the Federal Register that would override: (i) an NOSB finding of potential hazard under the Organic Foods Production Act (OFPA) and (ii) a Board policy to recommend restrictions (or annotations) during the Sunset review process. As illustrated below, this proposed rule does not follow the process for determining exemptions set forth in OFPA and it runs contrary to the legislative intent of the Act. Given the NOSB's undisputed legal authority over the National List, CFS finds it highly irregular that the May 3, 2013 Proposed Rule would completely override three NOSB recommendations on carrageenan, cellulose, and List 3 inerts. This contravenes the letter and intent of the statute and, as such, the draft rule must be revoked.

OFPA's longstanding National List procedures grant NOSB—not NOP—recommendation authority over substances added or removed from the NL.<sup>6</sup> This role is clearly acknowledged by the NOP on

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<sup>3</sup> Preparation for the 1990 Farm Bill: Hearing Before the S. Commee. On Agric., Nutrition, and Forestry, 101<sup>st</sup> Cong. 37 344 (1989) (statement of Enid Wonnacott).

<sup>4</sup> *Id.* at 373-76.

<sup>5</sup> § 205.600--§ 205.607

<sup>6</sup> 7 U.S.C. § 6518(k); "The national list *shall* be based on a proposed national list or proposed amendments to the National List developed by the [NOSB]." 7 U.S.C. § 6517(d). "Shall means shall. The Supreme Court and this circuit have made clear that when a statute uses the word 'shall,' Congress has imposed a mandatory duty upon the subject of the command." *Forest Guardians v. Babbitt*, 174 F.3d. 1178, 1182-84, 1190-91 (10th Cir. 1999).

the front page of its website: “the Organic Foods Production Act grants the NOSB sole authority to recommend adding materials to or removing materials from the National List.”<sup>7</sup> Therefore, if the NOSB proposes that a substance remain on the NL (with annotations) then that annotated substance is what the Board intends to be on the list, and not the substance minus the annotation. This authority is made clear in OFPA as well, which grants unlimited authority to NOSB to amend the list, necessarily restricting the Secretary’s role: “[t]he Secretary may not include exemptions for the use of specific synthetic substances in the National List *other than exemptions contained in the Proposed National List or Proposed Amendments to the National List*” (emphases added).<sup>8</sup>

*NOSB Sunset Review Policy Creates a Narrow Exception of Allowing the Secondary Backup Recommendation to Take Effect Only When Rulemaking Extends Beyond Sunset*

The Sunset review process has been the subject of ongoing discussions at biannual NOSB meetings, particularly with respect to questions about how to increasingly restrict the use of certain materials as new information becomes available related to health hazards, environmental impacts, and commercially available alternatives for existing materials on the NL.<sup>9</sup> The NOP understands its role this way: “[O]ur responsibility is to take your [NOSB] recommendation and put it into rulemaking, so that’s our job and we’ll handle it... [I]f you’re clear on your intent, of what you want to do with the annotation, we can implement that.”<sup>10</sup>

During NOSB discussions about the need to amend its Sunset policy, the NOP expressed the need to create a safety net for organic food producers so that commerce is not adversely impacted or interrupted in cases where draft rules may not be able to be finalized in a timely manner. To address both concerns, the NOSB struck an agreement with the NOP clarifying the Sunset process, which is acknowledged in Deputy Secretary Miles McEvoy’s public memo, issued on 27 September 2012. All parties agreed that the NOSB would pass two motions for those materials that it recommends to remain on the National List with a more restricted use. The primary recommendation is intended to provide new restrictions in the form of annotations, given changes in a substance’s use patterns and scientific understanding. The alternative (second) recommendation is intended to allow the continuation of the existing listing, pending the completion of the rulemaking process. The purpose of this second motion is to serve as a backup—*only* if the NOP is unable to amend the annotation within the legally mandated timeframe of the Sunset process. In significant part the Memo reads: “For each of these three substances, the NOSB also recommended to renew the existing listing [the backup motion]. The backup motions are passed, as per the NOP’s request, to allow for a continuation of the current use of a substance *if it is not possible to amend the annotation during the Sunset rulemaking.*”<sup>11</sup>

The carrageenan recommendation provides a case in point both with respect to how the agreed NOSB/NOP policy was implemented at the Board meeting and how the AMS overrode this policy. The NOSB first passed a motion to restrict carrageenan use in infant formula due to health

<sup>7</sup> AMS. National Organic Program: National Organic Standards Board. Available at: <http://www.ams.usda.gov/AMSV1.0/NOSB>.

<sup>8</sup> 7 U.S.C. § 6517(d)

<sup>9</sup> NOSB. 2010. NOSB Meeting Transcript, 26 October, pp. 450-485; NOSB Meeting Transcript, 28 October, pp 314-348.

<sup>10</sup> NOSB. 2010. NOSB Meeting Transcript at 330.

<sup>11</sup> McEvoy, Miles. 2012. Memo to the NOSB, September 27.

concerns. The Board was clear on its intent: “At this time we would recommend the relisting of Carrageenan on the National List ... [with] the following two annotations.”<sup>12</sup> Subsequently, it passed a second “backup motion”—no annotation added—for carrageenan to remain on the NL, in case the NOP did not meet the statutory deadline for publishing the final rule on carrageenan its use could continue.

Yet, in the draft rule AMS chose to ignore the NOSB/NOP agreement and instead issued a draft rule based exclusively upon the second backup motion, ignoring its duty to formulate the Proposed Rule based upon NOSB’s intended recommendation. The NOSB recommendation to add a stricter annotation by prohibiting the use of carrageenan in infant formula is noticeably absent. This not only violates OFPA and directly contravenes the NOSB/NOP policy agreement, but it also directly conflicts with the principles of organic production and the tenets of the National List.

*NOSB Policy to Restrict Materials Use through Annotations during Sunset is Consistent with OFPA*

Specifically regarding the addition of an annotation during Sunset, it is entirely consistent with OFPA for the NOSB to make recommendations that increasingly restrict the use of materials as a part of that process. The justification to take such action was reinforced by the NOSB in its amended policy, passed in October 2010.<sup>13</sup> The policy allows expanded annotations of materials to be adopted during Sunset in order to ratchet down and restrict material use. Such annotations were contemplated before OFPA was even passed: “The list should be amended as time goes on, on the basis of science. The process of challenge to some of these materials could begin as soon as the implementation phase begins.”<sup>14</sup> Yet, the AMS has completely ignored both the intent of amending the NL and the NOSB’s specific recommendation to expand annotations for carrageenan, cellulose, and List 3 inerts in the draft Rule, as per the law. CFS finds this action highly irregular and without legislative or legal authority.

**NOP IS ABUSING THE SUNSET REVIEW POLICY—THE CASE OF CARRAGEENAN**

*Proposed Rule’s Stated Reason for Rejecting the NOSB’s Recommendation Violates OFPA*

AMS’s decision to reject the NOSB recommendation on carrageenan and its justification for doing so is uneven and biased, particularly in its presentation of the public debate that has taken place on the issue. Rather than acknowledge increased public input as more people have become aware of what is at stake, the AMS criticizes the public for not coming forward sooner with more comments, prior to the release of the draft Sunset recommendation in 2012. In the draft rules, AMS privileges reproducing comments from the food processing industry while noticeably downplaying the public comments that are critical of both allowing the use of carrageenan in food altogether and restricting its use in infant formula in particular. In fact, it is worth noting that

<sup>12</sup> May 22, 2012 Sunset 2013 Proposed Recommendation Carrageenan.

<sup>13</sup> The policy was reiterated in: McEvoy, Miles. 2012. Memo to the NOSB, September 27.

<sup>14</sup> Preparation for the 1990 Farm Bill: Hearing Before the S. Commee. On Agric., Nutrition, and Forestry, 101<sup>st</sup> Cong. 37 344 (1989) (statement of Enid Wonnacott).

while 78 people commented on the NOSB draft recommendation, 62 opposed its relisting and only 16 supported it.<sup>15</sup>

Organic foods are better for human and animal health and the environment, due to the nature of organic production systems. The added value they bring to the marketplace is that they are minimally processed and that synthetic, toxic additives are avoided. Organic consumers know this and trust this to be the case when they purchase products that bear the USDA organic seal. They are savvy ingredient readers and if there is one product that they are likely to expect to be of the highest quality and to adhere to the purest standards, it is infant formula.

To be sure, the jury is still out regarding the extent of the health risks associated with the ingestion of carrageenan. Yet, the possibility of carrageenan being absorbed by the immature gut and prospects of adverse immune system function impacts is further cause for concern and restrictions, particularly in the face of repeated calls for this additional research. That is why it is so important that the NOSB and NOP take precautionary action to restrict the use of carrageenan in organic food, eliminate the threat of harm, and preserve organic integrity.

*GRAS is Not as Protective as OFPA and Cannot Be Used as Justification for Overriding NOSB Recommendations*

OFPA specifically prohibits the Secretary of Agriculture or any government agency from expanding or contracting uses of materials beyond the recommendations put forth by the NOSB. Yet, the AMS inappropriately used FDA food safety standards (21 CFR 172.5, 172.620 & 172.626) as a justification for overriding NOSB recommendations to restrict the use of carrageenan as a food additive in infant formula.

FDA's "Generally Recognized As Safe" (GRAS) concept emerged as an exception to the Food Additives Amendment, exempting a substance that it generally recognizes to be safe under the conditions of its intended use, from the new additive premarket approval process.<sup>16</sup> Over the years, FDA has weakened GRAS standards to a point where industry self-certification (also known as "Notification") is common. GRAS standards are simply not as strict as OFPA and, therefore, should not form the basis of a Sunset Rule on organic materials. Moreover, citing the standards or analysis of another agency (or private party) such as FDA, does not give the AMS authority to blatantly ignore the rule of law by failing to address the NOSB recommendations in its draft rule.<sup>17</sup> This is unlawful and it serves not only to thwart the stricter NOSB recommendations but it also contravenes the intent of OFPA, which is to strictly regulate food grown and produced in a manner that protects human and animal health and the environment.

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<sup>15</sup> Public Comment on the NOSB Subcommittee Recommendation on Carrageenan, February 21, 2012. Docket Number AMS-NOP-12-0017.

<sup>16</sup> 62 Fed. Reg. 18937, 18938 - 18939 (April 17, 1997); 21 U.S.C. § 321(s).

<sup>17</sup> "We agree with the general proposition that when Congress has specifically vested an agency with the authority to administer a statute, it may not shift that responsibility to a private actor such as the CPD." *Cf. A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 537, 79 L. Ed. 1570, 55 S. Ct. 837 (1935).

With respect to the GRAS determination for carrageenan, it was first made in 1958. The last time it was reviewed was in 1973<sup>18</sup>— *40 years ago*. Clearly, this outdated standard must not be used as a basis for overriding the NOSB’s decision, especially in light of the additional research that has been conducted on carrageenan since then. Even as early as 1973, the FDA review committee concluded that although “no evidence in the available information on carrageenan demonstrates a hazard to the public when it is used at levels that are now current and in the manner now practiced,” uncertainties exist and additional studies are warranted.<sup>19</sup> Since that time, new studies have been published that demonstrate negative effects from consumption of food grade carrageenan, many of which are addressed in the NOSB’s most recent technical review (TR). Yet, the AMS has noticeably failed to mention them in its discussion on carrageenan, which represents yet another notable flaw in the draft rule.

Given the wide ranging health and environmental concerns posed by adding carrageenan to organic foods, as discussed below, the NOSB is well within its authority to restrict its use in an annotation, especially in those products intended for the most sensitive and vulnerable populations – infants.

#### *Carrageenan Impacts Human Health—The National List Prohibits Such Substances*

Carrageenan has been studied by scientists worldwide, and its negative health effects have been identified for decades. Published research has shown a number of detrimental effects in laboratory animals and *in vitro* studies.<sup>20</sup> While some of the current compelling research is being conducted by Dr. Joanne Tobacman and her team, most of the studies were completed by other researchers. The earliest study to show ulcerative colitis in lab animals from food-grade carrageenan was conducted in 1969, and other studies have shown similar effects since then.<sup>21</sup> One of the main concerns with the ingestion of carrageenan is that it leads to inflammation, especially in the gut. Recent *in vitro* studies have begun to determine the pathways by which carrageenan causes inflammation in the human intestinal tract.<sup>22</sup> Inflammation of the intestinal lining and digestive tract can be associated with a number of human diseases and thus presents a human health concern.

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<sup>18</sup> USDA NOP. 2011. Lines 395-400.

<sup>19</sup> USDA NOP. 2011. Lines 399-403.

<sup>20</sup> Watt J & Marcus R. 1969. Ulcerative colitis in the guinea-pig caused by seaweed extract. *Journal of Pharmacy and Pharmacology*, 21:1875-1885.; Wilcox DK, Higgins J, Bertram TA. 1992. Colonic epithelial cell proliferation in a rat model of non-genotoxin-induced colonic neoplasia. *Laboratory Investigation*, 67:405-411.; Borthakur A, Bhattacharyya S, Dudeja PK & Tobacman J. 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): G829-838.; Bhattacharyya S, Dudeja PK & Tobacman J. 2008. Carrageenan-induced NkappaB activation depends on distinct pathways mediated by reactive oxygen species and Hsp27 or by Bcl10. *Biochimica and Biophysica Acta*, 1780(7-8): 973-982.

<sup>21</sup> Watt J & Marcus R. 1969.; Watanabe K, Reddy BS, Wong CQ, Weisburger JH. 1978. Effect of dietary undegraded carrageenan on colon carcinogenesis in F344 rats treated with azoxymethane or methylnitrosourea. *Cancer Research*, 38:4427-4430.; Arakawa S, Okumua M, Yamada S, Ito M, Tejima S. 1986. Enhancing effect of carrageenan on the induction of rat colonic tumors by 1,2-dimethylhydrazine and its relation to  $\beta$ -glucuronidase activities in feces and other tissues. *Journal of Nutritional Science and Vitaminology*, 32:481-485.; Wilcox DK, Higgins J, Bertram TA. 1992. Colonic epithelial cell proliferation in a rat model of non-genotoxin-induced colonic neoplasia. *Laboratory Investigation*, 67:405-411.

<sup>22</sup> Borthakur A, et al. 2007; Bhattacharyya S, Dudeja PK & Tobacman J. 2010. Tumor necrosis factor alpha-induced inflammation is increased but apoptosis is inhibited by common food additive carrageenan. *Journal of Biological Chemistry*, 285(50): 39511-39522.

It is important to note that most studies are conducted with food-grade carrageenan and not the degraded form (poligeenan). Even so, studies have suggested that carrageenan may be digested into degraded carrageenan (poligeenan) in the digestive tract.<sup>23</sup> Degraded carrageenan is associated with numerous negative health effects including bleeding and ulceration of the colon in mammal lab tests.<sup>24</sup> Industry sources have defended food-grade carrageenan and attributed the negative results to poligeenan. However, testing from the industry itself to determine the percentage of poligeenan in samples of food-grade carrageenan has shown varying results.<sup>25</sup> This shows that a consistent methodology for accurately assessing poligeenan content in food-grade carrageenan has not yet been determined. More concerning is that all the samples showed some level of poligeenan content, even if very low. This contradicts the industry's argument that food-grade carrageenan is completely safe and free of poligeenan.

### *Infant Sensitivity to Carrageenan*

The sensitivity of infants to inflammation and the fact that infant formula can be the sole source of food for those who are not breast fed, magnify the concerns around the use of carrageenan in infant formula. Several international organizations have cautioned about its ingestion by infants, which is reason enough for it to be prohibited in organic, as per the NOSB's recommendation. An international expert group (IEG) convened by The European Society for Pediatric Gastroenterology, Hepatology and Nutrition to study the additive concluded "from the safety point of view, the IEG recommends to avoid the addition of... carrageenan to infant formula."<sup>26</sup> The restricted use of carrageenan in infant formula was also recommended by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) as well. As noted in the TR:

JECFA advised that carrageenan should not be used in infant formula intended for children under 13 months of age based on a concern over the narrow margin of exposure between the level of carrageenan consumed through infant formula and the lowest doses reported to cause inflammatory responses in laboratory rats and mice.<sup>27</sup> Similarly, the European Commission Scientific Committee on Food (now the European Food Safety Authority) concluded in

<sup>23</sup> USDA NOP. 2011. Lines 571-582; Tobacman, J. K. 2001. Review of harmful gastrointestinal effects of carrageenan in animal experiments. *Environ Health Perspect* 109:983-994; Carthew, P. 2002. Safety of carrageenan in foods. *Environ Health Perspect* 110:a176-a176; Borthakur, A., Bhattacharyya, S., Dudeja, P. K., Tobacman, J. K. 2007. Carrageenan induces interleukin-8 production through distinct Bcl10 pathway in normal human colonic epithelial cells. *AJP – GI* 292(3):G829-G838.; Benard, C., Cultrone, A., Michel, C., Rosales, C., Segain, J. -P., et al. 2010. Degraded carrageenan causing colitis in rats induces TNF secretion and ICAM-1 upregulation in monocytes through NF-κB activation. *PLoS ONE* 5(1): e8666

<sup>24</sup> USDA NOP. 2011. Lines 558-561.

<sup>25</sup> Marinalg International. nd. Status Report of 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. Available at: <http://marinalg.org/wp-content/uploads/2012/09/Final-Full-Report.pdf>.

<sup>26</sup> Agostoni, C. & Domellof, M. 2005. Infant Formulae: From ESPGAN Recommendations Towards ESPGHAN-coordinated Global Standards. *Journal of Pediatric Gastroenterology and Nutrition*, 41:580-583.

<sup>27</sup> Benford, D. J., Harrison, R. A., Strobel, S., Schlatter, J., Verger, P. 2008. Carrageenan and processed Eucheuma seaweed (addendum). In WHO Food Additive Series: 59. Safety evaluation of certain food additives and contaminants. Prepared by the Sixty-eighth meeting of the Joint FAO/WHO expert committee on food additives (JECFA). World Health Organization, Geneva, 2008. Available online at [http://libdoc.who.int/publications/2008/9789241660594\\_eng.pdf](http://libdoc.who.int/publications/2008/9789241660594_eng.pdf).

2003 that there is no evidence of adverse effects in humans from exposure to food-grade carrageenan, yet advised against use of carrageenan in infant formula due to a lack of information regarding possible absorption of carrageenan in the immature gut and effects of carrageenan on the immature immune system.<sup>28,29</sup>

As this assessment suggests, the risks are substantial enough to warrant restrictive use in infant formula.

AMS's justification for disregarding the NOSB's annotation comes from its summary dismissal of a March 2003 European Commission Scientific Committee on Food (SCF) report on carrageenan.<sup>30</sup> This report, a revised version of its 1992 report, reinforces its previous conclusion that: "It remains inadvisable to use carrageenan in infant formulae [sic] that are fed from birth, including those in the category of foods for special medical purposes."<sup>31</sup> The report further highlights the absence of data needed to assess both the possibility of carrageenan absorption by the immature gut and the adverse impacts on immune functions, an issue that appears to be included in the SCF restrictions for foods for "special medical purposes."

AMS also briefly mentions that the American Association of Pediatrics' *Pediatric Nutrition Handbook* fails to mention the European Commission and the FAO/WHO committees<sup>32</sup> concerns about carrageenan as further justification for rejecting the NOSB annotation. It asserts that they have reviewed the *Handbook* and found no mention of concerns about carrageenan. However, as the following quote from the May 2012 NOSB meeting transcript makes clear, the Handling Committee was not saying that the *Handbook* itself discusses carrageenan:

The reason for the second annotation regarding infants is based on concerns that have been raised by the EU Scientific Committee on Food, specifically that with the use of carrageenan in infant formulas for newborns. The SCF's concern is based on facts that the Pediatric Nutrition Handbook explains that in newborn infants, the neonatal intestine is uniquely capable of absorbing macromolecules via endocytosis. This is the reason why it is recommended by pediatricians not to feed infants solid foods until they are four to six months old to help prevent food allergies, as printed in the Pediatric Nutrition Handbook. The SCF had no objections for the use for older infants or in weaning foods for young children.<sup>33</sup>

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<sup>28</sup> EC SCF (European Commission Scientific Committee on Food). 2003. Opinion of the Scientific Committee on Food on carrageenan. SCF/CS/ADD/EMU/199 Final. Available online at [http://ec.europa.eu/food/fs/sc/scf/out164\\_en.pdf](http://ec.europa.eu/food/fs/sc/scf/out164_en.pdf).

<sup>29</sup> USDA NOP. 2011. Lines 592-600.

<sup>30</sup> EC SCF. 2003.

<sup>31</sup> EC SCF. 2003.

<sup>32</sup> AMS NOP. 2013. Sunset Review. Federal Register, Vol. 78, No. 86. May 3, 2013.

<sup>33</sup> National Organic Standards Board. 2012. Transcript of the Meeting of the NOSB, May 24, 2012, Statement of Harold Austin. Page 61. Available at: <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5101949>.



This comment from the meeting transcript (the only mention of the *AAP Handbook*) shows that the *Handbook* reference only pertains to the sensitivity of neonatal intestines and their ability to absorb macromolecules and *not* the AAP's findings on carrageenan. Thus, the Handling Committee's rationale focused in part on the SCF recommendation to prohibit carrageenan's addition in infant formula and in part on AAP discussions about the ability of neonatal intestines to absorb macromolecules more generally. AMS dismissed the *Handbook* reference outright by completely misunderstanding its significance in the context of the NOSB's recommended annotation. By stating that carrageenan is not specifically mentioned in *Handbook* completely missed the point made by the Handling Committee altogether.

As stated previously, the AMS does not have the authority to bypass the primary NOSB recommendation in favor of a secondary recommendation that is intended as a stop-gap measure if rules cannot be promulgated before the Sunset date. With numerous studies identifying health concerns or uncertainty, and several international bodies recommending against the use of carrageenan in infant formula, it is not unreasonable for the NOSB to act to restrict this additive in infant formulas as a safeguard against negative effects.

OFPA requires that the NOSB consider human health as an important evaluation criterion against which proposed substances are measured before they can be added to organic products and the National List. As CFS has argued in the past, the health risks are substantial enough to warrant a prohibition in the use of all organic products.<sup>34</sup>

### **NOP IS ABUSING THE SUNSET REVIEW POLICY— THE CASE OF INERTS**

CFS believes that the review of the U.S. Environmental Protection Agency's former List 3 inert ingredients in pesticides is a pressing topic for the organic community to address. We have previously supported the NOSB proposal to review all inerts used within a timely manner. The AMS has exceeded its legal authority by adopting the NOSB's backup motion as discussed in detail previously with respect to carrageenan, and we urge the AMS to reissue the draft rule with the inclusion of the first recommendation as proposed.

As our scientific understanding of chemical ingredients and their reactivity, toxicity, and ecological impacts evolves, it has become clear that many substances formerly listed as "inert" can be both toxic and active. These ingredients often comprise the majority of ingredients in a given pesticide formulation and they are not necessarily as harmless as the "inert" designation implies. On the contrary, the nature of their hazards range from acute toxicity to endocrine disruptors – hazards that should never be allowed in organically produced products. Some of the products formally found on Lists 3 and 4 may now be classified as inerts of toxicological concern, which are prohibited in organic.<sup>35</sup>

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<sup>34</sup> Center for Food Safety. 2012. Comments to the National Organic Standards Board May 2012 Meeting. May 3, 2012. Available at: <http://www.centerforfoodsafety.org/files/cfs-nosb-comments-3-may-2012.pdf>

<sup>35</sup> OFPA provides at 2118(c)(1)(B)(ii) that substances on the National List may not contain inerts classified by EPA as inerts of toxicological concern.

In light of these concerns, CFS supports the first NOSB recommendation for reviewing inerts used in organic production as soon as possible. NOP should prioritize the review of all inerts, even those used in passive pheromone dispensers that are important tools in organic production. Continuing to delay this review compromises organic integrity and the organic label.

## **CONCLUSION**

For the foregoing reasons, CFS believes that the Proposed Rule is wholly inadequate. NOP cannot simply override the NOSB's recommendation to include more restrictive annotations designed to protect human health simply because it believes that "FDA regulations provide for [a substance's] safe use" or "more information is needed from the industry" about the properties of a substance. OFPA necessitates taking a precautionary approach when evaluating materials for inclusion on the National List, only allowing the use of synthetics after NOSB has fully vetted them. If the NOSB finds reasons for concern about a substance and determines a restrictive annotation is the most prudent approach, then NOP cannot override its decision. If NOP questions an NOSB recommendation, the appropriate action would be for it to return the recommendation to the NOSB for more information, and to release a revised recommendation for public comment as well. Accordingly, CFS urges the USDA to withdraw its May 3, 2013 Proposed Rule and to reissue a corrected rule in strict accordance with NOSB recommendations and OFPA requirements, and with an opportunity for public comment.

Thank you for your consideration of our comments.

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