

October 7, 2015

Ms. Michelle Arsenault National Organic Standards Board USDA-AMS-NOP 1400 Independence Avenue, SW Room 2648-So., Ag Stop 0268 Washington, DC 20250-0268

Docket: AMS-NOP-15-0037

RE: Handling Subcommittee –Petition to revise the annotation for Natural Flavors on 205.605(a)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment to the National Organic Standards Board (NOSB) on the petition to require the use of organic flavors when they are commercially available.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing organic businesses across 50 states. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's Board of Directors is democratically elected by its members. OTA's mission is to promote and protect the growth of organic trade to benefit the environment, farmers, the public and the economy.

Summary

OTA has long advocated for the use and development of organic flavors. In the current listing for "Flavors" on §205.605(a) as a broad category allowance, commercial availability does not apply, and there is no requirement that organic alternatives be used when available. All use of organic flavors is voluntary. We believe the organic flavor supply has grown to a size where it is no longer appropriate to simply allow the use of non-organic natural flavors when organic forms may be commercially available. At the same time, the number of available certified organic flavors is not sufficient to completely meet the current needs of the marketplace, given the numerous and different types and forms used by the organic sector.

In order to further the use and development of organic flavors, OTA submitted a petition to revise the listing of natural flavors on § 205.605 of the National List to require the use of organic flavors in products labeled "organic" when the flavors are commercially available in the necessary quality, quantity or form. We are not requesting that commercially availability be applied to natural flavors used in "made with organic X" products. Natural flavors used in the 30% of a "made with" product would continue to be allowed provided they are non-synthetic, non-GMO and made without the use of synthetic solvents, carriers and artificial preservatives.

¹ Commercially available. The ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan.



Since the first recommendation by NOSB to include the use of Natural Flavors in organic foods in 1995, there has been the expectation that over time, manufacturers would begin to produce certified organic flavors, and efforts would be made to support the use and development of organic flavors. In 2007, the National Organic Program (NOP) recognized that Accredited Certifying Agents (ACAs) were certifying flavors and that over time there would be more sources. During the NOSB 2012 Sunset Review, in response to public comments, NOSB acknowledged the evolution of the organic flavor industry and the investment in further developing organic alternatives. At that time, NOSB stated on record that it could envision a time when flavors would not need to be listed. NOSB also communicated its belief in the final Sunset recommendation that "the full category should not be relisted in five years when next reviewed for sunset."

OTA, through the work of its Flavor Task Force formed in 2010 by the request of NOSB, has conducted extensive outreach to organic stakeholders including flavor manufacturers (organic and natural), certifying agents, organic manufacturers using flavors (organic and natural), and suppliers of minor ingredients used in natural and organic flavors. We received widespread support for the submission of our petition, and we continue to receive positive feedback for moving forward.

As with any change that places additional organic requirements on certified operators, we acknowledge the inherent challenges and additional resources that will be involved. We recognize that certified companies, including certified flavor manufacturers will need to increase the time and resources spent on sourcing organic flavors. We also recognize that certifying agents will need to spend more time and resources verifying the commercial availability claims made by operators unable to find organic flavors. Given the growing supply of organic flavors and the roughly **180 certified flavor** companies in business at this time, OTA does not believe the organic sector can afford to continue its business without including some requirement to use organic flavors. We believe that that the organic sector must embrace the growth challenges we've mentioned and move forward.

Revising the annotation on natural flavors is the right thing to do. OTA is requesting that NOSB and the organic sector at-large encourage and support continuous improvement by mandating the use of organic flavors in products labeled "organic" when commercially available.

We offer our more detailed comments:

The Supply of Organic Flavors

Natural flavors appear on the National List as a broad category listing. Therefore, many different natural forms are allowed. Examples include extracts, oleoresins, essential oils, compounded flavors, and distillates. The types of flavors allowed must be consistent with the FDA definition of "natural flavors" codified in 21 CFR 101.22².

The term natural flavor or natural flavoring means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional.

² 21 CFR 101.22 Foods; labeling of spices, flavorings, colorings and chemical preservatives.



Even though organic certification of natural flavors is not required, many operators have voluntarily chosen certification because of the great demand by consumers. Below are the results of a survey of ACAs by The Accredited Certifiers Association Inc. in 2011. (See Appendix A for an explanation of the following categories.)

3. Indicate the number of natural flavors you certify under the following categories:								
Natura Flavor 11 respons	Extracts 11 responses	Essential Oils 11 responses	Distillates 9 responses	Oleoresin 7 responses	Essence 9 responses	Powders 9 responses	Emulsions 8 responses	Other 7 responses
TOTA	L TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL
1,978	964	1,341	125	33	112	177	12	26

This survey also reported that 157 companies were being certified at the time. The actual number may be even higher. A similar survey was sent in September 2014 with the following results:

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3. Indicate the number of natural flavors you certify under the following categories:									
Natural Flavor (Compounded flavor) 5 responses	Natural Flavor (WONF) 7 responses	Extracts 6 responses	Essential Oils 5 responses	Distillates 4 responses	Oleoresin 5 responses	Essence 4 responses	Powders 5 responses	Emulsions 4 responses	Other 2 responses
TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL
2,146	405	272	1,645	4	18	33	254	19	0

This survey reported that 189 companies are being certified at this time. However, since there were fewer responses submitted than in the 2011 survey, this number may be significantly higher.

When flavors were initially included on the National List, the number of flavor compounds comprising natural flavors was estimated number up to 100 or more. There were no known companies making organic flavors at that time. The data from the ACA surveys demonstrate that these numbers have grown substantially, not only for natural flavors in general, but certainly for certified organic flavors.

Commercial Availability of Organic Flavors

Applying commercial availability to flavors is largely consistent with the original 1995 NOSB Recommendation (**see Appendix B**) to make efforts toward the ultimate production of an organic natural flavor, and it will satisfy NOSB's 2012 Sunset Review statement that "the full category should not be relisted in five years when next reviewed for sunset."

A review of the ACA survey results as well as a quick run down the aisles at an organic foods grocery store reveals that the number of certified organic flavors currently in the marketplace is substantial. Applying commercial availability to natural flavors would be a **significant step in the right direction** and it would lay the critical foundation to build upon for the next Sunset Review. A requirement to use organic flavors when they are available will require companies currently using non-organic flavors to start sourcing organic flavors to find out if they meet the requirements of their products in the quantity, quality and form needed. This research and sourcing process married with a requirement to use organic flavors when they are commercially available will further stimulate the development of organic flavors, which, in



turn, will increase the supply. Flavor manufacturers will be able to enter into the organic arena with confidence that their organic flavors must be used if they meet the necessary quality, quantity and form of the end-user product.

Take for example peppermint extract. Currently, a certified operator can use **non-organic** peppermint extract <u>without any requirement</u> to explore an organic form let alone use it. Organic peppermint extract is made using organic alcohol and organic peppermint. The product is not complex and organic forms are readily available. The commercial search and documentation process between a certified operator and its certifier in this case would be fairly straight-forward. A complex flavor on the other hand, such as a compounded natural strawberry flavor, would be much more difficult to source, and the documentation process for demonstrating its commercial availability status would be much more involved. None-theless, organic natural strawberry flavor does exist and it could conceivably work in many different types of products. However, at this time, manufactures of certified organic products are not required to investigate its potential.

OTA is aware of the inherent problems associated with the commercial availability clause in the organic regulations, namely that it is a good effort process operating in a capitalistic supply and demand economy. It is understood, or at least expected, that if there is demand, the supply will come. But, if operators are not mandated to use an organic ingredient and can instead demonstrate that a flavor, for example, does not meet the quality or form they are looking for, then they can use the non-organic form rather than demanding an organic version. Commercial availability doesn't always work as well as it was intended! OTA recognizes the need to improve the rigor of the verification process for determining commercial availability, and we accept that a revision to the annotation won't create a perfect result. However, we strongly believe that it will move us in the right direction along the continuous improvement spectrum, and create enough change to help swing the pendulum more permanently in favor of organic flavors.

Retention of Flavors on 205.605 (a) with a requirement to use organic when available

OTA believes that it is appropriate to retain flavors on § 205.605 of the National List (listing for allowed non-agricultural substances) and apply commercial availability to the entire broad category listing. Certified operators will then work with their certifiers to determine the types of organic flavors available in the required quantity, quality and form. The process of parsing out and sourcing organic flavors is going to be a process best facilitated by ACAs.

Removing individual types of flavors such as simple flavor extracts or attempting to move some or all flavors from §205.605 to §205.606 would cause a significant disruption to the industry, and require resources NOP and NOSB simply do not have. First, the complexity of such a broad category listing makes it impractical to individually list flavors on the National List. This was acknowledged by NOSB at both previous Sunset Reviews. Second, if flavors as a broad category were moved to §205.606, then non-agricultural flavors would no longer be allowed according to the requirements for inclusion on §205.606: Non-organically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

Flavors are both agricultural and non-agricultural, and it would be extremely difficult to separate out the **literally thousands of flavors** into agricultural and non-agricultural categories. The OTA Flavor Task Force explored this option extensively and concluded that it was not a reasonable or practical approach. Also, some non-agricultural flavors can be produced organically because they are derived from or



produced using agricultural source material. Flavors produced via fermentation are a great example, and are analogous to yeast, which is used as a flavor as well and classified as non-agricultural. Several products of fermentation are classified as non-agricultural, yet they can be produced organically provided the agricultural source material is certified organic and all other ingredients and processing aids meet the NOP product composition requirements for labeling a product "organic." Additionally, some flavors are derived from agricultural material but the isolated flavor component is classified as non-agricultural according to the current NOP definition of non-agricultural. Again, similar to yeast, the "non-agricultural" distinction does not preclude the ability for the flavor to be certified organic due to the agricultural source material.

To consider to sunset some flavors but not others, or to move some to § 205.606 would be an arbitrary exercise that would take resources we do not have. NOSB as well as accredited certification agents would have to make thousands of determinations about which flavors were agricultural and allowed. This would be a time-consuming and costly endeavor that, at this time, would be done without final guidance from NOP on how to make agricultural and non-agricultural determinations. At the end of the day, certifiers and certified operators need only search for organic flavors and make determinations between organic and non-organic flavors.

Finally, precedent has been set for applying commercial availability to certain substances on 205.605. NOSB on October 28, 2010, applied the concept of commercial availability to yeast, listed on §205.605a, when used as a food or fermentation agent in products labeled as "organic." And on February 11, 2010, a petition was submitted to NOSB to remove silicon dioxide from §205.605(b) because rice hulls can serve as an alternative. The final decision by NOSB on December 2, 2011, was to add an annotation for silicon dioxide stating, "Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available." In both these cases, NOSB recognized that organic alternatives had been developed and were available for use although not sufficiently available. Through the decisions to extend the concept of commercial availability to non-agricultural non-synthetic (205.605(a), NOSB has encouraged the organic sector to continuously increase its use of organic ingredients and to invest in the development of organic alternatives to other substances or ingredients used in organic handling operations.

OTA is requesting that NOSB recognize the complexity of flavors and apply the precedent set with yeast and silicon dioxide, and again encourage and support continuous improvement by mandating the use of organic flavors when commercially available while retaining the broad category listing of flavors on §205.605a.

Formal guidance from NOP is needed on commercial availability practices

As mentioned earlier, OTA recognizes the need to improve the rigor of the verification process for determining commercial availability. If our petition is adopted and a rule change is made to require organic flavors when they are commercially available, the ultimate success of the rule change will partly

³ Non-agricultural substance. A substance that is not a product of agriculture, such as a mineral or a bacterial culture, that is used as an ingredient in an agricultural product. For the purposes of this part, a non-agricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.



rely on the success of the certification process and certifier's due diligence in verifying commercial availability claims. OTA believes that many certifiers are doing an excellent job on this front, but there is room for improvement along with greater consistency in practice between one certifier to the next.

In May 2006, NOSB passed a "Recommendation for establishment of Commercial Availability Criteria" when making commercial availability decisions regarding the use of materials on 205.606. To date, NOP has not acted on this recommendation. In the fall of 2005, NOSB passed a recommendation for guidance on commercial availability of seed. NOP did, in fact, act on this recommendation and final guidance became effective on March 4, 2013. In favor of making the commercial availability clause function as it was intended in certified organic products, OTA requests that NOSB urge NOP to prioritize action on the 2006 recommendation and release proposed guidance for public review and comment.

Standardized questionnaire to verify compliance

During the spring 2015 NOSB comment period, NOSB asked the public if a standardized questionnaire on natural flavors would be helpful. OTA responded by saying that there <u>is</u> a Natural Flavor Questionnaire (Affidavit/Declaration) in use by several accredited certifiers. This questionnaire was developed by a group of certifiers with technical assistance from flavor manufactures and flavor chemists. It appears to be one of the most thorough affidavits in circulation. However, it may not be in use by all ACAs. **See Appendix C.** Although the use of this questionnaire is outside the scope of our petition, we believe its use is important for verifying the compliance of natural flavors used in organic products. It could also be revised to include questions about the commercial availability of organic flavors. Therefore, OTA requests that NOSB make a recommendation to NOP requesting that the flavor questionnaire be formally recognized and offered to ACAs in guidance as the standardized questionnaire to use.

In closing, we thank the Board for its time and commitment and for considering this timely and very important petition.

Again, on behalf of our members across the supply chain and country, OTA thanks NOSB for the opportunity to comment and for your commitment to furthering organic agriculture.

Respectfully submitted,

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Senior Director of Regulatory and Technical Affairs

Organic Trade Association

cc: Laura Batcha

Executive Director/CEO

Organic Trade Association

Appendix A: Flavor Nomenclature – "Types of Flavors



Appendix B

NATIONAL ORGANIC STANDARDS BOARD - FINAL RECOMMENDATION ADDENDUM NUMBER 14 THE USE OF NATURAL FLAVORS IN ORGANIC FOODS - Date adopted: October 31, 1995

Additionally, manufacturers shall provide written documentation in their Organic Handling Plan showing efforts made toward the ultimate production of an organic natural flavor as listed in the stepwise progression below:

Natural flavor constituents and non-synthetic carrier base and preservative agents (ex. grain ethanol, non-synthetic glycerin and non-synthetic acetic acid.).

Organic flavor constituents, organic carrier base, and organic preservative agents.

Organic flavor constituents extracted using organically produced solvents, organic carrier base, and organic preservative agents.

Appendix C: Natural Flavor Questionnaire

Type of Flavor (Typically referred to as Flavor Nomenclature)

Compounded Flavor: A mixture of ingredients such as extracts, essential oils and natural isolates. In most cases, it's usually dissolved in a solvent or it would be too concentrated.

Compounded WONF: Combination of a compounded flavor and a natural flavor WONF (with other natural flavor).

Distillate: A clear, flavorful liquid produced from fruits, herbs, roots, etc., by distillation; also the condensed product separated by distillation.

Extracts: Extracts are products that use solvents (typically alcohol or alcohol-water mixture) to pull out certain volatile and non-volatile fractions from raw materials such as spices and herbs, cocoa and vanilla, or flowers. Extracts found on the grocer's shelf, such as orange, almond, lemon, etc. are essential oils dissolved in an alcohol-water mixture.

Essential Oil: A volatile oil. An essential oil is what gives a botanical its aroma and can be the aromatic essence of a spice, flower, root, leaf or peel. It's made by steam distillation or cold pressing.

Essential Oil Isolate: Isolate of an essential oil – see above.

Isolate: A chemical or fraction obtained from a natural substance. For example, citral can be isolated from lemon oil or lemongrass.

Oleoresin: Solvent extracts of spices where the solvent has been completely removed. An oleoresin will contain the essential oil plus other important non-volatile components that characterize the flavor, color and other aspects of the starting raw material. For example, the oleoresin of pepper will contain its aroma as well as its taste sensations of heat and spice.

Single flavor chemical: A single molecule that provides flavor. These can be naturally or artificially derived, but they are specified to have a greater than 95% purity.

Others – could include:

Add-Back Flavor - Adds back flavor lost during processing. For instance, orange juice can lose much of its flavor during the concentration process but flavorists can add orange oil during the formulation to increase the flavor. Add-back flavors imply that all ingredients of the flavors are derived from the named fruit.

Essence: Concentrated fragrance or flavorant. In some countries, essence is used to designate volatile oils, but in the U.S. this term is commonly applied to alcoholic solutions of volatile oils.

Natural Flavor WONF – A natural flavor that contains both a characterizing flavor from the named material and other natural flavor, which simulates, resembles or reinforces the characterizing flavor.

Single-fold Oil: The oil as it is produced from the plant (distillation or expression), without concentration.

References

George A. Burdock. Fenaroli's Handbook of Flavor Ingredients, 5th ed. Washington D.C. CRC Press.

Primo Bader and Steve Phelps. January-March 2007. The Flavor Factor: Exploring Today's Taste-Improving Technology. *Organic Processing Magazine*.



NATURAL FLAVOR PRODUCT QUESTIONNAIRE - NATIONAL ORGANIC PROGRAM USE

The USDA National Organic Program (NOP) allows the use of certain natural (non-synthetic) substances, including flavors, in products labeled as "Organic" or "Made with Organic...(specified ingredients or food groups)" providing they comply with provisions established in the USDA NOP (7 CFR Part 205).

The NOP defines **Non-synthetic** (natural) in 7 CFR 205.2: a substance that is derived from mineral, plant or animal matter and does not undergo a synthetic process as defined in section 6502 (21) of the Act (7 *U.S.C.* 6502(21)). Under the terms of the Act, "**synthetic**" means a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.

Non-synthetic Flavors authorized under the NOP, Section 205.605 (a)(9) must be from non-synthetic sources only and must not be produced using synthetic solvents, carrier systems or any artificial preservative. In addition, Sections 205.105 (e)(f)(g) respectively prohibit so-called "excluded" methods (GMOs), ionizing radiation or sewage sludge, defined in 205.2, from being applied to any ingredients or products under the NOP.

FDA Definition of Natural Flavors FDA 21 CFR Part 101.22(a)(3): "... **natural flavor** or **natural flavoring** means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors include [but not exclusively] the natural essences or extractives obtained from plants listed in §§182.10, 182.20, 182.40, and 182.50 and part 184 of this chapter, and the substances listed in §172.510 of this chapter."

The use of this questionnaire is to determine compliance of a natural flavor for use in an "organic" or "made with organic..." product under the terms of the NOP. **Oregon Tilth may request additional information as needed.**

Identification of Natural Flavor Product (code/Name):						
Supplie	er Name, Address:					
Type of	f flavor (select one or more as	necessary):				
	Compounded flavor	Extracts	Isolate			
	Compounded WONF	Essential oil	Oleoresin			
	Distillate	Essential oil Isolate	Other (please specify):			
<u>Natura</u>	l Flavor Product					
	or constituents Do all of the <u>flavor</u> constituer <u>above</u>)? Yes No	nts in the natural flavor product n	amed above meet the FDA definition of a natural flavor (see			
2.	Natural flavors authorized for use in NOP "organic" or "made with organic" products, in addition, must not be produced using synthetic extraction solvents. Extraction may only use nonsynthetic, non-petroleum based solvents (see below)*. ➤ Is/are the natural flavor constituent(s) made using NOP-suitable extraction solvents*? ☐ Yes ☐ No					
	➤ If the solvent used to extract the natural flavors <u>is not</u> listed as an example of one of the NOP-suitable extraction solvents* please disclose:					

*Allowed natural extraction solvents include water, natural ethanol, super-critical carbon dioxide, authentic

essential oil, and natural vegetable oils. No hydrocarbon solvents, or chlorinated, or halogenated solvents may be used.

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Propane, hexane, and freon are examples of solvents that are prohibited.



B. Non-flavor constituents and other ingredients

glycerides, benzoic acid, polysorbate 80, medium	e.g., propylene glycol, polyglycerol esters of fatty acids, mono- and di- chain triglycerides, BHT, BHA, triacetin, etc. Acceptable carriers, IUST BE either organic, nonsynthetic, or on the National List at				
➤ Please list any carrier system(s) used in this Natura	l Flavor Product or attach an Ingredient Statement: N/A				
Carrier:	Source Material:				
Please list any preservative(s), or other additives of Ingredient Statement:	r foodstuff ingredients used in this Natural Flavor Product or attach an N/A				
Preservative/Additive/Foodstuff:	Source Material:				
2. If any of the above are synthetic, are they listed on	the NOP National List at § 205.605(b)?				
C. Genetically Modified Organism (GMO) products may not be used at any stage in the process of making natural flavor products for NOP goods. Excluded methods (= GMO use) – a variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include but are not limited to recombinant DNA technology (including gene deletion, gene doubling, introduction of a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology); therefore, GMO-plant extracts may not be used nor may natural flavors be the product of GMO-yeast fermentation, for example. > This natural flavor product, including any solvents, carriers, preservatives or other or processing aids used or contained therein, was produced or handled using excluded (GMO) methods? \[\textstyle{\t					
D. Ionizing Radiation is prohibited for all uses involving food preservation, pest control and pathogen control in NOP products. Other radiation uses, including food inspection, are permitted providing such use meets applicable FDA regulations, which establish limitations applicable to all (organic and non-organic) food products. ➤ Ionizing radiation as described in 21 CFR 179.26 was used in the processing of this natural flavor product? ☐ Yes ☐ No					
E. Sewage Sludge (as a crop fertilizer) is solid, semisolid, or liquid residue generated during the treatment of domestic sewage in a treatment works. Sewage sludge includes but is not limited to: domestic septage; scum or solids removed in primary, secondary, or advanced wastewater treatment processes; and a material derived from sewage sludge. It is not permitted in the manufacture of any ingredients used in NOP products. This natural flavor product was derived from products using sewage sludge in their agricultural production: \[\textstyle{\textstyl					
This questionnaire is only to be	e signed by a qualified technical person ¹ :				
Pursuant to 7CFR §205.605(a)(9) and §205.105(e)(f)(g), I, on behalf of the supplier, hereby attest that the information provided in this form is accurate and truthful to the best of my knowledge.					
	_Phone/e-mail:				
Printed Name:	Title ¹ :				
Signature:	Date:				
¹ Falsifying statements to ACA's or the Secretary under the NO	OP will be subject to possible fines.				

1. **Natural flavors** authorized for use in NOP "organic" or "made with organic" products must not contain any **synthetic** carrier systems or any artificial preservatives. This extends to synthetic processing aids, emulsifiers or antioxidants; i.e.

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