



March 19, 2013

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-12-0070

RE: Crops Subcommittee – Tetracycline

Dear Ms. Arsenault:

The Organic Trade Association¹ (OTA) thanks you for this opportunity to provide comment on the Crops Subcommittee proposal on Oxytetracycline. The Subcommittee proposes to remove the existing expiration date of October 21, 2014, for oxytetracycline and replace that with a new expiration date of October 21, 2016. This would be for use in both apples and pears for control of fire blight.

In summary:

- **OTA is committed to ending the use of antibiotics in organic apple and pear production.** We agree that antibiotics should be phased out of organic production, and we support all efforts to develop effective alternatives. Researchers and orchardists have committed years of research into developing alternatives to antibiotics for fire blight control. These developments have been supported by over \$600,000 in grower-funded research for non-antibiotic, organic-compliant controls and practices, along with over \$5 million in research support from USDA's Agricultural Research Service. Excellent progress has been made, but more time is needed in order to support the widespread adoption of newly emerging alternatives. We expect that **by 2017**, recently funded research and field-testing and a resulting grower publication (expected out in 2016) will provide organic growers new tools allowing them to end the use of antibiotics.
- **A 2017 expiration date will support current research and testing, and allow for grower education and success.** The most sensible course is to extend for a limited amount of time the ability for growers to use tetracycline as restricted under NOP standards while the new alternative materials are fully proven. Based on the status of emerging alternatives and existing research funded under USDA, **the reasonable expiration date that will support product**

¹ 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 49 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.

registration and availability, commercial scale-up, and grower experience is 2017. We believe this is an extremely rigorous timeline. However, unlike 2016, it takes into account an additional season of grower education and experience based on the results of a critical USDA-funded Organic Research and Education Initiative (OREI) research project running through 2015 that will help validate the newly developed practices. OTA does not support any further allowance beyond 2017.

- **Expiration dates need to be based on research-based timelines, not political compromise.** Expiration dates that are the result of compromise will continue to fail. They will continue put us in the exact situation we're in. The 2014 expiration date was not based on scientific evidence or a research-based timeline. We knew when the recommendation passed in 2011 that it would fall short of the time needed to develop commercially viable alternatives. We knew it would fall short not for lack of trying, but because of the known amount of time it takes to move from the development of a material to its widespread adoption. OTA urges NOSB to pass a time-limited extension based on the OREI research-supported time-frame we have described in our comments.
- **OTA supports the subcommittee resolution.** In accordance with existing organic regulations, the use of tetracycline must *continue* to be highly regulated. As stated in the organic regulations, producers may only apply synthetic materials when physical, biological, and cultural practices, and biological or botanical substances are not effective, provided conditions are documented and approved in their organic system plan. We expect that growers will be trialing the new and emerging alternative materials if they haven't done so already. Such use and activity are required to be documented in their organic system plan and approved by certifying agents.
- **OTA recognizes the role organic agriculture can play in developing an approach that will ultimately be adopted in conventional orchards.** The phasing-out of antibiotics by allowing development of effective alternative solutions offers the opportunity for NOSB to engage agriculture experts, growers, and consumers, and to lead a public-private effort to foster the adoption of these new techniques in conventional orchards and non-antibiotic controls by other growers on many thousands of acres.

We offer the following more detailed comments.

OTA is committed to ending the use of antibiotics in organic apple and pear production.

The organic sector recognizes that this issue is highly controversial due to concerns about the use of antibiotics in livestock production and the general prohibition of their use in organic agriculture. We understand and share this concern. Therefore, we support the efforts being made to transition the current practice to an alternative but effective approach—one that does not include antibiotics.

Research on biological controls of fire blight has been ongoing since the 1980s. Instrumental products such as Blight Ban A506 and Serenade were introduced in the 1990s, Bloomtime Biological in the 2000s, and Blossom Protect in 2012. New copper products are currently being tested, and research on the biology of fire blight and other possible controls are on-going. These developments have been supported by over \$600,000 in grower-funded research for non-antibiotic, organic compliant controls and practices, along with over \$5 million in research support from USDA's Agricultural Research Service. A system referred to as LAMP (loop-mediated isothermal DNA amplification) is also under development for in-field monitoring of fire blight. This system would enable growers to refrain from

treatment if bacterial levels were low despite weather conditions favorable for infection.

A critical component that has recently accelerated efforts is a USDA-funded Organic Research and Education Initiative (OREI) research project running through 2015 that will help validate the newly developed practices. Growers need the results of the OREI project, and then time to test and integrate them into their management. A grower guidance publication that builds upon the research is expected to follow in 2016. This publication is necessary to support grower education, bolster grower confidence, and, ultimately, foster the adoption of a non-antibiotic approach to controlling fire blight. We expect that by **2017**, this research and field-testing will provide organic growers new tools allowing them to end the use of antibiotics.

A 2017 expiration date will support current research and testing and allow for grower education and success. OTA respectfully urges NOSB to recommend an expiration date that can be tied to a fact-based research-supported timeline as we have described above. Great strides have been made towards the adoption of a non-antibiotic approach, and success is on the near horizon. However, a 2014 deadline falls short of critical research that will validate newly developed practices, and 2016 will cut short the time needed for grower education and experience. Many growers have not tried the new and emerging alternatives, and are concerned about the risk of catastrophic disease in the absence of proven controls. The most sensible course is to extend for a limited amount of time the ability for growers to use tetracycline as restricted under NOP standards, while the new alternatives are fully proven in a number of different growing climates and regions.

The reasonable **expiration date** that will support product registration and availability, commercial scale-up, and grower experience is **2017**. We believe this is an extremely rigorous timeline. However, unlike 2016, it takes into account an additional season of grower education and experience based on the results of the OREI project.

Growers need effective and proven alternatives.

In a 2012 organic grower survey, 93 percent of growers said they would reduce organic apple or pear production or exit it entirely (return to conventional farming) with the loss of antibiotics without proven consistent alternatives because of the high potential to lose *entire orchards* to fire blight. New orchards cost \$12,000-20,000 to establish per acre. It also takes five to seven years to bring an organic orchard to maturity, making it economically devastating for farmers to lose an orchard to disease.

It's important to realize many growers, including the 93 percent responding to the survey, only use tetracycline during periods of high risk. Treatments are not applied in situations when disease models do not indicate sufficient risk. According to data provided by the USDA-NASS Agricultural Chemical Usage database, which includes oxytetracycline, the percent of apple acres treated in a given year nationally ranges from 1-9%; thus a small portion of the crop is treated with this allowed material in any given year. However, although oxytetracycline is used infrequently, without alternatives it may be essential when disease models indicate high risk of infection.

Once an orchard is infected with fire blight, there are no curative methods other than cutting out infected limbs or trees and removing them from the orchard. Most growers are not willing to risk this loss. Thus, they need not only access to alternative materials but also the time and experience to be confident they work. If growers exit organic production due to fire blight risk, we expect to see a significant reduction in the supply of U.S.-grown organic apples and pears, and a corresponding increase in price for consumers. Premature loss of tetracycline will undermine the tremendous expansion in organic apple and pear production that has occurred.

Growers need alternative tools to control fire blight, and they need to be confident they will work. As new materials, practices, and genetics become available, researchers validate them under different conditions and within overall orchard management systems to reduce the risk of failure or unanticipated side effects in grower orchards. This process is then followed by a period of education and grower experience to again refine their use in the diverse settings and environments encountered in commercial orchards. The process of moving a material from being available, to proving its efficacy, to integrating its use into an overall management system, to educating growers, is a multi-year effort, often five or more years. **Understanding this process is a key consideration when setting timelines to phase out existing key pest control tools.** The following timeline reflects a partial history of fire blight control under organic management systems. The key dates extend to 2017.

***Fire Blight Control Timeline**

1950s		Streptomycin first used to control fire blight
1970s		Oxytetracycline registered as an alternative to streptomycin
1980s		Biocontrol research for fire blight expanded
1990s		Antibiotics allowed under private certification standards for fire blight control in tree fruit
2000s		Biocontrol research continues; predictive disease models improved
	2002	Initial NOP standards allow streptomycin and oxytetracycline for fire blight control in apples and pears, with sunset review every five years
	2008	NOSB reviews petition for a new form of tetracycline, and assigns 2012 expiration date assuming that a petition for removal would be received and alternatives would be available. This was done without public comment.
	2011	NOSB extends expiration date to 2014 after hearing testimony that effective alternatives are not yet widely available; Organic Tree Fruit Work Group formed at request of NOSB. Organic fire blight control project funded by OREI.
	2012	Blossom Protect receives U.S. EPA registration in February 2012. Blossom Protect generally works well, but quantities are limited
	2013	NOSB proposes to extend allowance of oxytetracycline until 2016
	2014	Current expiration of oxytetracycline and streptomycin – organic growers will no longer be allowed to use these two materials
	2016	First extension publications on non-antibiotic control available to growers utilizing results from the OREI fire blight project
	2017-2020	Growers have both the information resources and field-testing experience with alternative controls to decide whether they are able to manage orchards without the use of antibiotics. This would have been the originally scheduled sunset date

*See Appendix A for a more complete history of alternative controls

Expiration dates need to be based on realistic timelines, not political compromise.

We understand that NOSB’s recommendation in 2011 on oxytetracycline represents a compromise between the petitioner’s request to drop the date from the annotation and NOSB Crop Committee’s recommendation to let the use of the material expire in October 2012. We also understand that the NOSB proposed a time-limited extension for tetracycline to allow for the continued use of the material while encouraging the industry to increase its efforts to research and develop commercially viable, cost-effective alternatives to the use of antibiotics in the organic pear and apple industry. The recommendation essentially conveyed the urgency of consumer and public interest groups’ advocacy of eliminating the use of tetracycline in organic tree fruit production. The recommendation did not take into account the time it would take to develop and adopt effective alternatives.

Expiration dates that are the result of compromise will continue to fail. However, if we make decisions based on fact, everyone is likely to stick to them. The 2014 expiration date was not based on scientific

evidence or a research-based timeline, and we knew when the recommendation passed that it would fall short of the time needed to develop commercially viable alternatives. We knew it would fall short, not for lack of trying, but because of the known amount of time it takes to move from the development of a material to its widespread adoption. This has unfortunately led to unwarranted media attention containing inaccurate information that is harming the entire organic sector.

Our goal should be to successfully transition as many organic growers as possible to a non-antibiotic control regime. This will minimize disruption to the organic sector and, most importantly, will support overall decreased usage of antibiotics. We should be working to retain every organic acre currently in organic production, rather than penalizing organic growers that have, in good faith and full organic compliance, built their livelihoods around the production of organic apples and pears.

Organic apple and pear producers have been allowed to use tetracycline as a last resort material since the implementation of the National Organic Program, and even earlier under private standards. Some growers may rarely use it, and other growers may never use it. However, the material has at least been available in the case that an orchard is faced with devastating fire blight conditions. There are some growers, early adopters for example, that have recently transitioned their mature orchards to a non-antibiotic control system, but they have been able to do so knowing they have the last resort option of tetracycline.

Organic growers need to know they have materials that will provide the same level of protection against fire blight. Otherwise, they are likely to move to conventional production. Therefore, OTA urges NOSB to pass a recommendation that supports a time-frame that will allow for the greatest number of organic farmers to successfully transition to non-antibiotic management of fire blight. While it's difficult to accurately predict a single best expiration date prior to the results of the OREI project, if we assume success, we can expect that by **2017** research and field-testing will provide organic growers new tools allowing them to end the use of antibiotics.

OTA supports the subcommittee resolution.

We commend the subcommittee for declaring its commitment to phasing out of oxytetracycline and for putting forth a resolution. USDA organic standards have allowed the use of the antibiotics tetracycline and streptomycin as last resort preventive controls for fire blight since the establishment of federal organic standards in 2002. The use of these materials, as with all pest control materials, in organic orchards is highly regulated. Current NOP standards as written prohibit producers from relying solely on the use of any materials for disease control, and fire blight management is no different. Producers may only apply synthetic materials when physical, biological, and cultural practices, and biological or botanical substances are not effective, provided conditions are documented and approved in their organic system plan.

Some commenters are suggesting that an annotation be assigned to oxytetracycline mandating that a producer document his or her movement up the disease management hierarchy. While we are completely in agreement about the requirement, OTA disagrees with an added annotation because the requirement is already stated elsewhere in the regulations. Guidelines or annotations that reiterate existing requirements, or any other practice standard, are redundant and unnecessary. More so, they cause confusion in the certification process and inconsistencies in how allowed materials are evaluated. If stakeholders are concerned with the certification process and/or NOP's enforcement responsibility, the matter should be addressed separately.

In support of the Resolution and the organic sector's commitment to end the use of antibiotics, we support any extra efforts that can be made to encourage certified operators to try as many alternative practices and materials as possible. We also support increased USDA-funded support for research into alternative practices and materials. With respect to the certification process, we expect that certifiers will *continue* to uphold the NOP regulatory requirements described above as the course of the annual certification process. The certification processes effectively verifies that growers are following their farm plan and are operating in compliance with organic requirements.

Conclusion

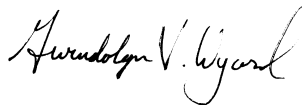
Once again, OTA urges NOSB to recommend an expiration date that can be tied to a fact-based research-supported timeline as we have described in our comments. The reasonable expiration date that will support product registration and availability, commercial scale-up, and grower experience is 2017.

There is undeniable evidence that growers small and large, across the country, packers and handlers, and many other stakeholder organizations are committed to developing and implementing a non-antibiotic approach to controlling fire blight in apple and pear production. University and grower research has been ongoing for over 20 years. Current efforts to find effective alternatives are moving as fast as possible for a perennial tree system with limited abilities for multiple trials per year. Given the substantial progress that's been made, OTA is optimistic that by 2017, we can end the use of antibiotics without serious loss of organic acreage, and we are committed to this expiration date.

Organic production continues lead all of agriculture in the development of natural and sustainable pest control solutions. The phasing-out of antibiotics by allowing for development of effective alternative solutions is no difference. Successful adoption of a non-antibiotic control regime on a commercial scale not only supports existing organic producers and handlers, it also offers the opportunity for NOSB to engage agriculture experts, growers, and consumers, and to lead a public-private effort to foster the adoption of these new techniques in conventional orchards and of non-antibiotic controls by other growers on many thousands of acres.

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

Respectfully submitted,



Gwendolyn Wyard
Regulatory Director of Organic Standards and Food Safety
Organic Trade Association (OTA)

CC: Laura Batcha
Executive Vice President
Organic Trade Association (OTA)

Attachment A: OTA Comments on the Proposed Rule for Oxytetracycline
Appendix A: Extended Fire Blight Control Time Line

Appendix A

Fire Blight Control Time Line

1950s		Streptomycin first used to control fire blight
1970s		Oxytetracycline registered as an alternative to streptomycin
1980s		Biocontrol research on fire blight expanded
1990s		Biocontrol research continues; predictive disease models improved (CougarBlight, MaryBlyt, Zoller Degree Hour Model) Antibiotics allowed under private certification standards for fire blight control
2000s		Biocontrol research continues; many scientific successes but few commercial successes – big barrier is inconsistent efficacy
	2002	Streptomycin and oxytetracycline included on first NOP National List for fire blight control in apples and pears only
	2002	Serenade® <i>Bacillus subtilis</i> QST 713 biopesticide registered, commercialized
	2002	A fire blight resistant pear (US 71655-014) from USDA breeder is first tested in Hood River, OR.
	2008	NOSB reviews petition for a new form of tetracycline, and assigns 2012 expiration date assuming that a petition for removal would be received and alternatives would be available. This was done without public comment.
	2008	Blossom Protect (A.p.) from German research first tested in USA
2010s		Other control strategies being investigated (L. Pusey) – stigma exudates, osmoregulation, bacteriophage, microencapsulation of biocontrol agents
	2010	Four more ‘Geneva’ rootstocks released; nurseries having propagation problems, availability is low
	2010-2012	Field tests of Blossom Protect, new coppers, host resistance elicitors and combinations of materials for fire blight control
	2011	Testimony at NOSB meeting that suitable alternatives to antibiotics are not ready, leads to change of expiration date for antibiotics to 2014; Organic Tree Fruit Work Group formed at request of NOSB.
	2011	Johnson et al. organic fire blight control project funded by OREI
	2012	Blossom Protect receives US EPA registration Feb. 2012; severe fire blight in areas of Washington, Blossom Protect generally works well but quantities are limited
	2012	Organic grower survey – 73% have tried non-antibiotic fire blight control, 33% found it successful, 93% supported an extended expiration date for antibiotics
	2012	10 years of testing a fire blight resistant pear (US 71655-014) completed, cultivar still not released. Horticultural evaluation on-going.
	2014	New copper products for fire blight registered (?)
	2014	Current expiration of oxytetracycline and streptomycin – organic growers will no longer be allowed to use these two materials.
	2014	Planting a 0.6 acre test block of US 71655-014 fire blight resistant pear in Hood River for grower evaluation, test marketing, assessment of field disease resistance
	2015	OREI ² fire blight project is completed
	2016	EPA registration/re-review of oxytetracycline
	2016	First Extension publications on non-antibiotic control available to growers
	2017-	Growers have both the information resources and experience with non-antibiotic control to

² OREI – Organic Research and Education Initiative, the flagship USDA grant program for organic agriculture.

References

[Characteristics of Conventional and Organic Apple Production in the U.S.](#) A 2011 report from USDA-ERS based on the 2007 national ARMS apple survey.

Excerpts from the Washington State University Extension (EM046E) report, “Status of Organic Tree Fruit in Washington State,” prepared by Elizabeth Kirby and David Granatstein, and from a PowerPoint presentation, “Recent Trends in Organic Tree Fruit Production, Washington State, 2011,” also prepared by Kirby and Granatstein.

Granatstein, D., 2013. Fire Blight Introduction, OTA Task Force Meeting, January 21, 2013.

Granatstein, D., 2013. New knowledge is changing fire blight management. *The Organic Report*, Spring edition.

Johnson, K.B., Elkins, R.B., Smith, T. 2013. Research update on non-antibiotic control of fire blight. *The Organic Report*, Spring edition.

Ken Johnson, 2012. Fire Blight Control in Organic Pome Fruit Systems Under the Proposed Non-antibiotic Standard. <http://www.extension.org/pages/62448/fire-blight-control-in-organic-pome-fruit-systems-under-the-proposed-non-antibiotic-standard>.

January 9, 2012

Toni Strother, Agricultural Marketing Specialist
National Organic Program, USDA-AMS-NOP
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Room 2646-So., Ag Stop 0268
Washington, DC 20250-0268

RE: National Organic Program, Proposed Amendments to the National List of Allowed and Prohibited Substances (Crops, Livestock and Processing)

Comment on Docket number AMS-NOP-11-0058-0001

Dear Ms. Strother:

Thank you for the opportunity to comment on the proposed rule to extend oxytetracycline on the National List until Oct 21, 2014. This proposed rule would amend § 205.601 by changing the annotation at paragraph (i)(12) to add an expiration date and specify the permitted use for oxytetracycline.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. 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, and its mission is to promote and protect the growth of organic trade to benefit the environment, farmers, the public and the economy (<http://www.ota.com/>). OTA represents hundreds of certified operations that will be impacted by the final rule.

OTA supports the complete phase-out of antibiotics in organic tree fruit production. However, we're concerned that the proposed deadline of 2014 is not based on scientific evidence, and will not allow for the time needed to identify and develop commercially viable alternatives.

OTA is committed to supporting research and efforts to finding alternative materials and methods for controlling fire blight without the use of antibiotics. The National Organic Standards Board (NOSB) proposed a time-limited extension for tetracycline to allow for the continued use of the material while encouraging the industry to increase its efforts to research and develop commercially viable alternatives. It also included a deadline of 2014 in the material's annotation to convey the urgency of consumer and public interest groups' advocacy of eliminating the use of tetracycline in organic tree fruit production. However, based on the information we have received from both our member growers as well as researchers, we believe that the time needed to address the use of oxytetracycline in organic tree fruit production is much longer than 2014. It is useful to note in the USDA-NASS Agricultural Chemical Usage database, which includes oxytetracycline, that the percent of apple acres treated in a given year nationally ranges from 1-9%; thus a small portion of the apple crop is treated with this allowed material in any given year.

The proposed expiration date of 2014 is as arbitrary as the current expiration date of 2012 because it is not based on well-documented scientific evidence as to the availability of proven alternatives. Based on the research collected and presented by the Organic Tree Fruit Group¹ at the Fall 2011 NOSB meeting, there are organic-compliant biocontrol materials registered for fire blight, but published scientific data have shown that these are not stand-alone replacements for antibiotics. Additionally, changing rootstock to alternative resistant varieties of apples and pears does not address infections that occur on the top of a tree. Furthermore, “Geneva”² rootstock will not be available in commercial quantities before 2014 or 2015. Good progress is being made on alternative controls for fire blight in organic systems. However, according to a recently funded USDA-OREI project in Oregon, Washington, and California, effective biological fire blight control without antibiotics will not be available until 2016. A switch to “resistant” varieties will take a much longer time, likely a decade, and such varieties must be proven acceptable to consumers or they will not be viable choices.

As presented in the petition to remove the expiration date of 2012 and in the Organic Tree Fruit presentation, the premature loss of oxytetracycline for control of fire blight in organic apples and pears will result in a significant net reduction in the amount of organic apples and pears produced in major pome fruit-producing states such as California, Michigan, and New York, but particularly in the Pacific Northwest. Despite this information, the proposed rule was not classified as “significant.” We are concerned that the National Organic Production (NOP) may have underestimated the impact the loss of the material will have. Thus, we ask that special attention and careful consideration be given to the comments received describing the financial impact the proposed rule will have on farmers and businesses.

Based on a preliminary economic assessment³ conducted by David Granatstein for the state of Washington, the loss of oxytetracycline would cause economic impact both through increased costs to growers (manually cutting infected limbs and trees) and loss of organic price premiums for those acres likely to be removed from organic status. This could result in an annual cost for Washington growers ranging from \$8.77-16.54 million per year. This would account for an estimated 80-85% of the national economic impact to organic growers. Organic handlers and distributors would also be significantly affected due to the amount of organic apples and pears used in processed products, particularly as organic apple juice used in other juices and as an organic sweetener used in several other types of products. According to *OTA's 2011 Organic Industry Survey*, beverages accounted for 13.2% of U.S. organic food sales in 2010 and of that, fresh, canned and bottled juice accounted for 26.7% totaling 884 million dollars in consumer sales. Based on juice production reports from our members, we estimate that at least 7-10% of those sales can be attributed to organic pear and organic apple juice.

Given the lack of commercially available effective alternatives to oxytetracycline and the essential role it currently plays in the successful production of organic pears and apples (used infrequently, but essential when disease models indicate high risk of infection), OTA is extremely concerned that the 2014 expiration date is premature and the loss of use of oxytetracycline will have significant impact on the organic sector. OTA supports the development and adoption of a phase-out plan that includes clear science-based benchmarks for progress with non-antibiotic fire blight control that can be periodically monitored and communicated to NOSB.

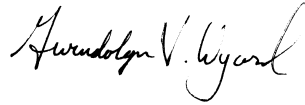
¹ An Organic Tree Fruit Group was formed at the request of the NOSB to help keep it informed of progress with non-antibiotic control techniques.

² The expiration date of 2014 recommended by NOSB was partly predicated on the availability of “resistant” varieties of apples and pears, including the new ‘Geneva’ apple rootstock series.

³ <http://www.tfrec.wsu.edu/pages/organic/fireblight>

On behalf of our members across the supply chain and the country, OTA thanks NOP for the opportunity to comment on this Proposed Rule.

Respectfully submitted,



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Organic Trade Association

cc: Laura Batcha
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