

Date: October 5, 2020

Docket: AMS-NOP-17-0065

Re: Strengthening Organic Enforcement Proposed Rule – Accepting Foreign Conformity Assessment Systems

Thank you for this opportunity to provide comment on the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS) National Organic Program (NOP) Proposed Rule on Strengthening Organic Enforcement. The Organic Trade Association is submitting individual comments on each topic in the proposed rule to help NOP in its process of finding and navigating our positions and recommendations. We have also submitted all of our comments bundled into a single PDF including a cover letter. This comment addresses Section #10: Accepting Foreign Conformity Assessment Systems.

Summary of the Organic Trade Association's (OTA) Positions and Recommendations

- OTA supports the use of equivalence determinations as a tool for facilitating international organic trade, and supports the proposed rule to codify AMS's authorities and baseline procedures in the regulations.
- OTA supports the identification and elevation of the conformity assessment system as equally important as technical requirements in an equivalency determination.
- OTA supports the authority of AMS to describe scope of equivalence determination based on outcomes of AMS's assessment of a foreign government's organic program. OTA also recommends that data transparency and communication be addressed as part of AMS's assessment of a foreign government's organic program.
- OTA does not support inclusion of specific audit timeframes as written in the proposed rule. OTA recommends regulatory revisions that will allow AMS to negotiate the terms of audit timeframes based on the findings of AMS's assessment.
- OTA recommends regulatory revisions that will allow AMS to negotiate termination procedures as part of the equivalency determination based on the findings of AMS's assessment.
- OTA sees increased risks with recognition agreements compared to equivalency arrangements as currently implemented across a number of issues including data transparency, communication, and enforcement.
- OTA asks NOP to clarify whether recognition agreements are intended to be covered by the equivalency determination process described in the proposed rule, and explain what will happen to current recognition agreements as a result of this rulemaking action.

- OTA supports the implementation of the proposals in this section (with OTA requested revisions) within one year after publication of the final rule.

Background

The Organic Foods Production Act part 6505(b) states (emphasis added), “Imported agricultural products may be sold or labeled as organically produced if the Secretary determines that such products have been produced and handled under an organic certification program that provides safeguards and guidelines governing the production and handling of such products that are at least equivalent to the requirements of this chapter.” This provision allows agricultural products that are certified to another country’s equivalent organic certification program to be imported and represented as organic in the United States. These international partnerships have served as an effective tool for facilitating trade of organic products without requiring certified operations to have multiple organic certifications.

Currently USDA is engaged in several international trade arrangements that facilitate trade of organic products. Each arrangement has its own unique terms and scope. **Equivalency arrangements** have been established with Canada, European Union, Japan, South Korea, Switzerland, and Taiwan (UK is pending). Equivalency arrangements are partnerships in which the United States and another country determine that each other’s organic programs are equivalent so that organic products can be sold in either country with just one organic certification. **Recognition agreements** have been established with India, Israel and New Zealand. Recognition agreements are partnerships in which the United States authorizes another country’s government to accredit certifying agents in that country to certify organic operations in that country to the USDA organic standards, and those certified products can then be sold in the United States as organic.

NOP Questions

1. ***AMS seeks comment regarding whether the public sees a differential risk to enforcement associated with certain organic trade relationships. Specifically, compared with organic equivalence determinations, are there increased risks associated with recognition agreements where other countries’ governments oversee the implementation of NOP certification?***

Yes. OTA sees increased risks with recognition agreements compared to equivalency arrangements across a number of issues including data transparency, communication, and enforcement. We also asks NOP to clarify what will happen to current recognition agreements as a result of this rulemaking action. Please see below for more information about OTA’s position on recognition agreements.

OTA's Positions and Recommendations

- **OTA supports the use of equivalence determinations as a tool for facilitating international organic trade, and supports the proposed rule to codify AMS's authorities and baseline procedures in the regulations.** There are currently multiple bilateral and unilateral organic equivalency arrangements in play between the U.S. and our larger trading partners. These equivalency arrangements are key factors in facilitating trade, yet they also strengthen government to government relationships. The provisions of the proposed rule are effective to provide more transparency in the procedures used by NOP to establish these partnerships. The current regulations do not contain specific procedures used by AMS to establish equivalency arrangements. Such procedures have historically been maintained in the NOP Program Handbook. Two documents have been archived¹ (NOP 2100 and NOP 2014) and one instruction² on Recognition Agreements is effective (NOP 2200). An Audit Report³ by the USDA Office of Inspector General in 2017 OIG Report identified two findings that are relevant to the topic of foreign conformity assessments (Finding #1 - Equivalency Determination Process Not Fully Transparent; Finding #4 - Onsite Audits Not Conducted Timely).
- **OTA supports the identification and elevation of the conformity assessment system as equally important as technical requirements in an equivalency determination.** Historically, the primary method of evaluating equivalency was through overcoming barriers to differences in practice standards and allowed or prohibited inputs. As there are several major agreements up for renewal or are being revised, there is now a larger consideration of oversight and integrity at the center of these discussions. It is critical that foreign governments have sufficient oversight, accreditation, compliance and enforcement control in place to ensure that their organic technical requirements are applied and enforced. All equivalency arrangements should be based on systems of comparable rigor and standards, and this follows for continuous compliance assessment. The integrity of the conformity assessment system is pivotal to ensuring the continued success of equivalency arrangements and recognition agreements.
- **OTA supports the authority of AMS to describe the scope of equivalence determinations based on outcomes of AMS's assessment of the foreign government's organic program.** The terms and scope of any equivalence determination should be customized to the unique characteristics of the foreign government's organic program conformity assessment system and technical requirements. The assessment process is a critical step in collecting information to determine the terms and scope of any potential future equivalence determination. To ensure clarity of the items that should be included in the AMS assessment, the regulations should include specific references to conformity

¹ <https://www.ams.usda.gov/sites/default/files/media/NOP-ArchivedDocs.pdf>

² <https://www.ams.usda.gov/sites/default/files/media/2200.pdf>

³ <https://www.usda.gov/sites/default/files/01601-0001-21.pdf>

assessment system and technical requirements. Additional key elements such as data transparency and communication should also be included. AMS should negotiate terms of the equivalence determination, such as audit time-frames and termination procedures, based on the findings of AMS's assessment of a foreign government's organic program. AMS also should have the authority to amend the scope and terms of an equivalence determination as needed based on the outcomes of its assessment and any subsequent audits.

→ **Recommendation:** Revise §205.511(b) to specifically identify items that should be included in AMS's assessment of the foreign government's organic program. *See OTA's requested revisions in Table 9 below.*

- **OTA recommends that data transparency be addressed as part of AMS's assessment of a foreign government's organic program.** From the trade side, there is increasing skepticism from the private sector that we are losing data transparency. Organic producers and handlers certified to an equivalent foreign country's systems do not currently provide the same level of data transparency as USDA-certified organic operations that are listed in the NOP Organic Integrity Database. Equivalence determinations should include an assessment of the foreign country's system of data collection and reporting and work towards greater transparency of data. Ideally, information on certified operations (certificates) and certifiers (accreditation documents) should be available, comparable to the NOP Organic Integrity Database. We support global use of the NOP Organic Integrity Database, but if not possible, we recommend investing in the development of some additional system that gives organic operations and certifying agents access to the same type of information about certified operations around the world operating under equivalency arrangements or recognition agreements and selling product into the United States. The system should include operations in equivalent countries eligible to export to the U.S. as organic and operations certified to the USDA regulations by a certifier operating under a recognition agreement.

→ **Recommendation:** Revise §205.511(b) to include data transparency as an element to be addressed by AMS in its assessment of a foreign government's organic program. *See OTA's requested revisions in Table 9 below.*

- **OTA recommends that communication be addressed as part of AMS's assessment of a foreign government's organic program.** Communication is a key element of a foreign country's conformity assessment system that must be evaluated during equivalence determinations. The extent to which parties are notified of adverse actions affecting the certification of an operation or accreditation of a certifying agency should be assessed. The capacity to transfer information among certifiers and between authorities to support investigations should be taken into consideration as part of the assessment. As described throughout the proposed rule, information sharing among certifiers is a critical part of oversight and enforcement capabilities. The same benefits extend to communications between the enforcement authorities

of trading partners, certification bodies in regions and countries covered by equivalency arrangements and recognition agreements, and other institutions that protect organic integrity. The capacity to provide clear, accurate, and timely communications will help achieve the broader goal of oversight and integrity.

→ **Recommendation:** Revise §205.511(b) to include communication as an element to be addressed by AMS in its assessment of a foreign government's organic program. *See OTA's requested revisions in Table 9 below.*

- **OTA does not support inclusion of specific audit timeframes as written in the proposed rule.** The regulations must avoid overly prescriptive review and reassessment schedules, and protect flexibility to accommodate unavoidable limitations of each country to participate in audits. Prescriptive timelines are ill-advised especially if they would implicate the other country to comply, as it may not be reasonable to expect other countries to comply with this prescriptive regulatory text.

Furthermore, the proposed rule text is unclear about the several aspects of the audits. The proposed rule refers to both a 2-year audit cycle and a 5-year audit cycle, but the purpose and scope of each of these types of audits are unclear. The proposed rule is unclear about whether these audits implicate the other country, or if either of the audits are required to be onsite. The proposed rule text is also unclear on the intent behind the proposed 2-year cycle. The preamble describes that the mid-term audit cycles are intended to mirror ISO standards, and are intended to provide flexibility in scheduling the mid-cycle reviews to accommodate unavoidable factors in both countries that can impact timing. However, the prescriptive 2-year time line is *not flexible* and would result in *two* mid-cycle reviews per 5-year reassessment cycle. It is also not clear whether the 2-year review is intended to be onsite and how the scope of the 2-yr review differs from the 5-year reassessment.

OTA recommends regulatory revisions that will allow AMS to negotiate the terms of audit timeframes based on the findings of AMS's assessment. The regulations should allow flexibility for AMS to negotiate the terms of the renewal timing, frequency, and procedures for reassessing the equivalency termination. AMS should negotiate these terms as part of the equivalence determination based on the findings of AMS's assessment of a foreign government's organic program. Certain countries' programs may warrant more frequent or less frequency re-reviews based on the unique characteristics of the program's conformity assessment systems. OTA recommends an audit timeframe that is agreed to by both parties during the equivalency determination process based on outcomes of AMS's assessment of the other country's systems. There should be two kinds of audits. The first type should be a mid-term audit that should only implicate NOP and not implicate the other country. The second type is a full reassessment of the arrangement that involves both countries' governments and should be conducted on a longer timeline than the mid-term audits. The audit timeframes must allow for flexibility to accommodate unavoidable limitations of each country to participate in audits.

- ➔ **Recommendation:** Revise §205.511(c) to allow flexibility for AMS to negotiate terms of renewal audit cycles as part the equivalence determination based on the findings of its assessment of the foreign government’s organic program, and revise §205.511(d) to remove prescriptive audit schedules. *OTA’s requested revisions in Table 9 below.*

If NOP does not accept OTA’s recommended revisions, we ask NOP to please provide an explanation of NOP’s intent behind the scope and timing of the proposed 2-year audit cycle to address our concerns described above.

- **OTA recommends regulatory revisions that will allow AMS to negotiate termination procedures as part of the equivalency determination based on the findings of AMS’s assessment.** Although the proposed rule identifies the conditions under which an equivalency determination may be terminated, it does not specify the procedures that should be followed by each party to carry out a termination. AMS should negotiate termination procedures as part of the equivalency determination so that termination of trade arrangements can be carried out in an orderly manner. For example, procedures should in place to provide an appropriate transition period to allow time for certifiers to get accredited under a new foreign government, and/or for certified operators to switch certifiers, and to give public notice to trade in advance of terminating an agreement.

- ➔ **Recommendation:** Revise §205.511(c) to allow flexibility for AMS to negotiate terms of termination procedures as part the equivalence determination based on the findings of its assessment of the foreign government’s organic program. *See OTA’s requested revisions in Table 9 below.*

- **OTA sees increased risks with recognition agreements compared to equivalency arrangements.** In the proposed rule, AMS asks for comments regarding whether the public sees a differential risk to enforcement associated with certain organic trade relationships: Specifically, compared with organic equivalence determinations, AMS asks if there are increased risks associated with recognition agreements where other countries’ governments oversee the implementation of NOP certification. As described above, recognition agreements are partnerships in which the U.S. authorizes another country’s government to accredit certifying agents in that country to certify operations within that country to the USDA organic standards. The U.S. has established recognition agreements with India, Israel and New Zealand.

OTA sees increased risks with recognition agreements compared to equivalency arrangements as currently implemented across a number of issues including data transparency, communication, and enforcement. The lack of data transparency is one of the top cited concerns with recognition agreements. While all other NOP-certified operations are listed in the NOP Organic Integrity Database, the operations certified

under recognition agreements are not included. Currently there is no transparency on the identities and certification status of certified operations, thus posing significant difficulties for trading partners to validate organic certificates. Also information on accreditation status and authorized scope of certification agencies is not available comparable to that available in the NOP Organic Integrity Database for USDA-accredited certification agencies. We also see concerns raised about the extent to which governmental authorities are implementing the NOP rule including associated guidance and policy. Lastly, we are concerned about the lack of alignment on decertification, revocation and reinstatement procedures of other countries operating under recognition agreements.

As currently implemented, recognition agreements are distinct from equivalency arrangements and would not appear to fit in to the equivalency determination process as described in the proposed rule. However, NOP does not explain whether recognition agreements are intended to be covered by this process of equivalence determination, and this needs clarification. Parts of the preamble in the proposed rule would suggest that recognition agreements ***are covered*** by this process of equivalence determination. For example, in the preamble AMS describes that the equivalence determination process has been used to establish trade arrangements for organic products with 10 other countries, 3 of which are recognition agreements. However other parts of the proposed rule would suggest that that recognition agreements ***are not covered*** by this rulemaking action. The text proposed in §205.511(a) in the proposed rule refers only to foreign product that is “certified under the USDA organic regulations by a USDA-accredited certifying agent” or “produced and handled under another country’s organic certification program.” It doesn’t seem that a recognition agreement would fall under either of these options because the product is not certified by a USDA-accredited certifying agent nor is certified by its own country’s equivalent organic program (recognition agreements use USDA’s organic programs, not its own). Also, the way that NOP phrases its request for comments asks about recognition agreements as “compared [to] organic equivalence determination,” implies that recognition agreements are not equivalence determinations. **OTA asks NOP to clarify whether recognition agreements are intended to be covered by the equivalency determination process described in the proposed rule, and explain what will happen to current recognition agreements as a result of this rulemaking action.**

- OTA supports the implementation of the proposals in this section (with OTA requested revisions) within one year after publication of the final rule.

Table 9: OTA’s Requested Revisions to the Proposed Rule and Recommendations for Guidance

Action & Section	Proposed Rule Text	Revisions and/or Guidance needed to implement OTA’s Positions and improve the quality, clarity or utility of the proposed rule
205.2 Add new term	<i>Conformity assessment system.</i> All activities undertaken by a government to ensure that the applicable technical requirements for the production, handling, and processing of organic agricultural products are fully and consistently applied from product to product.	<p>Revision needed to clarify elements that should be included in the conformity assessment:</p> <ul style="list-style-type: none"> • Examples from preamble: accreditation and oversight of certifying agents, and compliance and enforcement activities <p>Revision needed to clarify what is meant by “product to product.”</p>
<p>OTA Requested Revision: <i>Conformity assessment system.</i> All <u>oversight, accreditation, compliance and enforcement</u> activities undertaken by a government to ensure that the applicable technical requirements for the production, handling, and processing of organic agricultural products are fully and consistently applied <u>and enforced from product to product across all certified entities and products.</u></p>		
205.2 Add new term	<i>Technical requirements.</i> A system of relevant laws, regulations, regulatory practices, and procedures that address the production, handling, and processing of organic agricultural products.	<p>Revision needed to clarify elements included in the assessment of technical requirements:</p> <ul style="list-style-type: none"> • Add Examples from preamble: development of standards, policies and procedures • Add production practices and inputs
<p>OTA Requested Revision: <i>Technical requirements.</i> A system of relevant laws, regulations, regulatory practices, <u>standards, policies,</u> and procedures <u>(and the development thereof)</u> that address the production, handling, and processing of organic agricultural products, <u>including but not limited to production practices, processing and handling practices, and allowed and prohibited inputs.</u></p>		
205.511(a) Add new section	Accepting foreign conformity assessment systems.	

<p>205.511(a) Add</p>	<p>Foreign product may be certified under the USDA organic regulations by a USDA-accredited certifying agent and imported for sale in the United States. Foreign product that is produced and handled under another country’s organic certification program may be sold, labeled, or represented as organically produced in the United States if AMS determines that such organic certification program provides technical requirements and a conformity assessment system governing the production and handling of such products that are at least equivalent to the requirements of the Act and the regulations in this part (“equivalence determination”).</p>	<p>Revision needed to clarify what is an equivalency determination.</p> <ul style="list-style-type: none"> • Add definition to §205.2 using language from this section.
<p>OTA Requested Revision: Add to 205.2: <u>Equivalence determination. A determination by AMS that another county’s organic certification program provides technical requirements and a conformity assessment system governing the production and handling of products that are at least equivalent to the requirements of the Act and the regulations in this part.</u></p>		
<p>205.511(b) Add</p>	<p>Countries desiring to establish eligibility of product certified under that country’s organic certification program to be sold, labeled or represented as organically produced in the United States may request an equivalence determination from AMS. A foreign government must maintain compliance and enforcement mechanisms to ensure that its organic certification program is fully meeting the terms and conditions of any equivalence determination provided by AMS pursuant to this section. To request this determination, the requesting country must submit documentation that fully describes its technical requirements and conformity assessment system. If AMS determines it can proceed, AMS will</p>	<p>Revision needed to implement OTA’s Positions described above regarding AMS’s assessment, data transparency and communication. The regulations should specifically identify items that should be included in AMS’s assessment of the foreign government’s organic program.</p> <ul style="list-style-type: none"> • Add conformity assessment system • Add technical requirements • Add data transparency • Add communication • Additional detail could be reserved for guidance as needed.

	conduct an assessment of the country's organic certification program to evaluate whether it is equivalent.	
<p>OTA Requested Revision: Countries desiring to establish eligibility of product certified under that country's organic certification program to be sold, labeled or represented as organically produced in the United States may request an equivalence determination from AMS. A foreign government must maintain compliance and enforcement mechanisms to ensure that its organic certification program is fully meeting the terms and conditions of any equivalence determination provided by AMS pursuant to this section. To request this determination, the requesting country must submit documentation that fully describes its technical requirements and conformity assessment system. If AMS determines it can proceed, AMS will conduct an assessment of the country's organic certification program to evaluate whether it is equivalent. <u>AMS's assessment must include an evaluation of the country's conformity assessment system and technical requirements as defined in 205.2, as well as the country's systems for data transparency and communication.</u></p>		
205.511(c) Add	AMS will describe the scope of an equivalence determination.	<p>Revision needed to implement OTA's Positions described above regarding audit timeframes and termination procedures. The regulations should allow flexibility for AMS to negotiate terms of renewal audit cycles and termination procedures as part the equivalence determination based on the findings of its assessment of the foreign government's organic program.</p> <ul style="list-style-type: none"> • Add renewal audit timelines • Add termination procedures • Additional detail could be reserved for guidance as needed.
<p>OTA Requested Revision: AMS will describe the scope of an equivalence determination, <u>as well as terms and conditions regarding renewal audits and termination procedures of the equivalence determination, based on AMS's assessment of the foreign government's organic program as described in 205.511(b).</u></p>		
205.511(d) Add	AMS will conduct reviews on a two-year cycle, beginning at the close of the prior review, to assess the effectiveness of the foreign government's organic certification program. AMS will reassess a country's	<p>Revision needed to implement OTA Position on audit timeframes. The regulations must avoid overly prescriptive review and reassessment schedules, and protect flexibility to accommodate unavoidable limitations of each country to participate in audits.</p>

	<p>organic certification program that AMS has recognized as equivalent every five years to verify that the foreign government’s technical requirements and conformity assessment program continue to be at least equivalent to the requirements of the Act and the regulations of this part, and will determine whether the equivalence determination should be continued.</p>	<ul style="list-style-type: none"> • Remove prescriptive timelines. • Add requirement to comply with renewal terms of the arrangement, which we recommend to be negotiated during the equivalency determination based on AMS’s assessment of the foreign government’s organic program (<i>see OTA Requested Revision at §205.511(c) above</i>) • Add allowance for AMS to amend scope of termination the equivalence determination based on the outcome of audits.
<p>OTA Requested Revision: AMS will conduct reviews on a two-year cycle, beginning at the close of the prior review, to assess the effectiveness of the foreign government’s organic certification program. AMS will reassess a country’s organic certification program that AMS has recognized as equivalent every five years to verify that the foreign government’s technical requirements and conformity assessment program continue to be at least equivalent to the requirements of the Act and the regulations of this part, and will determine whether the equivalence determination should be continued. <u>AMS will comply with the renewal terms and conditions of the equivalence determination. Audit findings may cause AMS to amend the scope or terminate the equivalence determination.</u></p>		
<p>205.511(e) Add</p>	<p>AMS may terminate an equivalence determination if the terms or conditions established under the determination are not met; if AMS determines that the country’s technical requirements and/or conformity assessment program are no longer equivalent; if AMS determines that the foreign government’s organic control system is inadequate to ensure that the country’s organic certification program is fully meeting the terms and conditions under the determination; or for other good cause.</p>	<p>Revision needed to implement OTA Position on <u>termination procedures</u>.</p> <ul style="list-style-type: none"> • Add requirement to comply with terminations terms of the arrangement, which we recommend to be negotiated during the equivalency determination based on AMS’s assessment of the foreign government’s organic program (<i>See OTA Requested Revision at §205.511(c) above</i>) <p>Revision needed clarify proposed rule text.</p> <ul style="list-style-type: none"> • Remove subjective wording (“good” is too subjective; AMS should be able to terminate for any cause)

OTA Requested Revision: AMS may terminate an equivalence determination if the terms or conditions established under the determination are not met; if AMS determines that the country’s technical requirements and/or conformity assessment program are no longer equivalent; if AMS determines that the foreign government’s organic control system is inadequate to ensure that the country’s organic certification program is fully meeting the terms and conditions under the determination; or for other ~~good~~-cause. AMS will comply with the termination terms and conditions of the equivalence determination.

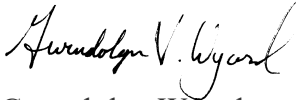
205.500(c) Remove	<p>(c) In lieu of accreditation under paragraph (a) of this section, USDA will accept a foreign certifying agent's accreditation to certify organic production or handling operations if:</p> <p>(1) USDA determines, upon the request of a foreign government, that the standards under which the foreign government authority accredited the foreign certifying agent meet the requirements of this part; or</p> <p>(2) The foreign government authority that accredited the foreign certifying agent acted under an equivalency agreement negotiated between the United States and the foreign government.</p>
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On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Program for your commitment to protecting organic integrity.

Respectfully submitted,



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 Farm Policy Director



Gwendolyn Wyard
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cc: Laura Batcha
 Executive Director/CEO