October 25, 2016

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-16-0049

RE: Crops Subcommittee – Strengthening and Clarify the Requirements for Use of Organic Seed **(Discussion)**

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Crops Subcommittee's Discussion Document on areas in which the National Organic Program's Guidance titled "Guidance on Seeds, Annual Seedlings, and Planting Stock in Organic Crop Production (NOP 5029)" could be clarified and strengthened.

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 organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

Summary of OTA's Position
OTA thanks the Subcommittee for its willingness to listen to stakeholders and for carefully studying the issue of how to keep seeds used in organic systems from being contaminated with GMO content. We agree that strengthening the provisions in the organic regulations on the use of organic seed is one very important part of a total solution. We also agree that NOP's seed guidance of March 2013 (NOP 5029) did not go far enough, and the next practical next step would be a recommendation from NOSB to NOP to revise the guidance to reflect the current state of the organic seed industry and to further address the use of "at-risk" non-organic seed. Increasing support for organic seed lines through a stronger seed requirement is essential to further reducing unintended GMO presence and limiting the extent to which seeds outside of NOP purview are used in certified farming systems. It is also essential to ensuring the consistent application and enforcement of organic seed requirements, which, in turn, will promote the breeding, development and production of a greater diversity of varieties well suited for organic production systems.

We offer the following more detailed comments:
OTA strongly believes that one of the best areas that NOSB can continue its work on the topic of seed purity is through strengthening the seed provisions in the regulation through the guidance process. We

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agree that NOP's seed guidance in March 2013 did not go far enough, and an excellent next step would be a recommendation from NOSB to NOP to revise the guidance to further address the current state of the organic seed industry and non-organic seed that is at-risk of GMO contamination (e.g. corn, soybeans, alfalfa, canola, and cotton).

Tremendous strides have been made in the past decade to increase the availability of organic seed and planting stock, yet much greater improvement is needed. According to a 2016 Organic Seed Alliance survey that included responses from certified organic farmers in 47 states, only 27% reported that they used 100% organic seed. This demonstrates a minor improvement compared to 2009 data, where 20% of farmers were using 100% organic seed. Specific to field crops (including corn and soy), field crop growers, on average, planted 78% of their acreage to organic seed compared to 72% in 2009. More encouraging is that 56% reported using 100% organic seed for field crop acreage compared to 47% in 2009. Most respondents had less than 80 acres in field crops, whereas 13% of respondents had more than 480 (Hubbard, K. and J. Zystro. 2016. *State of Organic, 2016*, Organic Seed Alliance).

The intent of the allowance in 7 CFR § 205.204(a) to use non-organic seed under certain conditions was to provide a transition time for the industry while the production of organic seed and planting stock caught up to its demand. However, almost 15 years later, the increased use of organic seed and planting stock has been less than robust. Commercial availability has been applied inconsistently since the implementation of the rule, and the level at which certifiers monitor and enforce the use of organic seeds and planting stock varies significantly. Therefore, a regulatory change or improved NOP guidance is crucial to help remedy the situation.

OTA was pleased to see the NOP Final Guidance released on March 4, 2013. However, we were also disappointed by its content because it left out critical areas that were suggested and strongly supported through the public comment process on the Draft Guidance. We understand the complexity of organic seed issues, and we recognize that the organic seed sector has not yet caught up to fully meet the diverse and regional demands of organic production. Still, in part due to a poor regulatory framework, the guidance as written does not reflect the progress that has been made in the organic seed sector since the regulations and the 2005 and 2008 NOSB recommendations were written. Since then, the number of companies supplying organic seed has grown ten-fold, and more educational resources and tools exist to support the sourcing and planting of organic seed. For these reasons, it is time NOP's guidance on sourcing organic seed is updated.

Strengthening NOP's guidance to reflect the current state of the organic seed industry

OTA believes that NOP's guidance (NOP 5029) should be revised to more accurately reflect the current state of the organic seed industry, and it should include additional guidance specific to the use of "at-risk" non-organic seed. We believe the recommended steps below are both appropriate and necessary for supporting organic producers, the organic seed sector, and the broader organic food and fiber industry. They also support existing NOP regulations. Please note that the recommendations below were formed in collaboration with OTA members and the Organic Seed Alliance.

1. NOP's Seed Guidance does not address the prohibition on excluded methods

The regulations require that non-organic seed is non-GMO. However, NOP's guidance on seed is silent on this requirement. NOP's Guidance should reiterate that certified operators may only use non-GMO non-organic seed or planting stock. While the development of a Seed Purity Standard is the ultimate goal,

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in the interim we request that NOP reiterate the already existing prohibition on excluded methods, and specifically state in the guidance that organic producers must be able to provide ACAs with documentation demonstrating non-GMO status. Only in the absence of an organic equivalent variety ***and*** documentation to demonstrate its non-GMO status should producers be able to use non-organic seed.

OTA RECOMMENDATION: NOP's Seed Guidance should be updated at 4.1 (Sourcing of Seeds, Annual Seedlings, and Planting Stock) to provide organic producers with guidance on the use of non-organic, non-GMO seed:

> Add an additional section (4.1.6) to the guidance to specify that the organic regulations allow for the use of non-organic seed only if equivalent organically produced varieties of organic seeds and planting stock are not commercially available and they are produced without the use of excluded methods. Organic producers must provide ACAs with supporting documentation demonstrating that non-organic seed is non-GMO.

2. NOP's Seed Guidance sets the minimum search bar too low at three sources

OSA's *State of Organic Seed* findings show that when certifiers encourage producers to take additional steps to source organic seed beyond consulting three sources, the result is increased organic seed usage. Since the implementation of NOP, and even prior under some state and private standards, that status quo when searching for organic seed is to contact a minimum of three sources. We would like to see this "status quo number" adjusted to reflect state of the organic seed industry. There are now over 100 companies that offer organic seed, and in all categories of seed (e.g. field crops, vegetables, fruits, herbs, flowers) there are at least a dozen.

Many public comments submitted in response to NOP's draft guidance pointed to "three" sources as inadequate due to the increased availability of organic seed and planting stock varieties. We believe that no less than five sources should be contacted. In addition to a *minimum of **five** sources*, we believe it would be helpful to explain that the appropriate number of sources contacted should be relative to the potential number of suppliers of organic seed.

OTA RECOMMENDATION: In addition to specifying a ***minimum*** of five sources, we urge NOP to adopt the language provided in OTA's August 12, 2011, comments on the Draft Guidance:

> Certified operations should contact seed or planting stock sources to ascertain the availability of organic seed or planting stock for all crops grown.
>
> 1. These sources must be companies that offer organic seed and planting stock.
>
> 2. The number of seed or planting stock sources contacted should be relative to the number of companies potentially supplying the organic equivalent variety being procured and to the quantity (commercial vs. backyard) of seed needed.
> 3. Documentation regarding this search should be maintained as part of record-keeping and should include the dates of organic seed sourcing attempts. Sourcing dates should be verified to confirm the grower attempted sourcing efforts in sufficient time to actually be possible (e.g.

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3-6 months for off-the shelf quantities and 12-18 months for large quantities of high-density crops such as baby leaf lettuce, spinach, arugula, kale, etc.).

3. NOP's Seed Guidance does not establish organic seed usage as an Organic System Plan goal

There is no guidance in identifying specific Organic Systems Plan goals for reasonable and measurable increases in organic seed usage, including plans for transitioning to organic varieties and reviewing increases by percentage used or acreage planted. While we're glad the guidance states (section 4.4) that certifiers should review an operation's progress in obtaining organic seed by comparing current source information to previous years, the document lacks strong language indicating that this is an important OSP goal that moves us toward continuous improvement.

In the farmer survey included in the *State of the Organic Seed, 2016,* farmers were asked if certifiers had over the last three years requested that greater steps be taken to source organic seed. The results from the 2016 survey demonstrated a marked decrease from the figures that were reported in 2009. Only 40% of farmers responding said their certifiers made such a request whereas more than 60% reported this request in 2009. As mentioned earlier, the 2016 survey as well as the 2009 survey include compelling data demonstrating that when certifiers request that farmers take greater steps to source organic seed, farmers respond by sourcing more organic seed (on average a 12.5% increase across seed types).

OTA RECOMMENDATION: To improve ongoing efforts to use organic seed, the guidance should be amended to require certifiers to work with producers on gauging measurable and reasonable annual increases in organic seed usage. Our suggestion is based on the 2008 NOSB recommendation and the comments we submitted to NOP on its draft version. OTA urges NOP to add the following language under section 4.2.1(b) of its final guidance:

> Records showing whether, from year to year, the operation has, through continuous improvement, increased the overall use of organic seed and planting stock. For example:
>
> - For row crops/field crops and specialty crops grown on substantial amounts of acres, the percentage of total crop acreage planted with organic seed and/or planting stock year after year would be an appropriate measure of improvement.
> - For specialty crops grown in diverse varieties on smaller acreages, an appropriate measure of improvement would be no less than 5% increase.

4. NOP's Seed Guidance does not address the requirements of the certified buyer (handler) purchasing seed/planting stock for contractual growing purposes.

It is critical that NOP's guidance address certified operations (i.e. handlers) that contract with growers and mandate specific types of seed or planting stock. Buyers are often certified handlers who contract with producers to grow certain varieties that are often not available as certified organic. If a certified handler (buyer) mandates a particular variety to be planted ***and the buyer/handler is responsible for sourcing the seed***, the certified handler should be held responsible for determining if the variety is commercially available as organic and this information should be included in the producer's Organic System Plan. It should also apply to certified seed handling operations such as brokers, and to growers who contract with operations that raise annual seedlings for transplants. Questions about contractual agreements and seed/planting stock should be raised during inspections and the information must be addressed in the producer's Organic Systems Plan, since in reality these contracts, not the farmers, dictate whether organic or non-organic seed/planting stock is purchased and planted.

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This consideration was included in the 2008 NOSB recommendation but was not included in NOP's final guidance despite requests made in public comments. NOP's response to the changes requested but not made was as follows:

> **Handlers Purchasing Seed for Contracted Growers**. Several commenters stated that 7 CFR § 205.204 applies to handlers purchasing seed for contractual growing purposes, and that language should be included in the guidance emphasize this. However, this guidance is applicable to crop producers subject to requirements of § 205.204, and handlers are not typically certified as crop producers subject to this requirement. All growers must meet the same standard and use organic seeds unless they can demonstrate that organic seeds are not commercially available. All producers must provide the necessary documentation regarding lack of commercial availability of organic seeds to justify use of non-organic seed or planting stock. Contracted growers should inform their buyers of the need to use organic seeds unless they are not commercially available.

OTA acknowledges that the organic seed use requirements in the regulation specify "producers." This is exactly why guidance in this area is needed because the reality is that the buyer/handler is responsible for sourcing the seed while it is the producer's responsibility to demonstrate the sourcing efforts to the certifier. Guidance that explicitly references the producer's responsibility to include sourcing information in the Organic Systems Plan would support growers in their ability to collect this information. Furthermore, the regulatory definition of a "handler" includes "producers who handle crops or livestock of their own production."

> **OTA RECOMMENDATION**: The final guidance should be amended to apply to handlers that source seed for contractual growing purposes. A 'handler' is defined in the organic regulations as "Any person engaged in the business of handling agricultural products, including producers who handle crops or livestock of their own production, except such term shall not include final retailers of agricultural products that do not process agricultural products." If a certified 'producer' is using seed based on the sourcing efforts of the company they are growing for, sourcing efforts carried out by the company ('handler') should be clearly detailed in the producer's Organic Systems Plan and the sourcing documentation submitted to the inspector and certifier. The sourcing efforts made by the handler must be communicated to and documented in the producer's Organic Systems Plan. Including guidance for this type of situation will help enable growers in their efforts to collect this information from the handlers and buyers they are working with. Furthermore, NOSB should require handlers and brokers to demonstrate progress (through timely seed ordering and/or the mutual development of organic seed sources) in fostering the production of organic seed that meets the requirements of their end-users. Again, this information should be included in the organic producer's Organic Systems Plan.

5. NOP's Seed Guidance does not reference helpful resources such as the Organic Seed Finder

Perhaps the most important tool that can help certified operators and certifying agents in their efforts to source and evaluate the availability of organic seed and planting stock is a searchable national database of available organic varieties. Certifiers evaluate the availability of organic seed without a complete reference of organic seed. Thankfully, such a database now exists (Organic Seed Finder), but we are finding that it is not being fully utilized by industry, certifiers and certified operations.

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OTA Recommendation:
NOP has endorsed the Organic Seed Finder as a resource for national organic seed availability data. Accordingly, it would be extremely helpful if NOP would engage and further serve the organic community by advocating for the participation and use of the Organic Seed Finder (www.organicseedfinder.org) through its marketing materials, certifier trainings and communication channels, and by including an explicit reference in the seed guidance for certifiers, inspectors, and producers to use this database as a seed-sourcing tool. In order to alleviate concerns of promoting one service over another and to further assist searching efforts, NOP could also include reference to other helpful seed resources such as Pick A Carrot (https://www.pickacarrot.com/), ATTRA Directory of Organic Seed Suppliers (https://attra.ncat.org/attra-pub/organic_seed/) and SeedWise (https://www.seedwise.com/). Referencing these tools in AMS marketing materials, guidance and certifier trainings would increase their visibility to certifiers and producers, and encourage their use to spur further engagement and investment.

Increased certifier and inspector trainings in organic seed
Certifiers have the important job of communicating organic seed requirements to organic producers and handlers, granting approval for the use of non-organic seed due to the commercial unavailability of organic seed, issuing non-compliances when adequate searches are not conducted and reinforcing the need for continuous improvement as appropriate. This job comes with great challenges given the time, resources and complexity involved in verifying a claim that a particular seed variety is "commercially unavailable."

Consistent implementation of the organic seed requirements and NOP guidance will significantly be improved through trainings for certifiers and inspectors. For example, the State of the Organic Seed Industry Survey includes the results of a certifier survey that delivers responses from 22 ACAs representing 68% of certified operations in the U.S. More than half of the respondents agree that additional trainings are needed to help certifiers and inspectors understand seed issues from a farmer perspective.

OTA sees two kinds of trainings that need to happen: 1) NOP trainings to ensure that certifiers are fully aware of and understand the requirements of the rule and its accompanying guidance; 2) General trainings at organic seed conferences, ACA trainings, etc., that provide certifiers with a greater understanding of seed issues from grower and handler perspectives.

OTA Recommendation:
In addition to strengthening NOP's seed guidance, the recommendation from NOSB to NOP should include a request for periodic NOP trainings to ACAs on carrying out commercial availability determinations for organic seed. The trainings should focus on the regulatory requirements and guidance, include seed database resources, and emphasize that ACAs monitor their clients' use of organic seed and planting stock for evidence of increased usage. Additionally, monitoring by ACAs of organic seed or planting stock usage should be included as part of NOP's accreditation reviews of ACAs.

Creating a framework for methodically "closing the loophole"
Demand for organic seed is growing. U.S. sales of organic products totaled more than $43 billion in 2015, and 11% increase compared to 2014. Food purchases represent $39.7 billion of this total. Yet, as

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demonstrated in the *State of Organic Seed, 2016,* the organic seed supply isn't keeping up with this growth, and most organic farmers still rely on conventionally produced seed for at least part of their operation. There are many reasons for the less than robust progress, but the barrier that stands out from a regulatory perspective is the challenge of adequately enforcing the commercial availability clause in the organic regulations and the data needed to carry out that process.

As mentioned earlier, the allowance to use non-organic seed under certain conditions was to provide a transition time for the industry while the production of organic seed and planting stock caught up to its demand, with the goal of eventually achieving 100% organic seed usage. The reality is that progress is being made at many different levels and availability depends on crop, variety and region. For some crops such as corn, it is arguable that we are very close to maintaining an organic supply in the quality, quantity and supply needed and the exception to use non-organic corn should be closed. For other crops, we are years off. At any rate, there should come a time when the use of organic seed for a particular crop type becomes a requirement without exception.

There is a need for a methodical process for reviewing and reporting organic seed availability each year (crop by crop and region by region) to determine if and when there is adequate diversity and volume to require the use of organic seed for a particular crop type. One approach for NOSB to explore is the European Union (EU) model where a standing seed committee or expert group could be established that that would advise NOSB on the availability of organic seed by crop and region and on an annual or biannual basis (see Appendix A, pages 271- 275).

In the EU model, the responsibility of enforcement lies with the national governments of each of the 27 EU member states and the regulation stipulates that governments must host an online database listing the available organic varieties and their suppliers. Some member states, such as the Netherlands and Denmark, use formalized expert groups to identify which species and (sub) species are available in organic form and which ones should be provided with exceptions according to designated exception categories developed by the member states. While the exact model used in the EU may not perfectly translate to the United States, we think the model is generally worth exploring.

OTA Recommendation:
OTA recommends that NOSB explore the formal development of a seed expert group or seed committee that would advise NOSB on the availability of organic seed (crop by crop and region by region) to determine if and when there is adequate diversity and volume to require the use of organic seed for a particular crop type. We recommend that NOSB pursue this effort outside of a recommendation to NOP to update its seed guidance. We envision that the Crops Subcommittee would work with the Certification, Accreditation and Compliance Subcommittee and develop a discussion document that would explore the structure and function of a seed expert committee as well as other possible avenues that would support a methodical approach to closing organic seed use exceptions.

Conclusion
OTA continues to be extremely supportive of moving recommendations forward to NOP that will improve the practices used to keep GMOs out of organic seed, feed and crops. We agree that strengthening the provisions in the organic regulations on the use of organic seed is one very important part of a total solution. Therefore, we are extremely pleased to see a Discussion Document that focuses specifically on these efforts.

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OTA strongly supports the further development of the organic seed and planting stock industry, and we are committed to finding solutions to meet this goal. The goal of our efforts should be to promote the continued growth and improvement in organic seed and planting stock production, and subsequent usage by organic growers without hurting or putting undue burdens on growers. The intent is not to have non-compliances handed down to farmers trying to comply with the seed and planting stock commercial availability section of the Rule. Instead, the intent is to maintain NOP guidance that will help ensure the consistent application and enforcement of organic seed requirements, which, in turn, will promote the breeding, development and production of a greater diversity of varieties well suited for organic production systems.

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,

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cc: Laura Batcha
Executive Director/CEO
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Appendix A: The meta-governance of organic seed regulation in the USA, European Union and Mexico: Renaud, E.N.C., Lammerts van Bueren, E.T. & Jiggins, J. Org. Agr. (2014) 4: 25. doi:10.1007/s13165-014-0063-5

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The meta-governance of organic seed regulation in the USA, European Union and Mexico

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Abstract: Seed governance in agriculture is a challenging global issue. This paper analyses the evolution of organic seed regulation in the USA, the European Union and Mexico as model cases of how these challenges are being addressed, based on a study conducted between 2007 and 2014. It highlights how growth of the organic sector is hindered by regulatory imbalances and trade incompatibilities arising from divergent stakeholder interests along the organic seed value chain, and the varying capacity for self-organising governance of the seed sector in relation to the state's regulatory role. Progress towards regulatory harmonisation in the organic seed sector among the three cases has been slow. The paper concludes with an assessment of the regulatory processes described including what the regions may learn from each other and lessons for key areas of regulatory policy and practice.

Keywords: organic agriculture; organic seed regulation; harmonisation of standards; trade incompatibilities; USA; European Union; Mexico.

Reference to this paper should be made as follows: Renaud, E.N.C., Lammerts van Bueren, E.T. and Jiggins, J. (2016) 'The meta-governance of organic seed regulation in the USA, European Union and Mexico', *Int. J. Agricultural Resources, Governance and Ecology*, Vol. 12, No. 3, pp.262–291.

Biographical notes: Erica N.C. Renaud received her Doctoral degree from Wageningen University in the Netherlands in 2014 in Organic Plant Breeding. Presently, she is the Regional Business Manager for Vitalis Organic Seeds, North America, the organic division of the Netherlands-based breeding and seed production company Enza Zaden. She was responsible for launching the brand in Canada, the USA and Mexico in 2007. She is the co-chair of ASTA.

She also works with both the OSA and the OTA to address issues of organic seed sourcing, seed purity and to determine methods of collecting market data on organic seed sector growth.

Edith T. Lammerts van Bueren holds an endowed Chair at Wageningen University in Organic Plant Breeding, and is a senior scientist at the Louis Bolk Institute. She focuses on the ethical, ecological and social values of organic agriculture and the consequences for breeding programs for cultivars better adapted to organic, low-input and diverse farming systems. She is developing models of collaboration between commercial breeding companies and farmer breeders to realise improved cultivars for Western niche markets as organic agriculture. She is leader of the Section Organic and Low-Input Agriculture of European Association for Research on Plant Breeding (EUCARPIA).

Janice Jiggins has contributed to national, regional and global assessments of food security and sustainable farming futures, including the IAASTD. She has held academic positions or served on examining boards for universities in the UK, Ghana, Canada, South Africa, Australia and the USA. From 1998 to 2001 she served as Professor of Human Ecology at the Swedish University of Agricultural Sciences, Uppsala, where she helped establish a new department for Rural Development Studies. In 2014 she retired, after serving for a number of years as Guest Researcher, Knowledge, Technology & Innovation theme, Wageningen University, the Netherlands.

1 Introduction

In the context of a rapidly growing global organic market, estimated at $72 billion in 2014 (Willer and Lernoud, 2015), regulators have taken steps to bring order to the organic sector. This paper deals specifically with organic seed regulation, a significant component of organic production systems. Although organic values and norms require organic farmers to use seeds that originate from organic production, the sector continues to depend largely on conventionally produced seed. Certified organic seed is defined by the International Federation for Organic Agriculture Movements (IFOAM) as seed from cultivars that may be derived from conventional breeding programs (excluding genetic engineering) and that are produced under organic farming conditions for one growing season for annual crop species, and two growing seasons for perennial and biannual crop species (IFOAM, 2014). Use of synthetic chemical herbicides and pesticides is not allowed. Evolving standards for organic agriculture worldwide are pushing the organic sector towards restricted use of conventional seed in favour of certified organic seed. Market recognition that the integrity of organic production systems begin with organic seed has caused organic seed production and seed sales to increase annually and new players in seed provision to enter the market (Döring et al., 2012).

However, the organic seed sector has been slow to overcome both technical and institutional obstacles and an appropriate assortment in sufficient quantity of organic seed is not yet available. Moreover, organic seed regulations in different countries vary in the ways in which they support the organic seed sector and this impairs trade in organic seed and products. This paper focuses on how divergent practices and interpretations among stakeholders of organic seed regulations in three jurisdictions create new risks in seed

supply and in international trade that potentially limit further expansion of the sector. We hypothesise that harmonisation of organic seed regulations would enable (a) growers to have greater access to organic seed, (b) seed companies and seed growers to be governed by the same rules, and (c) the integrity of the organic brand to be upheld. The paper builds on the work of Thommen (2007) for the European Union (EU), Renaud et al. (2014) for the USA and Sonnabend (2010) for Mexico. These three regions have been selected first because demand for organic products in the USA and the EU together account for over 90% of the global revenue in organic products (over 47 billion euros) (Willer and Lernoud, 2015). The agricultural area under organic production is 2.1 million hectares in the USA, 11.5 million hectares in the EU, and over 500,000 hectares in Mexico. Mexico is included because: (1) it depends to a large extent on import of organic seed from these two regions, (2) over 80% of Mexican organic exports are destined for the US market, where consumer demand for organic products is growing at a rate of 11.5% annually (OTA [Organic Trade Association], 2014), and (3) because Mexico might benefit from the experience of others while in the process of developing its own federal organic regulation.

The USA formalised its national organic standard in 2002 (USDA AMS, 2002), the EU in 1991 and in 2007 (EC, 2007), and Mexico in 2006 (COFEMER, 2006). The EU first sought to achieve harmonisation at member state level in a 2007 regulatory revision (Michelson, 2009). The USA and the EU harmonised their general organic standards in 2012 in order to enhance transatlantic trade and align practices (Haumann, 2012), while Mexico is still in the process of formalising its domestic regulations (SAGARPA, 2013). The current organic regulations in the three cases each include a clause that requires organic seed usage in certified organic farming systems but they have not (yet) been able to establish a level playing field. An international task force on harmonisation and equivalence in organic agriculture has examined selected technical components of domestic regulatory and trade regimes (UNCTAD et al., 2009). Other researchers have carried out cross-country comparison of organic farming policies among EU member state (e.g. Michelson, 2009), and of the trade impacts of non-harmonisation (e.g. Disdier et al., 2008). However, these studies do not provide insight into the regulatory processes at work or address the differences in regulatory regimes governing organic seed.

Regulation is about determining priorities and avoiding undesired trade-offs in relation to the formulation, interpretation and enforcement of standards and practices that balance public and private interests. Regulation thus acts as a form of governance that typically applies both formal and informal instruments, and involves a range of individual and organisational actors, including but not limited to governments. The Organisation for Economic Co-Operation and Development (OECD) has stressed that in an era of globalising trade, governments are seeking to coordinate regulatory objectives, processes and enforcement, and to eliminate divergence and redundancies (OECD, 2014). The pragmatic purpose of this paper is to reveal and analyse the processes that create or remove obstacles to organic seed access, and in trade relations among the three jurisdictions treated in this paper, through empirical observation of the evolving regulatory standards and interpretations. The OECD (2014) has emphasised that this kind of evidence is urgently needed in order to capitalise on the lessons learned, and to further develop the potential of such governance arrangements and instruments.

Three interwoven interpretative frames inform the presentation: (i) *Normalisation processes*: May and Finch (2009) explain the processes of implementing, embedding and integration of regulatory policies in terms that emphasises the contingent and normative factors that promote or inhibit enactment of complex interventions in a field of practice. Their approach focuses on exact descriptions of an intervention, analysis of how it was operationalised, and the reported benefits/disadvantages. This paper contrasts the normalisation experiences of the organic seed sector in the USA, EU and Mexico, and identifies where the differences are creating new barriers to international trade in organic seed. (ii) *Meta-governance*: The concept of meta-governance is based on a presumed need for public regulation of devolved and decentralised decision-making organisations. The academic literature identifies three ideal-typical forms of meta-governance (hierarchy, network and market), with the more recent addition of the EU's open method of coordination (e.g. Bevir, 2013). Here, the particular role of self-organising networks is explored to determine whether such networks compete with or are independent of the state in contexts in which a common regulatory framework for the governance of the organic seed sector has not yet stabilised. (iii) *Regulatory harmonisation*: The OECD (2014) and its member governments have compared regulatory harmonisation by means of different approaches. These are: supranational organisations; specific regional agreements (such as treaties and conventions); formal regulatory cooperation partnerships; international organisations; regional agreements with regulatory provisions; mutual recognition agreements; trans-governmental networks of regulators; formal requirements to consider relevant frameworks in other jurisdictions in the same field; recognition and incorporation of international standards; and soft law, principles, guidelines, codes of conduct, centred on dialogue and information exchange. The mix of such approaches taken in and between the three cases is examined. Finally, lessons are drawn from the analysis and discussion that may advance the interests of the organic sector as a whole.

Table 1 Institutions' and organisations' acronyms used in article

Abbreviation	*Definition*
ACA	Accredited Certifier Association
AMS	Agricultural Marketing Service
AMSAC	Mexican Seed Trade Association
APHIS	Animal and Plant Health Inspection Service
AOSCA	Association of Official Seed Certifying Agencies
ASTA	American Seed Trade Association
ATTRA	Appropriate Technology Transfer for Rural Areas
COFEPRIS	Mexican Federal Commission for the Protection against Phytosanitary Risk
COFEMER	Mexican Federal Commission of Regulatory Improvement
ECO PB	European Consortium for Organic Plant Breeders
ESA	European Seed Association
FAS	Foreign Agriculture Service of the United Nations

Table 1 Institutions' and organisations' acronyms used in article (continued)

Abbreviation	*Definition*
FAO	Food and Agriculture Organisation
IFOAM	International Federation of Organic Agriculture Movements
IPPC	International Plant Protection Convention
NAPPO	North American Plant Protection Organisation
NOP	National Organic Program
NOSB	National Organic Standards Board
OFPA	Organic Food and Production Act
OMRI	Organic Materials Review Institute
OSA	Organic Seed Alliance
OTA	Organic Trade Association
SAGARPA	Mexican Ministry of Agriculture, Livestock, Rural Development, Fisheries and Food
SCOF	Standing Committee Organic Farming
SENASICA	Mexican Sanitary, Food Safety and Food Quality National Service
SOS	State of Organic Seed
USDA	United States Department of Agriculture

2 Methodology

This paper is based on research conducted from mid-2007 through 2015. The US organic seed sector study (Renaud et al., 2014) was initiated by identification of stakeholder categories, the key stakeholders within each category, and the interests affected directly and indirectly by the evolving organic seed regulation. Interviews were conducted with individuals drawn from each stakeholder category to explore stakeholders' perceptions of the draft organic seed regulation, their respective role in the process, and their perceptions of opportunities for or constraints to regulatory development. 74 in-depth interviews with individuals and representatives of organisations, identified by their high level of influence within each stakeholder category, were conducted. The stakeholder categories identified were organic certifiers (n = 8), organic growers (n = 40), organic food buyers (n = 5), representatives of formal seed companies involved in organic and/or conventional seed production (n = 10), administrative personnel (n = 5), and non-profit organisation representatives (n = 6) with influence. The information from the interviews was recorded and analysed manually by means of qualitative analysis, by applying content analysis, and discourse analysis presented here in narrative form in order to reveal the unfolding processes and interests that shape the emergent regulatory outcomes in each case.

The studies of the organic seed sector in the EU and in Mexico are based on interviews with selected stakeholders in the organic seed sector (in the EU, n = 12; and in Mexico, n = 15), who were identified through similar though less rigorous procedures as those outlined above for the US study. In all three jurisdictions, the respondents were

asked to provide their perspectives on their respective organic seed regulations, and, in the case of Mexico, also on the organic seed regulations in the country to which they export organic product.

Relevant grey literature, expert reports and policy documents were reviewed for all three jurisdictions as no peer reviewed literature on organic seed regulation in the case study countries has been published. The first two authors also participated, in varying roles as researchers and stakeholders, in key organic seed meetings held in the USA, the EU and Mexico throughout the study period. The methodology emphasises the importance of within-case analysis and detailed process tracing.

3 Developments in organic seed regulation

3.1 The US case

The 2002 organic regulatory standard governing the US organic sector is known as the National Organic Program (NOP). It prescribes the use of organic seed in organic production systems whenever such seed is commercially available. Interpretations of the seed clause, and the development of monitoring tools for compliance, have evolved through successive guidance documents issued to the NOP by a statutory authority charged with oversight of implementation, the National Organic Standards Board (NOSB). However, because after 20 years of consultation and redrafting of recommendations, no official endorsement by the NOP of the NOSB's recommendations has emerged, and because the framing legislation provides neither deadlines nor penalties for non-compliance, interpretive practices diverge. The main findings and analysis of these developments are discussed in detail in Renaud et al. (2014), and summarised briefly below. A chronology of the main events is outlined in Table 2.

Table 2 Summary of key events in the evolution of US organic seed regulation 1990–present

Timeline	*Regulatory position change*	*Outcome*
28 November 1990	OFPA signed into law as Title 21 of the 1990 Farm Bill	US Organic Agriculture Law
22 December 2000	USDA NOP standard published in the Federal Register	Proposed US Organic Agriculture Rule
7 March 2001	Commercial Availability: Docket Number TMD-00-02-FR	Definition of Commercial Availability
22 October 2002	USDA NOP standard approved	Approved US Organic Agriculture Standard
17 August 2005	NOSB to NOP Recommendation: Commercial Availability of Organic Seed	Organic Seed Guidance Document Version 1
30 November 2007	NOSB to NOP Recommendation: Further Guidance on the Establishment of Commercial Availability Criteria	Organic Seed Guidance Document Version 2
3 April 2008	NOSB JC & CAC Committee Recommendation: Further Guidance on Commercial Availability of Organic Seed	Organic Seed Guidance Document Version 3

Table 2 Summary of key events in the evolution of US organic seed regulation 1990–present (continued)

Timeline	*Regulatory position change*	*Outcome*
22 September 2008	NOSB JC & CAC Committee Recommendation: Further Guidance on Commercial Availability of Organic Seed	Organic Seed Guidance Document Version 4
19 November 2008	Formal Recommendation by the NOSB to the NOP: Commercial Availability of Organic Seeds	Submitted Organic Seed Guidance Document Version 5
13 June 2011	NOP Guidance released for public comment	NOP Guidance proposal
4 March 2013	NOP Guidance: Seeds, Annual Seedlings, and Planting Stock in Organic Crop Production	NOP Final Organic Seed Guidance

Source: Adapted from Renaud et al. (2014)

Primary responsibility for enforcement of the organic seed clause is assigned to organic certifiers (NOSB JC & CAC, 2008a; NOSB JC & CAC, 2008b; NOSB JC & CAC, 2008c). Certifiers are required to ensure growers attempt a rigorous organic seed sourcing process, and that they increase their organic seed usage year-on-year. Growers for their part must demonstrate clearly the steps that they take to source organic seed. Growers' principal concerns are the availability of sufficient quantities of quality seed and a diverse assortment of organic seed varieties, and the fact that in general certified organic seed costs more than conventional seed. Seed prices, however, are not taken into account in the exemptions permitted by the regulation. If growers use conventional instead of organic seed, they must justify in their Organic Systems Plan that the seed traits and characteristics of the conventional seed are not available in organic form. While data contained in the plans have the potential to inform the organisation of organic seed supply, procedural differences among certifiers with respect to the review and enforcement of the plans has led to significant inconsistencies (Renaud et al., 2014). A residual level of regulatory enforcement responsibility is allocated to retail market buyers and food processors, who are supposed to monitor the seed usage of their suppliers, particularly if the buyer's contract specifies a particular variety. According to the interviews, they consider such monitoring to be a costly administrative expense that is often avoided. In addition, food buyers may face a conflict of interest in relation to the varieties they want and the quality, characteristics, price or volume of the organic seed available to produce the variety (Dillon and Hubbard, 2011).

The lack of a comprehensive organic seed database lies at the heart of many of these tensions NOSB's guidance indicates that a database should list the availability of varieties aligned to certified organic growers' trait preferences, and the equivalent conventional seed options in the case that an organic seed variety is not yet commercially available. At least eight organisations have created, or attempted to create, a database to ensure transparency in the claims made about organic seed varietal availability. Up to end 2015, none of the databases has achieved comprehensive coverage and none is officially endorsed by the NOP. The Organic Material Review Institute's (OMRI) attempt is the most ambitious, aiming to provide a comprehensive national database for all growers and certifiers in the USA. However, there is a lack of clarity about who

should bear the cost of registering and organising the information, and the initial user fee is considered too high by some stakeholders. OMRI's ability to mobilise long-term funding for the database was undermined. In 2012 the Organic Seed Alliance (OSA), in collaboration with the database host organisation Association of Official Seed Certifying Agencies (AOSCA), coordinated a multi-stakeholder initiative to relaunch the database (Hubbard, 2012). All the US study respondents recognise that without an endorsed and fully populated database requests for exceptions to the organic seed rule will persist and will discourage organic seed producers from meeting the demand, thereby sustaining the pressure to grant exemptions, an impasse that undermines the integrity and limits the potential growth of the US organic sector (see Table 3).

Table 3 US stakeholder perspectives on an organic seed database (n = 74)

Stakeholder category	*Stakeholder type*	*Stakeholder level of Influence*	*Perspective on organic seed database*
Organic certifiers (n = 8)	Key	High	–Valuable tool for certifiers to assist in the interpretation of a growers attempt at sourcing organic seed in the inspection process –An organic seed database would make assessing an organic growers attempt at sourcing organic seed more efficient and less costly
Small-scale organic growers (n = 26)	Primary	Low to high	–Valuable tool to identify possible organic seed sources commercially available that are unknown to the grower –Growers should not be limited to database sources for production operation use as many rare and unusual varieties are not available in organic form. Do not want to limit on-farm genetic diversity
Large-scale organic growers (n = 14)	Primary	Low to high	–Valuable tool to identify possible organic seed sources commercially available that are unknown to the grower –Growers should not be limited to database sources for production operations as many varieties used by commercial growers are not grown organically or are produced under longer term contracts
Organic food buyer (n = 5)	Intermediate	Low	–Potentially valuable tool to identify sources of organic seed to support contracts and ensure compliance of organic seed regulation guidance –Do not want to be limited by varieties available on the database because the varieties may not meet contract requirements

Table 3 US stakeholder perspectives on an organic seed database (n = 74) (continued)

Stakeholder category	*Stakeholder type*	*Stakeholder level of Influence*	*Perspective on organic seed database*
Formal seed companies (n = 10)	Primary	Low to high	–Valuable tool if all companies with organic seed participate and keep availability updated –Excellent nearly free marketing and promotion opportunity –Potential to gather information on varieties that growers would like organically, but are not available –Unnecessary costly and time-consuming uploading process –Do not want to participate if the company has a conventional untreated seed division as it will jeopardise their sales
Non-profit organisations (n = 6)	Intermediate	Low to high	–A two-way organic seed database is a stepping stone towards transparency of what varieties are available in organic form as well as those that are not available –A needed tool in order to set derogations/ exception by crop group and to set timelines –Valuable to a broad stakeholder range in the organic seed chain
Policy & legislative body (n = 5)	Key	High	–Valuable tool to demonstrate availability and support organic certifiers, growers and food buyers in identifying availability –Will include in guidelines, but not make it mandatory
Stakeholder type	*Definition*		*Levels of Influence*
Primary	Those who are directly affected, either positively or negatively		Low to high
Intermediate	The intermediaries in the delivery or execution of research, resource flows, and activities		Low to intermediate
Key	Those with the power to influence or 'kill' activity		High

Sources: Stakeholder analysis (columns 1–3, 2007); stakeholder interviews and participant observation (column 4, 2007–2014); adapted from Renaud et al. (2014)

In the absence of a strong convergence of interests at the national level, new organisations with a regional focus have emerged to help manage local seed concerns. Their scope variously includes the testing of organic seed varieties with farmers, supporting participatory breeding (e.g. OSA), the development of local organic seed production (e.g. Family Farmers Seed Cooperative), and funding for preparation and maintenance of organic seed lists or databases (e.g. OMRI, AOSCA). Although over

100 US seed production companies have developed niche markets in organic seed, the expansion of the seed sector remains challenged by the lack of reliable information about the requirements of organic growers for desired varieties. Nevertheless, several stakeholder groups have demonstrated a willingness to engage in the concerted development of the organic seed sector (Renaud et al., 2014). Others, such as large-scale commercial baby lettuce leaf and spinach growers in California, where seed costs form a relatively large part of their cost structure, have less incentive to proceed towards compliance.

The spread of compliance responsibilities among growers, certifiers, and buyers remains contentious, with the interested parties continuing to react in response to each other's initiatives (Renaud et al., 2014). The study findings indicate that while an increasing number of private actors have come to the negotiating table to represent their various interests, the lack of a common agenda, and of policy instruments such as an endorsed national organic seed database that would encourage advancement towards regulatory compliance at the national level, has allowed dissent and fragmentation to persist. The NOP's lack of endorsement of any of the various initiatives taken so far seems to indicate that the government still expects this sector to self-organise.

3.2 The EU case

In the EU state actors have demarcated clearly stakeholders' roles and responsibilities, set deadlines for compliance, and established procedures for monitoring and for penalising non-compliance. In 1991, the European Commission (EC) established an EU-wide organic standard, followed by revisions in 2009 (Council Regulation European Economic Community (EEC) No 834/2007). In 1999, an amended regulation was adopted, specifying that organic growers, with exceptions as outlined in Commission Regulation (No 1452/2003), by 31 December 2003 must use organic seed. The responsibility for enforcement lies with the national governments of each of the 27 EU member states, coordinated by government representatives of each member state in the Standing Committee Organic Farming (SCOF). The regulation further stipulates that governments must host an online database listing the available organic varieties and their suppliers, including the identification of exception allowances, and that they are responsible for supplying the EC with an annual report of the exceptions granted in the member state. The timeline for the chronology of events in the EU case is outlined in Table 4.

Table 4 Summary of key decisions and events in the evolution of the European organic seed regulation

Timeline	*Regulatory position change*	*Outcome*
1991	Council Regulation (EEC) No 2092/91	EU Organic standard implemented
1999	Council Regulation (EC) No 1804/1999	EU standard amended with derogation to enforce organic seed usage by December 2003
2002	EU commission to perform organic seed evaluation	Reform of 1999 Council Regulation (EC) No 1804/1999
2003	Commission regulation (EC) No 1452/2003	Retracted December 2003 derogation closure date. Requirement for all EU countries to establish national organic seed databases and annual derogation granting report for full availability disclosure

Table 4 Summary of key decisions and events in the evolution of the European organic seed regulation (continued)

Timeline	*Regulatory position change*	*Outcome*
2003	Formation of the European Consortium for Organic Plant Breeding (ECO PB)	Organisation formed with the goal to harmonise EU members processes on organic seed databases and annual reports
2004	EC Organic Seed Regime 2004	Started implementing the derogation regimes for organic seed
2007	EU project EEC 2092/91 Organic Revision	Project included a report with revisions to the original organic standard including the section on organic seed
2008	ECO PB Position Document on Cross Country Regional agreements on derogations	Set goal to identify five crops that in the coming 3–5 years to work towards reductions in derogations or in category 1 list
2008	Motion on banning protoplast fusion at the IFOAM General Assembly accepted	Proposed ban on varieties derived from and use of protoplast fusion in organics
2009	ECO-PB Position Document on protoplast fusion	Requested that national databases indicate varieties derived from protoplast fusion
2009	Council Regulation (EC) No 834/2007	Revised EU Organic Standard
2009	Council Regulation (EC) No 889/2008	Revised of organic seed regulation
2010	IFOAM Standards for Organic Breeding under consultation	IFOAM included standards for organic breeding and defined the breeding techniques compatible with organic values
2012	IFOAM Final Document	IFOAM definition of organic plant breeding finalised
2012	ECO PB Meeting	ECO PB met on EU organic seed expansion and developed strategic framework

Sources: Döring et al. (2012), EC (2007, 2013), Gibbon (2008), IFOAM (2014), Lammerts van Bueren et al. (2008), Rey et al. (2009), and Wilbois (2006)

The European Seed Association (ESA) in 2002 carried out an assessment of seed companies' capacity to deliver the requisite quantities of organic seed by the end of the following year, concluding that it should be possible for seed companies to do so. However, the assessment also showed that despite overall availability, and in the quantities required, organic growers of particular crops in certain regions would in fact not be able to access all of their seed requirements in organic form by the deadline. Thus, the regulation was amended again to allow exceptions on request so that growers could use conventional seed provided the seed was not chemically treated and organic seed was not available. The perspective of seed company stakeholders' on the potential for achieving 100% organic seed is outlined in Table 5. Most member states base exceptions on the following categories: (1) no exception for species and sub-species with enough acceptable assortment of varieties available in organic form, (2) case-by-case authorisation for exceptions for those species and sub-species with some varieties

available in organic form but not a sufficient assortment of the main varieties required in the organic sector, and (3) general exception for species and sub-species without any (appropriate) varieties available in organic form (Thommen, 2007).

Table 5 European seed company perspectives on prospects for regulatory closure in the EU (n = 7)

Seed company category	*Stakeholder type*	*Stakeholder level of influence*	*Key concerns relating to the organic seed market and prospects for achieving regulatory closure*
Conventional seed companies (n = 2)	Intermediate	Low	No commitment to support regulatory closure Market is too small to invest in See no added value in organically produced seed Fear for loss of conventional seed sales Conflicts with GMO and chemical agriculture divisions No infrastructure to support organic certification requirements
Conventional seed companies with an organic division (n = 3)	Primary	Med to high	Market is evolving and professional organic growers require their professionally bred varieties Regulatory enforcement and derogation rigor required Harmonisation among member states needed More transparent access to grower varietal requirements Fear for loss of conventional seed sales and trade-offs in profitability Organic seed production and breeding capacity Organic seed quality (seed borne diseases and vigour)
Organic seed companies (n = 2)	Primary	High	Market opportunity is there Market requires varieties bred for organic production systems Regulatory enforcement and derogation rigor required Harmonisation among member states processes Value of biodiversity needs to be considered in varietal assortment Organic seed quality (seed borne diseases and vigour) Organic seed production and breeding capacity

Note: Stakeholder typology, definition and level of influence, see sub-table of Table 3.

Sources: Stakeholder analysis (columns 1–3, 2007); content analysis of stakeholder interviews (column 4, 2007–2014)

Several member states support regulatory implementation by developing tools for database development, communicating availability criteria, and encouraging closure to exceptions for certain crop groups (Döring et al., 2012). Some member states, such as the Netherlands and Denmark, use formalised expert groups to identify which species and (sub) species are allocated to each of the above-noted exception categories. Expert group advice in these countries, in combination with approval by their respective Ministries of Agriculture, informs exception approval or disapproval by the member state's certification body. The composition of expert groups, and the method of analysis used to evaluate exceptions, is unique to each member state. For example, some member states allow grower representatives to participate in expert groups together with seed producers and advisors. Others do not, believing growers may influence exception allowances in their favour. Still others, including Switzerland (noting that Switzerland is not part of the EU but an associated European country), do not work with exception categories at all, preferring to consider all requests on a case-by-case basis, using publicly available variety equivalence lists for each species and (sub) species (ECO-PB, 2013).

Encouraged by the rigour of the procedures for the granting and reporting of exceptions, there are several ongoing efforts by both public and private actors to achieve 100% organic seed use, beginning with a limited range of crops. Bio Suisse, a Swiss certification body, has created a fund to address the price difference between organic and conventional seed. If a grower needs to use conventional seed because there is no comparable variety in organic form, the grower pays the difference in the cost of the seed into a fund that supports organic seed-breeding and multiplication, such as variety trials (Thommen, 2007). In the Netherlands, a government-funded project provides for growers to organise in national crop groups and, for crops with low availability of organic seed, to communicate their organic variety needs to breeders and seed companies (Lammerts van Bueren et al., 2008). This initiative, in combination with yearly publication of varietal exception requests by the national organic certifier, helps seed companies in the Netherlands to identify appropriate varieties for which a secure organic market exists (see www.biodatabase.nl).

The EU supports compliance with the organic seed regulations by means of clear enforcement guidelines. The most comprehensive movement towards 100% compliance has been achieved in the more affluent north-western member states. In Denmark, France, the Netherlands and Sweden, for instance, crops such as cucumber and lettuce are now closed to exceptions. Progress in some other member states is challenged by a number of factors, including the lack of a national vegetable seed industry. Growers in Portugal, Estonia and Bulgaria still have limited access to organic seed that meets the volume, quality and varietal requirements for primary crop groups, and so they continue to use predominantly conventional seed (Alonso and Rundgren, 2011). None the less, study respondents emphasise that the EU organic seed regulation has stimulated the organic seed sector by allocating enforcement responsibility to the national governments of member states, by requiring that each member state maintain a national seed sourcing database, and by requiring the submission of an annual report on exceptions to a central coordinating authority (Döring et al., 2012). The EC Agriculture & Rural Development website (EC, 2013) lists over 300 organic seed suppliers throughout the EU, totalling 80 in Germany, 30 in the Netherlands, and 26 in France. Döring et al. (2012) and ECO-PB (2013) note, however, that further effort is needed to harmonise annual reports, install a European wide seed database, encourage wider recourse to appropriately constituted national expert groups, enhance communication and cooperation between member states

in order to achieve a level playing field for exporters, and to develop cross-compliance with national and EU-wide legislation related to biodiversity conservation and the conservation of landraces (FSO, 2010).

In 2014, the EC proposed a new regulation for organic agriculture in order to meet consumer expectations, prevent fraud and adapt the legislation to the fast-growing sector and market (EC, 2014). One provision was to adopt 2021 as the deadline for closure of the use of non-organic inputs, such as conventional seeds. However, this proposal as presented was not approved and a revised proposal is in process. The IFOAM-EU Group urges that the provisions support breeding programs that broaden the diversity of varieties well-adapted to organic agriculture (IFOAM-EU, 2015).

3.3 The Mexico case

Mexico first sought to regulate the organic sector in 1995–1997 by issuing an official standard. However, the standard was never enforced and was officially cancelled in 2010. In 2006, the government enacted the Organic Products Law that requires all organic products to be certified in accordance with an international organic standard (COFEMER, 2006). This laid the foundation for draft regulations negotiated with Mexico's main trading partners in organic products. These were approved by the Mexican Federal Commission of Regulatory Improvement (COFEMER, 2010) and subsequently by the Sanitary, Food Safety and Food Quality National Service (SENASICA), released in 2010 as 'Guidelines for the Organic Operation of Agricultural and Animal Production Activities' (SAGARPA, 2010). The guidelines required the use of organic seed in certified organic agriculture systems. Notably, there was no provision for exception for the use of conventional untreated seed (SENASICA, 2012), and the organic regulation was redrafted in 2012. This withdrew the 100% organic seed use requirement and permitted the use of conventional treated seed if the chemical treatment was 'washed off' prior to planting (Article 35; SAGARPA, 2012b). The latest Mexican Organic Regulations retained these provisions and was published on 29 October 2013 (COFEMER, 2012; SAGARPA, 2013).

Stakeholder interviews and participant experience suggest that the US regulatory regime has greater impact on the organic sector in Mexico than the efforts to develop effective domestic law, because the major part of Mexico's organic crop production is exported to the US market and must therefore meet the requirements of the US organic regulation. In the US conventional seed treatments are not permitted under organic regulations and organic growers have access to diverse organic seed sources and the opportunity to secure exceptions to the use of organic seed. In Mexico there is a limited domestic supply of organic seed and the major part of the seed used in Mexico is supplied mainly by companies based in the USA and the EU, i.e. the organic sector in Mexico is dependent on the importation of organic seed from foreign companies and on seed regulation and certification standards in their main export markets.

This gives rise to further complications. Imported seed must be accompanied by an organic certificate issued by a certification agency recognised by Mexico's Ministry of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA) (Sonnabend, 2010), as outlined in the Organic Products Law of 2010 (COFEMER, 2010). In addition, imported seed is subject to the phytosanitary requirements outlined in Mexico's Federal Phytosanitary Law (NOM-006-FITO-1995) that requires imported seed to be treated with a particular chemical seed treatment. Because such treatments are not permissible in

organic systems, an alternative treatment was proposed that complied with the letter and intention of Mexico's Federal Phytosanitary Law. However, the treatment was neither consistent with the phytosanitary requirements of Mexico's primary organic trading partners, nor proven effective as a blanket phytosanitary control for all crops or all diseases.

Considering the severity of restrictions placed on the Mexican organic sector by foreign organic seed regulations and the phytosanitary restrictions on seed importation, stakeholders are encouraged to seek other ways forward. Exception grants from SAGARPA are available for growers who solicit a grower-specific importation permit, thus allowing them to import seed directly and avoid a seed distributor, and to work directly with the authorities to authenticate potential phytosanitary risks. This has results in inconsistent certification standards with respect to enforcement of the seed importation process. Mexican growers also import seed from their own supplier networks, encouraging use of seed that is not certified organic and of conventional seed treated chemically (that might or might not be washed off). Moreover, organic growers may receive exception to the seed rule even when organic seed is available. The testing of imported seed for acceptability also has numerous loopholes. For instance, inspectors might or might not divulge the test criteria, and might or might not choose to exercise their discretionary authority to label a seed lot as unacceptable (thus requiring that it be sent back to the country of origin at the grower's expense, or be surrendered to the inspector for destruction) (Dunkle, 2011). More significantly, industry stakeholders report the growing practice of furtive acquisition of conventional seed for organic purposes that might or might not be treated in accordance with phytosanitary requirements, resulting in the growing illegal movement of seed into and around Mexico. We examine these points in more detail below, with reference to three instances.

i The Mexican company Horticola Camarillos S.A. de C.V. was certified as complying with the organic certification requirement of the USA by producing an Organic Farm Plan. Upon review, the company was found to have used treated seed for one crop, to have insufficient documentation for another crop, and to have violated a USDA NOP rule for seed treatment and phytosanitary requirements applicable in the USA. Organic grower Isidro Camarillo Zavallo, General Manager of Camarillo, argued in 2010 during his appeal against loss of certification status that compliance with US regulations requires Mexican growers to break the laws of Mexico. He reported practices that routinely include purposefully deceptive packaging, absent or inaccurate labelling, and ambiguous responses to the different phytosanitary requirements of trade partners. He further stated that it was the company's effort to comply with US regulations that had caused their certification to come into question. The organic certifier, the Organic Crop Improvement Association (OCIA), denied the appeal and cancelled Camarillo's certification for three years, on the grounds that evidence was lacking that chemical treatment of imported seed is compulsory in Mexico, and that USDA NOP regulations may not be circumvented to meet organic regulatory requirements outside the USA (USDA Marketing Service, APL-027-08).

ii The contradictions posed by differing phytosanitary requirements have been an issue between Mexico and the USA for some time. Before 2009 Mexico had approved, on a restrictive basis, a limited number of alternative seed treatments for phytosanitary purposes that were also approved under the NOP. These included '*Natural II*',

an Agricoat product (approved in 2005), and importation of untreated organic seed that was accompanied by phytosanitary certification based on seed testing and post-entry quarantine inspections (approved in 2008). The Natural II allowance was cancelled in 2008 because the product had not been approved by the Mexican Federal Commission for the Protection against Sanitary Risk (COFEPRIS), and because any new treatment proposed for use in organic agriculture requires prior COFEPRIS approval. US companies seeking COFEPRIS approval of seed treatments subsequently reported that the data submission requirements are unclear and that the cumbersome approval process is a restraint to trade (seed company interview, 2010). Only in 2011 did SAGARPA accept that the approval of new organic seed treatment options no longer required the prior approval of COFEPRIS, opening the door to valid organic seed treatments compliant with the USDA NOP.

iii The option of allowing importation and use of untreated seed if accompanied by the appropriate certification is described in Article 89 of the original Mexican Organic Products Law (COFEMER, 2007). The law provides for an exception when a seed importer presented technical or scientific evidence demonstrating an alternative to the required chemical treatments. In 2009, a biological seed treatment was approved for organic seed and the option to import organic untreated seed was removed (SAGARPA, 2009). Its use proved problematic because the company that had exclusive manufacturing rights was unable to meet the initial demand. In addition, inconsistent enforcement of what counts as acceptable seed continued at Mexico's borders. The minimum dosage rates for seed treatment were set at a high level, not all crops were approved for the treatment, some seed producers encountered germination problems, and research analyses found only limited evidence to support the claim that it prevented seed-borne diseases (Cummings et al., 2009). Since 2009 the number of crops approved for the treatment has expanded from the original list of six but some crops remain excluded. In 2012, two new organic seed treatments were approved by SAGARPA to support the entry of organic seed into Mexico (SAGARPA, 2012a; SAGARPA, 2012c). However, these were originally not commercialised in the USA for seed application and were not permitted on all crops. Since the end of 2013 these seed treatments are allowed on a selected group of crops in specific combinations of country of origin of export and production. In Table 6, the key decisions and events in the evolution of the Mexico organic and phytosanitary regulations are summarised.

Table 6 Summary of key decisions and events in the evolution of the Mexico organic and phytosanitary regulations

Timeline	*Regulatory position change*	*Outcome*
1995	Mexican Phytosanitary Regulation NOM-006-FITO-1995 published	Mandatory chemical seed treatment imposed
1997	Mexico official organic standard NOM-037-FITO-1995 published	Mexico's first organic standard proposal
2005	Natural II an organic seed treatment approved	First organic treatment permitted for seed entry into Mexico
7 February 2006	Organic Products Law published	Mexico Organic Product Law
June 2008	Approval of importation of organic untreated seed	Use of organic untreated seed allowed

Table 6 Summary of key decisions and events in the evolution of the Mexico organic and phytosanitary regulations (continued)

Timeline	*Regulatory position change*	*Outcome*
2008	Approval for use of Nature II organic seed treatment retracted	Entry of organic seed treated with Natural II banned
2009	Allowance of importation of organic untreated seed retracted	Entry of organic untreated seed banned
2009	Approval of T-22 as only method for organic seed importation	Entry of organic seed with T-22 treatment approved
2009	Approval of hot water treatment for seed importation	Entry of six crops treated with hot water
2009	AMSAC Organic Seed Committee formed	Committee formed to identify new methods for organic seed entry
1 April 2010	Organic Products Law approved by COFEMER	Mexico Organic Regulation approved
11 May 2010	Cancellation of Mexico organic standard: NOM-0337-FITO-1995	Mexico's initial organic standards cancelled
25 May 2010	Mexico Organic Regulations draft published by SENASICA	Draft Mexico Organic Regulations published (includes requirement that growers use 100% organic seed)
June 2010	Dutch agricultural delegation met with SAGARPA	The Netherlands and Mexico seek a bilateral agreement on seed trade
July 2010	Organic certifiers organise a multi-stakeholder meeting on organic seed importation into Mexico	Multi-stakeholders share with government authorities the impact of conflicting organic and phytosanitary requirements on their operations
August 2010	US government inter-agency group including the USDA (NOP, APHIS, FAS, AMS) and OTA meet in the USA with SAGARPA to develop bilateral agreement on seed importation issue	US authorities seek to create a strategy for bilateral agreement on (organic) seed trade with Mexican authorities
October 2011	ASTA hosts multi-stakeholder meeting with US and Mexican government authorities to develop a strategy on seed importation	Authorities on agricultural trade brought together by ASTA to develop strategy for organic seed importation
August/November 2012	Approval of Mycostop and Actinovate treatments for seed importation	Entry of organic seed with Mycostop, Actinovate and hot water seed treatment on select crops
14 November 2012	SAGARPA submits revised draft of Mexico Organic Regulations to COFEMER for review after public comment	Revised draft of Mexico Organic Regulation submitted for review (includes requirement that growers use organic seed if commercially available or use of conventional treated seed with treatment washed off)

Table 6 Summary of key decisions and events in the evolution of the Mexico organic and phytosanitary regulations (continued)

Timeline	*Regulatory position change*	*Outcome*
30 November 2012	COFEMER provides response to SAGARPA's draft regulation	COFEMER requests clarification on organic seed section of regulation
8 February 2013	AMSAC revitalises Organic Seed Committee	Committee revitalised to develop strategy on organic seed issue
6 July 2012	Approval of more crops treated with Mycostop and Actinovate	Mycostop and Actinovate approved for nine and 14 species, respectively
29 October 2013	Mexican Organic Regulation recorded in the Federal Register	Approved Mexican Organic Regulations (includes requirement that growers use organic seed if commercially available or conventional treated seed with treatment washed off)
17 June/ 30 July/ 14 August 2014	SAGARPA approves 13 companies to import 15 crops in untreated seed form	Under strict phytosanitary guidelines and Mexican approved lab retesting, untreated seed imported into Mexico
7 May 2015	SAGARPA approves an additional ten crops to untreated seed importation list	More crops added to importation of untreated seed by the same 13 approved companies
9 May 2015	Implementation of Mexican Organic Regulation extended	Implementation date extended to 29 October 2016

Note: Content analysis of policy documents over 2007–2015.

Sources: COFEMER (2006, 2007, 2010, 2012), Dunkle (2011), Guzman Contro (2009), SAGARPA (2009, 2010, 2012a, 2012b, 2012c, 2013, 2014, 2015), SENASICA (2012), Salcido (2011) and Sonnabend (2010)

Three preliminary comments on the organic regulatory situation in Mexico can be made. First, Mexican organic growers bear the costs of multiple organic certifications, additional phytosanitary treatments, and of securing complex import permissions that place them at significant disadvantage compared with US and EU growers, who produce for the same markets. Secondly, certifiers and sellers in Mexico if they wish to stay in business, in practice, are forced to break the laws of either or both the seed's country of origin and of the destination markets for organic products. This significantly reduces the potential for trade while significantly increasing the potential for movement of diseased seed. Thirdly, despite the complications documented above, Mexican organic production continues to grow at a rate of 20–30% annually, involves more than 170,000 growers, being the third largest number of organic producers by nation state globally on over 500,000 certified hectares of land (Guzman Contro, 2009; Salcido, 2011).

4 Contrasts and comparisons

This section first reports and analyses the study's findings on regulatory harmonisation among EU member states. The US and EU regulatory processes then are compared. It is

suggested that the USA might learn from the EU process a number of important lessons. Finally, an analysis is made of how Mexico's organic sector regulatory process is stifled by the conflicting regulatory requirements.

4.1 Harmonisation of organic seed regulation among EU member states

According to the participants in the meetings observed in this study a comprehensive EU-wide database for all crops and varieties for which sufficient organic seeds are available and exceptions are not permitted is a shared and a realisable objective, although. Differences in legal languages, eco-climate zones, and agricultural and cultural traditions continue to pose challenges. The emergent regulatory regime combines a strong, clear, enforceable framework at the level of the EU with flexibility in interpretation and implementation at the level of each member state. Additional initiatives undertaken to enable and encourage greater harmonisation of interpretation are proving helpful. For instance, in 2004, the EC funded an inventory and analysis of member states' organic seed policies. A report of this study by Thommen (2007) highlighted the need for a shared interpretation of the term 'non-availability of an appropriate variety' as a criterion for exception to the organic seed rule. It further recommended the EU-wide use of a standard checklist to define the appropriateness of an assortment of varieties for a (sub) species, and this has been adopted. In addition, the European Consortium for Organic Plant Breeding (ECO-PB) since 2003 has assumed responsibility for organising joint meetings of stakeholders from member states, approximately every two years, to share experiences and develop regulatory recommendations and practices. The authority of decisions made at ECO-PB meetings has been recognised by member state governments, and several representatives of governments regularly attend, to better understand sector-wide problems and to collaborate on finding ways forward. The meetings serve to reinforce stakeholders' commitment to achieving zero exceptions and communicate the lessons of experience. Further, participants note that although the EU regulation currently allows growers to use conventional seed to trial new varieties on a small scale, if the crop is listed in the 'no exception' category for annual crops, trial managers have to wait at least a year before the organic seed of the desired variety is produced and on the market. In order to follow up new developments without delay, the Netherlands has introduced a 'flexibility rule' that allows their growers to use conventionally produced but chemically untreated seed of a new crop variety for one year for annual crops, or two years for biannual crops, provided that a seed producer agrees to start organic seed production of the requested variety (Lammerts van Bueren et al., 2008). Participants in the ECO-PB joint meetings have identified also the seed companies that are primary seed suppliers for particular crops but not interested in pursuing organic seed production. They recommend that official organic seed variety trials should exclude the varieties produced by companies that are not interested in pursuing organic seed production, arguing that this also would stimulate growers to learn about the organic varieties that are offered by other companies committed to organic seed supply (Rey et al., 2009).

These and other instances suggest that progress towards regulatory harmonisation among EU member states is a product not only of the bottom-up commitment of stakeholders in the organic sector to achieve a common goal, but also of strong support and direction from national authorities and the EC. ECO-PB members themselves draw the lesson that the EC should seek stricter and more coordinated management of exception criteria among member states, as well as a common format for the national

reports on exceptions so that the reports can be used to compare progress in regulatory implementation and improve trade (Döring et al., 2012). There is evident willingness to engage in and provide support for learning from experience and this has assisted the process of normalising regulatory requirements among member states. In an analysis of the organic food industry, Lee (2009) cites evidence that self-organising networks are mobilising their members to comply with regulatory requirements, while those responsible for meta-governance of the regulatory regime are seeking to create a level playing field among the interested parties. The EU's level playing field can be described in terms of the OECD's harmonisation categories as an approach that combines formal regulatory cooperation partnerships, a regional agreement with clear, time-bounded regulatory provisions, and a body of soft law that enforces principles, guidelines, and codes of conduct through provision for structured dialogue at expert, national, and EU levels. The EU's experience further suggests the importance, and perhaps the necessity of a central body that takes responsibility for developing and applying appropriate substantive and procedural policy instruments that provide incentives, penalties and support for compliance. These lessons potentially have policy impact worldwide, as discussed in the following section.

4.2 The USA, EU and Mexico compared

In both the EU and the US numerous stakeholders with diverse interests none the less want to ensure that the principles of organic agriculture are considered in the process of developing and implementing an effective regulatory regime (Klein and Winickoff, 2011). In the EU the normalisation of these principles into regulatory practice is assigned to member states (Padel et al., 2009), operating within common, clear and enforceable regulatory standards. In the USA, responsibility for enforcing compliance with organic principles is spread among stakeholder categories (organic certifiers, growers, and buyers), thereby creating potential for conflicts of interest and diverse interpretation of principle into practice.

In the EU the processes of integrating seed regulation into organic practices assisted by the databases and expert groups have moved at a faster pace and with broader stakeholder compliance than in the USA. The content and discourse analyses revealed five main contributing factors. (1) Most US respondents recognise the necessity for the information that only a database provides. The various database initiatives, each serving different clients and using different criteria, have been funded and organised by diverse coalitions of stakeholders rather than by a governmental authority, resulting in the fragmentation rather than harmonisation of the sector. (2) Maintenance of the US databases is currently reliant on the continuation of grants, and the uploading of varieties into any database relies on companies' willingness to pay for inclusion. This perpetuates competition for financial support and market advantage. (3) The EC requires that each member state submit on time national annual reports on organic seed exceptions. The US regime makes no such provision for reporting and progress towards regulatory compliance cannot be monitored. (4) EU member states have developed common guidelines for types of exception and for the practices and procedures of exception review committees. The USA has no formal procedural instruments for harmonising exceptions and organic seed usage. The onus is placed primarily on the interpretation of independent certifiers, growers and buyers. (5) Expert groups in an increasing number of EU member states advise regulatory bodies and certifiers in their decision-making

regarding exceptions. The USA relies on stakeholders to oversee the integrity of the exception procedure. Taken together these factors suggest that the USA in the near to medium term will not be able to approach 100% compliance with the organic seed regulation for any crop group, while this is in prospect for many crop groups within the EU, at least in certain EU regions.

The disharmony between the organic and phytosanitary standards of Mexico and the USA places significant non-tariff barriers to trade on seed companies, organic growers who directly import seed and on buyers of organic food products that must comply with organic standards. As awareness of Mexico's regulatory dilemma spreads, international organic certifying bodies are responding by imposing stricter certification requirements, increasing the risk that Mexican growers will lose the certification that allows them to produce for their main markets. Individual state authorities within Mexico are developing seed regulations and phytosanitary seed treatment requirements for each of their states and this hinders rather than supports the evolution of the organic sector. Self-organising networks have emerged to exploit opportunities for organic production and trade within and across state borders but they operate in the margins of legality, dampening the future growth prospects of individual producers and the sector as a whole. The material in Table 7 suggests three main outcomes: normalisation processes so far have been counter-productive; no single authority is responsible for meta-governance of the organic sector; and regulatory harmonisation, both internally and externally, is not in the short term within reach.

Table 7 Mexican organic seed system stakeholder categories: their type, level of influence and key concerns 2007–2013 (n = 15)

Stakeholder category	*Stakeholder type*	*Stakeholder level of influence*	*Key concerns relating to the organic seed regulation, availability and the sector overall*
Organic certifiers (n = 3)	Key	High	Restrictive importation processes that result in lack of available certified organic seed for growers
			Lack of 'fair process' in the development of federal organic regulation resulting in short public comment processes and redrafting
			Dependency of Mexico on foreign owned seed supply companies due to lack of domestic seed production capacity
			Capacity for large-scale commercial organic growers to attain organic seed through questionable means, while smaller-scale growers have more limited genetic resources
			Restrictive importation processes on organic seed entry contributes to the increase the illegal movement of potentially diseased seed

Table 7 Mexican organic seed system stakeholder categories: their type, level of influence and key concerns 2007–2013 (n = 15) (continued)

Stakeholder category	*Stakeholder type*	*Stakeholder level of influence*	*Key concerns relating to the organic seed regulation, availability and the sector overall*
Organic growers (n = 5)	Primary	Low to high	Restrictive importation processes that result in lack of available seed variety needs and increases costs
			Capacity for large-scale commercial organic growers to attain organic seed through questionable means, while smaller-scale growers have more limited genetic resources
			Seed treatment requirements for organic seed importation increase costs for growers, potentially decrease seed viability and require long delays in seed acquisition process
			Organic certifiers representing foreign export market locations hold Mexican organic growers to the same or higher standards than growers in export country, e.g. the USA
			Concern of high price for organic seed
Seed companies (n = 3)	Primary	Low to high	Restrictive importation processes that result in lack of available organic varieties for growers
			Seed treatment requirements for organic seed importation increase costs for seed companies, potentially decrease seed viability and require long delays in movement of seed
			Limited to no collated market data on organic production acreage and varietal requirements for organic growers
			Capacity for commercial organic growers to attain seed importation exceptions, but professional seed companies cannot
			Proposed Federal Organic Law includes confusing and inconsistent language on organic seed use allowances
			Access to information on which organic certifiers are working in Mexico and the consistency in their inspection processes around organic seed are unclear

Table 7 Mexican organic seed system stakeholder categories: their type, level of influence and key concerns 2007–2013 (n = 15) (continued)

Stakeholder category	*Stakeholder type*	*Stakeholder level of influence*	*Key concerns relating to the organic seed regulation, availability and the sector overall*
Policy & legislative bodies (n = 4)	Key	High	Ensure movement of potentially diseased seed is managed under rigorous phytosanitary laws and procedures
			Development of clear federal guidelines for organic seed through the Mexican organic law
			Develop bilateral agreements with the USA and EU to mitigate the risk of movement of seed-borne diseases and ensure that supply of organic seed to growers
			Work with seed treatment companies to identify new organic products to mitigate potential phytosanitary issues
			Develop procedures for growers and seed companies to import organic seed through a risk analysis

Note: Stakeholder typology, definition and level of influence, see sub-table of Table 3.

Sources: Stakeholder identification process (columns 1–3, 2008); stakeholder interviews and participate observation (column 4, 2007–2014)

4.3 Further considerations

The situation within and among the three countries is further constrained by three related considerations, that are discussed briefly below.

Plant protection: Mexico remains in default of its obligations as a signatory of the International Plant Protection Convention (IPPC) of the Food and Agriculture Organisation (FAO) and remains one of only three countries in the world that requires a blanket chemical treatment under its phytosanitary regulation of imported seed. The organic seed rules and standards of most EU member states and the USA comply with the IPPC standards (IPPC, 2013).

Breeders' rights and seed availability: The EU acknowledges UPOV '91 (the International Convention for the Protection of New Plant Varieties, 1991) that governs and protects breeders' rights worldwide. The EU maintains a common catalogue containing each variety marketed in the EU that meets the UPOV '91 criteria of Distinctness, Uniformity and Stability (DUS) and that has been tested to assess the variety's Value for Cultivation and Use (VCU). A compulsory varietal registration and release system in the EU provide protection to farmers against the potential purchase of poor-quality seed of questionable varieties, make illegal the marketing of seeds from unregistered varieties, including seeds grown and traded among farmers. In the USA seed labelling and testing laws prescribe that seed packaging labels include information on the crop, variety name, percentage germination and purity but the USA does not enforce strict varietal testing and registration procedures (Chable et al., 2012). In consequence

EU seed companies tend to handle fewer varieties than their US counterparts, who are able to release and market varieties more easily. The more limited assortment of registered varieties available to growers in the EU, combined with more rigorous organic seed standards, has forced organic growers to cope with a smaller, more regulated assortment than continued use of conventional untreated seed would allow (Bocci, 2009). The organic sector in the USA operates under regulatory guidance that allows frequent and continued recourse to conventional untreated seed, in a context in which a large portfolio of varieties is available and new varieties are brought easily to market. These conditions in themselves impose significant barriers to development of a single US-wide organic database. In the absence of stronger state involvement and a clear allocation of authority and responsibility among stakeholders it seems likely that the USA will not be able to compete on level terms with the EU organic sector for some time.

Consequences for trade relations: The regulatory differences that now exist between the EU and the USA raise the question of how trade relations between the two continents might develop. What are the implications for trade in organic products if the EU achieves 100% organic seed for certain crops and the USA does not? On the one hand, organic growers in the USA would be able to produce crops at lower cost by not having to use organic seed and would have a broader genetic diversity to choose from. Growers in the EU would continue to pay more for their seed than their US counterparts but also have access to a greater variety of organic seed. Because the integrity of the organic value chain is what safeguards its market position, US growers might find an increasing number of markets closed to them. There is no indication that market-led competition is driving the regulatory regimes of the USA, the EU and Mexico towards convergence. In addition, it can be noted that the relevant provisions of the trade treaty between the USA, Mexico and Canada (the North America Free Trade Agreement – NAFTA), and of the proposed trade treaty between the USA and the EU (the Trans-Atlantic Trade and Investment Partnership – TTIP), do not lend to themselves resolving the regulatory divergences among the three jurisdictions addressed here.

US, EU and Mexican stakeholders none the less are attempting to formulate through structured dialogue a better-coordinated response. For instance, the Mexican Seed Trade Association (AMSAC) comprised of seed companies functioning in Mexico, and in 2009 set up its own task force to identify legitimate ways for organic untreated seed to be imported into Mexico. The American Seed Trade Association's (ASTA) organic committee and the Animal and Plant Health Inspection Service (APHIS) under the USDA have identified priority crops and potential seed-borne disease risks, testing procedures and treatments, as the basis for proposing to SAGARPA a risk assessment procedure that could secure entry into Mexico of untreated seed of sufficient phytosanitary quality (ASTA, 2011), and form the basis of a bilateral trade agreement. In 2012, the North American Plant Protection Organisation (NAPPO), which is the phytosanitary standard setting organisation recognised by NAFTA, hosted a meeting specifically to address seed importation and phytosanitary issues affecting the growth of the organic sector. This meeting was directly followed by a Seed Summit between governmental, trade and agricultural organisations from the USA and Mexico focusing on the same issue, but from a more organic orientation (Rosmann, 2013). This resulted in the formation of the Mexico Organic Seed Task Force that requested in a joint letter to the USDA, FAS and NOP alternatives to the mandatory conventional seed treatments on seed used in organic agriculture. Simultaneously, the Dutch Ministry of Agriculture in 2010 and 2014 sent a broadly composed organic stakeholder delegation to Mexico to discuss trade-related issues and determine next steps. Plantum, the Dutch seed trade

association, also carried out a risk analysis of potential seed-borne diseases and treatments of the major organic export crops, in order to demonstrate to SAGARPA that Dutch seed intended for export to Mexico meets international phytosanitary standards, and to develop a bilateral agreement for organic seed importation. In 2014, several companies received import allowances for untreated seed for nine crops (organic or conventional) if they fulfilled the phytosanitary import requirements for Mexico, followed by another nine crops six months later (SAGARPA, 2014; SAGARPA, 2015).

The major players currently recognise three compelling reasons for taking coordinated action: (1) the organic market identity will not tolerate gross violation of its integrity; (2) the seed sector can fulfil its potential only if regulations are aligned across borders, and (3) the seed industry (associations and companies), the organic sector (associations and growers) and government bodies (organic regulation and phytosanitary regulators) must work together to clear a pathway forward.

Table 8 provides an overview of the comparative progress in each jurisdiction towards these goals by end 2014.

Table 8 Instruments influencing the success of achieving 100% organic seed usage, and their status in the USA, EU and Mexico (2015)

Instruments influencing organic seed sector development	*Stakeholders' perception of level of influence*	*USA*	*EU*	*Mexico*
National (or regional) Organic Standard	High	✓	✓	✓
Organic Seed Regulation	High	✓	✓	*In process*[1]
Interpretive Seed Regulatory Guidelines	High	✓	✓	--
Organic Seed Database	High	*In process*	✓	--
Deadline for Compliance	High	--	✓	--
Derogation or Exception Process	Medium	--	✓	--
Expert Groups	Medium	--	✓	--
Annual National Reports	Medium	--	✓	--
Phytosanitary Restrictions	Medium	NA	NA	✓
Organic Seed Production Activities	Med-High	✓	✓	--
Organic Plant Breeding Program	Medium	✓	✓	--
Compulsory Variety Registration Process	Low	NA	✓	NA

Notes:

✓ instrument is in force in particular region

In process – instrument is under development in particular region

-- – instrument is not yet in process in particular region

NA – instrument does not apply to particular region

[1]Mexico organic regulations published 29 October 2013 with scheduled enforcement 29 October 2016.

Sources: Content analysis of stakeholder interviews (n = 96) and document analysis and participant observation (2007–2015)

5 Conclusions

Stakeholders in the USA are locked in an institutional impasse that perpetuates inconsistent regulatory interpretation and enforcement among stakeholders who have not been able to organise among themselves an effective form of meta-governance. In Mexico the net effect of disparate initiatives is to restrict access to organic seed, increase production costs, encourage the illegal movement of potentially diseased seed, and increase the risks of loss of certification and the potential to trade with the USA and the EU. In the EU, member state governments under the overall guidance of the EC have assumed responsibility for defining, enforcing, communicating and supporting a clearly defined regulatory policy that is achieving significant if not yet universal progress through an effective form of meta-governance.

This study suggests that the way ahead lies in organic seed market and trade interests pushing further and more urgently towards coordinated regulatory action in the following areas: (1) formally endorsed organic seed guidance that communicates detailed criteria for enforcement and an appropriate allocation of responsibility among stakeholders in the interpretation and enforcement of the organic seed clause; (2) modification and harmonisation of the definitions of *equivalency* and *commercial availability* criteria in order to enable certifiers to make better decisions regarding exceptions; (3) sector-wide procedures for granting exceptions, and the steps required to move towards 100% crop-specific closure; (4) compliance with database requirements; (5) capacity-building for the informal and formal organic seed production and breeding; (6) a governance body specific to the organic seed sector, with authority to inform the NOP, EU and SAGARPA of the needs of the diverse organic seed sector stakeholders and that can support overall sector development and regulatory interpretations; and (7) formalised collaboration between regional seed trade associations, regional organic regulators, and phytosanitary bodies to develop coherent policies to support this growing industry. These measures have the potential to hasten the transition rate and increase the chances of success, and offer important lessons for the regulation of the organic seed sector worldwide.

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