## 1 CHAD A. READLER Acting Assistant Attorney General 2 MCGREGOR W. SCOTT 3 United States Attorney ERIC R. WOMACK Assistant Branch Director, Federal Programs Branch DANIEL HALAINEN 5 Trial Attorney (MA Bar No.694582) 6 U.S. Department of Justice Civil Division, Federal Programs Branch 7 20 Massachusetts Avenue, NW Washington, DC 20530 8 Tel.: (202) 616-8101 9 Fax: (202) 616-8470 Email: daniel.j.halainen@usdoj.gov 10 Attorneys for Defendants 11 12 UNITED STATES DISTRICT COURT EASTERN DISTRICT OF CALIFORNIA 13 SACRAMENTO DIVISION 14 SUNRISE FOODS INTERNATIONAL 15 INC., 16 Plaintiff, Case No. 2:18-cv-00688-JAM-EFB 17 v. 18 **DECLARATION OF OSAMA EI-LISSY IN** SONNY PERDUE, in his official capacity SUPPORT OF DEFENDANTS' 19 as Secretary of Agriculture, et al., **OPPOSITION TO PLAINTIFF'S** MOTION FOR TEMPORARY 20 Defendants. **RESTRAINING ORDER** 21 22 23 24 25 26 27 28 Sunrise Foods International Inc. v. Perdue, Case No. 2:18-cv-00688-JAM-EFB Declaration in Support of Defendants' Opposition to Motion for Temporary Restraining Order

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#### **DECLARATION OF OSAMA EL-LISSY**

Since 2013, I have served as the Deputy Administrator for the United States

For nearly two years before becoming PPQ's Deputy Administrator, I served as

From 2000 to 2005, I served as the APHIS National Coordinator for cotton pest

I have previous career experience in the private sector that includes more than

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I, Osama El-Lissy, hereby declare and certify as follows:

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diseases.

Department of Agriculture Animal and Plant Health Inspection Services' (APHIS) Plant Protection and Quarantine (PPQ) program unit. In this position, I lead and direct a nationally

dispersed staff that safeguards U.S. animal and plant resources from destructive pests and

the Associate Deputy Administrator responsible for policy and financial management within

the preparedness, response, and recovery from plant health emergencies in the United States.

This included working with Federal and State governments, industry stakeholders, and subject

matter experts to develop and implement comprehensive plans designed to safeguard American

agriculture against invasive pest outbreaks such as citrus black spot in Florida, European

programs. In that role, I provided the coordination for national cotton pest programs in the

United States and Mexico, including the boll weevil and pink bollworm eradication programs.

twelve years in managing large-scale pest control and eradication programs. As the director of

the Texas boll weevil eradication program from 1994 through 2000, I led one of the largest pest

eradication programs in the world, affecting approximately four million acres of cotton and

grapevine moth in California, and potato cyst nematode in Idaho.

PPO. Before that, I directed PPO's emergency management, providing national coordination in

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5. I earned a Master's Degree in international business administration from

providing services to several thousand cotton producers and landowners.

Georgetown University, a master's degree in public administration from American University,

and a bachelor of science in agriculture production and entomology from Cairo University.

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6. As the Deputy Administrator for the PPQ unit of APHIS, I oversee programs to safeguard U.S. agriculture and natural resources against the entry, establishment, and spread of economically and environmentally significant plant pests and noxious weeds. In addition to eradicating plant pests that enter the United States and managing those pests that become established, PPQ also plays a critical role in making sure that billions of dollars of agricultural commodities are traded safely, without artificially moving pests through commerce.

7. In addition to providing direction and coordination for PPQ programs and activities under the above-listed authorities, as the Deputy Administrator of PPQ, I am also responsible for: (1) Developing regulations (including quarantines) regarding noxious weeds and plant pests and diseases; (2) Cooperating with and providing technical assistance to State and local governments, farmer's associations, and individuals with regard to plant pest control; (3) Cooperating with and providing technical assistance to foreign governments with regard to plant pests and diseases; (4) Assisting in the development of sanitary and phytosanitary measures; (5) Serving as a member of the North American Plant Protection Organization, an organization composed of plant protection officials and industry cooperators from Canada, Mexico, and the United States; (6) Serving as the lead of the National Plant Protection Organization of the United States, which actively participates in the International Plant Protection Convention, an international plant health agreement between 181 countries that aims to prevent the introduction and spread of plant pests and promotes appropriate measures for their control; (7) Administering plant and animal pest and disease exclusion policies, procedures, and regulations at international ports of entry (land, sea, and air) relative to all plants and plant and animal products and associated materials (excluding livestock, pets, semen or embryos); and (8) Providing laboratory support, diagnostic services, methods development, and research activities in support of PPQ programs. See 7 C.F.R. § 371.3

#### **Plant Protection Act**

8. The PPA authorizes the Secretary of the USDA to issue regulations to prevent the introduction of plant pests into the United States or the dissemination of plant pests within the

United States. 7 U.S.C. § 7712(c). The Secretary delegated that authority to APHIS, an agency within USDA. 7 C.F.R. §§ 2.22(a), 280(a)(36). The Administrator of APHIS delegated that authority to PPQ, a program within APHIS. 7 C.F.R. § 371.3. As noted *supra*, I exercise that authority.

- 9. Section 7712 of the PPA provides that restrictions or prohibitions may be placed on the importation of any plant or plant product if deemed necessary to prevent the introduction of a plant pest or noxious weed into the United States, or the dissemination of a plant pest or noxious weed within the United States.
- 10. Noxious weed is defined within the PPA as follows: "Any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment." 7 U.S.C. 7702(10)
- 11. Plant pest is defined within the PPA to include protozoans, parasitic plants, bacteria, fungi, viruses and viroids, infectious diseases agents and other pathogens, and similar articles. 7 U.S.C. § 7702(14)
- 12. The corn-related regulations at issue in this matter, in 7 C.F.R. § 319.24 *et seq.*, "Subpart—Corn Diseases," and 7 C.F.R. 319.41 *et seq.*, "Subpart—Indian Corn or Maize, Broomcorn, and Related Plants," were issued prior to the promulgation of the PPA under statutory authorities repealed by the PPA. However, pursuant to § 7758 of the PPA, the repeal of the previous authority did not affect the validity of those regulations or impact the restrictions and prohibitions they contain.

## **Applicable Regulations And Manuals**

13. The importation of corn is subject to regulation. 7 C.F.R. § 319.41 contains a general prohibition on the importation of all raw or unmanufactured plant parts of corn (*Zea mays*), due to the risk of dissemination of a plant pest, European corn borer (*Ostrinia nubilalis* 

Hubn.), as well as "other dangerous insects, as well as plant diseases, not heretofore widely distributed in the United States."

- 14. 7 C.F.R. §§ 319.41-1 through 319.41-3 collectively provide that a permit must be obtained for the importation of any raw unmanufactured corn seed into the United States, unless the seed is from New Zealand. Permits issued pursuant to these sections restrict importation of raw unmanufactured corn seed for purposes other than planting to the following countries: Argentina, Paraguay, Romania, Turkey, Uruguay, and Canada. Importation of raw unmanufactured corn seed from all other countries is prohibited.
- 15. 7 C.F.R. § 319.24 also regulates the import of raw unmanufactured corn seed due to its ability to serve as a host for several injurious diseases including downy mildews including but not limited to *Peronospora maydis* and *Sclerospora sacchari*, and the Physoderma diseases of maize, *P. zea-maydis* and *P. maydis*. To prevent the entry and spread of these and similar diseases raw unmanufactured corn seed and other plant parts are prohibited from all countries where those diseases were known to occur when the regulation was enacted, including but not limited to Asia, Oceania, Malaysia, and the Philippines. Taken together, 7 C.F.R. §§ 319.41 and 319.24 collectively act as a blanket prohibition, with limited exceptions, regarding the importation of raw unmanufactured corn products, and those of corn relatives, into the United States. As discussed below, these prohibitions are warranted given the plant pest risk that may be associated with raw unmanufactured corn and corn products, and APHIS has a lengthy and rigorous process for proposing to lift them.
- 16. To implement 7 C.F.R §§ 319.41 and 319.24 and enforce the relevant permitting requirements and restrictions on entry, APHIS and CBP rely upon two USDA-issued manuals. The Seeds Not for Planting Manual (SNFP) provides the background, procedures and reference tables for the importation of raw unmanufactured corn seed for purposes other than planting or growing. The SNFP also provides guidance on appropriate remedial measures when raw unmanufactured corn seed contaminants are discovered in a shipment of other agricultural products. In contrast, the Miscellaneous and Processed Products Manual (MPPM) provides the

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background, procedures, and reference tables for regulating processed products that might serve to introduce plant pests.

- 17. Pursuant to the MPPM, certain material may be eligible for importation, even though it would be prohibited in its raw form, if it has undergone some form of processing such as milling, cooking, or heating that eliminates the risk of pest and disease on that product. The MPPM specifies the degree of processing needed to qualify as exempt from restrictions outlined in the regulations.
- 18. If during the inspection and clearing of cargo manifested as a processed product (e.g. cracked corn), CBP determines the product is not fully processed per APHIS standards, the product would be regulated per the requirements in the appropriate APHIS manual for unprocessed material: in the case of raw unmanufactured corn seed the SNFP manual.
- Within the MPPM, Table 3-36 provides that cracked corn does not need a permit 19. in order to be imported, but must be inspected before it is released by CBP. Similarly, Table 3-153 in the MPPM specifies that corn or corn relatives must be inspected and deemed "so thoroughly processed that all pests and pathogens would have been destroyed" before being released by CBP. Operationally, if during inspection, CPB determines the consignment does not meet entry requirements due to insufficient processing, infestation with pests or diseased material, or has a contaminant; it may be rejected or destroyed. A footnote to another table, footnote 2 of Table 3-136, clarifies that all milled corn products, including cracked corn, are admissible without a permit, but are subject to inspection. It further specifies that, if more than 28 unhulled kernels (raw unmanufactured corn seed) per quart are discovered in a shipment of milled corn, the shipment must be prohibited entry. Twenty-nine unhulled kernels of raw unmanufactured corn seed in a quart of sampled corn represents approximately 1 percent of the kernels in that quart, and provides the inspector with approximately 95 percent confidence regarding the presence of raw unmanufactured corn seed within the rest of the shipment. If more than 28 kernels of raw unmanufactured corn seed per quart are present, the consignment is no longer a processed product subject to the MPPM, and therefore disposition is based on the SNFP manual.

- 20. This is consistent with Tables 2-8 and 2-10 of the SNFP, which collectively provide that if prohibited raw unmanufactured corn seed is discovered as a contaminant of a shipment, unless the shipment can be cleaned or treated, it must be refused entry. Cleaning and treatment must be done in accordance with APHIS-approved methods. For reasons set forth later in this document, APHIS cannot consider the grinding proposed by the Plaintiff either cleaning or treatment.
- 21. Through the authority in the PPA and as stated in 7 C.F.R. § 352.3 Plant Quarantine Safeguard Regulations, Enforcement and Administration: "(a) Plants, plant products, plant pests, noxious weeds, soil, and other products and articles subject to the regulations in this part that are unloaded, landed, or otherwise brought or moved into or through the United States in violation of this part may be seized, destroyed, or otherwise disposed of in accordance with section 414 of the Plant Protection Act (7 U.S.C. § 7714)." APHIS uses this authority to enforce decisions on the disposition of commodities that do not meet APHIS requirements.
- 22. APHIS cooperates with CBP in enforcing these requirements. Section 421(a) of the Homeland Security Act of 2002 transfers certain agricultural import and inspection functions to the Secretary of Homeland Security from the Secretary of Agriculture. The 2003 "Memorandum of Agreement Between the United States Department of Homeland Security and the United States Department of Agriculture" (hereafter the "MOA") and Appendices, outline the delegation of authority to CBP to conduct inspections on APHIS's behalf and issue an Emergency Action Notification (EAN) if cargo is determined by CBP to be non-compliant. Under Article 4 of the MOA, APHIS agrees to provide training to CBP on specific agricultural import and entry inspection functions transferred to CBP. In this capacity, APHIS provides training to CPB officers on the use of APHIS Manuals, inspection procedures, and on the clearance of agricultural cargo.

# **APHIS' Process for Authorizing Imports from New Countries**

23. As noted above in paragraph 13, under 7 C.F.R §§ 319.24 and 319.41 collectively, the importation of raw unmanufactured corn seed is prohibited from most countries. APHIS utilizes a rigorous risk-based process to evaluate whether a prohibited plant product can

be authorized importation into the United States, in other words, whether the product may be granted "market access." 7 C.F.R. § 319.5, "Subpart—Requests to Amend the Regulations," provides that, if a country wishes to export a plant or plant product not authorized importation under the conditions in 7 C.F.R. part 319, it must formally request such authorization, and provide information needed in order for APHIS to conduct a pest risk analysis. The minimum categories of information are specified in § 319.5, with the caveat that APHIS may request any additional information from the requesting country if APHIS deems it necessary to complete the pest risk analysis.

- 24. Upon receipt of such a request, APHIS reviews the information for completeness. If it is determined to be complete, APHIS conducts a pest risk assessment (PRA). This assessment follows international standards that APHIS has agreed to adhere to as a member country of the International Plant Protection Convention (hereafter IPPC). *See* International Standards for Phytosanitary Measures (ISPM) No. 2, issued by the IPPC. It includes: A list of the plant pests known to exist in the exporting country; an assessment of whether these plant are quarantine pests (defined in ISPM No. 5 as "a pest of potential economic importance to the area endangered by it and not yet present there, or present but not widely disseminated and being officially controlled"), and an assessment whether the pest is likely to "follow the pathway" (that is, be present on the commodity when it is shipped to the United States). If a pest is identified as being a quarantine pest and likely to follow the pathway, the PRA assesses its likelihood of its introduction into the United States, the likelihood of establishment within the United States, and the consequences of such establishment.
- 25. Once the PRA is completed, APHIS makes it available to the general public for review and comment through an informal stakeholder consultation process. This helps ensure that the PRA has correctly identified and assessed the plant pest risk associated with the importation of the commodity. APHIS then drafts a document that recommends mitigations to address the plant pest risks identified by the PRA. Depending on length or degree of complexity, this document is referred to as a risk management document (RMD) or commodity import

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**Evolving Pest Status and Unassessed Risk** 

to the comments in a final rule or notice that authorizes the importation of the commodity.

26. As noted above, the International Plant Protection Convention (IPPC) definition

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of a quarantine pest, which APHIS adheres to, hinges on whether the pest is known to exist in the United States, and, if so, whether it is widely disseminated or under official control. Implicit within this definition is the idea that a pest that was once not present in a country may be introduced, and a pest that was once present in limited distribution may become widespread. This introduction or dissemination may be a result of natural spread (e.g., the gradual movement of the pest throughout its ecological range) or artificial spread (the human-assisted movement of the pest into the country). Examples of artificial spread include importation of infested or infected commercial shipments of an agricultural commodity, the presence of infested or infected plant products in passenger baggage, and hitchhikers on non-agricultural commodities. Because of the realities of both natural and artificial spread, the pest status of a country is considered dynamic, rather than static.

27. This reality guides the market access process outlined above: An exporting country provides APHIS with current information regarding a commodity for which market access is requested, and APHIS evaluates that information and all available scientific information regarding the plant pest risk associated with the importation of that commodity

based on the best available current scientific information. In the absence of up-to-date information, APHIS may unintentionally assign insufficient mitigations to the importation of the commodity, and jeopardize American agriculture. To address this risk, APHIS provides the public with multiple opportunities to supply the Agency with additional information relative to its assessment of risk, first through informal stakeholder review of the draft PRA, then during the comment period for the rule or notice.

- 28. The dynamic nature of the pest status of a country is also one of the reasons why APHIS and CBP inspect agricultural commodities presented for entry into the United States, and why APHIS monitors international publications on an ongoing basis for evidence of a new detection of a quarantine pest in an exporting country.
- 29. If APHIS has not conducted a PRA regarding the importation of a prohibited agricultural commodity, the Agency does not allow the importation of the commodity until the risk is sufficiently understood by APHIS and appropriate mitigations established.

## Raw Corn Can Present a Plant Pest Risk

30. 7 C.F.R. §§ 319.41 and 319.24, APHIS' prohibitions on raw unmanufactured corn seed, are vital to protect American agriculture because quarantine pests of raw unmanufactured corn seed are known to exist in foreign countries. To cite a few examples within one genus of plant pathogen, *Peronosclerospora maydis*, or downy mildew, is a quarantine pest that is not present in the United States. This pathogen is endemic to Australia, Asia, and several countries in South America, and was identified in a recently completed (but not yet publicly available) APHIS PRA as existing in the Ukraine and potentially following the pathway on raw unmanufactured corn seed. *Peronosclerospora sacchari*, another mildew, is similarly endemic to Australia and Asia. Finally, *Peronosclerospora philippinensis*, or Philippines downy mildew, is not as widely distributed, but is designated by USDA as a select agent under the Agricultural Bioterrorism Act, 7 U.S.C. 8401 *et seq.*, because of its severity. *See* 7 C.F.R. § 331.3.

## Cracked Corn Is Not as High Risk As Raw Corn

31. Unlike raw unmanufactured corn seed, cracked corn is not a high-risk pathway for the introduction of quarantine pests. The milling used to produce cracked corn cracks the corn

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kernel and exposes the endosperm, which reduces the ability of the kernel to germinate. Scientific research suggests that cracking and propagative capacity are inversely correlated (that is, the more cracked the corn kernel is, the less likely it is to germinate). APHIS generally considers propagative material to present a greater risk of introducing plant pests than nonpropagative material because the former is far more likely to persist in the environment.

32. Milling also reduces the life of the kernel, and, in so doing, makes the corn kernel a less commodious host for pathogenic fungi, which tend to be biotrophic (that is, dependent on a living host to survive).

# Milling Corn Overseas Presents Less of a Risk of Disseminating Plant Pests than **Processing Within the United States**

33. Milling presents some risks, however. Milling can release spores from an infected kernel onto the processing equipment, as well as into the air of the processing facility. This presents a risk of contamination of the processing equipment, cross-contamination of other corn products processed at the facility, and possible aerosol-borne contamination of any unprocessed products stored in the same facility (as well as aerosol-borne recontamination of the processed product). Additionally, if the facility is not adequately safeguarded, airborne spores could escape the facility and establish in the surrounding environment. If the size of the shipment exceeds the capacity of the facility, and raw unmanufactured corn is stored outside of the facility pending processing, this also increases the risk of dissemination of plant pests, particularly if the raw unmanufactured corn is stored for an extended period of time. Finally, the movement of the raw unmanufactured corn from port environs to the processing facility also carries with it the risk of spillage and breach of safeguards. For all of these reasons, milling a potentially infected shipment of raw unmanufactured corn outside of the United States presents less of a risk of introducing plant pests into the United States than milling within the United States.

# Plaintiff's Shipment Contains Impermissible Raw Corn Prohibited from Entry

34. According to the information provided by CBP to APHIS, Plaintiff's shipment was manifested with Turkey as the country of origin. Through information provided to APHIS 2 pos
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by the Agricultural Marketing Service (AMS) National Organic Program (NOP), APHIS possesses material evidence that the corn in the shipment actually originated from Russia, Kazakhstan, and Moldova. APHIS has not assessed the plant pest risk associated with the importation of raw unmanufactured corn from these three countries, and APHIS prohibits entry of raw unmanufactured corn from these three countries pursuant to 7 C.F.R §319.41.

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35. CBP identified a significant number of raw unmanufactured corn kernels during their inspection of the shipment. CBP provided APHIS with visual documentation (two photos) of the raw unmanufactured corn identified in the shipment. APHIS reviewed the photos and determined that the shipment was not admissible, and instructed CBP to issue Emergency Action Notifications (EANs) regarding the shipment. Based on the number of raw unmanufactured corn kernels in the photos, APHIS does not consider the corn sufficiently processed to mitigate plant pest risk.

The Plaintiff requested to grind the corn at Penny Newman, a processing facility 36. in Stockton, as a remedial measure. Grinding is a form of milling in which the resulting product is meal. In the SNFP manual Table 2.1, APHIS allows for the cleaning or grinding of shipments containing contaminants, including raw unmanufactured corn as a contaminant, if the cleaning or grinding will address plant pest risk and is operationally feasible. APHIS took into account a number of factors in our determination that grinding at Penny Newman was not an acceptable remedy. As referred to above, Table 2.1 addresses contaminants in shipments of authorized material where APHIS is familiar with the plant pest risks associated with that commodity and country of origin. The shipment in question did not originate from an authorized country, but originated from Russia, Kazakhstan, and Moldova. As a result, APHIS can only speculate about what plant pests are associated with the shipment. APHIS can only authorize cleaning and grinding if APHIS determines it can adequately safeguard the shipment throughout the process: Unloading, storage, milling, and disinfection of milling equipment, which can become contaminated with diseased material. For the reasons cited below, APHIS does not have confidence we will be able to provide adequate safeguards to protect domestic stakeholders including but not limited to: Grain processors, producers, and grain exporters who rely on

freedom from quarantine pests to maintain export markets. In addition, significant USDA and CBP resources would be required to ensure that the corn is processed without risk of contamination, diverting resources from the Agency's other risk mitigation duties.

## Grinding at a Domestic Facility Would Present Unacceptable Risks

- 37. According to information provided to APHIS by CBP, Plaintiff's shipment is 25,000 metric tons. Penny Newman informed APHIS that grinding the shipment at their facility could take an estimated 3-4 months given the grinding capacity at the facility.
- 38. Storage bins at Penny Newman containing the raw unmanufactured corn could be as close as 30 feet to the grinder, and would not exceed approximately 150 feet from the grinder. In other words, any grinding of Plaintiff's shipment could present significant risks of spreading quarantine pests to unground corn stored nearby.
- assessed the plant pest risk associated with the importation of raw unmanufactured corn from these countries. APHIS does know that quarantine pests of corn exist in foreign countries, including a country, the Ukraine, that neighbors Russia and Moldova. Without ample time to assess the pest complex in the country(s) of origin, APHIS cannot develop a mitigation strategy to address potential pest risk from the point of unloading the bulk shipment through processing. Any safeguards APHIS proposes would be based on incomplete information and conjectural. This increases the risk of entry and dissemination of quarantine pests and diseases.
- 40. Beyond risks of spreading quarantine pests to unground corn at Penny Newman, this is also a bulk shipment, meaning the raw unmanufactured corn is not stored in self-contained bags, but is open in the hold of the ship. Even if the corn is removed directly from the hold of the ship into Penny Newman's facility, the fact that it is open introduces risk of spillage during the unloading process.
- 41. Moreover, the volume of the shipment proportionally increases the likelihood of inadvertent spillage or breach of safeguarding at some point during unloading the raw unmanufactured corn at Penny Newman.

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42. For all of the foregoing reasons, APHIS does not have adequate assurances that allowing the raw unmanufactured corn to be ground at Penny Newman's facility will not result in the dissemination of plant pests of corn into the surrounding environment. As a result, I cannot consider it the least drastic action that is "feasible and adequate to prevent the dissemination of plant pests into the United States." See 7 U.S.C. § 7714(c).

- 43. APHIS regulations in the form of import requirements are an effective measure to mitigate the entry of quarantine pests into the United States. APHIS develops these import requirements in collaboration with trading partners through a regulatory process that evaluates plant pest risk and invites public comment on regulatory actions. Deviations from this process in order to facilitate international trade are for low-risk material that has undergone an acceptable level of processing prior to importation to eliminate plant pest risk. APHIS also accepts a base level of risk on all imports through the establishment of tolerances for contaminants; however, this allowance in no way precludes APHIS from exercising its statutory authority at ports of entry to prevent the possible introduction of plant pests and noxious weeds within the United States. For prohibited material such as raw unprocessed corn from Russia, Kazakhstan, and Moldova, APHIS must be allowed to exercise its authority in refusing entry for commodities that do not meet import requirements. Authorizing import of this shipment under the condition of further processing in the United States would set a dangerous precedent. If APHIS allows domestic processing of this shipment, we would set a precedent by which any prohibited material would gain entry if there was the option to process domestically. This would significantly increase the risk of introducing pest and diseases threatening U.S. agriculture and natural resources. It would also undermine the lengthy market access process that we employ and consider necessary in order to assess the risk associated with the importation of plants and plant products accurately.
- 44. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

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Executed on the 11th day of April, 2018. Osama El-Lissy Deputy Administrator Plant Protection and Quarantine Animal and Plant Health Inspection Service United States Department of Agriculture 

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