Interpreting the "Same Level of Public Health Protection" in Produce Safety Rule Variances

LAUREN R. WUSTENBERG*

ABSTRACT

As the Food Safety Modernization Act Produce Safety Rule (FSMA PSR) enters implementation, regulators and stakeholders are examining their options in case some provisions do not suit their jurisdiction's circumstances. Under Subpart P, food safety agencies may apply for PSR variances if the agency proposes substitute measures that provide the "same level of public health protection." Through variances, the Food and Drug Administration (FDA) could regionalize PSR requirements and account for geographic variation in environmental conditions, agricultural practices, and industry technologies. Theoretically, variances can be as simple as an exception from one PSR provision for a single commodity or as complex as a waiver of all PSR requirements for all producers in a foreign country. Draft guidance began illuminating the same level of public health protection standard, but many questions remain unanswered. This Article examines analogous United States Department of Agriculture (USDA) and FDA programs, as well as international trade law, to discern how petitioners can show that substitute measures meet the same level of public health protection standard and how the variance process may differ based on the complexity of the request. After discussing the basic structure of the variance process and the only variance petition submitted to date, this Article examines legal precedent for analogous regulatory evaluation processes. Legal precedent examined includes FDA's Manufactured Food Regulatory Program Standards, USDA's Meat & Poultry Inspection equivalence program, and FDA's foreign systems recognition and foreign equivalence processes. Due to their influence on U.S. import regulation, this Article also examines U.S. obligations under the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (WTO SPS Agreement) to determine whether the PSR is open to challenge as a violation of international trade commitments. FDA should rely upon these analogous processes to inform its evaluation of PSR variance

* Lauren R. Wustenberg is a third-year law student at Vermont Law School. She authored this Article as an advanced student clinician in the Food and Agriculture Clinic working on the Extension Legal Services Initiative, a collaborative project between the VLS Center for Agriculture & Food Systems and the Northeast Center to Advance Food Safety with funding from the National Agricultural Library, Agricultural Research Service, U.S. Department of Agriculture. The project began with a national survey of stakeholders in the produce system. The ninety respondents, primarily made up of produce farmers and state regulators, identified variances as one of twelve priority topics for further research and clarification. Thank you to the supervisors who made this project possible, including Sophia Kruszewski, Elizabeth Newbold, and Christopher Callahan, and to the fellow FSMA clinicians who provided camaraderie and diligent feedback on this Article, including Sedona Chavez, Lindsay De May, and Samuel Ingraham. This Article won second place in the 2020 H. Thomas Austern Student Writing Competition. Thank you to FDLI and the editors of the *Food and Drug Law Journal* for generous help in preparing this Article for publication.

petitions. Doing so will clarify petition requirements, improve procedural efficiency, and help ensure FDA's consistency when reviewing similar variance requests.

I. INTRODUCTION

Foodborne illness outbreaks continue to pose a serious, yet preventable, threat to consumers in the United States. The Centers for Disease Control and Prevention estimates that one in six Americans get sick, 128,000 are hospitalized, and 3,000 die due to foodborne illnesses every year.[1] In 2018, fifteen major pathogens caused over 95% of the foodborne illnesses and deaths in the U.S. and cost an estimated $17.6 billion.[2]

To better protect the public from foodborne illness, Congress passed the Food Safety Modernization Act (FSMA) in 2011—"arguably the most significant expansion in federal regulation of farming methods ever undertaken."[3] FSMA expanded federal oversight of the production, handling, holding, and transportation of domestic and imported food intended for human and animal consumption in the United States.[4] Congress specifically directed the U.S. Food and Drug Administration (FDA) to address food safety concerns related to fresh fruits and vegetables.[5]

Produce poses a particular threat to public health because of the diversity of produce farms, the prevalence of foodborne illnesses tied to produce consumption, and the importance of fresh produce to a healthy diet.[6] FSMA's statutory mandate reflected the array of public health risks stemming from fresh fruit and vegetable production. Congress directed FDA to craft uniform produce safety standards that addressed risks of contamination from agricultural water, soil amendments, worker hygiene, packaging, temperature controls, and animal contact in growing areas, whether those risks were naturally occurring, accidentally introduced, or intentionally introduced.[7] However, the regulations could not conflict with conservation and environmental practice standards or the national organic program.[8]

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[1] *Estimates of Foodborne Illness in the United States*, CTRS. FOR DISEASE CONTROL & PREVENTION (Nov. 5, 2018), https://www.cdc.gov/foodborneburden/estimates-overview.html [https://perma.cc/JWN4-VBU8].

[2] *Cost Estimates of Foodborne Illnesses*, U.S. DEP'T OF AGRIC., ECON. RSCH. SERV. (Mar. 10, 2021), https://www.ers.usda.gov/data-products/cost-estimates-of-foodborne-illnesses/.

[3] Margot J. Pollans, *Regulating Farming: Balancing Food Safety and Environmental Protection in a Cooperative Governance Regime*, 50 WAKE FOREST L. REV. 399, 399 (2015).

[4] FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (codified in scattered sections of 21 U.S.C.) (2011).

[5] 21 U.S.C. § 350h(a)(1)(A) (2011) ("[T]he Secretary . . . shall . . . establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables . . . that are raw agricultural commodities for which . . . such standards minimize the risk of serious adverse health consequences of death.").

[6] RENÉE JOHNSON, CONG. RSCH SERV., IF11092, FOODBORNE ILLNESSES AND OUTBREAKS FROM FRESH PRODUCE 1 (2019) (stating that outbreaks associated with produced sickened from 900 to 3,000 people annually from 1998 to 2016); CTR. FOR SCI. IN THE PUB. INT., OUTBREAK ALERT! 2015: A REVIEW OF FOODBORNE ILLNESS IN THE U.S. FROM 2004–2013 5 (2015) (showing that produce accounted for more solved outbreaks in the U.S. than any other category of food, accounting for 19% of solved outbreaks).

[7] 21 U.S.C. §§ 350h(a)(3)(A)–(C) (2011).

[8] *Id.* §§ 350h(a)(3)(D)–(E).

Congressional floor debate focused on balancing the need to protect public health with the need to account for the diversity of farm operations covered by FSMA's new regulatory regime.[9] What resulted was a dual mandate for FDA: 1) to establish strict minimum standards for produce safety to protect public health; and 2) to provide flexibility in the standards to account for various business entities, farm sizes, and diverse produce production systems.[10] Two sources of flexibility were statutorily required for any regulations passed by FDA. First, Congress directed FDA to create exceptions from produce safety regulations for "small" and "very small" businesses.[11] Second, Congress directed FDA to allow states and foreign countries from which food is imported into the United States to petition for a variance from produce safety regulations if the authority can show that the requested variance provides "the same level of public health protection" as regulations promulgated by FDA.[12]

There were many complications associated with creating nationally applicable regulations for the fresh produce industry. The sheer diversity of farming operations covered by these rules is immense, from farms nestled in the mountain valleys of the Northeast, to the wide expanses of Arizona's produce fields, to the sprawling hot orchards of California's Central Valley. On-farm practices may reduce the risk of produce contamination. For example, installing drip or furrow irrigation drastically reduces exposure to water-borne contaminants.[13] Certain crops, such as those with impermeable rinds and tissues—like citrus and onions—may naturally be less susceptible to contamination.[14] And, certain industry-standard practices, like dry curing onions, also significantly reduce the risk of contamination by eliminating pathogens from produce before it enters the stream of commerce.[15] There is no one-size-fits-all regulation that could address every geographic location, crop, and industry practice that alters the risk of contaminating produce with pathogens.

Under FSMA, FDA promulgated eight new rules, including the Produce Safety Rule (PSR) in 2015.[16] The PSR established science-based minimum standards for the safe production and harvesting of fruits and vegetables to minimize the risk of serious adverse health consequences or death from consuming contaminated produce.[17] The PSR's requirements apply to almost all producers and handlers, domestic and foreign,

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9 Neva Hassanein, *Matters of Scale and the Politics of the Food Safety Modernization Act*, 28 AGRIC. & HUM. VALUES 577 (2011).

10 21 U.S.C. §§ 350h(a)(1)(B), (a)(3).

11 21 U.S.C. § 350h(b)(3); *see generally* RENÉE JOHNSON, CONG. RSCH. SERV., RL34612, FOOD SAFETY ON THE FARM: FEDERAL PROGRAMS AND LEGISLATIVE ACTION 14–16 (2010) (describing the Tester-Hagan amendment that established modified FSMA requirements for small and very small businesses).

12 21 U.S.C. § 350h(c)(2).

13 U.S. FOOD & DRUG ADMIN., FINAL QUALITATIVE ASSESSMENT OF RISK TO PUBLIC HEALTH FROM ON-FARM CONTAMINATION OF PRODUCE 18 (2015).

14 *Id.* at 44, 52.

15 Gretchen L. Wall, Donna P. Clements, Connie L. Fisk, Donald M. Stoeckel, Kristin L. Woods & Elizabeth A. Bihn, *Meeting Report: Key Outcomes from a Collaborative Summit on Agricultural Water Standards for Fresh Produce*, 18 COMPREHENSIVE REVS. FOOD SCI. & FOOD SAFETY 1, 8 (2019).

16 Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. 74,353, 74,353 (Nov. 27, 2015) (to be codified at 21 C.F.R. pt. 11, 16, 112) [hereinafter PSR – Preamble].

17 PSR – Preamble, 80 Fed. Reg. at 74,353.

of raw produce intended for human consumption in the United States.[18] FDA estimates that the regulation covers as many as 40,000 domestic produce farms and almost 15,000 foreign farms.[19]

To effectively protect the public from foodborne illnesses, the regulations apply uniform risk prevention standards across all covered operations. The standards apply to vegetables and fruits that are usually consumed raw.[20] All produce in that category must meet the PSR's uniform produce safety standards regardless of the crop's natural susceptibility to contamination, geographic characteristics of the production region, or industry-standard practices employed in its production. [21]

The PSR is a set of flexible minimum standards that allow farmers to determine the best practices—based on crop type, level of contamination risk, and local environmental factors—to meet those standards.[22] Yet, even with that built-in flexibility, meeting the minimum standards may prove burdensome for some farmers. Several factors may increase the difficulty farmers face in complying with PSR standards. Small farms may lack sufficient resources to comply with new testing, monitoring, or recordkeeping requirements.[23] Farms that rely on multiple agricultural water sources bear heavier testing requirements than those that rely on only one source.[24] In tropical regions, *E. coli* may naturally persist in the soil, reducing the usefulness of the *E. coli*-based water testing requirements.[25] The burden of water testing requirements varies with the proximity of farms to qualified laboratories and water testing resources.[26] Large farms may have difficulty monitoring for evidence of animal intrusion, and it may be impractical or unaffordable for small farms to install wildlife exclusion fencing or netting.[27]

The inability to predict all the diverse circumstances of producers and handlers across the globe is why Congress, through the language of FSMA, directed FDA to provide some flexibility where PSR standards prove overly burdensome.[28] As one

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[18] Produce Safety Rule, 21 C.F.R. §§ 112.2, 112.4–112.5 (2019) (defining differences between covered and non-covered produce and characteristics of farms exempt or qualified exempt under the rule); 21 C.F.R. § 112.1(a) ("This includes a produce [raw agricultural commodity] that is grown domestically and a produce [raw agricultural commodity] that will be imported or offered for import in any State or territory of the United States.").

[19] JOHNSON, *supra* note 6, at 1–2.

[20] 21 C.F.R. §§ 112.1, 112.2(a) (2021).

[21] *Id.* § 112.1.

[22] Pollans, *supra* note 3, at 399–400.

[23] PSR – Preamble, 80 Fed. Reg. at 74,373–74.

[24] *Id.* at 74,433.

[25] Helena M. Solo-Gabriele, Melinda A. Wolfert, Timothy R. Desmarais & Carol J. Palmer, *Sources of* Escherichia coli *in a Coastal Subtropical Environment*, 66 APPLIED & ENVTL. MICROBIOLOGY 1, 230 (2000).

[26] *See* Cal. Certified Organic Farmers, Comment Letter on Proposed Rule on Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 14 (Dec. 15, 2014), https://beta.regulations.gov/comment/FDA-2011-N-0921-1369 [https://perma.cc/3W42-ZV3D]; Nat'l. Sustainable Agric. Coal., Comment Letter on Proposed Rule on Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 29–30 (Dec. 15, 2014), https://beta.regulations.gov/comment/FDA-2011-N-0921-1339 [https://perma.cc/C6ZP-VTEP].

[27] PSR – Preamble, 80 Fed. Reg. at 74,482–83.

[28] *Id.* at 74,369–70.

option, regulatory bodies may request a "variance" from PSR standards on behalf of their constituents.[29] When requesting a variance, the regulatory body must also propose a substitute method for fulfilling the public health objectives—the "spirit"—of the PSR in lieu of complying with the letter of the regulations.[30] Variance applications may be initiated by food safety regulatory bodies of states, foreign countries, and federally recognized tribes.[31] Only these "competent authorities"—not individuals, corporations, or trade associations—may request a variance.[32]

For FDA to approve a variance, the competent authority must demonstrate that the substitute protective measures proposed in the variance petition provide the same level of public health protection as the PSR's standard requirements.[33] FDA has issued draft guidance on how the agency will assess the same level of public health protection standard.[34] The overarching principle presented in the draft guidance is that a "[same level of public health protection] determination should be supported by sound scientific evidence that is analyzed by competent individuals, taking into account any unique measure-specific considerations."[35] The guidance goes on to provide "points to consider" to illuminate a general, but not comprehensive, framework for evaluating the adequacy of a variance petition.[36] Despite this guidance, questions remain as to how a regulatory authority for a state, tribe, or foreign country might navigate the variance process, including how an authority can effectively demonstrate that a proposed substitute measure meets the same level of public health protection standard.

In 2020, FDA spurred new questions about the implementation of FSMA PSR and the applicability of variances when it announced the *New Era of Smarter Food Safety*—an umbrella policy serving as a blueprint for agency efforts to improve food safety.[37] The blueprint is based around four core elements: 1) tech-enabled traceability; 2) smarter tools and approaches for prevention and outbreak response; 3) new business models and retail modernization; and 4) food safety culture.[38] The first two elements are intended to build upon the prevention-based framework FSMA established, by improving FDA's ability to trace outbreaks back to the root cause.[39] The last core element ties directly to the purposes and methods of the PSR; FDA seeks to transform

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[29] 21 C.F.R. § 112.171 (2021).

[30] *Id.* §§ 113.171, 112.173.

[31] *Id.* § 112.172.

[32] PSR – Preamble, 80 Fed. Reg. at 74,515 ("We are limiting this provision to competent authorities for a State, tribe, or foreign country because these entities with legally delegated or invested authority for food safety issues are the most appropriate to represent a State, tribe, or foreign country in food safety regulatory matters.").

[33] 21 C.F.R. § 112.173.

[34] U.S. FOOD & DRUG ADMIN., FDA-2017-D-0397, DRAFT GUIDANCE FOR INDUSTRY: CONSIDERATIONS FOR DETERMINING WHETHER A MEASURE PROVIDES THE SAME LEVEL OF PUBLIC HEALTH PROTECTION AS THE CORRESPONDING REQUIREMENT IN 21 CFR PART 112 OR THE PREVENTIVE CONTROLS REQUIREMENTS IN PART 117 OR 507 (2018) [hereinafter DRAFT GUIDANCE ON SLPHP DETERMINATIONS].

[35] *Id.* at 5–6.

[36] *Id.* at 6, 7–11.

[37] *See generally* U.S. FOOD & DRUG ADMIN., NEW ERA OF SMARTER FOOD SAFETY: FDA'S BLUEPRINT FOR THE FUTURE (2020).

[38] *Id.* at 6–7.

[39] *Id.*at 6.

the food safety culture on farms by addressing the practices and behaviors that increase produce safety risks.[40] Though the *New Era of Smarter Food Safety* represents a major policy initiative by FDA, it does not modify the purposes or goals of FSMA PSR or the need for variances; questions regarding the process and structure of variance requests to the PSR remain.

Producers and regulators alike will benefit from answers to questions about how a competent authority can request a variance. Variances are a promising mechanism for regionalizing PSR's uniform requirements to account for differences in geography, industry practices, and other factors. If similarly situated states pool data and collaborate on regional variance requests, collaboration could better tailor the PSR to fit the region's producers.[41]

In an attempt to clarify how FDA will assess PSR variances, this Article looks to other established processes for evaluating the comparability of food safety programs. Examining existing federal programs helps predict how the complexity of the variance request will affect 1) the information that regulatory agencies must include to show the same level of public health protection, and 2) FDA's petition review process. The more complex the petition request, the more expensive it may be for the requesting agency to assemble and for FDA to review the petition.

First, this Article will describe the basic process and structure of a variance petition process and examine the variance petition submitted by the Guatemala Ministry of Agriculture—the first and only PSR variance petition submitted to FDA to date. Next, to infer how FDA will assess variance petitions, the Article will examine existing federal approaches for assessing the comparability of state and foreign food safety programs, and the influence of international law in harmonizing regulatory comparability assessment processes. The analogous federal and international comparability assessment systems selected use standards very similar, if not identical, to the same level of public health protection standard of the PSR, and the stakeholder audiences are strikingly similar. Analogous federal approaches for assessing domestic food safety program comparability in the U.S. include the FDA Manufactured Food Regulatory Program Standards and the U.S. Department of Agriculture Food Safety Inspection Service (USDA FSIS) equivalence standard. Analogous federal approaches for assessing the comparability of foreign food safety programs include FDA foreign systems recognition and equivalence assessment. This Article will conclude by discussing the role of international trade law in harmonizing comparability assessments of food safety regulations globally.

II. VARIANCE PETITIONS: BASIC STRUCTURE & DEMONSTRATING "SAME LEVEL OF PUBLIC HEALTH PROTECTION"

Congress directed FDA to allow states and foreign countries to petition for variances from FSMA.[42] Based on that mandate, FDA established a system for variances from PSR standards where the provisions are ill-suited to particular

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[40] *Id.* at 7.

[41] *See, e.g.*, discussion *infra* Section I(C).

[42] 21 U.S.C. § 350h(c)(1)(F).

geographical regions, production systems, or individuals.[43] Before state agencies can begin assembling variance petitions, state regulatory authorities and food safety advocates need additional information on the PSR variance process and requirements.[44] What follows is not a complete recitation of the rules regarding a variance petition, but rather a summary of what a variance must include at a bare minimum and a discussion of the same level of public health protection determination as the most important piece of the petition. Food safety advocates will also benefit from this information because they can support state agencies in identifying farms or industries well-situated for a variance, gathering data, and crafting strong petitions.

A. Eligibility

Only food safety regulatory authorities for states, foreign countries, or federally recognized tribes that import food into the United States may request a variance.[45] FDA refers to these entities as "competent authorities."[46] FDA limited the authority to request variances to competent authorities because they have legally delegated or invested authority for food safety issues and formally represent a state, tribe, or foreign country in food safety regulatory matters.[47] If a competent authority is considering a variance request, FDA encourages the agency to consult directly with FDA before submitting a citizen petition.[48] FDA also encourages pre-petition review to "facilitate FDA's timely review and decisions on variance petitions."[49]

Individuals and industry groups cannot submit petitions on behalf of themselves or their members.[50] However, in draft guidance, FDA stated that scientific and technical evidence provided in a variance petition do not have to be assembled by the competent authority itself.[51] FDA anticipated that "[i]nterested parties may work independently

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[43] PSR – Preamble, 80 Fed. Reg. 74,414 (Nov. 27, 2015) (to be codified at 21 C.F.R. pt. 11, 16, 112) (see response to Comment 142).

[44] This research was undertaken as part of the Extension Legal Services Initiative (ELSI), a collaboration between the Northeast Center to Advance Food Safety (NECAFS) and Vermont Law School's Center for Agriculture and Food Systems with funding from the National Agricultural Library, Agricultural Research Service, U.S. Department of Agriculture. The project began with a national survey of stakeholders in the produce system. The 90 respondents, primarily made up of produce farmers and state regulators, identified variances as one of twelve priority topics for further research and clarification.

[45] U.S. FOOD & DRUG ADMIN., FDA-2018-D-3631, DRAFT GUIDANCE FOR INDUSTRY: STANDARDS FOR THE GROWING, HARVESTING, PACKING AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION 139 (2018) [hereinafter FDA DRAFT GUIDANCE FOR INDUSTRY].

[46] 21 C.F.R. § 112.172; (2021); *see* 80 Fed. Reg. at 74,515 ("A competent authority is commonly understood to be a person or organization that has the legally delegated or invested authority, capacity, or power to perform a designated function. For the purposes of the produce safety regulation, a competent authority is the regulatory authority for food safety for a State (*e.g.*, State Department of Agriculture, etc.), tribe, or a foreign country importing food into the United States.").

[47] PSR – Preamble, 80 Fed. Reg. at 74,515.

[48] *Id.* at 74,516 (see response to comment 403) ("FDA also welcomes pre-petition consultations . . . to facilitate the development of variance petitions, including a discussion of the types of data and information . . . needed to support the specific variance the State, tribe, or foreign country expects to request.").

[49] *Id.* at 74,516–17.

[50] *Id.* at 74,515.

[51] DRAFT GUIDANCE ON SLPHP DETERMINATIONS, *supra* note 34, at 11 (2018) ("An SLPHP evaluation may be conducted by . . . a competent authority[;] . . . an individual farm or facility; an importer; a trade or other industry association; a private food safety scheme; or other stakeholder.").

or in collaboration with their [competent authority] to compile supporting information for use [in] . . . a variance petition."[52] Those interested parties may include individuals, trade associations, commodity boards, industry groups, corporations, local governments, other government agencies, or nongovernmental organizations.[53] Food system stakeholders may be able to contribute to or work collaboratively with their state's competent authority to request a petition.[54]

Especially because the competent authority must describe with particularity who the variance will apply to within their jurisdiction, stakeholders may benefit from ongoing collaboration with their competent authority regarding potential variance requests.[55] Stakeholders could best support their competent authority by providing industry or commodity-specific data on how industry standards or local environmental conditions provide the same level of public health protection as PSR requirements.[56]

B. Scope

Variance petitions may request relief from or propose substitutes for any of the requirements in Subparts A through O of the PSR.[57] Subparts A through O include all FSMA standards related to farm food safety compliance, including: personnel training; recordkeeping; health and hygiene; wild and domesticated animal exposure; equipment and building sanitation; and commonly used growing, harvesting, packing, and holding requirements.[58] The remaining subparts—P through R—are not eligible for a variance as they establish the process for receiving variances, address compliance and enforcement of the Act, and lay out the process for withdrawing qualified exemptions.

C. Submission Process & Requirements

To request a variance, competent authorities must submit a citizen petition using the process outlined in 21 C.F.R. § 10.30.[59] FDA welcomes pre-submission consultations to guide petitioners in preparing petitions and developing the "necessary scientific basis to support such requests."[60] Once filed, FDA publishes a notice in the Federal Register, requesting public comment on the filed petition and any comments become part of the docket file.[61] From the date of filing, FDA has 180 days to rule upon the petition.[62]

Prior to a ruling or referral, the petitioner may supplement, amend, or withdraw their petition without agency approval, and such actions do not prejudice the petition

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[52] PSR – Preamble, 80 Fed. Reg. at 74,516.

[53] *Id.* S*ee also* PSR – Preamble, 80 Fed. Reg. at 74,515.

[54] DRAFT GUIDANCE ON SLPHP DETERMINATIONS, *supra* note 34, at 11–12.

[55] *Id.*

[56] *Id.*

[57] 21 C.F.R. § 112.182 (2021).

[58] FDA DRAFT GUIDANCE FOR INDUSTRY, *supra* note 45, at 139.

[59] 21 C.F.R. §§ 10.20, 10.30(b), 112.172.

[60] PSR – Preamble, 80 Fed. Reg. 74,353, 74,517 (Nov. 27, 2015) (to be codified at 21 C.F.R. pt. 11, 16,112).

[61] 21 C.F.R. § 10.30(d).

[62] *Id.* § 10.30(e)(1)–(2).

upon resubmission.[63] After a ruling, a petitioner may only supplement, amend, or withdraw a petition with FDA approval—at which time FDA will decide whether withdrawal of the petition post-ruling will or will not prejudice against resubmission.[64]

Once a final decision has been made, FDA will respond to the petitioner both in writing and through a public notice on FDA's website announcing the agency's final decision.[65] FDA may deny a petition, grant it in part, or grant it in whole and will "specify the persons to whom the variance applies."[66] The agency may also issue a tentative response indicating why the agency has not reached a decision, or dismiss the petition if changes in law, facts, or circumstances have rendered the petition moot.[67]

For example, say an arid state, like Arizona, requested a variance to use a higher microbial die-off rate[68] (greater than the 0.5 log daily reduction in *E. coli* required under 21 C.F.R. § 112.45(b)) and to use a direct pathogen detection test instead of the generic *E. coli* test required under 21 C.F.R. § 112.44. FDA could grant a variance to use a different microbial die-off rate and deny the portion requesting the use of a different testing methodology. FDA would then specify which growers in the state are eligible to use the different microbial die-off rate in their agricultural water quality calculations.

FDA could also extend the variance to another state, tribe, or foreign country where FDA believes the variance would apply to "similarly situated persons" within the other jurisdiction.[69] For example, when FDA opened comments on Arizona's petition, New Mexico could submit comments showing that the variance requested by Arizona should also apply to similarly situated producers in New Mexico. As both states have similar arid climates, FDA might find the different microbial die-off rate is also appropriate for producers in New Mexico.

After granting a variance, FDA may modify or revoke the variance if, for any reason, FDA determines the variance is insufficient to provide the same level of public health protection as the established PSR provision.[70] Competent authorities may then request a hearing about FDA's determination that a particular variance should be modified or revoked before FDA issues its final decision.[71]

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[63] *Id.* § 10.30(g).

[64] *Id.*

[65] 21 C.F.R. § 112.176(a)–(c) (2021).

[66] *Id.* § 112.176(c).

[67] *Id.* § 10.30(e)(2)(iii)–(iv).

[68] U.S. FOOD & DRUG ADMIN., MEMORANDUM ON REVIEW OF MICROBIAL DECAY CONSTANTS REPORTED IN FIELD TRIALS OF CONTAMINATED PRODUCE 4 (2014) (citing WORLD HEALTH ORGANIZATION, WHO GUIDELINES FOR THE SAFE USE OF WASTEWATER, EXCRETA AND GREYWATER, VOLUME II: WASTEWATER USE IN AGRICULTURE 27 (2006) (listing low humidity and high temperature as drivers of higher pathogen die-off rates)).

[69] 21 C.F.R. § 112.177 (2021).

[70] *Id.* § 112.180.

[71] *Id.* § 112.181.

D. The First of Its Kind: A Variance Petition from the Guatemala Ministry of Agriculture

The only variance petition submitted to FDA to date is from the Guatemala Ministry of Agriculture, on behalf of the Association of Independent Banana Producers of Guatemala.[72] FDA's consideration of the petition affects a significant portion of bananas consumed in the U.S.—Guatemala is the third largest exporter of bananas worldwide, and 95.4% of Guatemalan banana production is exported to the United States.[73] On September 23, 2019, the Guatemala Ministry of Agriculture withdrew the petition due to FDA's extension of compliance dates and review of PSR agricultural water standards.[74] Given FDA's ongoing reconsideration of the agricultural water standards in Subpart E, the questions raised by this variance petition remain unanswered. In this Article, Guatemala's petition is discussed to show how the only PSR petition submitted to date attempted to justify that the requested variance provided the same level of public health protection as standard PSR requirements. No other variance petitions are currently under consideration by FDA.

In 2019, the Ministry of Agriculture requested a variance for Guatemalan banana producers from the agricultural water quality requirements of PSR Subpart E.[75] The petition contained three sections required by FDA for citizen petitions: 1) the "Action Requested," listing the PSR provisions relevant to the requested variance;[76] 2) the "Statement of Grounds";[77] and 3) the "Economic Impact."[78]

The first section, which FDA calls the Action Requested and petitioner called the "Required Actions," listed the specific provisions of PSR Subpart E that applied to the requested variance.[79] This section of the Guatemalan petition was likely insufficient compared to the petition requirements under 21 C.F.R. § 10.30(b)(3)(A). The submitted petition merely listed the provisions to which the competent authority requested a variance. However, FDA requires that the Action Requested not only identify relevant provisions, but also detail the proposed substitute method of reaching

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[72] U.S. FOOD & DRUG ADMIN., FDA-2019-P-1781-0001, CITIZEN PETITION FROM ASSOCIATION OF INDEPENDENT BANANA PRODUCERS OF GUATEMALA (ENGLISH VERSION) (2019) [hereinafter FDA CITIZEN PETITION].

[73] *Id.* at 9.

[74] U.S. FOOD & DRUG ADMIN., FDA-2019-P-1781-0003, WITHDRAWAL LETTER FROM ASSOCIATION OF INDEPENDENT BANANA PRODUCERS OF GUATEMALA TO FDA CFSAN (2019) [hereinafter FDA WITHDRAWAL LETTER].

[75] FDA CITIZEN PETITION, *supra* note 72, at 1.

[76] 21 C.F.R. § 10.30(b)(3)(A) (2021); FDA CITIZEN PETITION, *supra* note 72, at 2; *id.* (calling the "Action Requested" section required under 21 C.F.R. § 10.30(b)(3)(A) by the alternative title "Required Actions").

[77] 21 C.F.R. § 10.30(b)(3)(B); FDA CITIZEN PETITION, *supra* note 72, at 2 (calling the "Statement of Grounds" section required under 21 C.F.R. § 10.30(b)(3)(B) by the alternative title "Declaration of Cause").

[78] 21 C.F.R. § 10.30(b)(3)(C)–(D) (providing that petitioners may include, or FDA may request that petitioners include, sections on the environmental or economic impact of a variance).

[79] FDA CITIZEN PETITION, *supra* note 72, at 3 (identifying 21 C.F.R. § 112.43(b), requiring producers to monitor any treatment of agricultural water on a regular basis, and 21 C.F.R. § 112.44(a), requiring producers to use agricultural water with no detectable *E. coli* present when it will come in direct contact with produce during harvest, as the relevant provisions for this variance petition).

compliance with those requirements. In this petition, the petitioner did not describe the requested substitute provisions until much later in the document.[80]

Section two, which FDA calls the Statement of Grounds and petitioner called the "Declaration of Cause," documented the factual and legal grounds relied upon to support the requested variance. In this section, petitioner must demonstrate that substitute measures provide the same level of public health protection as PSR standard requirements and are "necessary in light of local growing conditions."[81] This section must cite all relevant facts, legal information, and views that support the claim.[82] Petitioner must also acknowledge any "representative information known to the petitioner[,] which is unfavorable to the petitioner's position."[83]

Here, the Guatemala Ministry of Agriculture collaborated with a national trade association to support the claim that the banana is a "low-risk crop" that should be exempted from PSR requirements to regularly test agricultural water and only use agricultural water with no detectable *E. coli* if that water will come in direct contact with produce during or after harvest.[84] Evidence used to support that claim included descriptions of the geography of banana production in Guatemala, the agricultural water sources used by banana producers, standard industry practices, and physico-chemical characteristics of bananas that make the crop resistant to contamination.[85] The petitioner did admit to information unfavorable to their petition: this section began by admitting that "at least 90% of surface waters in Guatemala are contaminated with feces" and the rivers upstream from the banana-producing region traverse hundreds of villages without treatment before serving as the main source of agricultural water for most banana producers.[86]

However, petitioner argued that the cost, especially for large producers, of treating water sourced from these rivers would be "untenable and unaffordable" and the benefit would be slim at best.[87] Instead, petitioner argued that the physico-chemical characteristics of bananas and standardized industry practices sufficiently limited the risk of contamination from agricultural water.[88] The petition provided the results of risk analyses conducted by the Association of Independent Banana Producers—the primary trade association for banana producers in the country—to show that contamination levels of produce remain low when sprayed directly with untreated water and that even when the peel of a banana is contaminated with *E. coli* the edible part of the fruit remains uncontaminated.[89] Scientific data from the trade association supported the fact that "historically there has never been any case reported of contamination by *E. coli* in banana."[90]

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[80] *Id.* at 9.

[81] 21 C.F.R. § 112.173(a) (2021).

[82] *Id.* § 10.30(b)(3)(B).

[83] *Id.*

[84] FDA CITIZEN PETITION, *supra* note 72, at 3–10.

[85] *Id.*

[86] *Id.* at 3.

[87] *Id.* at 4.

[88] *Id.* at 7.

[89] *Id.* at 5–6.

[90] *Id.* at 7.

The third section, Economic Impact, is one of two optional sections FDA allows petitioners to include (and in some cases FDA may request) on the economic and environmental impacts of PSR requirements and proposed variances.[91] When requested, this section may be beneficial for petitioners who can show a compelling economic or environmental benefit of employing different, but equivalent, provisions to certain producers in their state.

The Ministry of Agriculture used this section to demonstrate the estimated annual cost of complying with PSR agricultural water testing and treatment requirements.[92] The Ministry estimated that complying with water testing requirements would cost each farm around $3,000 USD annually.[93] But, water treatment requirements posed an even greater economic concern to banana producers who had already invested millions in their operations to make up for the lack of state water quality management and treatment programs.[94] Water treatment systems cost from $400–3,000 USD per cubic meter of water, not including the cost of conditioning wells and the energy costs of pumping water before treatment.[95] Alternatively, disinfecting the water to PSR-required treatment levels increased the cost by 100–1,000% and occasionally resulted in a "burned" fruit of lower quality.[96]

Ultimately, the public never got to see how FDA would evaluate such a petition. In March 2019, a month before Guatemala submitted its petition, FDA extended compliance dates for all agricultural water requirements under PSR Subpart E to reconsider "questions about the practical implementation of [the standards] . . . and to consider how [the agency] might further reduce the regulatory burden or increase flexibility while continuing to protect public health."[97] In October 2019, Guatemala withdrew its petition until FDA finalizes the PSR agricultural water standards.[98] If FDA evaluated Guatemala's petition, the central question would be whether Guatemala sufficiently supported its statement that industry practices and other methods of protecting consumers from foodborne illnesses in bananas provided the same level of public health protection as the letter of PSR's agricultural water requirements.

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91 21 C.F.R. § 10.30(b)(3)(C)–(D) (2021); FDA CITIZEN PETITION, *supra* note 72, at 10–11.

92 FDA CITIZEN PETITION, *supra* note 72, at 10.

93 *Id.* at 10.

94 *Id.* at 10–11.

95 *Id.* at 11.

96 *Id.* at 11 (discussing two alternative methods for disinfecting postharvest wash water, the first of which would increase costs 100–600% and the second of which would increase costs 700–1000%).

97 Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E, 84 Fed. Reg. 9,706 (Mar. 18, 2019) (to be codified at 21 C.F.R. pt. 112).

98 FDA WITHDRAWAL LETTER, *supra* note 74.

E. Demonstrating the Same Level of Public Health Protection in Variance Petitions

The same level of public health protection determination is the heart of two sources of PSR flexibility: 1) variances,[99] and 2) alternatives.[100] Alternatives, briefly discussed here, appear similar to variances but are markedly different. Alternatives are adopted by individual producers and are limited to certain provisions within the PSR agricultural water standard.[101] Variances, on the other hand, are submitted by state, foreign, or tribal governments seeking FDA approval of measures that can act as substitutes for any number of PSR requirements.[102]

Under 21 C.F.R. § 112.12 and § 112.49, an individual producer—independently and without prior approval by FDA—may use an alternative to pathogen testing methods and testing frequencies if that producer can provide sufficient scientific documentation that the alternative testing measures provide the same level of public health protection as PSR testing requirements.[103] The lack of pre-approval for alternatives places the full burden of using an alternative water testing criterion, number of samples, or microbial die-off rate upon the producer. If FDA inspects the producer's operation and deems the alternative insufficiently supported by the producer's scientific evidence, then FDA will determine that the producer is out of compliance with PSR requirements and unable to sell their produce.

The PSR raises interesting questions for produce farmers about legal liability related to foodborne illness as it expands the definition of "adulterated" under the Federal Food, Drug, and Cosmetic Act to include produce from farms not in compliance with PSR requirements.[104] The structure of alternatives enhances liability concerns by placing the full liability for noncompliance on individuals should FDA find that the use of an alternative is not sufficiently scientifically supported. But FDA does not

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[99] 21 C.F.R. § 112.171(b) (2021).

[100] 21 C.F.R. § 112.12(b) (2021). Note: At the time of this writing, FDA had not updated the agricultural water standard after announcing the extension of compliance dates in March 2019, so this Article uses the original words of PSR Subpart E.

[101] *Id.* ("You may establish and use an alternative to any of the requirements in [subpart E]."); 21 C.F.R. § 112.49 (2021) (listing the four agricultural water quality alternatives that individuals may establish and use: (a) an alternative microbial quality criterion to indicate fecal contamination; (b) an alternative microbial die-off rate and time interval; (c) an alternative minimum number of samples for an initial survey of untreated surface water; and (d) an alternative minimum number of samples used for an annual survey of untreated surface water).

[102] 21 C.F.R. § 112.171 ("A State, Federally-recognized tribe (or 'tribe'), or a foreign country from which food is imported into the United States may request a variance from one or more requirements . . . ."); 21 C.F.R. § 112.182 (2021) ("A variance(s) may be requested for one or more requirements in subparts A through O of [the PSR].").

[103] 21 C.F.R. § 112.12 (establishing the "same level of public health protection" standard for FDA review of alternatives); 21 C.F.R. § 112.49 (2021) (defining the four PSR provisions that individual producers may use an alternative for if they have scientific evidence to support their use). *See* DRAFT GUIDANCE ON SLPHP DETERMINATIONS, *supra* note 34, at 5 ("We rely on an overarching principle that [a "same level of public health protection] determination should be supported by sound scientific evidence that is analyzed by competent individuals, taking into account any unique measure-specific considerations.").

[104] *See generally* NE. CTR. TO ADVANCE FOOD SAFETY & VT. L. SCH. CTR. FOR AGRIC. & FOOD SYS., PRODUCE FARMS, FOODBORNE ILLNESS, AND LEGAL LIABILITY (2020) (fact sheet answering producers' questions about their civil or criminal liability if foodborne illness is traced back to their produce operation and how compliance with FSMA PSR may mitigate a producer's financial or criminal responsibility should a lawsuit arise).

provide individuals the opportunity for pre-approval of potential alternatives. Essentially, alternatives are a mirage of flexibility. The risk they carry is so great that it is doubtful farmers will adopt them unless FDA puts some pre-approval mechanism in place. After FDA finishes reconsidering the provisions in Subpart E, alternatives may change.

In contrast, a competent authority may request a variance for essentially any provision in the PSR, not only for the four agricultural water testing requirements available to individuals through alternatives.[105] Variances provide a pathway for competent authorities to request pre-approval of an alternative on behalf of producers across their jurisdiction. FDA has not provided many examples of potential variances. In fact, the examples of variances provided in 21 C.F.R. § 112.182 are the same four water testing requirements that individual farmers may adopt an alternative to under § 112.49.[106] By requesting FDA's approval of a variance from one of these four testing requirements, a state agency could effectively ask FDA to pre-approve the use of that alternative on behalf of producers across the state.

But variances can be much broader than alternatives. FDA has essentially left the limits of variances up to the imagination.[107] For one example of a broader variance, say the Oregon Department of Agriculture demonstrates that the dry curing practices used in the state's dry bulb onion industry result in a particular log removal of pathogens.[108] The state determines that the effectiveness of dry curing at sufficiently removing pathogens depends on the number of drying days, whether drying occurred indoors or outdoors, climatic conditions during drying, and storage conditions. Based on these factors, Oregon could request that those onion producers in the state that use a longer dry curing time outdoors during sunny, dry weather be exempt from many of the agricultural water and biological soil amendment standards of the PSR. The success of that variance request depends on Oregon's ability to identify industry pathogen reduction practices that, given the general agricultural water source quality in the state, result in a sufficiently protective log removal of pathogens that fully negate the benefit of testing and treating water.[109] That may be a long shot, but if the state can show that PSR water testing requirements lack any public health benefit beyond current practices, the imbalance between the burden of the compliance costs and the public benefit of testing may persuade FDA's decision on the merit of the variance request.

This Article does not further discuss the issue of alternatives under the PSR. The same level of public health protection standard applies to both alternatives and variances, and variance petitions can request the same substitute measures available to individual farmers directly under PSR alternatives. By requesting that FDA approve an alternative for use across a state, the state can secure pre-approval of the alternative for producers, providing them with regulatory certainty. Approval of one alternative

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[105] *Compare* 21 C.F.R. § 112.182 (2021) (allowing competent authorities to submit variance petitions for any provisions in subparts A through O), *with* § 112.49 (limiting the alternatives available to individuals to four specific water testing criteria under subpart E).

[106] 21 C.F.R. § 112.182(a)–(c) (2021).

[107] DRAFT GUIDANCE ON SLPHP DETERMINATIONS, *supra* note 34, at 7.

[108] See PSR – Preamble, 80 Fed. Reg. 74,353, 74,445–46 (Nov. 27, 2015) (to be codified at 21 C.F.R. pt. 11, 16, 112), for FDA's response to comment 220, which inspired this example.

[109] See *id.* for FDA's response to Comment 220 for FDA's concerns about how this level of health protection could be sufficiently demonstrated to negate water testing requirements.

that fits the needs of an entire region may also lead to harmonized use of the alternative across the jurisdiction. Without a variance to harmonize the use of an alternative, each producer could potentially adopt a different alternative under § 112.44, creating a patchwork of protective measures across the jurisdiction. From here on, this Article focuses solely on variances.

To support any variance petition, the petitioning agency must collect the scientific information necessary to support the use of the variance by some or all producers in the state, tribe, or foreign country exporting food to the United States.[110] That scientific information must show that the variance provides the same level of public health protection as the PSR test requirement.[111] If FDA approves the variance request, then producers in the jurisdiction are able to utilize the substitute measures proposed in the jurisdiction without having to independently prove that scientific evidence sufficiently supports the use of the substitute measures during inspection.

The main issue facing competent authorities interested in submitting a variance petition of any kind is how to show that the substitute measures suggested in the petition provide the same level of public health protection as PSR requirements.[112] FDA will not grant a variance without evidence in the petition that the substitute measures are reasonably likely to provide the same level of public health protection.[113] As variance petitions can apply to a broad range of requirements, evaluating the comparability of those diverse requirements must also cover a broad range of considerations.[114] The petitioner must show that their same level of public health protection determination was sufficiently robust for a variance request to succeed. Factors FDA will consider include: 1) the sufficiency of the data and methodology used to obtain relevant data; 2) the competency of the evaluator; and 3) the thoroughness of the recordkeeping employed throughout the process.[115]

Variance requests can range in complexity, from very simple to very complicated. On the most basic end of the spectrum, a variance may request that a different agricultural water quality metric be used by produce farmers in a given state or country (say, testing for *Clostridium perfringens* instead of generic *E. coli*). Evidence supporting this variance request could include scientific information comparing the precision and accuracy of *C. perfringens* as an indicator and information on why *C. perfringens* is a more effective indicator than generic *E. coli* due to the physical

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[110] 21 C.F.R. § 112.173 (2021).

[111] DRAFT GUIDANCE ON SLPHP DETERMINATIONS, *supra* note 34, at 8 ("The use of a measure to address a specific hazard should be supported by credible scientific and technical evidence.").

[112] DRAFT GUIDANCE ON SLPHP DETERMINATIONS, *supra* note 34, at 7 ("The type and extent of information available for review is likely to vary depending on the context in which the evaluation is conducted and the nature of the measure involved.").

[113] 21 C.F.R. § 112.178 (2021) ("We may deny a variance request . . . if we determine that the variance is not reasonably likely to . . . provide the same level of public health protection as the requirements of this part.").

[114] DRAFT GUIDANCE ON SLPHP DETERMINATIONS, *supra* note 34, at 7 ("[R]equirements may be quantitative or qualitative in nature, and may address various aspects of food production, such as the design of equipment or infrastructure, manufacturing processes, monitoring and verification procedures, laboratory tests and sampling methods, personnel training, and documentation.").

[115] DRAFT GUIDANCE ON SLPHP DETERMINATIONS, *supra* note 34, at 8–12.

characteristics of that jurisdiction.[116] For example, scientific literature includes abundant evidence of *E. coli* regrowth in tropical environments.[117]

More complicated variance petitions may request that different standards apply to farm buildings and equipment in the state. During the comment period, FDA received several requests to exempt aquaponic farming (the raising of produce and fish together in an integrated, closed system) from produce safety regulations.[118] Growers advocated that aquaponic water containing fish waste fertilizer does not contact the harvestable portion of the plants and that fish waste does not contain *E. coli*.[119] FDA was unpersuaded at the time.[120] But a state agency could still request a variance on behalf of aquaponics growers in its jurisdiction if that petition is supported by sufficient scientific data.

For example, aquaponics growers could determine specific control methods to prevent contamination of aquaponics systems. If those growers, through the agency, can show that the substitute control measures are reasonably likely to provide the same level of public health protection as PSR requirements, FDA may be willing to approve that variance. To support a complex petition like this, the petitioner would need to understand the industry's standard production practices, building codes, biological control methods, and how changes to practices and building requirements might affect the likelihood of produce contamination from aquaponics water and growing media.[121] Effectively gathering and providing that information to FDA likely requires agencies to collaborate more closely with regulated industries seeking a variance.

The complexity of the analysis may affect the type and amount of data needed to demonstrate comparability, as well as the qualifications an evaluator needs in order to be considered competent.[122] The nature of the data collected—quantitative, qualitative, or a combination of the two—is also likely to influence the determination. Increased complexity of the determination may translate to increased cost and administrative burden on the competent authority developing the variance request. Pre-submission consultation with FDA increases the efficiency of evaluating the same level of public health protection, as FDA has offered to guide petitioners in identifying the data needed prior to filing.[123]

There is great potential for variances to create regionally appropriate standards that still provide the same level of public health protection as the PSR. Perhaps the greatest opportunity lies in regional collaboration among states with similar geographic and

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[116] *See generally* Roger S. Fujioka & Lyle Shizumura, *Clostridium Perfringens, a Reliable Indicator of Stream Water Quality*, 57 J. WATER POLLUTION CONTROL FEDERATION 986 (1983).

[117] C.M. Hardina & R.S. Fujioka, *Soil: The Environmental Source of Escherichia coli and Enterococci in Hawaii's Streams*, 6 ENV'T TOXICOLOGY & WATER QUALITY 185 (1991).

[118] PSR – Preamble, 80 Fed. Reg. 74,353, 74,366–67 (Nov. 27, 2015) (to be codified at 21 C.F.R. pt. 11, 16, 112).

[119] *Id.*

[120] *Id.*

[121] 21 C.F.R. § 10.20(i).

[122] DRAFT GUIDANCE ON SLPHP DETERMINATIONS, *supra* note 34, at 8–11.

[123] PSR – Preamble, 80 Fed. Reg. 74,353, 74,516–17 (Nov. 27, 2015) (to be codified at 21 C.F.R. pt. 11, 16, 112).

environmental conditions.[124] For example, imagine that states pool resources to show that the measures needed to protect the public in the Northeast differ from those required in the Southwest. Then, there is a chance that FDA could gradually approve a regionalized food safety regime that accounts for geographic variation across the country. But for variances to meet their potential, there must be clearer guidance on how authorities can demonstrate the same level of public health protection. The next section of this Article talks about what such guidance should look like by examining analogous federal processes for assessing the comparability of state food safety regimes.

III. ANALOGOUS APPROACHES TO PUBLIC HEALTH EQUIVALENCE ASSESSMENT

Under FSMA, FDA established a set of uniform standards intended to reduce the occurrence of produce contamination from foodborne illness pathogens. Where the uniform federal standards are inapplicable or inappropriate for local circumstances, variances provide a source of flexibility. Similar approaches to risk assessment, regulation, and variance approval exist in other divisions of FDA and USDA FSIS. Both agencies have systems for assessing the equivalence of government food safety programs, whether in the U.S. or in foreign countries. Assessments of food safety comparability may require FDA to review everything from the food safety procedures of a single producer to the parity of a foreign country's entire food regulatory system.[125] Assessing the relative comparability of a single agricultural practice applied to a single commodity (e.g., curing onions to mitigate risks of contamination by agricultural water) is a simpler assessment than determining whether a foreign country's entire produce safety regulatory system provides the same level of protection as the U.S. regulatory program. Most comparability assessments rest on essentially the same standard as the FSMA PSR: the same level of public health protection.

FDA and USDA FSIS both assess the equivalence of state food safety programs. FDA uses the Manufactured Food Regulatory Program Standards (MFRPS) to assess the equivalence of state manufactured food regulatory regimes. USDA FSIS assesses the equivalence of state meat and poultry inspection (MPI) programs. MFRPS and MPI represent two ways that FDA could harmonize the comparability determination process for variances across the U.S. Under MFRPS, FDA provides ten standards upon which to determine the comparability of a state's processed food regulatory system. When assessing state MPI programs, USDA FSIS requires states to submit annual evaluations on the effectiveness and equivalency of state-run inspection programs. How FDA can likewise develop a clear framework for evaluating PSR variance petitions is discussed in Section II.A.1, *infra*. An established framework could better inform competent authorities about the qualitative and quantitative information required, guide self-evaluation of petitions before submission, and optimize competent authorities' ability to navigate the variance process.

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[124] *Id.* at 74,518 ("FDA agrees that some variances may be appropriate on a regional basis, not just at a State level. . . . [Subpart P - Variances] provides a variety of mechanisms for applying some or all parts of a variance to other similarly situated persons, including to a region, rather than to a single State.").

[125] *Id.* at 74,517–18 (discussing in the response to Comment 408 that the relationship between PSR variance evaluations and systems recognition, which evaluates the robustness of a foreign country's oversight of their food system, is not yet clearly defined).

In reviewing foreign systems, FDA has two established programs—equivalence and foreign systems recognition—that apply a same level of public health protection standard. Foreign systems recognition requires FDA to assess the comparability of a foreign government's entire food safety regulatory system. When undergoing system recognition, FDA provides MFRPS-style standards that guide the evaluation process. Systems recognition is a complex process that can take decades to complete. Where a variance petition requests exceptions to a wide swathe of PSR requirements or claims that the entire produce safety regulatory system of a foreign country is equivalent to the requirements of the PSR, the information required to support that petition would be similar to the information required for a systems recognition assessment. This concept is discussed further in Section II.B.1, *infra*.

Alternatively, FDA equivalence assessments involve a narrower comparability assessment. They consider the equivalence of a foreign food safety regulation for a single commodity. The process for FDA equivalence assessments of state and foreign regulatory systems are discussed in Section II.A.2 and Section II.B.2, respectively, *infra*. Equivalence provides a helpful corollary for variance requests covering a single practice or a single commodity. These assessments require a thorough analysis of risk-reduction measures taken in a given industry. A similar approach would strengthen variance requests with a narrow scope.

A. FDA and USDA Assessments of State Food Safety Programs

1. FDA Manufactured Food Regulatory Program Standards

FDA developed the MFRPS as part of establishing the national Integrated Food Safety System.[126] The goal of MFRPS is to implement a nationally integrated, risk-based food safety system that provides a uniform foundation for protecting public health.[127] The standards establish a uniform system for measuring and improving the prevention, intervention, and responses of manufactured food regulatory programs across U.S. states and territories.

Though the language of MFRPS does not cite a specific same level of public health protection standard, it does require state regulatory regimes to achieve and sustain "conformance."[128] State regulatory programs must be either "equivalent"—adopted verbatim from federal standards—or "equivalent in effect," where state regulations have the "same regulatory effect" as relevant federal provisions.[129] In essence, the evaluative standard employed by FDA in assessing MFRPS is the same as the same level of public health protection standard used to assess variances. Both systems, the PSR variance and MFRPS, require that if a state regulatory system departs from federal requirements, the state system must be reasonably likely to provide at least an equivalent level of protection to the standard federal requirements.

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[126] *Constituent Update: Manufactured Regulatory Program Standards 2019 Updates*, U.S. FOOD & DRUG ADMIN. (Oct. 15, 2019), https://www.fda.gov/food/cfsan-constituent-updates/manufactured-food-regulatory-program-standards-2019-updates [https://perma.cc/KH42-EFK6].

[127] *Id.*

[128] U.S. FOOD & DRUG ADMIN., MANUFACTURED FOOD REGULATORY PROGRAM STANDARDS 2 (2019).

[129] *Id.* at 6–7 ("Equivalent in Effect: means that the State law has the same regulatory effect as the relevant [Food, Drug, and Cosmetic Act] provision or CFR regulation.").

The structure of MFRPS is similar in structure to FSMA PSR, which seeks to integrate the federal oversight of food safety by regulating practices, not just products. Both represent efforts to harmonize food safety regulations: MFRPS addresses the safety of manufactured foods and the PSR addresses the safety of fresh fruits and vegetables.

MFRPS consists of ten standards and an overall objective framework designed to determine the robustness of a state's processed food safety system. Several MFRPS standards can be applied in the PSR context. The standards established for evaluating the comparability of state manufactured food regulatory programs illuminate relevant factors that competent authorities considering a PSR variance should address in their petition. What follows is a synthesis of relevant standards[130] from the MFRPS guide and an analysis of how a similar standard could be adopted to guide FDA's equivalence assessment of a state's produce safety regulations in response to a variance petition.

a. Standard 1: Regulatory Foundation

FDA expects the state program to evaluate the scope of its legal authority and regulatory provisions to ensure that the agency has jurisdiction over the protection of manufactured food.[131] That agency must have the legal authority to protect public health by ensuring the safety and security of the manufactured food supply. Program evaluation must also determine how the state's regulatory foundation corresponds to FDA's regulatory foundation. If the state program lacks any part of FDA's regulatory foundation, the state agency must identify another state or federal program with that regulatory authority.[132]

Similarly, a state petitioning for a PSR variance should address its legal authority for regulating produce safety. The PSR is undergoing implementation now, and states across the country have varying forms and degrees of implementation.[133] At the time of this writing, twenty-nine states are conducting PSR inspections under state statutory authority, six are leaving PSR inspections within FDA's authority, and fifteen are credentialed by FDA to conduct PSR inspections.[134] In addition to PSR implementation, states may have additional state statutory authority to regulate produce safety beyond the scope of the regulation required under PSR. FDA is more likely to find that variances meet the same level of public health protection threshold where the state measure reflects a more stringent or restrictive requirement than the corresponding PSR requirement addressing the same hazard.[135]

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[130] *See generally id.* (showing information on current MFRPS standards. The standards not included in this Article are Standard No. 4—Inspection Audit Program and Standard No. 5—Food-Related Illness, Outbreak, and Hazards Response).

[131] *Id.* at 11–12.

[132] *Id.* at 11.

[133] *See* NE. CTR. TO ADVANCE FOOD SAFETY & VT. L. SCH. CTR. FOR AGRIC. & FOOD SYST., *State Implementation of the FSMA PSR Map*, EXTENSION LEGAL SERVICES INITIATIVE (2020), https://elsi.necafs.org/map/1 [ttps://perma.cc/95AX-QNLC] (depicting the various stages of FSMA implementation across all fifty states and the competent authority identified by each state).

[134] *Id.*

[135] DRAFT GUIDANCE ON SLPHP DETERMINATIONS, *supra* note 34, at 11.

b. Standard 2: Training Program

The state must have a training program for inspectors, including a written training plan to promote their development.[136] The state must also demonstrate that all inspectors who will conduct manufactured food inspections have completed the course curriculums, field training, and continuing education requirements necessary to adequately perform their work.[137] Robust training programs for protecting produce safety and standardized precautionary measures within a particular produce industry could strengthen a state's variance petition.

c. Standard 3: Inspection Program

The state program must administer a manufactured food inspection system that provides the foundation for inspecting food firms to determine compliance with laws administered by federal, state, and local governments.[138]

This standard provides a particularly helpful framework for PSR variances. To conform to Standard 3, states must show that they have a robust inspection program that can enforce state standards. They may do this, for example, by maintaining an inventory of regulated food manufacturing plants, categorized by risk level.[139] The guide also provides an example of risk classification criteria for categorizing food plants and tailoring regulatory oversight according to degree of risk.[140] Such a system is robust because it shows that the state is tracking all regulated operations and understands their varying risk levels. A competent authority with a similarly robust structure for their produce farm inspection program may support the state's claim that it can enforce every substitute standard proposed in its PSR variance petition.

d. Standard 6: Compliance & Enforcement Program

The state must have a written compliance program, which includes strategies, procedures, and actions to enforce laws and regulations.[141] The agency must review and record its compliance and enforcement actions annually and must calculate an overall rating to determine whether the agency followed its compliance and enforcement measures. Based on the results of the review, the agency must identify improvements and modify procedures. Competent state authorities that possess established systems of self-assessment and regulatory improvement like this may have stronger petitions. An established compliance program shows that the state devotes consistent attention to mitigating ever-evolving threats to produce safety. Additionally, if a petition is specific to an industry, the industry could show that it works with the state to evaluate potential risks and improve mitigation efforts.

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[136] U.S. FOOD & DRUG ADMIN., MANUFACTURED FOOD REGULATORY PROGRAM STANDARDS 13–19 (2019).

[137] *Id.*

[138] *Id.* at 20–25.

[139] *Id.* at 64.

[140] *Id.* at 70.

[141] *Id.* at 32–33.

e. Standard 7: Industry & Community Relations

The state must have a written procedure describing the methods used for communication with food industry stakeholders and consumers.[142] It must also participate in activities to support communication and information exchange among regulators, industry, academia, and consumers.[143] FDA will look for established communication methods with food industry stakeholders and consumers, agency sponsorship of or active participation by industry members in task forces or advisory boards, and tailored outreach efforts to disseminate relevant food protection information to the regulated community.[144]

This standard requires state agencies to establish relationships with the processed food industry and community. Relying on evidence like that required for Standard 7 of MFRPS could help a state demonstrate in its PSR variance petition that industry and community relations with the produce sector are strong. For example, say a U.S. state seeks a variance from a few inspection requirements. The state could show that it has cultivated a relationship with the produce industry like that required under MFRPS Standard 7. The petitioner could then point to these well-established industry and community relations to support a claim of existing strong state oversight of industry food safety practices and show that industry standards are sufficient to satisfy PSR requirements.

f. Standards 8 & 9: Program Resources & Program Assessment

The state agency should assess the manufactured food regulatory program's resource needs for staffing, equipment, and funding.[145] The program must also have a standard process for assessing and demonstrating its conformance to each of the program standards established under MFRPS.[146] The resources and process for regulating the industry should include managers who conduct periodic self-assessments against the criteria established by each standard.[147] Self-assessment results should determine program areas or functions needing improvement and should feed into a "strategic improvement plan" that includes timeframes for making needed improvements.[148]

Echoing the reasoning under Standard 6, if a state can show that it regularly assesses its own regulatory program for equivalence to PSR requirements, FDA will likely view the state's petition more favorably. FDA already anticipates that a "[same level of public health protection] determination should be revisited, as necessary."[149] If a state has built-in review of established produce safety recommendations, it is already anticipating the potential for new produce safety risks and considering how to respond to them.

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[142] *Id.* at 34–35.

[143] *Id.*

[144] *Id.* at 110–11.

[145] *Id.* at 36.

[146] *Id.* at 37–38.

[147] *Id.*

[148] *Id.*

[149] DRAFT GUIDANCE ON SLPHP DETERMINATIONS, *supra* note 34, at 11.

g. Standard 10: Laboratory Support

The state program must have access to the laboratory services needed to support manufactured food program functions and should document its laboratory capabilities, including agreements with external laboratories.[150] The laboratory capacity should include processing food and conducting routine and non-routine analyses using environmental and clinical samples (such as biological hazard determinations).[151]

If the variance requested by the state requires ongoing scientific assessment of produce contamination, the state would be wise to include reference to the laboratory services available to producers. If the state is proposing an alternative testing regime, for example, their variance would be best supported by evidence of in-state laboratories with capacity and capability of running the tests required under the variance.

h. Using MFRPS-Style Standards to Harmonize PSR Variance Petitions

To oversee the implementation of MFRPS, the Alliance for Advancing a National Integrated Food Safety System established the Manufactured Food Regulatory Program Alliance (MFRPA).[152] MFRPA works with the Association of Food and Drug Officials and FDA to increase coordination among state and federal manufactured food program regulators and industry stakeholders. MFRPA also provides tracking of state laws and regulations on food safety.[153]

The role of MFRPA in harmonizing the implementation and structure of processed food safety programs across the U.S. is similar to the role that the National Association of State Departments of Agriculture (NASDA) and Produce Safety Alliance play in harmonizing the implementation of and training on PSR standards. NASDA, similar to MFRPA, tracks changes in state laws and regulations related to produce safety regulation. MFRPA provides an additional service by then updating the MFRPS guide that coordinates national efforts to regulate manufactured food safety. Developing a parallel guide for the PSR could help streamline and coordinate state agency efforts to implement and enforce PSR regulations.

MFRPA also provides a helpful conduit between food processors and regulators. The Produce Safety Alliance is well-suited to serve as a similar conduit connecting regulated producers, state regulators, and FDA. The Produce Safety Alliance already trains producers on PSR requirements nationwide, so it is situated to collaborate with NASDA to track produce safety laws and regulations across the states, create recommendations to harmonize PSR implementation approaches, and make such information publicly available. Providing that service could 1) help increase communication with states regarding specific industries or geographic regions that are good candidates for a variance from PSR requirements, and 2) help FDA identify circumstances where a variance granted to one jurisdiction's producers should be extended to producers in another jurisdiction.

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[150] U.S. FOOD & DRUG ADMIN., MANUFACTURED FOOD REGULATORY PROGRAM STANDARDS 39–41 (2019).

[151] *Id.*

[152] *MFRPAlliance*, ASSOCIATION OF FOOD & DRUG OFFICIALS, http://www.afdo.org/mfrpa [https://perma.cc/CF3Z-D3D9] (last visited Apr. 24, 2020).

[153] *Id.*

FDA should create an infrastructure for harmonizing produce safety regulation similar to that already in place for the manufactured food industry. Greater public access to recommendations and resources on how to harmonize produce safety laws and PSR implementation can help competent authorities better determine when a variance request is appropriate and will streamline the petition review process. Providing a regulatory framework, or at a minimum, a set of self-evaluation worksheets like those provided in the MFRPS Guide, would benefit both FDA and petitioners by clarifying the quantitative and qualitative evidence needed to support claims and requests in variance petitions.

2. USDA—Food Safety Inspection Service & "Equivalence" Assessments

Under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), USDA's FSIS is tasked with regulating the sanitary quality of domestically produced and imported meat, poultry, and egg products.[154] Under both statutes, Congress mandated that USDA establish a federal-state cooperative system for managing inspections of facilities engaged in the slaughtering, canning, salting, packing, rendering, or similar processing of meat and poultry products.[155]

In states that enacted meat and poultry inspection laws, FSIS must cooperate with the state's inspection agency to develop and administer state meat and poultry inspection (MPI) programs.[156] To run independently from USDA's direct oversight and enforcement, state inspection programs must be "at least equal to" the inspection program requirements imposed by the FMIA.[157] Under the FMIA, a state may either 1) operate their own MPI program; or 2) relinquish inspection authority to USDA.

According to USDA, the at least equal to standard requires state MPI programs to operate "in a manner that is not less effective than those standards adopted for the Federal inspection program."[158] However, the standard "does not require the States to operate their MPI programs in a manner that is the same as or identical to FSIS's inspection program."[159] To show that state programs provide comparable protection, FSIS expects state MPI programs to submit annual self-assessments to FSIS's Federal-State Audit Branch.[160]

Each self-assessment must review nine program components to demonstrate that the state program is administered in a manner at least equal to federal inspection requirements: 1) statutory authority and food safety regulations; 2) inspection; 3) sampling programs; 4) staffing, training, and supervision; 5) humane handling; 6)

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[154] Federal Meat Inspection Act, 21 U.S.C. § 601 (2020); Poultry Products Inspection Act, 21 U.S.C. § 454 (2020).

[155] 21 U.S.C. § 661 (2020).

[156] *Id.* § 661(a)(1).

[157] *Id.* § 661(a)(3).

[158] FOOD SAFETY INSPECTION SERVICE, U.S. DEP'T OF AGRIC., "AT LEAST EQUAL TO" GUIDELINE FOR STATE MEAT AND POULTRY INSPECTION PROGRAMS 4 (2016).

[159] *Id.*

[160] *Id.* at 6.

compliance; 7) laboratory methods and quality assurance program; 8) civil rights; and 9) financial accountability.[161]

In addition to the self-assessment, state MPI programs are subject to on-site reviews at least once every three years to verify the accuracy and implementation of the self-assessment submissions. During an on-site visit, FSIS officials assess the implementation of the state's MPI program both in agency offices and at inspected processing establishments.

The at least equal to standard required under FMIA is similar to the same level of public health protection standard required under FSMA PSR. For states that receive a variance, FDA has indicated that the agency can withdraw the variance at any time if it finds that the competent authority no longer meets the same level of public health protection standard.[162] FDA may employ an oversight process similar to that in FSIS for ongoing monitoring of state variance requests and their same level of public health protection. The complexity of the required oversight depends upon the complexity of the variance granted from PSR standards.

FDA should draw from both evaluation approaches—under MFRPS and under MPIA equivalence—and apply them to the PSR variance process. Clear guidelines will help competent authorities self-evaluate the equivalence of food safety regulations, the measures established within their jurisdiction, and standard industry practices, before seeking a variance. A framework like those provided to states under MPIA and MFRPS can clarify the information needed from petitioners, increase the efficiency of the variance process, and improve FDA's consistency in reviewing similar variance petitions.

B. FDA Assessments of Foreign Food Safety Programs

The U.S. trades food products with over 200 countries, moving food products through over 300 U.S. ports.[163] FDA must ensure that all food imported into the U.S. from each country and through each port is safe to be sold in U.S. markets. Many of the imports entering the country consist of fresh fruits and vegetables regulated under PSR. As of 2019, 30% of fresh vegetables, 67% of berries, and almost 40% of melons consumed in the U.S. were imported.[164] Each U.S. trading partner's food safety system varies substantially in robustness.[165] Such variation challenges FDA's ability to develop an effective import control system.[166]

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[161] *Id.* at 7–8; FSIS Directive 5720.3, Methodology for Performing Scheduled and Targeted Review of State Meat and Poultry Inspection Programs (U.S.D.A. 2016).

[162] 21 C.F.R. § 112.180 (2016).

[163] *Frequently Asked Questions on Systems Recognition for Foreign Governments*, U.S. FOOD & DRUG ADMIN. (June 2, 2020), https://www.fda.gov/food/international-interagency-coordination/frequently-asked-questions-systems-recognition-foreign-governments [https://perma.cc/5M9S-4MVH].

[164] JACLYN KRAMER, SKYLER SIMNITT & LINDA CALVIN, U.S. DEP'T OF AGRIC., FRUIT AND TREE NUTS OUTLOOK (Mar. 31, 2020); GARY LUCIER & BRODERICK PARR, U.S. DEP'T OF AGRIC., VEGETABLES AND PULSES OUTLOOK (Apr. 17, 2020).

[165] Alexia Brunet Marks, *The Risks We Are Willing to Eat: Food Imports and Safety*, 52 HAR. J. ON LEGIS. 125 (2015).

[166] *CDC Research Shows Outbreaks Linked to Imported Foods Increasing*, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 14, 2012), https://www.cdc.gov/media/releases/2012/p0314_foodborne.html [https://perma.cc/CX7T-LTAS] (acknowledging that CDC figures "underestimate the true number of outbreaks due to imported foods as the origin of many foods causing outbreaks is either not known or not reported").

Further, the U.S. has international obligations under the World Trade Organization (WTO) to attempt to harmonize food safety laws, regulations, and standards with those established by the Codex Alimentarius. FDA and USDA FSIS have an interagency partnership to administer the U.S. Codex Program, a program aimed at fulfilling the U.S.'s international obligations and to increase the level of collaboration with foreign food safety authorities to secure a safe food supply globally.[167] FDA uses two main approaches to harmonize food safety systems: 1) foreign systems recognition, and 2) equivalence. FDA established these programs to allow the agency to assess food safety systems that differ from the U.S. system and determine whether foreign systems offer a similar set of protections to that of FDA, all based on a same level of public health protection standard. This standard stems from the WTO Agreement on the Application of Sanitary and Phytosanitary Standards (SPS Agreement), which requires WTO members to "accept sanitary or phytosanitary measures of other Members as equivalent, even if those measures differ from their own."[168] This language is similar to the same level of public health protection language that permeates FDA and USDA's comparability assessments.[169]

Equivalence and foreign systems recognition serve the same goal: to determine whether foreign food safety regulation provides the same level of public health protection as the U.S. system. The two systems are similar in concept but differ in scope and design. Equivalence determinations are used when specific commodities require detailed analysis to determine comparability of regulations, or when a particular industry, not an entire country, aims to benefit from the increased efficiency of bilateral cooperative regulation of a single industry.

Foreign systems recognition does not follow the same measure-by-measure approach of the equivalence assessment to evaluate system-wide comparability, as FDA believes that it is not required to ensure system-level protection.[170] Where particular high-risk commodities are concerned, an equivalence assessment may be used in conjunction with a foreign systems recognition determination.[171]

Both programs provide helpful examples of the types of data and the form that variance petitions should take, as well as guidance on the level of collaboration that

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[167] *The Codex Alimentarius Commission and The United States Codex Program*, U.S. DEP'T OF AGRIC., https://www.usda.gov/codex [https://perma.cc/3S35-RB9Z] (last visited Mar. 14, 2021) (listed as "Codex At-a-Glance"); *International Cooperation on Food Safety*, U.S. FOOD & DRUG ADMIN. (Dec. 21, 2020), https://www.fda.gov/food/international-interagency-coordination/international-cooperation-food-safety [https://perma.cc/G8TY-EUD2].

[168] Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) art 4.1, Apr. 15, 1994, 1867 UNTS 493 (emphasis added).

[169] USDA FSIS also has a similar process for performing equivalence assessments, but not foreign systems recognition, of foreign meat and poultry inspection programs. As this Article focuses on anticipating how FDA will assess the comparability of foreign systems, the following section will focus on analyzing FDA's foreign assessment procedures.

[170] *Frequently Asked Questions on Systems Recognition for Foreign Governments*, U.S. FOOD & DRUG ADMIN. (Sep. 5, 2018), https://www.fda.gov/food/international-interagency-coordination/frequently-asked-questions-systems-recognition-foreign-governments [https://perma.cc/NWA8-63QD] [hereinafter *FDA Foreign Systems FAQ*].

[171] *International Cooperation on Food Safety*, U.S. FOOD & DRUG ADMIN. (Dec. 21, 2020), https://www.fda.gov/food/international-interagency-coordination/international-cooperation-food-safety [https://perma.cc/U5XX-ZDRP] (e.g., FDA is currently assessing the equivalence of dairy regulations in Canada and New Zealand as additions to the foreign systems recognition agreements already established with each country).

FDA may require from petitioners before approving a variance. Foreign systems recognition parallels a variance request from multiple PSR requirements, while equivalence parallels a variance request for a single commodity or industry. Petitioners, especially foreign authorities, should look to the evidence required to establish foreign systems recognition and equivalence for guidance on how to craft a strong petition.

1. Foreign Systems Recognition

FDA uses foreign systems recognition to address concerns about imported foods by comparing a foreign country's food safety regulatory system with the U.S. system.[172] The assessment process is collaborative; it is a bilateral process, in which the foreign country simultaneously assesses the U.S. food regulatory system to determine comparability. General guidelines for the assessment are set forth in the draft International Comparability Assessment Tool (ICAT).[173] The ICAT is an adapted international version of FDA's 2010 MFRPS.[174] No such guideline exists to detail FDA's established approach for reviewing variance requests.

Foreign systems recognition is applied when FDA and a foreign country mutually recognize the two food safety systems as comparable.[175] Comparability means that FDA can rely on a foreign competent authority to implement science-based food safety regulatory programs and take regulatory action where necessary to address food safety concerns, thus ensuring the safety of food imported from that country.[176] FDA recognizes a foreign system as comparable when it provides: 1) a similar, but not necessarily identical, system of protection through legal authorities and regulations; and 2) similar controls, through oversight and monitoring, for food produced in the jurisdiction.[177] Recognizing the comparability of systems with similar structures rests on the assumption that "food safety systems with similar elements and similar levels of oversight lead to similar food safety outcomes."[178]

Since establishing the foreign systems recognition program in the late 2000s, FDA has recognized three foreign systems as comparable: New Zealand,[179] Canada,[180] and

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[172] U.S. FOOD & DRUG ADMIN., REPORT OF THE COMPARABILITY DETERMINATIONS OF THE FOOD SAFETY COMPONENT OF THE NEW ZEALAND MINISTRY FOR PRIMARY INDUSTRIES 3 (2012) (using the term "comparability" to describe the process of food safety systems evaluation before adopting the term "systems recognition").

[173] U.S. FOOD & DRUG ADMIN., INTERNATIONAL COMPARABILITY ASSESSMENT TOOL (2017).

[174] *FDA Foreign Systems FAQ*, *supra* note 170, at § III(A)(7).

[175] *Id.* at § III(A)(9) (Note: The ICAT and FDA's foreign systems recognition program currently only assesses comparability of human food regulatory systems. FDA is in the process of developing standards for animal feed regulatory programs.).

[176] *Id.* at § II(A).

[177] For discussion of FDA's MFRPS program, see *supra* Section II.B.1; U.S. FOOD & DRUG ADMIN., REPORT OF THE SYSTEMS RECOGNITION ASSESSMENT OF CANADA 1 (2018).

[178] *FDA Foreign Systems FAQ*, *supra* note 171, at § III(A)(1).

[179] U.S. FOOD & DRUG ADMIN., FDA – NEW ZEALAND MPI, FOOD SAFETY SYSTEMS RECOGNITION ARRANGEMENT (2012).

[180] U.S. FOOD & DRUG ADMIN., FDA – CFIA AND HEALTH CANADA, FOOD SAFETY SYSTEMS RECOGNITION AGREEMENT (2016).

Australia.[181] These past comparability assessments can help illustrate FDA's typical process for establishing foreign systems recognition and help predict how FDA will assess complex system-wide variance requests. In draft guidance on the PSR, FDA indicated that the agency's past experience with foreign equivalence assessments informs their approach to reviewing variance requests.[182]

To begin the process of establishing systems recognition, the foreign country must request that FDA initiate a comparability assessment.[183] Before beginning the bilateral comparability assessment, FDA begins with an internal data review of the country's compliance history—including the trade volumes, number of refusals of import admissions and reason(s) for refusal, and products subject to import alerts—and the country report information available in USDA's Global Agricultural Information Network.[184] Then, FDA arranges a consultation meeting with the competent authority of the country under review. Consultation participants review FDA's internal review findings, discuss systemic concerns with the country's food safety system, and clarify the country's goals and expectations behind the review request.[185]

At this point, the countries will decide whether to move forward with a full comparability assessment and foreign systems recognition, and then establish a schedule for completing the ICAT.[186] The requirement for countries to engage in consultation before moving forward was recommended by USDA FSIS, which uses the same process when determining international equivalence for meat and poultry.[187] Though USDA does not have a foreign systems recognition process, its established equivalence process was persuasive in FDA's structuring of its more complex foreign systems recognition process.[188] FSIS equivalence determinations only proceed where the country seeking review determines that they are likely candidates after reviewing the FSIS equivalence self-assessment tool and have the resources necessary to complete the full review.[189] This drives a level of self-selection, where countries with insufficiently developed food safety systems tend to withdraw from consideration after consultation with FSIS. FDA believes the foreign systems recognition applicants will exhibit that same tendency towards self-selection.[190]

The full comparability assessment consists of two stages. First, the petitioning country assembles the information requested in the ICAT and FDA reviews submitted materials to determine what food safety authorities and controls are in place. For the foreign country's system to pass the first stage, FDA must determine that the system

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[181] U.S. FOOD & DRUG ADMIN., FDA RECOGNIZES AUSTRALIA AS HAVING COMPARABLE FOOD SAFETY SYSTEM TO THE U.S. (2017).

[182] DRAFT GUIDANCE ON SLPHP DETERMINATIONS, *supra* note 34, at 6.

[183] FDA Foreign Systems FAQ, *supra* note 170, at § III(A)(3).

[184] *Id.* at § III(A)(3).

[185] *Id.*

[186] *Id.*

[187] *Id.* at § IV(1).

[188] *Id.*

[189] *Id.*

[190] *Id.*

contains ten elements, established in the ICAT, that are almost identical to the ten standards established in MFRPS. The ten elements in the ICAT are as follows:

(1) Regulatory Foundation.[191]

(2) Training Program.[192]

(3) Inspection Program.[193]

(4) Program Assessment/Inspection Audit Program.[194]

(5) Food-related Illness and Outbreaks Management.[195]

(6) Compliance and Enforcement.[196]

(7) Industry and Community Relations.[197]

(8) Program Resources.[198]

(9) International Communication and Harmonization.[199] All other standards are almost identical to MFRPS, except this one. Under the ICAT Standard 9, the competent authority must have established mechanisms for interacting with the international community regarding international food safety standards and communications mechanisms to enact during foodborne illness outbreaks and other food safety events of international concern.

(10) Laboratory Support.[200]

Reviewing the comparability of control systems is an extensive, data-intensive process that considers both a foreign country's internal food safety controls and border inspections. FDA uses a variety of data sources, including:

- Border examinations, testing of samples, and compliance
- Foreign inspections
- Facility registration
- The Foreign Supplier Verification Program (FSVP) under § 301 of FSMA
- The Voluntary Qualified Importer Program (VQIP) under § 302 of FSMA

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191 U.S. FOOD & DRUG ADMIN., INTERNATIONAL COMPARABILITY ASSESSMENT TOOL 4 (2017).

192 *Id.* at 5.

193 *Id.* at 6.

194 *Id.* at 7.

195 *Id.* at 8.

196 *Id.* at 9.

197 *Id.* at 10.

198 *Id.* at 11.

199 *Id.* at 12.

200 *Id.* at 13.

- Requiring the utilization of accredited laboratories for testing
- Reliance on the export programs of countries
- Third party certification through, for example, the accreditation of third-party auditors under § 307 of FSMA
- Requiring import certificates as provided under § 303 of FSMA
- Bilateral agreements and arrangements
- Systems recognition or equivalence assessments of foreign food safety systems.[201]

After FDA assesses all the documentation submitted with the ICAT and determines that the country's food safety system satisfies all ten identified standards, FDA moves to stage two. Stage two is an in-country systems recognition assessment.[202] During an in-country assessment, an FDA team of scientists, auditors, and investigators visit government agencies and food processing facilities to conduct interviews, review records, and verify implementation of programs outlined in the ICAT response.[203] Particular attention is paid to in-country oversight and enforcement of food safety regulations to determine whether the country's program, as implemented, reflects a system offering the same level of public health protection as the system implemented by FDA in the U.S.

After establishing a foreign systems recognition agreement with the other country, FDA continues to monitor comparability through bilateral communications and an annual review of relevant regulatory changes in both countries.[204] FDA then establishes a schedule for in-country reassessments at predetermined intervals. Either country may also initiate an unscheduled in-country review, especially if an unusual food safety incident or emergency arises that indicates a failure in food safety regulation within the country.[205]

FDA is still developing the process for foreign systems recognition assessments and is actively seeking comments from stakeholders on two particular aspects of assessment.[206] First, how to make meaningful comparisons between "food safety outcomes," especially those related to disease burden.[207] Second, how FDA should determine the appropriate number of on-site audits to conduct during an in-country assessment.[208]

The thorough, bilateral nature of foreign systems recognition is likely to apply to PSR variance assessments if a foreign country requests a broad variance from PSR requirements. Hypothetically, if a foreign country requests a variance from all PSR requirements, the variance petition would likely resemble the structure of the ICAT,

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[201] *FDA Foreign Systems FAQ*, *supra* note 170, at § II(C).

[202] *Id.* at § III(A)(3).

[203] *Id.* at § III(A)(12).

[204] *Id.* at § III(A)(14).

[205] *Id.*

[206] *Id.* at § III(B)(20) (although FDA states that it welcomes comments on these topics, it does not provide a docket number for submitting comments for review).

[207] *Id.* at § III(A)(4).

[208] *FDA Foreign Systems FAQ*, *supra* note 170, at § III(A)(13).

and FDA would employ an approach similar to foreign systems recognition. Before initiating a foreign systems recognition assessment process with New Zealand, Canada, or Australia, FDA established communication, data-sharing, and collaboration norms through bilateral agreements. FDA will almost certainly require pre-submission communication and, potentially, a formal bilateral agreement before performing a complex variance review of a foreign food safety program under PSR. At the very least, in draft guidance, FDA encourages foreign entities considering a variance petition to engage in pre-submission consultations with FDA.[209] Indeed, it is both logical and advisable to apply the same factors, bilateral communications, and scrutiny to these similar processes.

For countries that have established foreign systems recognition with the U.S., the variance process should be much more efficient than for countries who have not gone through the foreign systems recognition process. Bilateral recognition establishes heightened levels of regulatory cooperation and should make it easier for FDA to undertake a variance petition review.

2. Equivalence

Equivalence is different from foreign systems recognition, though it is conceptually similar. The term "equivalence" is principally used in the context of international trade. The term is used in the WTO and its associated agreements, such as the 1995 Agreement on the Application on Sanitary and Phytosanitary Measures (SPS Agreement), and in regional free trade agreements, such as the North American Free Trade Agreement.[210] Free trade agreements have strongly influenced the development of food safety regulation through international standards harmonization.[211]

While foreign systems recognition assesses the comparability of the entire food safety regime of another country, equivalence considers just one piece of that regime at a time. Specifically, equivalence most appropriately applies to assessing a foreign government's specific programs for regulating certain high-risk foods.[212] The assessment is a highly detailed comparison of each measure established to control risks associated with a particular commodity. The ultimate goal of equivalence assessments is to determine whether a "foreign food safety system achieves the same level of public health protection as the U.S. despite having different food safety controls" for a particular product.[213] Equivalence determinations are initially proposed in the Federal Register and open for public comment before FDA makes a final decision. After determining equivalence, imported commodities produced in accordance with the equivalent standards may enter U.S. markets. FDA has assessed two products for equivalence: 1) raw bivalve molluscan shellfish; and 2) Grade "A" dairy products.

Rather than functioning under one federal oversight system, both commodities rely upon federal-state programs to ensure coordination across the states with assistance

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[209] FDA DRAFT GUIDANCE FOR INDUSTRY, *supra* note 45, at 141.

[210] *FDA Foreign Systems FAQ*, *supra* note 170, at § III(A)(16).

[211] See *infra* Section III.

[212] *FDA Foreign Systems FAQ*, *supra* note 170, at § III(A)(16).

[213] *International Cooperation on Food Safety*, U.S. FOOD & DRUG ADMIN. (Oct. 4, 2018), https://www.fda.gov/food/international-interagency-coordination/international-cooperation-food-safety [https://perma.cc/66JR-XD8V].

from FDA.[214] Both of these cooperative federal-state programs identify FDA as their competent authority[215] should a foreign country request the U.S. undertake an equivalence assessment for those products.[216] FSMA PSR identified FDA as the competent authority for variance requests and vested it with the unilateral ability to assess and approve variance requests without conferring with the federal-state cooperative approach to PSR implementation.[217] Raw bivalve mollusks are similar in their deference to FDA's equivalence determinations, though FDA is required to coordinate with the National Shellfish Sanitation Program during the equivalence process.[218] In contrast, Grade "A" dairy identifies FDA as the competent authority, but the National Conference of Interstate Milk Shippers retains the right of final approval for any equivalence determinations.[219]

In short, if a foreign country requests a variance on behalf of a single commodity, FDA's review will likely resemble an equivalence assessment of the country's regulatory program for that commodity. Though FDA is not required to consult with a PSR federal-state cooperative as they are when considering the Grade "A" dairy equivalence, variances are not considered in a vacuum because FDA must open them up to public comment.[220] These past equivalence assessments provide helpful guidance on how the PSR variance process—especially the same level of public health protection determination—would apply in a single commodity variance request.

The U.S. equivalence determination for the European Union's raw bivalve molluscan shellfish regulatory program required FDA to compare the EU's regulatory program with the U.S. federal-state cooperative program that oversees the safety of fish and fishery products, including shellfish.[221] The National Shellfish Sanitation

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[214] 83 Fed. Reg. 10,488 (Mar. 9, 2018) (raw bivalve mollusks are regulated in interstate commerce through the National Shellfish Sanitation Program, which coordinates industry stakeholders, state regulators, and federal regulators overseeing mollusks.); U.S. FOOD & DRUG ADMIN., GRADE "A" PASTEURIZED MILK ORDINANCE iv (2015) (similarly, grade "A" milk and milk products are regulated through the Cooperative State-USPHS/FDA Program for the Certification of Interstate Milk Shippers, which coordinates industry stakeholders, state regulators, and federal regulators overseeing milk products).

[215] Note: The term *competent authority* is used in both equivalence assessments and under PSR's variance requirements.

[216] 83 Fed. Reg. 10,488 (Mar. 9, 2018); U.S. FOOD & DRUG ADMIN., GRADE "A" PASTEURIZED MILK ORDINANCE 131 ¶ 10 (2015). FDA must collaborate with these two federal-state cooperative boards to assess a foreign country's bivalve mollusk or Grade "A" milk industries. FDA must exclusively perform a commodity-specific equivalence assessment for these two products. FDA cannot simply incorporate an assessment of these products in a broader foreign systems recognition assessment—the agency must engage in a detailed commodity-specific assessment to determine whether it aligns with the U.S.'s system.

[217] 21 U.S.C. § 350h(c)(2) (delegating to FDA the authority to accept and review variances and managing food safety risks on behalf of the federal government).

[218] U.S. FOOD & DRUG ADMIN. & INTERSTATE SHELLFISH SANITATION CONFERENCE, GUIDANCE ON EQUIVALENCE CRITERIA FOR FOOD, INTERSTATE SHELLFISH SANITATION CONFERENCE RESOLUTION 11-003, at 376 (cited in U.S. FOOD & DRUG ADMIN., NATIONAL SHELLFISH SANITATION PROGRAM (NSSP) GUIDE FOR THE CONTROL OF MOLLUSCAN SHELLFISH (2011 Revision)).

[219] Grade "A" Pasteurized Milk Ordinance, 131 ¶ 10 (2015).

[220] 21 C.F.R. § 112.176 (2015).

[221] Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 381 (2020); Public Health Service Act, 42 U.S.C. §§ 201–300; Fish and Fishery Products, 21 C.F.R. § 123 (2019); Molluscan Shellfish, 21 C.F.R. § 1240.60 (2019).

Program oversees the federal-state cooperative and is supported by FDA and the Interstate Shellfish Sanitation Conference.[222]

This National Shellfish Sanitation Program also publishes a guide, the *Guide for the Control of Molluscan Shellfish*, that serves to harmonize the regulation of raw bivalve mollusks across the fifty states.[223] Together, the program and the guide comprise the framework for sanitation standards adopted by each participating U.S. state, with the guide serving as a model ordinance incorporated into state law even though it is not itself a federal regulation. Countries seeking an equivalence recognition of their bivalve mollusk industry must show that their regulations provide the same level of public health protection as the requirements established by FDA, the National Shellfish Sanitation Program, and the *Guide for the Control of Molluscan Shellfish*.

The FDA equivalence assessment for raw bivalve molluscan shellfish began in 1998.[224] In conducting the assessment, FDA collaborated with the European Commission's Directorate-General for Health and Food Safety, the EU's competent authority. During the review process, FDA conducted detailed reviews of shellfish-specific regulations, including growing water classification, testing policies, and safety protocols. Notably, the U.S. neither engaged in a foreign systems recognition process with the EU nor performed a system-wide assessment of the entire EU food safety regime. Rather, the U.S. operated a detailed, scientific review under the equivalency standard of the EU's food safety controls critical to ensuring the food safety of molluscan shellfish.

Based on this scientific review, FDA published notice on March 9, 2018 of its intention to officially recognize the EU regulation of raw bivalve molluscan shellfish as equivalent to U.S. regulations.[225] The comment period on the results of the equivalence determination ended in May 2018.[226] On September 24, 2020, FDA concluded over twenty years of equivalence assessment when the agency published a final ruling announcing the formal equivalence determination of food safety control measures for raw bivalve molluscan shellfish in Spain and the Netherlands.[227]

As with shellfish, interstate regulation of Grade "A" dairy products is overseen by a program that involves all fifty states, the District of Columbia, and U.S. Trust Territories.[228] The *Grade "A" Pasteurized Milk Ordinance* (PMO) is the basic standard used by the voluntary interstate conference and is recognized as the national standard for milk sanitation.[229]

The increased health and safety concerns associated with managing the sanitation of milk and milk products spurred the establishment of a complex federal-state cooperative regulatory regime in the U.S. Therefore, FDA alone does not have full oversight power over the safety regulation of Grade "A" dairy products. FDA was

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[222] Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 372; Public Health Service Act, 42 U.S.C. § 243.

[223] 83 Fed. Reg. 10,487, 10,488 (Mar. 9, 2018).

[224] *Id.*

[225] *Id.*

[226] *Id.*

[227] Food & Drug Admin. Equivalence Determination Regarding Implementation by Spain and the Netherlands of the European Union System of Food Safety Control Measures for Raw Bivalve Molluscan Shellfish with Additional Controls, 85 Fed. Reg. 60,172, 60,172 (2020) (Final Rule).

[228] U.S. FOOD & DRUG ADMIN., GRADE "A" PASTEURIZED MILK ORDINANCE iv (2015).

[229] *Id.*

identified as the competent authority for undergoing equivalence determinations of foreign dairy regulations, but it cannot unilaterally establish an equivalence determination without complete control of the oversight of the product. Given the complexity of the domestic regulation of Grade "A" dairy products, it is necessary for FDA to undergo a specific equivalence determination for this commodity to determine comparability. As the equivalence assessments for Grade "A" milk and milk products are still ongoing, there is not much information available on their procedures.

These two examples of equivalence determinations indicate that, in reviewing commodity-specific variance requests, FDA will employ a measure-by-measure comparison of the regulations intended to provide the same level of public health protection as the PSR. Competent authorities seeking to assemble a commodity-specific petition, like that initially requested by the Guatemala Ministry of Agriculture, should compile a list of the relevant regulations or industry standards that fulfill the objective of the PSR provision the agency seeks to waive. This process may be lengthy, given the example set by the two equivalence processes to date. But using past equivalence determinations as a guide when writing the variance petition will make the variance process more effective and efficient. Similarly, FDA should employ a similar review process for commodity-specific variance requests as that outlined by past equivalence processes. This will ensure consistency where the scope and standard of the comparability assessment request are, essentially, the same.

IV. FINAL CONSIDERATIONS: INTERNATIONAL TRADE LAW AND FOOD SAFETY HARMONIZATION

Though FSMA and PSR unilaterally imposed new produce safety requirements on foreign countries, the U.S. is not unfettered in its application of new rules to foreign producers. Existing international laws set parameters that members of the WTO, including the U.S., have agreed to obey. This places some boundaries around FDA's assessments, especially assessments of foreign countries, that are useful when thinking through PSR variances.

The relevant international trade agreements that establish these parameters around national food safety programs have existed for twenty-five years and rely on standards similar to the same level of public health protection standard employed by PSR. The most basic requirement is that the U.S. must accept a foreign country's food safety regulations as equivalent when they achieve the standard of protection established by the U.S. The equivalence standard employed under international trade law is almost identical to the same level of public health protection standard established under FSMA PSR for variances. This brief analysis of the influence of international trade law on FDA's variance assessments will focus on two agreements binding on the U.S. through the WTO: 1) the 1947 General Agreement on Tariffs and Trade (GATT 1947); and 2) the 1994 Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).[230]

GATT 1947 was the founding document of the WTO and remains the primary document establishing the trade commitments binding on the WTO's 198 member

[230] General Agreement on Tariffs and Trade, Oct. 30, 1947, 55 U.N.T.S. 194 [hereinafter GATT]; Agreement on the Application of Sanitary and Phytosanitary Measures, Jan. 1, 1995, 1867 U.N.T.S. 14 [hereinafter SPS Agreement].

states who represent 98% of global trade.[231] As a WTO member, the U.S. has three primary commitments: 1) to establish no quantitative restrictions on imports;[232] 2) to not treat some trade members preferentially to others;[233] and 3) to not treat domestically produced products preferentially to imported products through taxes or internal regulations.[234]

However, under the SPS Agreement, the U.S. may restrict imports (in violation of its GATT 1947 commitments) as long as the restrictions are intended to protect human life and health within the U.S. from foodborne risks.[235] But the ability of a member state to impede trade in the name of sanitary or phytosanitary protection is not unlimited. The measure established by the member must be "applied only to the extent necessary" and be "based on scientific principles" and "not maintained without sufficient scientific evidence."[236]

The PSR is precisely the kind of alternative measure anticipated by the SPS Agreement. Although Codex Alimentarius establishes thorough quality standards for produce in international trade, those standards focus on physical characteristics of the produce after it has entered interstate or international commerce. Codex standards do not regulate processes and production methods, like the on-farm production requirements established under PSR. Therefore, if a country challenges the PSR as overly trade-restrictive, the U.S. must show that PSR requirements are scientifically justified to survive challenge. This means that the U.S. can impose PSR requirements on foreign importers, but FDA must scientifically justify the requirements and cannot excessively apply them so as to create an unnecessary trade restriction.

To be scientifically justified, the higher standards must be based on a risk assessment that takes into account: available scientific evidence; relevant processes and production methods; relevant inspection, sampling, and testing methods; the prevalence of specific diseases or pests; the existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.[237] In determining what measure is appropriate to offset the risks, the member must try to minimize the negative trade effects of the regulation.[238]

The SPS Agreement is also the primary source of the standards used in FDA and USDA's assessment procedures for foreign systems recognition and equivalence. Under the SPS Agreement, member states are required to "accept sanitary or phytosanitary measures of other Members as equivalent, even if those measures differ from their own . . . if the exporting Member objectively demonstrates . . . that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection."[239] Upon request, each member must also enter into bilateral

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[231] *Who We Are*, WORLD TRADE ORGANIZATION, https://www.wto.org/english/thewto_e/whatis_e/who_we_are_e.htm [https://perma.cc/X8D4-PYKN] (last visited Apr. 25, 2020).

[232] GATT, *supra* note 230, at Art. XI.

[233] *Id.* at Art. I.

[234] *Id.* at Art. III.

[235] SPS Agreement, *supra* note 230, at Art. 2.

[236] *Id.* at Art. 2.2.

[237] *Id.* at Art. 5.2.

[238] *Id.* at Art. 5.4.

[239] *Id.* at Art. 4.1 (emphasis added).

or multilateral agreements and negotiations to recognize the equivalence of a particular sanitary or phytosanitary measure.

This process enables the U.S. to select its own "appropriate level of protection," either based on the international standard or higher, as long as it is scientifically justifiable. However, at any time, another WTO member may request that the U.S. review the foreign country's standards for equivalence. The U.S. cannot simply reject the other standards as inequivalent because the foreign measures differ from the measure established by the U.S. for that commodity; it must review the measures to see if they provide the same level of protection established by the U.S.

Take the example of Guatemala's variance petition from PSR agricultural water standards for its banana industry. Guatemala requested that the agricultural water standards not apply to its banana industry because irrigation water rarely touches the produce due to the height of the plants, the standard practice of wrapping the bunches in plastics for protection, and standard procedures for washing all harvested produce in chlorinated water.[240] If FDA had reviewed the petition, the agency could not have simply rejected the request outright for not mirroring the form of PSR water standards (e.g., by proposing a different sampling strategy). Instead, FDA would have to assess the scientific information proposed in Guatemala's variance requests to determine whether the low risk of contamination due to industry standard practices, even without water sampling or treatment, provides the same level of sanitary protection established by PSR standards.

The language of equivalence from international trade law permeates FDA's systems for comparability assessment of states and foreign governments. Further, the U.S.'s international trade commitments leave the PSR open to challenge by other WTO members who may believe that these regulations are overly trade-restrictive. To survive challenge, the U.S. must show that PSR requirements are scientifically justified, consistently applied, and enforced so as not to discriminate among trading partners.

V. CONCLUSION

Understanding the same level of public health protection standard and how it influences the PSR variance process is vital for potential petitioners to be able to move forward with assembling variance requests. As FDA is in the early stages of PSR implementation and enforcement, this is a key period of regulatory flexibility for industry stakeholders, agencies, and FDA to communicate about effective ways to regionalize PSR requirements.

FDA and USDA have existing law from their regulation of state and foreign food safety programs that help interpret the same level of public health protection standard as it is applied to the variance process. FDA's MFRPS program, USDA's MPI program, foreign systems recognition, and equivalence assessments are clear analogues that FDA can and should rely upon when assessing variance requests. These existing programs show the need for clearly enumerated assessment requirements when federal agencies must evaluate the comparability of food safety programs with federal requirements. They also demonstrate the usefulness of providing such

[240] U.S. FOOD & DRUG ADMIN., FDA-2019-P-1781-0001, CITIZEN PETITION FROM ASSOCIATION OF INDEPENDENT BANANA PRODUCERS OF GUATEMALA, 4–10 (posted Apr. 16, 2019) (petition withdrawn on Sept. 23, 2019).

guidance to regulated industries. Ultimately, states should rely on factors like those developed through the MFRPS, MPI, foreign systems, and equivalence assessments when drafting the Statement of Grounds portion of their petition.

FDA should learn from these analogous comparability assessment programs. Not only does the standard match, but the stakeholder audiences are strikingly similar. The individuals interacting with these programs are state and foreign regulators working in federally regulated industries. Therefore, they are likely familiar with working within this type of standard-driven system and have similar considerations when it comes to time, energy, and resources. Relying on existing federal programs to guide the PSR variance process can improve clarity and efficiency by specifying for regulators and stakeholders how these programs work and how the variance process will compare.

International law also provides helpful guidance on how to conduct comparability assessments of foreign food safety regimes. If FDA does not effectively assess variance petitions from foreign authorities, PSR could be challenged as a violation of the U.S.'s WTO trade commitments. To avoid challenge, the U.S. must apply PSR requirements even-handedly to its trading partners and assess variance requests with due diligence to determine if a country's or industry's substitute measures provide the same level of protection as FSMA PSR. It is likely that foreign countries will request variances moving forward and it is critically important that FDA clarify its requirements for variance petitions and the types of data required to justify different types of variance requests.

Domestic and international legal precedents provide helpful examples of how FDA can elaborate petition requirements and establish a petition review process that is less burdensome on the agency and petitioners. Publishing an explanation of petition requirements similar to those provided for MFRPS and in ICAT could increase the quality of submitted variance petitions, improve the efficiency of petition review, make the review process more consistent, and foster greater collaboration between FDA and competent authorities as they work together to determine best methods for identifying and managing evolving food safety risks in light of local growing conditions and industry practices worldwide. The disruptions to international supply chains during the recent and ongoing COVID-19 pandemic highlight the need for improved international collaboration in managing our global food system as well as a set of growing concerns over public health risks from agricultural markets. As each state, federally recognized tribe, and foreign country determines the best way to manage those public health and food safety risks, FDA should prepare to collaborate with those entities to effectively address how new risk mitigation strategies work in tandem with or in lieu of PSR requirements. Fortunately, existing processes provide FDA with a path forward that can offer clarity and efficiency to stakeholders and agency personnel alike.