IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED FOOD AND COMMERCIAL WORKERS UNION, LOCAL No. 227, *et al.* Plaintiffs, v. UNITED STATES DEPARTMENT OF AGRICULTURE, Defendant.	)	Case No. 1:20-cv-02045

DEFENDANT'S MOTION TO DISMISS

Defendant United States Department of Agriculture, by and through undersigned counsel, hereby moves for dismissal of the Complaint pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure. In support of this motion, Defendant submits the accompanying Memorandum of Points and Authorities and proposed Order.

Dated this 9th day of October, 2020.

Respectfully submitted,

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Plaintiffs,	)	Case No. 1:20-cv-02045
v.	)	
UNITED STATES DEPARTMENT OF AGRICULTURE,	)	
Defendant.	)	

DEFENDANT'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF ITS MOTION TO DISMISS

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INTRODUCTION

The Food Safety and Inspection Service ("FSIS"), an agency of the Defendant U.S. Department of Agriculture ("USDA"), is charged with protecting consumer health and welfare by ensuring that poultry food products sold to consumers are safe and unadulterated. To that end, FSIS inspectors monitor poultry slaughterhouse operations, including the use of automated evisceration systems that process poultry at particular line speeds. In the mid-1990s, FSIS began an initiative to modernize its inspection systems by focusing agency resources on increased inspection verification activities of the establishment's food safety systems to reduce or prevent foodborne pathogens from reaching poultry processing lines and allowing volunteer slaughterhouses to take an active role in identifying and removing carcasses with food safety concerns before the FSIS post-mortem inspection, and the production of unadulterated poultry at faster line speeds. After the D.C. Circuit upheld this initiative, FSIS established the New Poultry Inspection System ("NPIS"). The NPIS is optional and sets the maximum processing line speed for participating poultry facilities at 140 birds per minute ("bpm").

In 2018, FSIS invoked that authority and issued instructions to its regulated community explaining the criteria and process under which it would consider applications from NPIS facilities for waivers from the 140 bpm limit (the "Waiver Criteria"). Facilities receiving waivers would be permitted to operate up to 175 bpm so that FSIS could collect data to assess the ability of these facilities to produce safe poultry products at higher line speeds to inform a possible future rulemaking, if supported. Starting in October, 2018, FSIS issued 53 waivers before announcing in March, 2020, that it would have sufficient data from those establishments and had stopped accepting new waiver applications.

Plaintiffs are five local labor unions and their affiliated international labor union representing workers at seven establishments that received waivers from FSIS allowing lines to operate at 175 bpm. Plaintiffs assert three claims under the Administrative Procedure Act ("APA"), alleging that the Waiver Criteria (1) should have been issued using APA notice-and-comment rulemaking procedures, (2) do not comply with FSIS's waiver regulation, and (3) are arbitrary and capricious.

Although Defendant believes that these claims lack merit, this Court need not reach them because Plaintiffs lack Article III standing. Plaintiffs allege that the Waiver Criteria, and the grants of waivers at the individual plants where their members work, increase the risk of injury to workers on poultry processing lines. In so alleging, Plaintiffs assert standing under the theory of an increased *risk* of injury, rather than any *actual* or imminent injury. This is not the first time that organizations have sought to challenge USDA's actions under the NPIS system based on an increased risk theory. In 2015, a group of plaintiffs sought to challenge the regulatory scheme based upon a theory that the inspection system created an increased risk of illness, supported by studies that supposedly showed such a causal connection. But the D.C. Circuit held that Plaintiffs had not met the high bar required for such a showing, which requires "both (i) a *substantially* increased risk of harm and (ii) a *substantial* probability of harm with that increase taken into account." *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 914 (D.C. Cir. 2015) ("*FWW*").

Plaintiffs have similarly failed to properly allege either element of that standard here. As an initial matter, Plaintiffs have not even attempted to identify a member of their organization that has allegedly been injured by USDA's issuance of waivers, which is a fundamental requirement in this Circuit. *See, e.g.*, *Am. Chemistry Council v. Dep't of Transp.*, 468 F.3d 810, 815 (D.C. Cir. 2006). The reason for that requirement is demonstrated by this very case, where Plaintiffs allege

that the risk of injury that they fear concerns workers "on the line." Dkt. 1 at 5, Compl. ¶ 19. But Plaintiffs have not identified any such members in their Complaint.

Even beyond the failure to identify a specific members, Plaintiffs cannot satisfy the twin requirements of alleging a substantial increase in the risk of injury and a substantial overall risk from increasing line speeds by 35 bpm. Plaintiffs do not plausibly allege that the speed increment at issue leads to any appreciable increase in risk, let alone a substantial one, and the documents they cite are either silent on the question or undermine Plaintiffs' position.

In the event this Court determines that Plaintiffs have established standing, it should nonetheless dismiss Plaintiffs' Complaint for failure to state a claim, because Plaintiffs are attempting to shoehorn their worker-safety claims into a statute concerned with the safety of food to consumers. The interest in worker safety they seek to vindicate in this suit is the province of the separate statutory and regulatory apparatus of the Occupational Safety and Health Administration ("OSHA"), andfalls outside the zone of interests of the statute governing FSIS's inspections of poultry slaughter plants.

BACKGROUND

I. FSIS'S IMPLEMENTATION OF THE NEW POULTRY INSPECTION SYSTEM

FSIS administers the Poultry Products Inspection Act ("PPIA"), 7 C.F.R. § 2.53(a)(2)(i), which was enacted in 1957 to protect consumers "by assuring that poultry products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged." 21 U.S.C. § 451. To that end, the PPIA requires, among other things, that USDA inspectors conduct a "post mortem inspection of the carcass of each bird processed" at slaughterhouses. *Id.* § 455(b). Establishments that slaughter or process poultry must be operated in accordance with the USDA's regulations setting forth sanitary practices and labeling requirements. 21 U.S.C. §§ 453(h), 456-57.

Most poultry slaughterhouses operate using an "automated evisceration system" that allows them to process poultry at a faster slaughter "line speed" than is possible when poultry is eviscerated by hand. Modernization of Poultry Slaughter Inspection, 77 Fed. Reg. 4,408, 4,410 (Jan. 27, 2012). FSIS had traditionally assigned its inspectors to slaughterhouse evisceration lines where they would physically inspect carcasses to detect signs of adulteration. *Am. Fed'n of Gov't Empls., AFL-CIO v. Veneman*, 284 F.3d 125, 127 (D.C. Cir. 2002) ("*AFGE II*"). But this approach of visually detecting animal diseases is not capable of detecting pathogens causing foodborne human illness that can be present in animals but not showing signs of a disease and thus cannot be detected visually. 77 Fed. Reg. at 4,411. As a result, in the mid-1990s, FSIS started a comprehensive food safety initiative that shifted the agency's resources to focus on preventing invisible foodborne pathogens, such as *Salmonella*. *AFGE II*, 284 F.3d at 127. The initiative also sought to create incentives for plants to detect and eliminate adulterated carcasses before they reach an FSIS inspector. *Id.*

As part of this initiative, FSIS started a pilot study called the "Hazard Analysis and Critical Control Point-Based Inspection Models Project" ("HIMP"), through which it designed and tested new inspection models using trials in volunteer poultry slaughter plants. *AFGE II*, 284 F.3d at 127; *see also* Petition to Permit Waivers of Maximum Line Speeds, 83 Fed. Reg. 49,048, 49,408 (Sept. 28, 2018). Under HIMP, industry personnel were given primary responsibility for sorting normal from abnormal poultry carcasses on the evisceration line before the carcasses are presented for inspection, while one FSIS inspector was stationed at the end of the line to inspect each bird processed and another offline inspector oversaw the plant's implementation of its food safety system. *AFGE II*, 284 F.3d at 127-28. In addition, because the carcasses presented to the online inspector had been sorted prior to inspection, participating young chicken HIMP plants were

permitted to operate at a line speed of up to 175 bpm. 77 Fed. Reg. at 4,411. The 20 young chicken plants that participated in HIMP demonstrated to FSIS that they could produce safe poultry while operating at the line speeds authorized under HIMP. *Id.*

In 2002, the U.S. Court of Appeals for the District of Columbia Circuit held that the HIMP did not violate the PPIA's requirement that FSIS inspect "the carcass of each bird processed." *AFGE II*, 284 F.3d at 130. Furthermore, the D.C. Circuit rejected the argument "that the line speeds used" by HIMP plants "are too fast," and instead found that they "are appropriate," given that "[f]ewer adulterated poultry carcasses . . . will be presented for federal inspection under the modified program . . . ." *Id.*

In 2014, based on data it collected from the 20 HIMP plants, FSIS established the New Poultry Inspection System, an optional inspection system for young chicken and all turkey slaughter establishments, modeled on HIMP. *See* Modernization of Poultry Slaughter Inspection, 79 Fed. Reg. 49,566 (Aug. 21, 2014). Under the NPIS, establishment personnel are primarily responsible for the online identification of abnormal carcasses. 79 Fed. Reg. at 49,567. This has allowed FSIS to "shift[] Agency resources to conduct more offline inspection activities that are more effective in ensuring food safety." *Id.* While one FSIS inspector remains at the end of each poultry line to inspect carcasses, "additional offline verification inspectors . . . check to see [] that inspection protocols are being followed and conduct pathogen testing." *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 916 (D.C. Cir. 2015) (citing 77 Fed. Reg. at 4,422).

As for the maximum line speed for young chicken facilities using NPIS, FSIS originally proposed 175 bpm, but ultimately decided to retain 140 bpm (except for the 20 former HIMP facilities, who were allowed to continue using 175 bpm) so that FSIS could assess facilities' ability to maintain process control as they transitioned to NPIS. 83 Fed. Reg. at 49,048; *see* 9 C.F.R. §

381.69(a). In its notice of final rulemaking, FSIS explained that after the implementation of the NPIS on a wide scale for at least a year, the agency would consider line speeds at which NPIS facilities are capable of consistently producing safe poultry. 83 Fed. Reg. at 49,049.

USDA's actions with respect to poultry inspections were again challenged in federal court by a group of plaintiffs who asserted that the NPIS would substantially increase the risk of foodborne illness by decreasing inspections. *FWW*, 808 F.3d at 914. The D.C. Circuit ultimately held that those plaintiffs lacked standing because they had not adequately alleged "that the NPIS *substantially* increases the risk of contracting foodborne illness compared to the existing inspection methods." *Id.* (emphasis added).[1]

II. FSIS's 2018 LINE-SPEED WAIVER CRITERIA AND ISSUANCE OF WAIVERS

In 2017, FSIS received a petition from the National Chicken Council asking the agency to use its authority under 9 C.F.R. § 381.3(b) to implement a new waiver system that would allow poultry facilities to apply to waive the 140 bpm limit and operate without any maximum line speed ("Petition"). 83 Fed. Reg. at 49,049. Under section 381.3(b), FSIS's Administrator has the authority to "waive . . . any provisions of the [poultry inspection] regulations in order . . . to permit experimentation so that new procedures, equipment, and processing techniques may be tested to facilitate definite improvements," so long as such waivers "are not in conflict with the purposes or provisions of the [PPIA]." FSIS posted the Petition on its website,[2] announced the availability of

[1] In 2016, the D.C. Circuit summarily affirmed the dismissal of a separate challenge to NPIS, holding that "*Food & Water Watch* forecloses this appeal." *Am. Federation of Gov't Employees, AFL-CIO v. Vilsack*, 672 Fed. Appx. 36, 38 (D.C. Cir. Nov. 1, 2016).

[2] *See* Letter from Michael J. Brown, President, National Chicken Council to Carmen Rottenberg, Acting Deputy Under Secretary for Food Safety, FSIS (Sept. 1,

the Petition in an October 13, 2017 Constituent Update, solicited comments from the public, and accepted such comments until December 13, 2017. 83 Fed. Reg. at 49,049.

After considering all timely comments, FSIS issued its response to the Petition on January 29, 2018. 83 Fed. Reg. at 49,049. In that response, FSIS denied the Petition's requests that the agency establish a new, separate waiver-request system to provide line-speed waivers and that the agency allow facilities to operate without a maximum line speed. *Id.* The response added, however, that "in the near future" FSIS would consider, under its already existing waiver procedures, requests for waivers to operate at line speeds of up to 175 bpm from facilities that could meet certain criteria. *Id.* at 49,049-50.

A month later, on February 23, 2018, FSIS issued a "Constituent Update" ("2018 Constituent Update") announcing those criteria, including the requirement that a facility must have been operating under the NPIS for at least one year to receive a waiver.[3] 83 Fed. Reg. at 49,050. FSIS also explained that because it would be "evaluat[ing] the establishment's ability to maintain process control" at speeds in excess of 140 bpm, facilities receiving waivers must consistently utilize the higher speeds. *Id.* at 49,051. The 2018 Constituent Update concluded by stating that

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2017),https://www.fsis.usda.gov/wps/wcm/connect/7734f5cf-05d9-4f89-a7eb-6d85037ad2a7/17-05-Petition-National-Chicken-Council-09012017.pdf?MOD=AJPERES.

[3] FSIS, Constituent Update, FSIS' Criteria for Consideration of Waiver Requests from Young Chicken Slaughter Establishments to Operate at Line Speeds Up to 175 Birds Per Minute (Feb. 23, 2018), https://www.fsis.usda.gov/wps/wcm/connect/ee977696-7f87-4b87-8717-15a824ce0a81/ConstiUpdate022318.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=ee977696-7f87-4b87-8717-15a824ce0a81

FSIS would provide additional information in a future Federal Register notice, which FSIS issued on September 28, 2018 ("2018 Notice"). *Id.* at 49,048. Among other things, the 2018 Notice stated that FSIS would use the data collected from establishments receiving waivers along with data from the 20 HIMP facilities "to assess the ability of NPIS establishments to maintain process control at higher line speeds and to inform future rulemaking, if supported." *Id.* at 49,052.

The 2018 Notice also responded in detail to issues raised by the more than 100,000 comments FSIS received in response to the Petition. 83 Fed. Reg. at 49,052-60. FSIS received comments from an array of groups, including Plaintiff United Food and Commercial Workers International Union ("UFCW"). *See* Dkt. 1 at 10, Compl. ¶ 43. UFCW's comment argued that eliminating line-speed restrictions would "put hard-working poultry workers at greater risk of being injured." *Id.* Other commenters "argued that FSIS could not grant the NCC Petition under existing regulations, that the petition was inconsistent with the agency's stated position on line speed in the Final Rule, and that the maximum line speed could not be changed without undertaking notice-and-comment rulemaking under the APA. *Id.* at 11, ¶ 44.

In October 2018, FSIS started issuing line-speed waivers. *See* FSIS Constituent Update, FSIS No Longer Accepting Poultry Line Speed Waivers (Apr. 24, 2020). [4] By the end of 2018, there were 23 facilities that were allowed to operate up to 175 bpm, and by the end of April 2020, FSIS had granted a total of 53 waivers. *Id.* On April 22, 2020, FSIS issued a Constituent Update stating that the agency had stopped accepting new waiver requests on March 20, 2020, because,

[4]Available at https://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings/newsletters/constituent-updates/archive/2020/ConstUpdate042420

"[b]ased on the waivers FSIS has approved, the agency will have enough data from establishments to assess and determine whether to move forward with rulemaking."

PROCEDURAL BACKGROUND

Plaintiffs are the United Food and Commercial Workers International Union and five of its affiliated local labor unions whose members work at poultry plants that have received waivers allowing line speeds of up to 175 bpm. Dkt. 1 at 1, 4; Compl. ¶¶ 14. On July 28, 2020, they filed their Complaint, alleging that the 2018 Constituent Update and the 2018 Notice (which Plaintiffs collectively call the "2018 Waiver Program" but which Defendants call the "Waiver Criteria"), as well as individual waivers granted by FSIS to poultry plants at which Plaintiffs' members work, are invalid under the APA.[5] Plaintiffs' first cause of action alleges that the Waiver Criteria constitute a legislative rule that should have been issued using the APA's notice-and-comment rulemaking procedures. *Id.* at 15–16, ¶¶ 76–78. Their second cause of action contends that the Waiver Criteria and the individual waivers are inconsistent with FSIS's regulation allowing it to

[5] Plaintiffs state that they are seeking to challenge "seven waivers granted by FSIS to poultry plants at which Plaintiffs' members work." Dkt. 1 at 1, Compl. ¶ 1. However, the Complaint appears to list waivers at ten plants at which Plaintiffs represent workers: Tyson Foods plants in Robards, Kentucky; Corydon, Indiana; Dardanelle, Arkansas; Noel, Missouri; and Forest Mississippi (FSIS Establishment Nos. P-19514, P-1241, P-72, P-1362, and P-164); and Wayne Farms plants in Laurel, Mississippi; Albertville, Alabama; Danville, Arkansas; Jack, Alabama; and Decatur, Alabama (FSIS Establishment Nos. P-519, P-1317, P-1009, P-7485, and P-1235). *See id.* at 2–4, ¶¶ 9-13. In any event, Plaintiffs do not raise any individualized challenges to any particular waiver; rather, they challenge the Waiver Criteria and the waivers granted under those criteria as a whole.

grant waivers, and are thus contrary to law. *Id.* at 16, ¶¶ 79–84. Their third cause of action alleges that the Waiver Criteria and the individual waivers are arbitrary and capricious for failing adequately to consider the risks to workers' health of increasing maximum line speeds at NPIS plants from 140 bpm to 175 bpm. *Id.* at 17, ¶¶ 85–90. Plaintiffs seek declaratory and injunctive relief. *Id.*, Prayer for Relief.

STANDARD OF REVIEW

On a motion to dismiss for lack of subject-matter jurisdiction under Rule 12(b)(1), "the party invoking federal jurisdiction bears the burden of establishing its existence." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 104 (1998). In considering a motion to dismiss for lack of subject matter jurisdiction, including for lack of standing, the Court may consider the records generally available to it on a motion to dismiss for failure to state a claim, namely "the facts alleged in the complaint, any documents either attached to or incorporated in the complaint and matters of which [the Court] may take judicial notice," *EEOC v. St. Francis Xavier Parochial School*, 117 F.3d 621, 624 (D.C. Cir. 1997). "[W]here necessary," however, for a jurisdictional motion to dismiss, the Court may also consider "the complaint supplemented by undisputed facts in the record, or the complaint supplemented by undisputed facts plus the court's resolution of disputed facts." *Herbert v. Nat'l Acad. of Scis.*, 974 F.2d 192, 197 (D.C. Cir. 1992).

To survive a motion to dismiss for failure to state a claim, a plaintiff must show that the complaint "contain[s] sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Zukerman v. USPS*, 961 F.3d 431, 441 (D.C. Cir. 2020) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)).

ARGUMENT

I. THE COURT SHOULD DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION BECAUSE PLAINTIFFS LACK STANDING

Article III of the Constitution restricts the jurisdiction of the federal courts to "cases" or "controversies," and the "core component of standing is an essential and unchanging part" of that requirement. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). To establish Article III standing, Plaintiffs must satisfy three elements: (1) injury-in-fact; (2) causation; and (3) redressability. *Lujan*, 504 U.S. at 560-61. "[E]ach element must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation." *Id.* at 561.

An organization seeking to invoke the jurisdiction of a federal court "can establish standing in one of two ways." *Public Citizen, Inc. v. Trump*, 297 F. Supp. 3d 6, 17 (D.D.C. 2018). "It can assert 'associational standing' to sue on behalf of its members." *Id.* (citing *Hunt v. Wash. State Apple Advert Comm'n*, 432 U.S. 333, 343 (1977)). "Or it can assert 'organizational standing' to sue on its own behalf." *Id.* (citing *People for the Ethical Treatment of Animals v. USDA*, 797 F.3d 1087, 1093 (D.C. Cir. 2015) ("*PETA*")). Plaintiffs have failed to alleged facts sufficient to satisfy either standard.

To sue on behalf of their members, Plaintiffs must first identify a specific member who would have standing to sue, which they have not done. Even if they had identified a specific member, moreover, the Complaint would still warrant dismissal because Plaintiffs' theory of injury from an increased risk of harm does not satisfy Article III. Nor can Plaintiffs rely on organizational standing, because nothing in the complaint supports any possible inference of harm to Plaintiffs themselves in their capacities as labor organizations.

A. Plaintiffs' Allegations Cannot Support Associational Standing

An association invoking federal jurisdiction on behalf of its members "must plausibly allege or otherwise offer facts sufficient to permit the reasonable inference (1) that the plaintiff has at least one member who 'would otherwise have standing to sue in [her] own right;' (2) that 'the interests' the association 'seeks to protect are germane to [its] purpose;' and (3) that 'neither the claim asserted nor the relief requested requires the participation of the individual members in the lawsuit.'" *Public Citizen*, 297 F. Supp. 3d at 17–18 (quoting *Hunt*, 432 U.S. at 343)). Two independent defects prevent the Complaint from satisfying the first element of that test, and require dismissal. First, Plaintiffs have failed to specifically identify any member who they allege would have standing to sue in his or her own right. Second, their allegations of an increased risk of injury from higher line speeds are inadequate, as a matter of law, to establish Article III standing.

1. Plaintiffs' Failure to Identify an Individual Member Requires Dismissal

The first element of the associational standing inquiry requires the Plaintiff to allege "that at least one specifically identified member has suffered an injury-in-fact." *Am. Chemistry Council v. Dep't of Transp.*, 468 F.3d 810, 815 (D.C. Cir. 2006). "[I]t is not enough to aver that unidentified members have been injured." *Chamber of Comm. of U.S. v. EPA*, 642 F.3d 192, 199 (D.C. Cir. 2011). Nor is it "enough to show . . . that [plaintiffs] are part of the industry being regulated by the [challenged agency action], [or] that there is a substantial likelihood that at least one member may have suffered an injury in fact." *Am. Chemistry Council*, 468 F.3d at 820.

The Complaint here cannot surmount this basic hurdle. Plaintiffs allege that their members work at poultry plants that have received waivers permitting faster line speeds, *see* Dkt. 1 at 2, 3–5; Compl. ¶¶ 1, 9–14, but nowhere does the Complaint identify any specific member allegedly injured by the Waiver Criteria, or by the grant of any particular waiver. Nor do Plaintiffs allege

that any particular member faces imminent injury from the challenged agency actions. The Complaint's mere allegation that Plaintiffs represent members who work on the poultry processing lines at certain plants that have received waivers, *see id.*, do not specifically identify any individual who has suffered, or imminently will suffer, any injury-in-fact from the Waiver Criteria or the grant of any particular waiver.

This is not simply a technical pleading failure. Without knowing which members have purportedly suffered harm, this Court cannot properly assess whether the allegations demonstrate a substantial likelihood of injury from an increased risk of harm. For example, Plaintiffs allege that "line workers . . ." are likely to be harmed by an increase in line speeds, but they do not identify any members at a plant that has received a waiver who work on the lines. Moreover, Plaintiffs do not explain whether these members have suffered harm in the months since their plants have been operating under the waivers. Without such individual allegations, this Court is left to speculate as to the organizational plaintiffs' concrete interest in this lawsuit.

2. Plaintiffs' Allegations Fail to Demonstrate a Substantial Likelihood of Injury

Even if Plaintiffs were to specifically identify a member working on a processing line subject to a waiver allowing speeds of up to 175 bpm, however, the Complaint would still fall short of alleging an Article III injury. Plaintiffs do not allege that any worker has suffered, or imminently will suffer, any concrete physical injury as the result of a waiver allowing for faster line speeds, even though they have allegedly been working at plants with increased line speeds for months (or in some cases almost a year). Instead, Plaintiffs allege that the waivers put their "members at substantially increased risk of injury." Dkt.1 at 15, Compl. ¶ 73. But the D.C. Circuit has emphasized that Article III requires a "very strict understanding of what increases in risk and overall risk levels" are sufficiently "substantial" to count as an injury-in-fact in their own right,

and Plaintiffs' allegations do not clear that bar. *Public Citizen, Inc. v. Nat'l Highway Traffic Safety Admin*, 489 F.3d 1279, 1296 (D.C. Cir. 2007).

An "injury-in-fact" must be "concrete and particularized," and "actual or imminent" rather than "conjectural" or "hypothetical." *Lujan*, 504 U.S. at 560. For that reason, both the Supreme Court and the D.C. Circuit have been clear that general allegations of an increased risk of injury are not sufficient to establish an injury-in-fact: "Allegations of possible future injury do not satisfy the requirements of Art[icle] III. A threatened injury must be certainly impending to constitute injury in fact." *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990). Nor can a plaintiff plead around this requirement by claiming that "the 'increased risk is *itself* concrete, particularized, and *actual* injury for standing purposes." *Public Citizen*, 489 F.3d at 1297. Instead, the D.C. Circuit has explained, "the proper way to analyze an increased-risk-of-harm claim is to consider the ultimate alleged harm—such as death, physical injury, or property damage from car accidents—as the concrete and particularized injury and then to determine whether the increased risk of such harm makes injury to an individual citizen sufficiently 'imminent' for standing purposes." *Id.* at 1298.

The D.C. Circuit thus requires plaintiffs alleging "the possibility of increased-risk-of-harm" to show "*both* (i) a *substantially* increased risk of harm and (ii) a *substantial* probability of harm with that increase taken into account." *Id.* at 1295 (emphasis in original). To satisfy this "two-part analysis," Plaintiffs must demonstrate "(1) that the [waivers] substantially increase[] the risk of [physical injury] compared to existing [line-speed restrictions], and (2) a substantial probability that the [Plaintiffs'] members will [suffer a physical injury] given that increase of risk." *Food & Water Watch*, 808 F.3d at 915 (applying two-part test to risk of contracting foodborne illness).

The D.C. Circuit's decision in *Food & Water Watch* illustrates the "careful examination of Plaintiffs' allegations" that this analysis requires. *Id.* There, Plaintiffs had submitted detailed allegations about the differences between the NPIS and the existing poultry inspection systems, and outlining alleged flaws in the NPIS, but those allegations were insufficient to demonstrate a "substantial" increase in risk compared to existing inspection systems. *Id.* The *Food & Water Watch* plaintiffs alleged that NPIS would reduce the number of "online federal inspectors," and that each inspector would be less "effective in identifying adulterated poultry," but they failed to account for "the increase in offline inspections" under NPIS. *Id.* at 916. As a result, they failed to plausibly allege that "NPIS inspection *as a whole*" would be "*worse* than what plants do under existing inspection systems." *Id.* The court likewise faulted the plaintiffs' "isolated statistics" showing "higher" rates of *Salmonella*, when "the complaint does not specify how much higher the rates were." *Id.*

The Complaint falls well short of the "very strict" standard for alleging either (1) a "*substantial*" increase in the risk of harm, or (2) a substantial likelihood that Plaintiffs themselves would suffer harm. *FWW*, 808 F.3d at 915. Plaintiffs' allegations do not demonstrate that the purported increase in the overall risk of harm to workers is substantial. Although Plaintiffs generally allege that increased line speeds correlate with increased rates of injury, *see generally* Dkt. 1 at 4–9, ¶¶ 16–37, they make no effort to allege either (i) that increasing line speed to 175 bpm from 140 bpm leads to a *substantial* increase in risk of injury, or (ii) that the overall risk of injury at 175 bpm is itself *substantial*. Plaintiffs' failure to allege either a substantial increase or a substantial overall risk is particularly striking in light of the experience of the 20 plants in the HIMP program, which have been authorized to operate at 175 bpm for many years, *see id.* at 9, ¶

35, not to mention Plaintiffs' and their members' own experience in plants that applied for waivers as early as eight months before Plaintiffs filed their Complaint, *id.* at 14, ¶ 67.

Plaintiffs here are in precisely the same position as their counterparts in *Food & Water Watch*: At most, the Complaint alleges "higher" rates on injury at higher line speeds, but it does not even attempt to specify how much higher when the increase is limited to 35 bpm, leaving this Court with no way to determine whether the alleged increase, or the resulting overall risk level, is sufficiently "substantial" so satisfy the standing requirement.

The documents Plaintiffs cite, like the studies in Food and Water Watch, do not overcome this deficiency; indeed, the only one that discusses the actual experience of workers at a poultry plant that increased line speed to 175 bpm found no effect on worker health or injury rates. Plaintiffs cite four documents in their discussion of "poultry processing and worker safety." Dkt. 1 at 4–7, ¶¶ 16–24. Two of those documents say nothing at all about line speed, and thus cannot possibly establish that the particular speed increase at issue here causes a "substantial" increase in risk. *See id.*, ¶ 20 (citing Memo from Thomas Galsassi, Director Directorate of Enforcement Programs, Occupational Health and Safety Admin. (Oct. 28, 2015)[6]; OSHA Regional Instruction, Region IV, Directive No. CPL-2 02-02-030A (October 1, 2019)).[7] Another generally discusses the dangers of increased "work speed," but notes that "[w]ork speed is a combination of two facts, *line* speed and staffing," and does not make any effort to assess the particular increase in risk from

[6] Available at https://www.osha.gov/dep/enforcement/poultry_processing_10282015.html (last visited October 7, 2020).

[7] Available at https://www.osha.gov/sites/default/files/enforcement/directives/CPL_2_02-02-030A.pdf (last visited October 7, 2020)

increasing line speeds from 140 bpm to 175 bpm. Human Rights Watch, *When We're Dead and Buried, Our Bones Will Keep Hurting: Workers' Rights Under Threat in Meat and Poultry Plants*, at 49 (emphasis added).[8]

The final document Plaintiffs cite, a letter from the Director of the National Institute for Occupational Safety and Health ("NIOSH"), does discuss the experience of one poultry processing plant before and after changing from two lines at 90 bpm to one line at 175 bpm. *See* Letter from John Howard, Director, NIOSH, to Alfred V. Almanza, Administrator, FSIS (Apr. 7, 2014).[9] That letter noted "an alarming 42% prevalence of carpal tunnel syndrome (CTS) in exposed workers" in "its evaluation of the plant *before* any production line speed changes had occurred." *Id.* (emphasis added). But NIOSH inspectors observed "no change in exposure to repetitive and forceful motions for any individual worker" when it returned *after* the plant increased its line speed, and they found that "the changes made by the plant to production line speed did not result in an increase in production volume for the individual worker or the plant." *Id.* Overall, NIOSH concluded that "no conclusion can be drawn regarding the effect of line speed changes and health status." *Id.*

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[8] Available at https://www.hrw.org/sites/default/files/report_pdf/us0919_web.pdf (last visited October 7, 2020).

[9] Available at https://www.cdc.gov/niosh/topics/poultry/pdfs/LTR.Almanza.7.April_.2014.pdf (last visited October 7, 2020). The NIOSH letter does not specify the lines speeds that NIOSH observed, but it does cite a blog post by the FSIS Administrator that notes the speeds, available at https://www.usda.gov/media/blog/2014/03/26/food-safety-and-worker-safety-can-improve-poultry-facilities (last visited October 7, 2020).

Just as the plaintiffs in *Food & Water Watch* failed to account for the role of offline inspectors in the NPIS, and so failed to adequately allege that the system as a whole created a substantial increase in risk, Plaintiffs here have failed to account for the changes that plants can make to their production lines to accommodate greater speeds, such as changes to staffing levels, layout, and equipment, which the NIOSH letter shows can keep the overall level of exposure to repetitive and forceful motions for each worker steady. As a result, Plaintiffs have failed sufficiently to allege that the overall effect of the increased line speeds allowed by the waivers is to substantially increase the risk of injury, or even to increase that risk at all.

In short, Plaintiffs have not plausibly alleged that increasing line speeds from 140 bpm to 175 bpm creates a substantial increase in the risk of injury, let alone a substantial increased risk to their members, and the only document they cite with directly relevant empirical evidence found no such increase. Plaintiffs have thus failed to allege an injury-in-fact, and this Court should dismiss the Complaint for lack of standing.

B. Plaintiff's Allegations Cannot Support Organizational Standing

Organizations such as Plaintiffs may also invoke Article III jurisdiction in their own capacities, subject to the same requirements of injury-in-fact, causation, and redressability as individuals. *See, e.g.*, *PETA*, 717 F.3d at 1093. To show an injury-in-fact, an organization must allege a "concrete and demonstrable injury to [its] activities"; a "mere setback to [its] abstract social interests is not sufficient." *Id.* (quoting *Equal Rights Ctr. v. Post Props, Inc.*, 633 F.3d 1136, 1138 (D.C. Cir. 2011)). Although "standing is not precluded" when "the plaintiff is not [it]self the object of the government action or inaction [it] challenges," it is "substantially more difficult" to establish. *Lujan*, 504 U.S. at 562.

An organization can establish an injury-in-fact by alleging a "concrete and demonstrable injury to the organization's activities" that is "more than simply a setback to the organization's abstract social interests." *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982). But there are "two important limitations on the scope of standing under *Havens*." *Am. Soc'y for the Prevention of Cruelty to Animals v. Feld Entm't, Inc.*, 659 F.3d 13, 25 (D.C. Cir. 2011). "First, an organization seeking to establish *Havens* standing must show a 'direct conflict between the defendant's conduct and the organization's *mission*.'" *Id.* (quoting *Nat'l Treasury Emps. Union v. United States*, 101 F.3d 1423, 1430 (D.C. Cir. 1996)). Second, the organization must show that it has "used its resources to counteract that injury." *Id.*

As the Supreme Court has explained, the mere "deprivation of a procedural right without some concrete interest that is affected by the deprivation—a procedural right *in vacuo*—is insufficient to create Article III standing." *Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009). "There is no doubt, for example, that a plaintiff that is able to establish that an agency failed to comply with the notice and comment procedures of the APA would, nonetheless, have no recourse in an Article III court absent a showing that it suffered or will suffer a concrete injury as a result of policy produced through the allegedly flawed process." *California v. Trump*, --- F. Supp. 3d ---, 2020 WL 1643858, at *7 (D.D.C. Apr. 2, 2020) (citing *Swanson Grp. Mfg. LLC v. Jewell*, 790 F.3d 235, 244–46 (D.C. Cir. 2015)). To succeed in a procedural injury claim, a plaintiff must sufficiently allege a causal link connecting the omitted procedural step "to some substantive government decision that may have been wrongly decided because of the lack" of that procedural step, and a distinct causal link "connecting that substantive decision to the plaintiff's particularized injury." *Ctr. for Biological Diversity v. EPA*, 861 F.3d 174, 184 (D.C. Cir. 2017).

Plaintiffs do not appear to make any attempt in the Complaint to allege an organizational harm, and for good reason. Nothing in the Complaint establishes any concrete injury to the Plaintiffs *in their own rights* from increased line speeds. The only injuries mentioned in the Complaint are physical injuries, which can harm individual workers but not the organization to which they may belong, such as the Plaintiffs here. Plaintiffs thus cannot show any direct injury that they suffer, or imminently will suffer, as organizations from the Waiver Criteria or any individual waiver.

Nor does the Complaint suffice to establish organizational standing under *Havens*. Plaintiffs do not make any allegations about their organizational missions, beyond alleging that each Plaintiff "is a labor organization." Dkt. 1 at 2–3, Compl. ¶¶ 9–14. Nor does the Complaint make any allegations that the Waiver Criteria or the grant of any individual waiver has affected any Plaintiff's mission in any way, or that any Plaintiff has made any allocation of resources in response to the Waiver Criteria or the grant of any waiver.

Because Plaintiffs have failed to sufficiently allege any concrete injury-in-fact to themselves as organizations, they cannot rely on the alleged violation of the APA's notice and comment requirements alone to establish standing: Without any allegation of a concrete interest of Plaintiffs' that that procedural requirement might protect, any failure to proceed through notice-and-comment rulemaking amounts to no more than a procedural injury "*in vacuo*," and cannot establish standing.

II. THE COURT SHOULD DISMISS FOR FAILURE TO STATE A CLAIM BECAUSE PLAINTIFFS' ALLEGED INJURIES FALL OUTSIDE THE PPIA'S ZONE OF INTERESTS

Even if Plaintiffs could establish standing, the Court should nevertheless dismiss the Complaint for failure to state a claim. The APA restricts the claims that plaintiffs challenging administrative action can bring to those within the "zone of interests" of the statute at issue. The

PPIA, which establishes FSIS's inspection regime, is concerned with ensuring that poultry *products* are safe for *consumers*. Plaintiffs seek to vindicate their distinct interest in ensuring that poultry *plants* are safe for *workers*. But Congress established a separate statutory and regulatory regime to see to that interest, under the auspices of the Occupational Health and Safety Administration ("OSHA"). Plaintiffs' claims thus fall beyond the PPIA's zone of interests, and therefore beyond their ability to vindicate through the APA.

To state a claim under the APA, a plaintiff has the burden to show that "[t]he interest he asserts [is] arguably within the zone of interests to be protected or regulated by the statute that he says was violated." *Match-E-Be-Nash-She Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 224 (2012). The "zone of interests" test thus serves "as a limitation on the cause of action for judicial review conferred by the [APA]." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 129 (2014). "Protected interests are ones asserted either by 'intended beneficiaries' of the statute at issue or by other 'suitable challengers'—*i.e.*, parties whose interests coincide 'systemically, not fortuitously' with those of the intended beneficiaries." *Twin Rivers Paper Co. LLC v. SEC*, 934 F.3d 607, 616 (D.C. Cir. 2019) (quoting *Hazardous Waste Treatment Council v. Thomas*, 885 F.2d 918, 921–22 (D.C. Cir. 1989) ("*HWTC*")).

Plaintiffs challenge FSIS's actions under its waiver regulation, which authorizes FSIS to grant waivers to "permit experimentation so that new procedures, equipment, and processing techniques may be tested to facilitate definite improvements." 9 C.F.R. § 381.4(b). Plaintiffs allege that FSIS (1) acted contrary to law when it "d[id] not consider the increased risk to workers in evaluating improvement," Dkt. 1 at 16, Compl. ¶ 82, and (2) acted arbitrarily and capriciously when it "failed to consider the risks to workers' health of increasing the maximum line speed at NPIS establishments from 140 bpm to 175 bpm," *id.* at 17, ¶ 88.

Because Plaintiffs' claims fall outside the zone of interests of the PPIA, dismissal pursuant to Rule 12(b)(6) is warranted. Congress articulated the interests it intended to protect with the PPIA in the "Congressional statement of findings" in 21 U.S.C. § 451, and the "Congressional declaration of policy" in 21 U.S.C. § 452. There, Congress explained that "[i]t is essential in the public interest that the health and welfare *of consumers* be protected by assuring that poultry products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged," 21 U.S.C. § 451 (emphasis added), and that it is "the policy of the Congress to provide for the inspection of poultry and poultry products . . . to prevent the movement or sale in interstate or foreign commerce of . . . poultry products which are adulterated or misbranded," *id.* § 452. Likewise, the inspection provision of the PPIA provides for ante- and post-mortem inspection of poultry products "[f]or the purposes of preventing the entry into or flow or movement in commerce of . . . any poultry product which is capable of use as human food and is adulterated . . ." *Id.* § 455. That provision goes on to require the "condemnation" and "destr[uction] for human food purposes" of "[a]ll poultry carcasses and parts thereof and other poultry products found to be adulterated." *Id.* The unmistakable implication of those sections, taken singly or as a whole, is that Congress intended to protect the safety *of consumers of poultry products*. Workers in poultry plants are thus not the intended beneficiaries of the PPIA. *Cf., e.g.*, *Twin Rivers Paper Co.*, 934 F.3d at 617 ("sellers of paper . . . are not intended beneficiaries of the securities laws."). Instead, Congress has separately empowered OSHA with the statutory and regulatory authority to promulgate regulations regarding workplace health and safety. *See generally* 29 U.S.C. § 651 *et seq.* Indeed, Plaintiffs themselves rely on OSHA documents to substantiate their allegations regarding the risks of musculoskeletal problems among poultry workers. *See* Dkt. 1 at 5–6, Compl. ¶¶ 20–21.

Nor do the interests of poultry plant workers "systemically coincide" with those of poultry product consumers. The D.C. Circuit has explained that a group's interests do not systemically coincide with those of a statute's intended beneficiaries when the group would urge a particular regulatory priority "whether the effect on [the intended beneficiaries was] good, bad, or indifferent." *Twin Rivers Paper Co.*, 934 F.3d at 617 (quoting *HWTC*, 885 F.2d at 924–25). Thus, waste treatment facilities, which would always "stand to profit" from stricter regulation, could not challenge allegedly lax regulations under the Resource Conservation and Recovery Act because "overly stringent regulation might sometimes harm environmental interests." *Id.* Likewise, representatives of the paper industry could not challenge securities regulations permitting companies to post shareholder reports online. *Id.* The same is true here: There is no reason to believe that Plaintiffs' "unqualified preference" for greater worker safety measures "systemically aligns" with the interests of consumers in the safety of poultry products. *Id.* The Complaint itself, which does not mention any effect of the Waiver Criteria or any individual waiver on *consumer* safety, neatly illustrates this point. Because they are neither the intended beneficiaries of the PPIA, nor systemically aligned with the interests of those intended beneficiaries, Plaintiffs may not seek APA review for alleged violations of the PPIA.

CONCLUSION

For the foregoing reasons, the Court should dismiss the Complaint pursuant to Rule 12(b)(1) and Rule 12(b)(6) of the Federal Rules of Civil Procedure.

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Respectfully submitted,

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