In the United States Court of Federal Claims

No. 24-365

(Filed under seal: June 27, 2024)
(Reissued: July 15, 2024)

AIRBOSS DEFENSE GROUP, LLC,	)
Plaintiff,	)
and	)
STRING KING LACROSSE LLC,	)
Plaintiff-Intervenor,	)
v.	)
UNITED STATES,	)
Defendant,	)
and	)
NEW YORK EMBROIDERY STUDIO, INC.	)
Defendant-Intervenor.	)

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AUTHENTICATED U.S. GOVERNMENT INFORMATION GPO

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OPINION AND ORDER[1]

LETTOW, Senior Judge.

Plaintiff, AirBoss Defense Group, LLC ("AirBoss"), and plaintiff-intervenor, StringKing Lacrosse LLC ("StringKing") bring this bid protest against defendant, the United States of America, acting by and through the U.S. Department of Health and Human Services, Administration for Strategic Preparedness and Response ("the government" or "HHS" or "the agency"), and defendant-intervenor, New York Embroidery Studio, Inc. ("NYES"). The bid protest concerns a solicitation for personal protective equipment ("PPE") in the form of Level 2 Isolation Gowns (the "solicitation" or "RFP"), which was initially issued on June 28, 2022. AR 266-67, 277, ECF No. 48.[2]

This protest is before the court on plaintiff-intervenor's application for a temporary restraining order and motion for a preliminary injunction. Pl.-Intervenor's App. for a TRO and Mot. for a Prelim. Inj. ("Pl.-Intervenor's Mot."), ECF No. 54; Pl.-Intervenor's Mem. in Supp. of Pl.-Intervenor's Mot. ("Pl.-Intervenor's Mem."), ECF No. 54-1. Plaintiff-intervenor asks this court to prohibit HHS from proceeding with the solicitation at issue until the court resolves this bid protest on the merits.

FACTS[3]

AirBoss initiated this action on March 7, 2024, Compl., ECF No. 1, and filed its first amended complaint on March 25, 2024, First Am. Compl., ECF No. 26. StringKing sought intervention on April 12, 2024, which the court granted the same day. Order Granting Mot. to Intervene, ECF No. 30. StringKing then filed its initial complaint on April 23, 2024. Pl.-Intervenor's Compl., ECF No. 37. In the interim, the court on April 29, 2024, granted a request by the government to suspend future deadlines in this case—while HHS completed corrective action at the agency-level—to avoid the possibility of premature adjudication by this court. Order Suspending Future Deadlines, ECF No. 39. Thereafter, the court granted a joint motion

[1] Because of the protective order entered in this case, this opinion was initially filed under seal. The parties were requested to review the decision and provide proposed redactions of confidential or proprietary information. Redactions are shown by asterisks enclosed by brackets, *e.g.*, "[***]."

[2] Aside from page numbers 1045, 1046, 1048, 1049, and 1055 being inadvertently duplicated, the administrative record is consecutively paginated and will be cited as "AR __."

[3] The following recitations constitute findings of fact by the court, based on the administrative record of this procurement, filed pursuant to Rule 52.1(a) of the Rules of the Court of Federal Claims ("RCFC"). *See Bannum, Inc. v. United States*, 404 F.3d 1346, 1357 (Fed. Cir. 2005).

brought by plaintiffs to partially reinstate the deadlines in this case to allow for filing the administrative record. Order of May 6, 2024, Granting Mot. to Amend Sched., ECF No. 42. Thereafter, AirBoss filed its second amended complaint on June 11, Second Am. Compl., ECF No. 51, and StringKing filed its first amended complaint on June 12. Pl.-Intervenor's First Am. Compl., ECF No. 52.

This protest concerns a solicitation initially issued on June 28, 2022, for "ANSI [American National Standards Institute]/AAMI [Association for the Advancement of Medical Instrumentation] Level 2 Disposable Isolation Gowns Manufactured in the U.S. or its Outlying Areas." AR 277. The solicitation's stated purpose was to create a strategic national stockpile of disposable medical isolation gowns, to "enable the United States to ensure sufficient domestic availability of such items during national emergencies and/or pandemic events." AR 277. To this effect, the solicitation set out four factors—technical compliance, technical capability, similar experience, and price evaluation. AR 313. The technical capability factor had eight subfactors, one of which was shelf life. AR 313. Primarily at issue in this motion are the second and fourth factors—technical capability and price, respectively—as well as the agency's overall source selection process.

Offerors first submitted their proposals under the solicitation in November of 2022, and on September 25, 2023, HHS awarded a single contract to defendant-intervenor, NYES. AR 1344-47. In the following days, AirBoss, StringKing, and others received Unsuccessful Offeror Notices indicating their proposals had not been selected. AR 1380-1415. The following month, starting on October 2, 2022, six contractors, including AirBoss and StringKing, brought protests at the Government Accountability Office ("GAO") challenging HHS's award. *See* AR 1438-39, 1457, 1499. As a result of these protests, HHS issued a stop work order to NYES on October 5, 2023. AR 1437.

On October 27, 2023, HHS issued a Notice of Corrective Action and Request for Dismissal, which determined that HHS would, among other things, reconsider its technical evaluation of proposals and render a new source selection decision. AR 1628-29. On November 3, 2023, the GAO dismissed AirBoss's and StringKing's protests as academic. *See, e.g.*, AR 1636-37, 1646-47. On January 3, 2024, HHS finalized its competitive range determination, and on February 16, 2024, it issued Amendment 0008. *See* Def.'s Suppl. Resp. Ex. B, at 3, ECF No. 63-1; AR 1916-22. Amendment 0008, among other things, states that "[t]here is no evaluation factor providing a preference for longer or shorter shelf-life gowns." AR 1920.

Following another GAO protest, HHS issued a new Notice of Corrective Action and Request for Dismissal of StringKing's protest on March 26, 2024, which indicated the agency would, among other things, terminate the contract award to NYES, cancel the solicitation in its entirety, and reconsider its requirements. AR 2253. On April 9, 2024, after the GAO dismissed StringKing's protest, AR 2011-13, HHS issued a Revised Notice of Corrective Action and Request for Dismissal of StringKing's protest, in which the agency indicated that instead of canceling the solicitation it would now be reviewing and reconsidering its requirements under the solicitation, reconsidering its competitive range decisions, issuing an amendment "revising the current shelf-life requirements, engaging in discussions as needed and soliciting complete

revised final proposal revisions," and making a new award decision. Pl.-Intervenor's First Am. Compl. Ex. E, ECF No. 52-5.

Throughout this procurement, amendments to the solicitation have altered the role shelf life would play in the government's decision. The original solicitation stated, with respect to the technical capability factor, that "[t]he [g]overnment's overall best value determination will consider the cost of the product as it relates to the shelf-life at the time of delivery and the best value determination will also consider the time, effort, and cost to sustain product with lesser shelf-life." AR 163. On October 31, 2022, the agency issued Amendment 0005. AR 269-318. The corresponding portion of Amendment 0005 removes this language from Factor 2, subfactor 6, shelf life, and moves it to Factor 4: price. AR 316-317. As a result, Factor 4, price, contains the language that formerly appeared in the shelf-life subfactor, and the revised shelf life subfactor indicates that "[o]fferors' proposals will be evaluated to determine whether the product meets the shelf life requirements of this solicitation," and that "[a]t the time of delivery, product shall have no more than 20% of total shelf-life expended." AR 316. Additionally, the agency issued Amendment 0008 on February 16, 2024, which removed from Factor 4 (price) the shelf-life language quoted above. AR 1917.

At issue in the currently pending motion are Amendment 0009, which was issued on May 31, 2024, Pl.'s Second Am. Compl., Ex. 1 ("Amend. 0009"), ECF No. 51-1, and Amendment 0011, which was issued on June 14, 2024. Pl.'s Resp. Ex. 1 ("Amend. 0011"), ECF No. 57-1.[4] Among other things, Amendment 0009 purportedly reinstates shelf-life considerations that had been removed into the solicitation's requirements. Amend. 0009 at 2, 16, 44, 46, and 53. Specifically, Amendment 0009 establishes a three-year shelf life. Amend. 0009 at 16, 44, 46. Amendment 0009 required offerors within the competitive range to submit new proposals by June 17, 2024. Amend. 0009 at 2.

Amendment 0009 and Amendment 0011 contain changes to a few main aspects of the solicitation. First, while the solicitation previously stated its purpose that "the Government is attempting to increase the availability of domestically produced compliant PPE. This will enable the United States to ensure sufficient domestic availability of such items during national emergencies and/or pandemic events," the amended solicitation does not contain this language. *Compare* AR 277, *with* Amend. 0009 at 10, *and* Amend. 0011 at 6. Amendment 0009 does, however, state that stockpiled assets "are designed to supplement state and local medical supplies and equipment during public health emergencies." Amend. 0009 at 10. And Amendment 0011 clarifies "the purpose of the solicitation [is] . . . to procure domestically manufactured [gowns] used in healthcare settings to protect healthcare workers during public health emergencies," and that "the timing of these [emergencies] cannot be predicted." Amend. 0011 at 3-4. Second, while Factor 2 (technical capability), subfactor 6 (shelf life) of the solicitation previously stated that "[o]fferors' proposals will be evaluated to determine whether the product meets the shelf life requirements of this solicitation," the amended solicitation does not contain this language and

[4] Amendment 0009 and Amendment 0011 are consecutively paginated, and are exhibited by more than one party, to more than one of the briefings at issue before the court. As such, for the sake of clarity, the court sites to these amendments by name rather than by exhibit letter or number.

instead states that "[a] shelf life longer than 3 years will not be evaluated higher or considered to be an additional strength," and that "[o]fferor's proposals will be evaluated based on providing [a] signed certified manufacturer statement." *Compare* AR 316, *with* Amend. 0009 at 53, *and* Amend. 0011 at 6. Additionally, the amended solicitation requires that "at the time of delivery to the [stockpile], isolation gowns shall have no more than 3 months expended since the date of manufacture, as listed on the gown packaging labels." Amend. 0009 at 16; *see also* Amend. 0011 at 8 (containing relevantly similar language). Finally, with respect to Factor 4 (price), while the solicitation previously stated that "[t]he [g]overnment's overall best value determination will consider the cost of the product as it relates to the shelf-life at time of delivery and the best value determination will also consider the time, effort, and cost to sustain product with lesser shelf-life," the amended solicitation does not contain this language. *Compare* AR 317, *with* AR 1917, Amend. 0009 at 54, *and* Amend. 0011.

Since the issuance of Amendment 0009, StringKing and AirBoss have sought to extend the due date for proposals. *See* Pl.-Intervenor's Mem. Ex. F, ECF No. 54-7. When StringKing filed the currently pending motion on June 13, 2024, there was no clear indication that HHS would be extending the proposal deadline. *See id.* at 1. The following day, the government filed its response to plaintiff-intervenor's application for a temporary restraining order and motion for a preliminary injunction and indicated that HHS had issued Amendment 0011 that same day. Def.'s Resp. to Pl.-Intervenor's Mot. ("Def.'s Resp.") at 1, ECF No. 56. That same day, AirBoss filed its response in support of plaintiff-intervenor's application for a temporary restraining order and motion for a preliminary injunction. Pl.'s Resp., ECF No. 57. Among other things, Amendment 0011 extends the proposal deadline until June 28, 2024. Amend. 0011 at 2.

On June 14, 2024, this court held a motion hearing on plaintiff-intervenor's motion for preliminary injunctive relief. Hr'g Tr., ECF No. 65. During that hearing, the parties agreed to a supplemental briefing schedule with respect to plaintiff-intervenor's initial motion. *See* Scheduling Order of June 14, 2024, ECF No. 58. The parties completed briefing in accordance with that schedule. Pl.'s Suppl. Resp. in Supp. of Pl.-Intervenor's Mot. ("Pl.'s Suppl. Resp."), ECF No. 60; Pl.-Intervenor's Suppl. Pleading in Supp. of its Mot. ("Pl.-Intervenor's Suppl. Mot."), ECF No. 61; Def.'s Suppl. Resp. to Pl.-Intervenor's Mot. ("Def.'s Suppl. Resp."), ECF No. 63; Def.-Intervenor's Suppl. Resp. to Pl.-Intervenor's Mot. ("Def.-Intervenor's Suppl. Resp."), ECF No. 62. On June 25, plaintiff and plaintiff-intervenor sought leave to file replies in support of plaintiff-intervenor's motion, and the court granted such leave the following day. *See* Order of June 26, 2024, ECF No. 69; Pl.-Intervenor's Reply in Supp. of Pl.-Intervenor's Mot. ("Pl.-Intervenor's Reply"), ECF No. 70; Pl.'s Reply in Supp. of Pl.-Intervenor's Mot. ("Pl.'s Reply"), ECF No. 71. Accordingly, the motion is fully briefed and ready for disposition.

STANDARDS FOR DECISION

The Tucker Act provides this court subject matter jurisdiction over cases involving "an interested party objecting to a solicitation by a Federal agency for bids or proposals for a proposed contract . . . or any alleged violation of statute or regulation in connection with a procurement or a proposed procurement." 28 U.S.C. § 1491(b)(1). The party bringing the bid protest "bears the burden of establishing standing." *CliniComp Int'l, Inc. v. United States*, 904 F.3d 1353, 1358 (Fed. Cir. 2018). Under 28 U.S.C. § 1491(b), a party has standing to bring a bid

protest if it is an "interested party" who was prejudiced by a "significant error in the procurement process," meaning that "'*but for the error*, [the interested party] would have had a substantial chance of securing the contract.'" *Id.* (quoting *Labatt Food Serv., Inc. v. United States*, 577 F.3d 1375, 1378 (Fed. Cir. 2009)).

The Tucker Act empowers this court in a bid protest matter to award "any relief that it considers proper, including injunctive relief." *Veterans Contracting Grp., Inc. v. United States*, 133 Fed. Cl. 613, 621 (2017) (citing 28 U.S.C. § 1491(b)(2)). Rule 65 of the Rules of the Court of Federal Claims ("RCFC") guides this court in fashioning preliminary injunctions and temporary restraining orders. "[T]he factors considered in ruling on a temporary restraining order mirror those on motions for a preliminary injunction." *Acetris Health, LLC v. United States*, 137 Fed. Cl. 148, 152 (2018) (quoting 11A Charles A. Wright et al., Federal Practice and Procedure § 2951 (3d ed. 2013)).

In assessing whether emergency injunctive relief is appropriate, the court weighs four factors: "(1) whether plaintiff is likely to succeed on the merits of the case; (2) whether plaintiff will suffer irreparable harm if the [c]ourt withholds injunctive relief; (3) whether the balance of hardships to the respective parties favors the grant of injunctive relief; and (4) whether it is in the public interest to grant injunctive relief." *Loch Harbour Grp., Inc. v. United States*, 128 Fed. Cl. 294, 300 (2016). "Although the factors are not applied mechanically, a movant must establish the existence of both of the first two factors to be entitled to" emergency injunctive relief. *Altana Pharma AG v. Teva Pharm. USA, Inc.*, 566 F.3d 999, 1005 (Fed. Cir. 2009) (citing *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001)).

ANALYSIS

StringKing seeks an emergency injunction prohibiting HHS from moving forward with the solicitation at issue until this court adjudicates this bid protest on the merits. Pl.-Intervenor's Mot. at 1. StringKing avers that preliminary injunctive relief is appropriate because it will likely succeed on the merits of its claims, it will suffer immediate, irreparable harm absent such relief, the balance of hardships leans in its favor, and such relief lies in the public interest. *See* Pl.-Intervenor's Mem. at 15-21; Pl.-Intervenor's Suppl. Mot. at 10-19. AirBoss concurs that StringKing satisfies all four elements favoring preliminary injunctive relief, including in light of Amendment 0011 and its extension of the proposal deadline. *See generally* Pl.'s Resp.; Pl.'s Suppl. Resp.

At issue are four changes present in Amendment 0009, as extended by Amendment 0011, related to shelf-life. First, the solicitation's purpose is to secure "disposable medical Isolation Gowns used in healthcare settings," instead of the more specific purpose of resupplying the Strategic National Stockpile in preparation for national emergencies. *Compare* AR 277, *with* Amend. 0009 at 10. Second, the solicitation no longer assigns strengths to products with a longer shelf life. *Compare* AR 163, *with* Amend. 9 at 53, 54. Third, the solicitation removes the consideration of shelf life from the agency's price evaluation. *Compare* AR 317, *with* Amend. 0009 at 54. Fourth, as a result, the solicitation no longer requires HHS to consider shelf life in making its best value determination. *Compare* AR 317-18, *with* Amend. 0009 at 54.

A. Likelihood of success on the merits

To qualify for emergency injunctive relief, StringKing must first establish that it is "more likely than not" to prevail on the merits of its claim. *See Revision Mil., Inc. v. Balboa Mfg. Co.*, 700 F.3d 524, 525-26 (Fed. Cir. 2012). To prevail on the merits in a bid protest, a plaintiff must show, pursuant to the standard set forth in the Administrative Procedure Act, that the agency has acted in a manner that was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); 28 U.S.C. § 1491(b)(4). In this context, agency action is arbitrary and capricious if the agency has "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or [the decision] was so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *BINL, Inc. v. United States*, 106 Fed. Cl. 26, 36 (2012) (quoting *Ala. Aircraft Indus., Inc.-Birmingham v. United States*, 586 F.3d 1372, 1375 (Fed. Cir. 2009)). An agency's procurement decisions are entitled to a "presumption of regularity." *See Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977). Accordingly, the court's review of agency action in this context is "highly deferential." *Advanced Data Concepts, Inc. v. United States*, 216 F.3d 1054, 1058 (Fed. Cir. 2000).

Here, StringKing claims that HHS acted arbitrarily and capriciously "by eliminating shelf life from the evaluation criteria for Factor[] 2 (Technical Capability), Factor 4 (Price), and the overall best value determination." Pl.-Intervenor's Suppl. Mot. at 9-11; *see also* Pl.-Intervenor's Mem. at 16-18; Pl.-Intervenor's Reply at 6-7. It avers that, by eliminating shelf life as a substantive evaluation criterion, HHS has rendered products with a longer shelf life, which are more expensive to manufacture, uncompetitive. Pl.-Intervenor's Suppl. Mot. at 17. According to StringKing, the amended solicitation effectively "[c]onvert[s] the procurement into a lowest price technically acceptable [('LPTA')] procurement rather than a best value procurement." *Id.* at 11. It contends that this is a material change because shelf life was originally "the only true differentiator." Pl-Intervenor's Mem. at 17-18. Moreover, the solicitation as amended runs counter to the agency's purpose of the solicitation: to replenish the national stockpile for a potentially forthcoming national emergency. Pl.-Intervenor's Suppl. Mot. at 17-18. As a result of these changes, the government appears to seeking off-the-shelf gowns rather than gowns that are specially designed to meet the solicitation's purpose. *Id.* at 14-16.[5] To the extent the government's procurement needs and purpose have changed, such changes are material "and the

[5] This argument relies on Section 2.101 of the Federal Acquisition Regulations ("FAR"), which defines items that are commercially available-off-the-shelf ("COTS") as "any item of supply (including construction material) that is—(i) A commercial product . . . (ii) Sold in substantial quantities in the commercial marketplace; and (iii) Offered to the [g]overnment, under a contract or subcontract at any tier, without modification, in the same form in which it is sold in the commercial marketplace; and (2) Does not include bulk cargo, as defined in 46 U.S.C. 40102(4), such as agricultural products and petroleum products." FAR § 2.101. The government's apparent desire to procure a COTS item, StringKing asserts, runs contrary to the solicitation's terms, which call for a "commercial product, not a COTS item." Pl.-Intervenor's Suppl. Mot. at 15-16, 16 n.8.

[a]gency should have cancelled this procurement pursuant to the FAR." *Id.* at 18; *see also* FAR § 15.206(e); Pl.-Intervenor's Reply at 4-6; Pl.'s Reply at 8-9.

StringKing also contends that the current submission deadline reflected in Amendment 0011 is arbitrary and capricious because proposals must be substantially revised to reflect the changes made in the amended solicitation. Pl.-Intervenor's Suppl. Mot. at 11, 11 n.6, 13-16; Pl.-Intervenor's Mem. at 18-19.

AirBoss concurs with StringKing's assertion that it is likely to succeed on the merits of its claims. *See* Pl.'s Resp. at 3-5; Pl.'s Suppl. Resp. at 2-19. Regarding shelf life, AirBoss agrees that "Amendment 0009 effectively removes shelf-life as a consideration in this procurement" and, in doing so, runs counter to the procurement's purpose. Pl.'s Suppl. Resp. at 2-4. AirBoss also agrees that Amendment 0009 has effectively transformed the procurement into an LPTA procurement. Pl.'s Suppl. Resp. at 17-19. AirBoss adds that the amended solicitation improperly imposes a requirement that gowns be submitted within three months of being manufactured, *id.* at 1, 13-17, and unreasonably "relieves offerors from providing any support or validation of their shelf-life claims beyond the offeror's certification of shelf-life." *Id.* at 3.

Additionally, by effectively eliminating shelf life as an evaluation criterion, AirBoss claims the government has failed to properly "include cost or price to the [f]ederal [g]overnment as an evaluation factor" under 41 U.S.C. § 3306(c)(1)(B) and has failed to "[d]iscuss how life-cycle cost will be considered" or, "[i]f it is not used, explain why" as required by 7.105 of the FAR. *See* Pl.'s Resp. at 4-5; Pl.'s Suppl. Resp. at 4-7. Under the amended solicitation, "the [g]overnment considers a gown with three years of shelf-life to have no [lesser] value than a gown with six or nine years of shelf-life, despite the obvious increased cost to the [g]overnment of having to replenish" the expired gowns. Pl.'s Resp. at 4-5; Pl.'s Suppl. Resp. at 4-7. Put differently, instead of properly evaluating cost to the federal government, the amended solicitation will "produce[] a misleading result," by "ignoring altogether the higher costs associated with gowns with a shorter shelf-life, relying instead on the misleading, and illusory unit price of lower-quality gowns." Pl.'s Suppl. Resp. at 7. According to AirBoss, HHS has erroneously ignored "the cost of *replacing gowns that are disposed of because they have expired*" in the consideration of life-cycle costs. *Id.* at 6-7; *see also* Pl.'s Reply at 4-5.

Beyond this, AirBoss asserts that the agency's effective elimination of the shelf-life requirement from this procurement is "simply arbitrary," as it results from a series of contradictory and unexplained decisions. Pl.'s Suppl. Resp. at 7-10; *see also* Pl.'s Reply at 2-3 ("the [g]overnment does indeed have to provide a 'more detailed' explanation for its complete reversal of policy").[6] And AirBoss argues that the explanations HHS does provide are nonsensical. Pl.'s Suppl. Resp. at 8-10; Pl.'s Resp. at 4. Specifically, in defending its three-year shelf-life requirement, HHS stated that "[i]t is unknown if isolation gowns with any varying

[6] AirBoss also argues HHS arbitrarily backtracked on its prior assessment of the industry standard shelf life, changing its articulation of this norm from five years to up to ten. Pl.'s Suppl. Resp. at 9-10. Subsequently, the agency, without explanation, removed shelf life from the agency's determination altogether, via Amendment 0008. *Id.* at 9. And now, although HHS apparently reinstated the shelf-life requirement, the agency effectively ignores it. *Id.*

designated shelf life will expire prior to the next public health emergency since the timing of these cannot be predicted." Amend. 0011 at 3-4. But, "[i]t is precisely *because* the timing of the next public health emergency *cannot* be predicted that shelf-life is an important consideration." Pl.'s Suppl. Resp. at 9-10; Pl.'s Resp. at 4.

Regarding the new proposal deadline, AirBoss avers that "offerors that previously proposed products with a longer shelf-life need time to explore alternative solutions that can compete with cheaper, shorter shelf-life gowns," and the new deadline allows insufficient time to do so. Pl.'s Resp. at 5-6; Pl.'s Suppl. Resp. at 10-13.

Moreover, AirBoss asserts that the current proposal timeline runs counter to the legislative basis for this procurement. Pl.'s Suppl. Resp. at 11-13. Specifically, "HHS's Acquisition Plan for this procurement explains that the RFP implements the Infrastructure Investment and Jobs Act (the 'IIJA')." *Id.* at 11; Pub. L. 117-58, 135 Stat. 429 (Nov. 15, 2021); *see also* AR 29, 93, 108, 1836. Relevant here, the IIJA articulates that "United States industry needs a strong and consistent demand signal from the [f]ederal [g]overnment" to "foster a domestic PPE supply chain." 135 Stat. at 1313, § 70952(4). But, AirBoss argues HHS is sending an inconsistent demand signal by implementing a shelf-life requirement that led AirBoss and StringKing to "invest[] in expanding their domestic supply chains and manufacturing capabilities," only to effectively remove the shelf-life requirement later. *See* Pl.'s Suppl. Resp. at 11-12. Offerors cannot "identify cheaper alternatives" or "build a supply chain and manufacturing capability that would produce those cheaper alternatives at the scale required by the RFP" within the current proposal timeline. *Id.* at 12.

Next, AirBoss argues that the amended solicitation's three-month date-of-manufacture requirement contravenes the Federal Acquisition Streamlining Act of 1994 ("FASA"), 41 U.S.C. § 3307(e)(2)(B), as implemented by part 12 of the FAR. Pl.'s Suppl. Resp. at 13-17. FASA establishes a preference for contract terms that are consistent with standard commercial practice. 41 U.S.C. § 3307(e)(2)(B); FAR § 12.101 to 12.603. Preliminary market research helps determine "whether a solicitation's terms are consistent with customary commercial practice." *See CW Gov't Travel, Inc. v. United States*, 99 Fed. Cl. 666, 676 (2011); *see also Palantir USG, Inc. v. United States*, 904 F.3d 980, 984 (Fed. Cir. 2018); FAR §12.101(a).

Market research was performed for this solicitation and, according to Airboss, "*[n]othing* in the Market Research Report indicates that commercial customers do not purchase gowns manufactured more than three months ago, regardless of how much shelf-life the gowns retain," nor does it indicate "that commercial purchases of isolation gowns impose date-of-manufacturing requirements that are not dependent on a gown's shelf-life." Pl.'s Suppl. Resp. at 15-16; *see also* AR 11-18. As such, AirBoss asserts that the three-month date-of-manufacture requirement is arbitrary and capricious insofar as it is not a customary commercial practice pursuant to FASA. Pl.'s Suppl. Resp. at 17.[7]

[7] AirBoss also asserts there is no indication the government sought or obtained a waiver with respect to the customary commercial practice requirement, pursuant to Section 12.302(c) of the FAR. Pl.'s Suppl. Resp. at 17; FAR § 12.302(c).

Moreover, to the extent the government relies on the assertion that real-time testing data to substantiate a longer shelf life was unavailable, Def.'s Suppl. Resp. at 14-15, AirBoss objects that this is unsupported by the record. Pl.'s Reply at 5-8. Specifically, AirBoss points to a Competitive Range Memorandum cited by the government which indicates that [***]." *Id.* at 5-6. And indeed, AirBoss and StringKing both identify that the government has previously "issued solicitations to stockpile [PPE] that require offerors to make a claim as to the shelf-life of the PPE and to provide supporting data to substantiate the shelf-life claim." *Id.* at 6-7; *see also* Pl.-Intervenor's Suppl. Mot. at 2. As such, the assertion that it was impossible to test a shorter shelf life of three years is unsupported by the record. Pl.'s Reply at 6-8.

In opposition, the government asserts that StringKing is unlikely to succeed on the merits of its claims. Def.'s Resp. at 3-4; Def.'s Suppl. Resp. at 13-19. In doing so, the government defends HHS's decision to require a three-year shelf life for gowns. Specifically, the government explains that HHS began requiring the "stockpiling disposable Level 2 isolation gowns . . . during the COVID-19 pandemic," at the same time that the IIJA "required domestic production of PPE." Def.'s Suppl. Resp. at 14-15. Given this limited timeframe, HHS reasonably decided "[***]. *Id.* at 15. Moreover, the new shelf-life requirement beneficially promotes competition because it is minimally restrictive considering HHS's needs, in accordance with the Competition in Contracting Act. *Id.* at 16 (citing 41 U.S.C. §§ 3301(a)(1), 3306(a)(2)(B)).

Moreover, the government disagrees that the deadline to submit revised proposals is too short. *Id.* at 17. Indeed, the government contends plaintiffs have been on notice of HHS's changes regarding shelf life since the issuance of Amendment 0008 on February 16, 2024. *Id.* Additionally, the government asserts the amended solicitation is not as demanding as plaintiffs claim, and that plaintiffs "are the only offerors [***] complaining about the changes to shelf-life requirements and the proposal due date." *Id.*

Finally, the government asserts that Amendment 0009 does not change the procurement into an LPTA procurement. Def.'s Suppl. Resp. at 17-19. Rather, the government maintains that this is a best value procurement, as evidenced by the plain language of the procurement itself, and further supported by the presumption that government officials act in good faith in discharging their duties, absent evidence indicating otherwise. *Id.*

NYES agrees that plaintiffs are unlikely to succeed on the merits of their claims because plaintiffs' arguments mischaracterize the status of the procurement and improperly seek to substitute their own judgment for that of the agency. Def.-Intervenor's Suppl. Resp. at 3-8. First, NYES asserts that plaintiffs mischaracterize the history of this solicitation. *Id.* at 4-5. Specifically, it contends that plaintiffs fail to address that Amendment 0005 also imposed "a drastic change to the shelf-life requirements." *Id.* at 4. Namely, following concerns raised during the initial protest of this solicitation, Amendment 0005 removed shelf-life language from the section detailing the best value determination, "and instead only included a reference to shelf-life in best value determination in relation to Factor 4, Price." *Id.* For this reason, NYES also asserts that plaintiffs' arguments surrounding the changes to shelf-life requirements with regard to the agency's best value assessment and the possible restriction in competition are

untimely, because plaintiffs were on notice of these changes after Amendment 0005 and should have either protested them or raised them in a Q&A at that time. *Id.* at 4 n.1, 5 n.3.[8]

Second, NYES avers plaintiffs improperly seek to substitute their own judgment regarding the solicitation's purpose, shelf-life considerations, and policy for that of the agency. Def.-Intervenor's Suppl. Resp. at 3-8. The administration directed HHS to "focus on quick production of PPE." *Id.* at 5-6. In following this policy, the agency rationally concluded "the shelf-life testing is not scientifically sound, and the industry standards do not support such weight on the shelf-life factors." *Id.* Because a contracting officer may amend the solicitation based on changes to the government's requirements "either before or after receipt of proposals," the solicitation was properly amended pursuant to the government's assessment of its own needs. *Id.* at 6-7 (quoting and adding emphasis to FAR § 15.206(a)). Plaintiffs "cannot substitute the [a]gency's judgment with their own best value opinion." *Id.* at 7.

Here, the court concludes that plaintiffs have not established that they are likely to succeed on the merits of their claim, because they have not demonstrated that the agency's decisions with respect to the shelf-life consideration, or the proposal deadline, are arbitrary, capricious, or an abuse of discretion. Indeed, an agency is entitled to alter its course and change its decisions in accordance with its "view of what is in the public interest." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 57 (1983) (quoting *Greater Bos. Television Corp. v. Fed. Commc'n Comm.*, 444 F.2d 841, 852 (D.C. Cir. 1970)). And when an agency makes such a change, it need not establish that its reasons "are *better* than the reasons for the old" decision, but rather simply "that there are good reasons for it, and that the agency believes it to be better." *Fed. Commc'n Comm. v. Fox Television Stations*, 556 U.S. 502, 514-15 (2009).

The agency's decision to alter the shelf-life requirement falls within its broad discretion to set and implement national public health policy. Specifically, the agency reasonably decided not to prioritize longer shelf-life gowns because "lengthy real-time aging testing is not available" given that these types of products "have been produced for a relatively short period of time." Def.'s Suppl. Resp. Ex. B, at 57. The agency also considered and ultimately limited its reliance on accelerated aging tests because "there is no clear guidance or standards regarding shelf-life claims for . . . non-surgical isolation gowns." *Id.* That said, the FDA set clearance requirements for surgical gowns and masks, "which can have a material similar" to domestic isolation gowns. *Id.* Based on this similarity, HHS aligned its practice with the "accelerated and real-time test

[8] Related to StringKing's portrayal of the history of this procurement, NYES laments that StringKing "spends considerable time attempting to paint a torrid history of this procurement through its bullet point timeline, including alleged communications with NYES and the [a]gency." Def.-Intervenor's Suppl. Resp. at 6. Based on this, NYES asserts that the administrative record in this case should be amended to include all communications between StringKing and the [a]gency." *Id.* at 6 n.4. The court agrees with NYES, however, that "no part of these communications is relevant to the [m]otion" currently before the court. *Id.* at 6. Indeed, the court does not consider StringKing's detailing of these communications, nor NYES's opposition thereof, to be pertinent to its present decision, and thus the issue of supplementing the administrative record is not necessary to resolve at this time.

practice" that the FDA used for surgical gowns and masks and required offerors to "certify a shelf-life of 3 years" rather than "provide aging test reports and supportive documentation." *Id.*

Moreover, the agency reasonably concluded that gowns with longer shelf lives were not required to fulfill the agency's minimum needs for this procurement. Instead, the procurement seeks to rapidly increase the inventory of isolation gowns in the Strategic National Stockpile. *See* Def.'s Suppl. Resp. Ex. A ¶ 4 (Decl. of Annette Wright). This specialized determination "is not for [the] court to second guess" at this time. *Savantage Fin. Servs., Inc. v. United States*, 595 F.3d 1282, 1286 (Fed. Cir. 2010) (quoting *Wit Assocs., Inc. v. United States*, 62 Fed. Cl. 657, 662 (2004)). In this case, the agency has represented that it is still conducting a best value acquisition, and the plaintiffs' arguments that the procurement is effectively an LPTA procurement do not overcome the presumption that agency officials are acting in good faith in discharging their duties according to their representations. Ultimately, that StringKing and AirBoss would have prioritized considerations such as shelf life more highly than the agency does in its amended solicitation does not render the agency's decision arbitrary or capricious.

Nor does the court find that plaintiffs have established that they are likely to succeed on the merits of their claim that the agency's proposal deadline is too short for offerors to prepare and submit new, competitive proposals. As defendants have identified, offerors should have been aware of the changing role that shelf life could play in this solicitation as early as the issuance of Amendment 0008 in February of 2024, or even Amendment 0005 in October of 2022. The ability to adapt to the changing circumstances of a solicitation is a quality a competitive offeror should possess, and here the agency's needs have not changed so substantially as to render it unreasonable that offerors could adapt accordingly. Indeed, the government represents that StringKing and AirBoss are the only offerors in the competitive range who have raised such concerns regarding shelf life or the corresponding proposal deadline, which suggests this is not a sufficient cause for concern in this context. *See* Def.'s Suppl. Resp. Ex. A ¶ 6 ("only two offerors—[StringKing] and AirBoss . . . —requested significantly extended proposal due dates") (Decl. of Annette Wright). Ultimately, plaintiffs have not sufficiently carried their burden of establishing that the agency's decisions with respect to shelf life, or the corresponding proposal deadline, were arbitrary and capricious at this stage.

B. Irreparable harm

A party seeking preliminary injunctive relief must show it will suffer irreparable harm absent such relief. Here, StringKing avers it will be irreparably harmed absent preliminary injunctive relief from this court. Pl.-Intervenor's Mem. at 19-20; Pl.-Intervenor's Suppl. Mot. at 11-12. Absent a preliminary injunction, "proposals will be due based on a flawed [s]olicitation," "StringKing would be forced to expend critical time and resources to prepare a fruitless proposal due to the [s]olicitation's defects," and "StringKing would be putting itself at a severe competitive disadvantage by submitting a proposal." Pl.-Intervenor's Mem. at 19-20; Pl.-Intervenor's Suppl. Mot. at 11-12. As such, StringKing asserts that the Solicitation as amended denies it the opportunity to "fairly compete in [the] procurement," thus losing the contract and any potential profits therefrom. Pl.-Intervenor's Mem. at 20.

Like StringKing, AirBoss asserts that it will suffer irreparable harm in the absence of preliminary injunctive relief, as it "will have no remedy if it is required to invest substantial time and effort in developing a response to the current solicitation over the next two weeks, and if this [c]ourt subsequently determines that the current solicitation is unlawful—particularly with respect to shelf life, the three-month date-of-manufacture requirement, and the RFP's incorrect statement that HHS will perform a best value tradeoff when it intends to award to the lowest-price, technically acceptable offeror." Pl.'s Suppl. Resp. at 19.

The government responds that StringKing has failed to show that it will suffer irreparable harm absent preliminary injunctive relief. Def.'s Resp. at 4-5; Def.'s Suppl. Resp. at 19-20. Specifically, the government contends that StringKing's "[m]ere allegations of an unfair competitive bidding process are not sufficient to demonstrate an irreparable injury," because "if they were, any bid protest would involve an irreparable injury." Def.'s Resp. at 5 (quoting *OAO Corp. v. United States*, 49 Fed. Cl. 478, 480 (2001)). Moreover, the government rejects StringKing's claim that it must create a new supply chain and product to meet the solicitation because the solicitation does, and always has, seek a commercial gown that is "in production or otherwise readily available." Def.'s Suppl. Resp. at 20.

NYES agrees that neither plaintiff can demonstrate immediate irreparable harm. Def.-Intervenor's Suppl. Resp. at 8-9. StringKing alleges only the risk of unfair competition, which is insufficient for preliminary injunctive relief. *Id.* at 8. And, AirBoss cannot cite as irreparable harm the need to secure an alternate means of responding to the procurement because that need exists regardless of whether the court enters an injunction: AirBoss's original sub-contractors have ceased operation or decommissioned their machinery, and AirBoss does not have an active Food and Drug Administration establishment registration for the 2024 year. *Id.* at 9.

Here, the court concludes that plaintiffs have not established that they will suffer immediate and irreparable harm in the absence of preliminary injunctive relief. As this court has previously concluded, "[m]ere allegations of an unfair competitive bidding process are not sufficient to demonstrate an irreparable injury." *OAO Corp.*, 49 Fed. Cl. at 480. In this case, plaintiffs allege that they will be irreparably harmed by the agency's decision to amend the solicitation with respect to shelf life, and by the corresponding proposal timeline, but such allegations are insufficient to establish an irreparable injury at this juncture. Indeed, plaintiffs' belief that the agency ought to conduct this procurement in a different manner, or according to a different timeline, is not sufficient to demonstrate that plaintiffs will suffer an immediate, irreparable harm, in the absence of emergency injunctive relief from the court at this stage. As such, plaintiffs have not demonstrated they would be irreparably harmed absent a preliminary injunction.

C. Balance of hardships

In determining whether to grant a preliminary injunction, the court also considers whether the balance of hardships weighs in favor of such relief, in light of the possible harm to the government and defendant-intervenor. *NetStar-1 Gov't Consulting, Inc. v. United States*, 101 Fed. Cl. 511, 530 (2011).

Here, StringKing avers the balance of hardships supports an injunction. Pl.-Intervenor's Mem. at 20; *see also* Pl.-Intervenor's Suppl. Mot. at 12. Specifically, the amended solicitation prohibits StringKing from fairly competing in this procurement process because the new solicitation erases any advantages associated with the longer shelf life of StringKing's gowns. Pl.-Intervenor's Mem. at 19-20; Pl.-Intervenor's Suppl. Mot. at 12. In contrast, the only possible harm HHS may suffer from a preliminary injunction is a delay to the procurement process, which is generally not considered a harm. Pl.-Intervenor's Mem. at 20; Pl.-Intervenor's Suppl. Mot. at 12. Even if such delay were considered a harm, the delay would be "minimal" in the context of this particular solicitation, which is meant "to stockpile goods for the *future*," not on an immediate basis. Pl.-Intervenor's Mem. at 20; Pl.-Intervenor's Suppl. Mot. at 12.

AirBoss concurs and asserts that the government "will not be harmed by a delay, particularly given that the [g]overnment has already delayed this procurement for over a year based on errors that the [g]overnment voluntarily took corrective action to try to remedy." Pl.'s Resp. at 6; Pl.'s Suppl. Resp. at 19-20. Because "the Government—not StringKing or [AirBoss]—is solely responsible for the delays to this procurement to date," its claim that further delay would be prejudicial is unpersuasive. Pl.'s Suppl. Resp. at 20.

The government responds that the balance of hardships cuts against plaintiffs, because the government would suffer "[s]ubstantial harm" if the court enjoined agency action and "interfere[d] with the [g]overnment's need to procure isolation gowns." Def.'s Resp. at 5. Moreover, delays to this procurement "could potentially compromise the readiness of healthcare workers during future public health events," and the funding for this procurement will expire at the end of September. Def.'s Suppl. Resp. at 21. Similarly, NYES concurs that the agency would suffer substantial harm in the face of a preliminary injunction given that this would "interfere with the [g]overnment's need to procure isolation gowns—a critical HHS need." Def.-Intervenor's Suppl. Resp. at 9-10.

Here, plaintiffs have not demonstrated that the balance of hardships weighs in favor of preliminary injunctive relief. Indeed, a preliminary injunction would impose further delays to a solicitation that aims to meet pressing national public health needs. And delaying this procurement risks weakening the nation's ability to respond to an imminent public health emergency. Even if plaintiffs were to suffer a competitive disadvantage in this procurement, this risk does not outweigh the government's obligation to ensure the nation's public health. As such, the balance of hardships cuts against preliminary injunctive relief.

D. Public interest

Finally, the court considers whether granting preliminary injunctive relief serves the public interest. One such public interest is "preserving the integrity of the procurement process by requiring the government to follow its procurement regulations." *Amazon Web Servs. v. United States*, 147 Fed. Cl. 146, 158 (2020) (quoting *Turner Constr. Co. v. United States*, 94 Fed. Cl. 561, 586 (2010) *aff'd* 645 F.3d 1377 (Fed. Cir. 2011)).

Here, StringKing asserts that a preliminary injunction would maintain the integrity of the procurement process and ensure this procurement fulfills the government's stated needs. Pl.-Intervenor's Mem. at 21; Pl.-Intervenor's Suppl. Mot. at 13. Preliminary injunctive relief would also preserve competition within the procurement process. Pl.-Intervenor's Mot. at 21.

The government responds that preserving integrity in the procurement process is an important but not dispositive factor in the public interest analysis. Def.'s Resp. at 5; Def.'s Suppl. Resp. at 21-22. By contrast, the government emphasizes the public interest in allowing agencies "to conduct procurements without excessive judicial infringement upon the agency's discretion." Def.'s Resp. at 5 (quoting *GEO Grp., Inc. v. United States*, 100 Fed. Cl. 223, 230 (2011)). NYES agrees that preliminary injunctive relief does not serve the public interest, as "it is critical for an agency such as HHS to be able to set its own policy objectives without undue intervention from judicial or other bodies," especially in the "nuanced and specialized" realm of public health. Def.-Intervenor's Suppl. Resp. at 10.

The court concludes that a preliminary injunction does not serve the public interest. At this juncture, plaintiffs have not demonstrated that the agency's actions compromise the integrity of the procurement process. The public interest is served by affording an agency the discretion to conduct procurements in accordance with its needs within a specialized and evolving landscape such as national public health. Plaintiffs have not demonstrated that the public interest favors preliminary injunctive relief.

CONCLUSION

StringKing and AirBoss have not met their burden to establish entitlement to preliminary injunctive relief. For the foregoing reasons, the court **DENIES** plaintiff-intervenor's application for a temporary restraining order and motion for a preliminary injunction.

It is so **ORDERED**.

s/ Charles F. Lettow
Charles F. Lettow
Senior Judge